



Pest Management
Regulatory Agency

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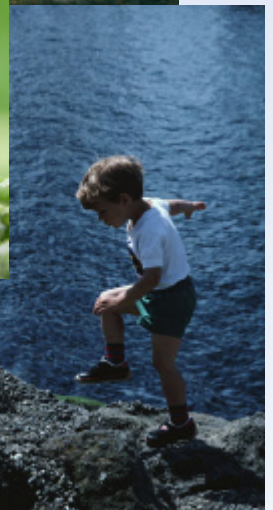
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Strategic Plan



Health
Canada

Santé
Canada

Canada

Our mission is to protect human health and the environment by minimizing the risks associated with pest control products in an open and transparent manner, while enabling access to pest management tools, namely, these products and sustainable pest management strategies.

Également offert en français sous le titre :
Plan stratégique 2003 à 2008

This publication is also available on the Internet at the following address:
www.hc-sc.gc.ca/pmra-arla/.

This publication can also be made available in/on computer diskette or CD Rom upon request.

For additional copies, please contact:

Publications Pest Management Regulatory Agency

2720 Riverside Drive

Ottawa, ON K1A 0K9

Telephone: 1-800-267-6315

Facsimile: 1-613-736-3758

Paper: ISBN: 0-662-68393-5 Catalogue Number: H114-14/2003

Internet: ISBN: 0-662-38044-4 Catalogue Number: H114-14/2003E-PDF

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Executive Summary

The Strategic Plan outlines the direction the Pest Management Regulatory Agency (PMRA) intends to take over the next five years as it implements the legislative mandate assigned by the government through the new *Pest Control Products Act*, continues to pursue harmonization, and as it takes action, in partnership with others, to support sustainable pest management.

The Agency has already implemented most of the recommendations of the Pesticide Registration Review that did not require legislative change, as directed by Cabinet. The next five years will see the focus on the new legislation, continued harmonization, and on support for sustainable pest management. The key initiatives that the PMRA will pursue in the next five years are grouped under three objectives.

To protect human health and the environment from unacceptable risks associated with pest control products through the use of sound, progressive science, modern risk assessment and risk management approaches, and innovative approaches to sustainable pest management.

The PMRA will achieve this objective by strengthening the risk management framework through sound science and consideration of sustainability; making decisions on new pest control products that are science based and protective of health and the environment; re-evaluating products to help ensure that they meet current safety standards; developing and implementing innovative approaches to sustainable pest management; helping to ensure that products are used legally, according to label instructions; supporting Canada's commitments to reduce pesticide risk on an international level; and requiring label information that will assist users in minimizing risk.

To meet the needs of Canadians for a transparent and participatory regulatory process, for timely access to new, safer and effective pest control products, and for timely re-evaluation of registered products.

The PMRA will achieve this objective by establishing a transparent regulatory framework with comprehensive legislation, regulations and guidelines communicated in a timely, efficient and effective manner; continuing to develop and implement a transparent decision-making process; inviting participation in regulatory development; providing timely access to new pest control products that have value and do not present unacceptable risks to health or the environment; meeting commitments to re-evaluate and make timely decisions regarding older pest control products; providing access to pest control products for minor crops, especially those that are reduced risk products; continuing to harmonize pest control product regulation through the North American Free Trade Agreement Technical Working Group on Pesticides and the Organisation for Economic Cooperation and Development Working Group on Pesticides; and meeting the commitment for accountability consistent with government policy and as required by the new *Pest Control Products Act*.

To create a workplace of choice in which employees can make an effective contribution to the mandate of the Agency and in which financial resources are effectively managed.

The PMRA will achieve this objective by continuing to improve the re-engineered electronic environment for the Agency; providing a supportive, motivating and engaging work environment for PMRA staff that fosters continuous learning; and continuing to practice sound financial management.

The Agency has many accomplishments to its credit. There is now an opportunity to make major advances, with a new legislative mandate, in the development of a high quality, responsive and transparent regulatory system; one in which Canadians can take pride and be confident.



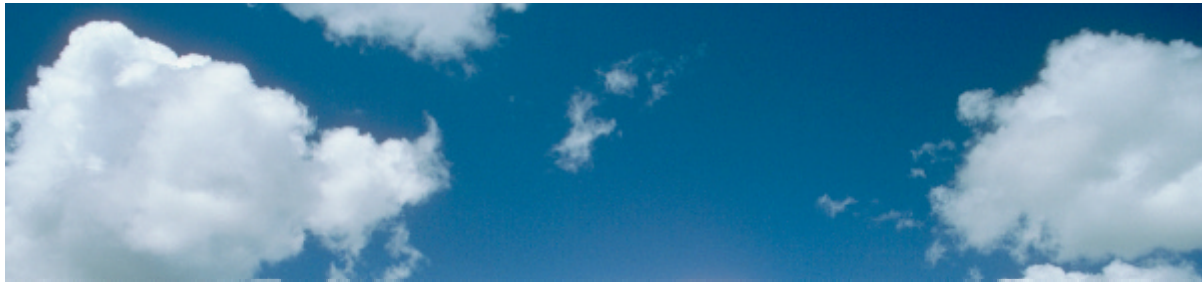


Introduction

In 1990, the multi-stakeholder Pesticide Registration Review team consulted with Canadians across the country to set the direction for major reforms to the pesticide registration system, as detailed in its *Recommendations for a Revised Federal Pest Management Regulatory System*, Final Report, December 1990. In 1994, the Government provided a detailed response via the *Government Proposal for the Pest Management Regulatory System*, October 1994, on how it would implement the recommendations. In 1995, the Government approved the formation of the Pest Management Regulatory Agency (PMRA), reporting to the Minister of Health.

Upon its creation, the PMRA began the task of implementing these reforms. The Agency has made significant progress during the past seven years, as outlined in the PMRA's *Progress Report 2003*. Highlights include the creation of PMRA from Agriculture and Agri-Food Canada, Natural Resources Canada, Environment Canada and Health Canada; harmonization activities with the United States under the North American Free Trade Agreement (NAFTA) and member countries of the Organisation for Economic Co-operation and Development (OECD); development and implementation of key new science policies; passage by Parliament of the new *Pest Control Products Act*; initiation of partnership projects on sustainable pest management; elimination of the backlog of submissions and introduction of a new way to manage submissions along with performance standards; development and implementation of the re-evaluation program; introduction of Administrative Monetary Penalties as an enforcement and compliance tool; development of working agreements with the provinces to improve cooperation on pesticide regulatory issues; implementation of cost recovery; and creation of a supportive, financially sound and electronically enabled work environment.

The purpose of this strategic plan is to set out how the Agency will continue implementing the regulatory reforms over the next five years in light of the need to reflect both the international and domestic context of pest control product regulation.



Overview of the Environment

The International Context

Governments in many countries are recognizing the benefits of international cooperation in carrying out regulatory activities. Increasingly, health and environmental issues are shared among countries; developing the science to address such issues and translate this science into regulatory approaches demands cooperation among scientists and regulatory organizations from around the world. Such cooperation also supports growing trade among countries.

Many of the Agency's activities have international linkages. Harmonization activities are well underway:

- activities with the NAFTA Technical Working Group on Pesticides;
- cooperation with the European Union (EU) and participation in the work of the OECD Working Group on Pesticides;
- joint reviews for new and existing pesticides with the United States Environmental Protection Agency (USEPA) as well as work sharing with the USEPA and other countries; and
- participation in international information technology initiatives with the USEPA, the EU, OECD, and the pest control product industry in Canada, the United States and Europe.

These activities have resulted in changes to processes to meet stakeholder needs. Traditional barriers continue to be reduced. Regulatory science is improved through the collective efforts of regulatory authorities.

There is growing recognition within pesticide regulatory authorities and the pesticide industry that maximum efficiency will be achieved through more the coordinated and collaborative efforts of regulators, the pesticide industry and other stakeholders on an international level. While considerable progress has been made between the PMRA and the USEPA, there will be an increasing focus on joint regulatory efforts with Mexico. Collaborative regulatory activity will also increase with OECD member countries. PMRA has seized the opportunity to influence, shape and participate dynamically in these activities so that they reflect Canadian needs for regulating pest control products, and in order for Canada to benefit from the earliest availability of the newest pest control product technologies as well as from the faster re-evaluation of older pesticides.

The Domestic Context

Because pest control products are intentionally released into the environment to control pests and because their actions may not be limited to effects on the target pest, there are public concerns about the effects of such products on health and the environment.

Passage by Parliament of the new *Pest Control Products Act* in December 2002 is a development that will influence the Agency over the next five years. The new Act offers a significant opportunity to increase the transparency of pest control product regulation and to build public confidence in the regulatory process, as well as to improve the regulation of pest control products. Development of the regulations and policies to support the bringing into force of the new Act at the earliest opportunity will be a key priority for the Agency during the period of this strategic plan.

Government investments in increased access to reduced risk and minor use pest control products offer the opportunity to facilitate the availability of these products in Canada. Coupled with a growing interest in sustainability and risk reduction in all sectors of pest control product use as well as increased government funding in this area, there is an important opportunity to work with stakeholders to provide access to newer, safer pest control products that are used within a sustainable approach to pest control.





Strategic Management Framework

This framework charts the direction for the PMRA for the period 2003–2008. Guided by its strategic objectives, the Agency will build on positive initiatives already in place and pursue new opportunities so that by 2009, it will have realized major gains in harmonization, risk reduction, and implemented the reform of the regulatory system.

Mandate

The PMRA's primary objective is to prevent unacceptable risks to people and the environment from the use of pest control products.

Consistent with this primary objective, Health Canada's Pest Management Regulatory Agency:

- supports sustainable development designed to enable the needs of the present to be met without compromising the ability of future generations to meet their own needs;
- seeks to minimize health and environmental risks posed by pest control products and encourage the development and implementation of innovative, sustainable pest management strategies by facilitating access to pest control products that pose lower risks and by other appropriate measures;
- encourages public awareness in relation to pest control products by informing the public, facilitating public access to relevant information and public participation in the decision-making process; and
- ensures that only those pest control products that are determined to be of acceptable value are approved for use in Canada.

Mission

To protect human health and the environment by minimizing the risks associated with pest control products in an open and transparent manner, while enabling access to pest management tools, namely, these products and sustainable pest management strategies.

Vision

A regulatory agency widely respected in Canada and abroad for the quality, transparency and efficiency of its science-based decisions and its commitment to sustainable pest management.



Strategic Objectives

The strategic objectives are:

To protect human health and the environment from unacceptable risks associated with pest control products through the use of sound, progressive science, modern risk assessment and risk management, and innovative approaches to sustainable pest management.

To meet the needs of Canadians for a transparent and participatory regulatory process, for timely access to new, safer and effective pest control products, and for timely re-evaluation of registered products.

To create a workplace of choice in which employees can make an effective contribution to the mandate of the Agency and in which financial resources are effectively managed.

Guiding Principles

The guiding principles that will enable the PMRA to meet these strategic objectives are as follows:

- maintain and enhance a regulatory framework that is responsive to the needs of Canadians;
- minimize the health and environmental risks associated with pest control products;
- continuously improve risk and value assessments and the risk management approach;
- maintain excellence in science as a basis of regulatory decision making;
- foster sustainable pest management strategies;
- maintain timely and open communication within our organization as well as with other government departments, diverse stakeholders and the public at large, through consultation and transparency of our actions;
- work in partnership with provincial, territorial, national, and international agencies on harmonized approaches to pest control product regulation;
- foster a workplace that values and actively promotes employees' health and well-being as well as supports their ability to fulfill the PMRA's mission;
- foster a learning and knowledge environment;
- provide effective and efficient service to the Minister, the public, industry and others involved in pest control product regulation and use; and
- respect the public trust in the efficient use of human, financial and information resources.





Strategic Objectives

1 *To protect human health and the environment from unacceptable risks associated with pest control products through the use of sound, progressive science, modern risk assessment and risk management approaches, and innovative approaches to sustainable pest management.*

The PMRA has been entrusted to safeguard the health and the environment of the Canadian people and the manufacturers of pest control products rely on public confidence to successfully market their products. Sound science is the cornerstone of our regulatory decision making and central to that responsibility. But science is not stagnant; it continually evolves. We have seen and will continue to see tremendous strides in the area of environmental and health risk assessment. Canada will remain at the forefront by continuously incorporating the best science in its regulatory activities so that Canadians can be assured that the risks from pest control products are minimized.

The legacy we leave for our children depends on steps we take today to safeguard the environment and to ensure that future generations have access to safe, effective pest control tools. Sustainable pest management tools and systems must be economically viable and meet Canadians' needs for human health protection, food and fibre production and resource utilization; these tools must conserve or enhance natural resources and the quality of the environment for future generations.

The PMRA will achieve this objective by:

- a) Strengthening the risk management framework through sound science and consideration of sustainability:
 - In cooperation with regulatory partners, developing new science policies, methodologies and guidelines to assess risk and value, including a PMRA policy on use of the precautionary principle;
 - Conducting aggregate and cumulative risk assessments;
 - Establishing priorities for research and monitoring as well as for maintaining strong science linkages with relevant organizations including academia, regulatory and research organizations in other countries, and with federal departments such as Agriculture and Agri-Food Canada, Environment Canada, Fisheries and Oceans Canada, the Canadian Food Inspection Agency, Natural Resources Canada and other parts of Health Canada;
 - Supporting and facilitating research in priority areas for pest control product regulation; and
 - In cooperation with the international community, continuing to identify opportunities to validate assumptions regarding risk assessment as resources become available.

- b) Making decisions on new pest control products (including new formulants) that are science based and protective of human health and the environment:
- Continuing to make high quality regulatory decisions that incorporate consideration of sustainability;
 - Facilitating the registration of pest control products that reduce risk; and
 - Incorporating new policies, risk assessment methodologies, and research and monitoring findings into decision making, including considerations for vulnerable groups and populations.
- c) Conducting re-evaluations and special reviews to help to ensure that registered pest control products meet current safety standards:
- Re-evaluating registered products and reviewing associated maximum residue limits to ensure that they meet current safety standards, and ensuring that users have access to updates concerning the regulatory status, labelling changes and product classifications;
 - Refining the approach to the conduct of special reviews of emerging issues according to the new *Pest Control Products Act*, and conducting such reviews as appropriate;
 - In collaboration with stakeholders, identifying and implementing risk management approaches that will provide for orderly transition;
 - Developing and implementing the mandatory and voluntary reporting of adverse effects to allow for early detection of health and environmental issues, and acting on findings;
 - Undertaking the re-evaluation of formulants that represent a health or environmental concern, and determining necessary action; and
 - Replacing the 0.1 ppm general maximum residue limit under the Food and Drug Regulations with the establishment of specific maximum residue limits for pest control products used on foods.
- d) Developing and implementing innovative approaches to sustainable pest management:
- Developing a risk reduction policy for pest control products and a regulation permitting use of pest control products at lower than label rates in specified circumstances;
 - Developing risk reduction strategies in consultation with federal government departments, provinces and territories, and other stakeholders. Integrated pest management concepts and crop profiles will continue to be used as a basis for the development of the risk reduction strategies;
 - Developing an approach to regulate low risk products;
 - Leading and supporting policies, programs and projects related to sustainability and pest control products, including risk reduction strategies and international risk reduction projects under NAFTA and the OECD;
 - Developing and maintaining a national pesticide sales database to meet requirements both inside and outside of the Agency for comprehensive, accurate and up-to-date information on provincial and national pest control product sales;
 - Developing an indicator(s) of pesticide risk to health and the environment, in collaboration with stakeholders, and supporting the collection of data that will permit the assessment of trends in pesticide risk reduction.

- e) Helping to ensure that pest control products are used legally, according to label instructions:
- Continuing to audit compliance and enforce the legislation through regular inspections and the investigation of suspected violations;
 - Expanding capability, at minimal cost, by strengthening and developing the network of activities that foster compliance, e.g., target applicator training and develop new compliance strategies and instruments that monitor and enforce compliance, such as the *Administrative Monetary Penalties Act*.
 - In partnership with comparable Canadian and international organizations that are responsible for promoting, inspecting and enforcing compliance, determining how, with finite resources, to target activities and measure user compliance, and developing measurement and reporting procedures; and
 - Enhancing the sharing of information and responsibilities regarding user compliance with provincial/territorial pest control product regulatory authorities.
- f) Supporting Canada's commitments to reduce pesticide risk on an international level:
- Implementing obligations under the Rotterdam Treaty (Prior Informed Consent obligations), including prompt notification of Canadian actions to ban or severely restrict a pest control product; and
 - Identifying pest control products that meet the criteria of persistent organic pollutants, and supporting international action in this regard.
- g) Requiring label information concerning pest control products that will enable users to minimize risk:
- Developing and implementing regulations that will require the provision of Material Safety Data Sheets to workplaces; and
 - In consultation with stakeholders, undertaking initiatives that will improve the labelling of pest control products, including label warnings in line with the Globally Harmonized System.

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To meet the needs of Canadians for a transparent and participatory regulatory process, for timely access to new, safer and effective pest control products, and for timely re-evaluation of registered products.

Every Canadian has the right to know that the pest control products being used in Canada have been rigorously assessed against high Canadian standards to protect human health and the environment, and that they can participate in the regulatory process, with access to full information. Manufacturers and users rely on timely and predictable access to newer, safer products to remain viable and competitive in a rapidly changing marketplace. As the regulatory system evolves, we will meet our accountability commitments, and we will continue to rely on the continuous feedback of our stakeholders to affirm that we are moving in the right direction.

The PMRA will achieve this objective by:

- a) Establishing a transparent regulatory framework with clear, comprehensive legislation, regulations and guidelines communicated in a timely, efficient and effective manner:
 - Implementing the new *Pest Control Products Act*, to reflect the reforms to the regulatory system recommended by stakeholders;
 - Developing regulations that support the legislation in a timely manner with consultation with stakeholders;
 - Communicating with stakeholders and the public on the stringent regulation of pest control products in Canada to improve understanding of the regulatory framework; and
 - Working with industry to ensure that their need for clear guidance on regulatory requirements is met, using appropriate means such as regulatory directives, training and the web.

- b) Continuing the development and implementation of a transparent decision-making process:
 - Continuing to solicit public input and comment regarding major regulatory decisions using Proposed Regulatory Decision Documents and Proposed Acceptability for Continuing Registration documents;
 - Continuing to provide information to interested parties regarding proposed and final regulatory decisions;
 - Providing public access to information used to make decisions on applications for registration for new technical active ingredients and major new uses, and on the re-evaluation of existing products, through a new electronic Public Registry and through access to confidential test data, as provided for under the new *Pest Control Products Act*;
 - Developing regulations and procedures to support the new legislative provisions concerning the reconsideration of decisions regarding pest control products;
 - Implementing transparency provisions of the new Act by establishing an electronic public registry; and
 - Sharing information with other federal departments, with provincial and territorial governments, with health professionals, and with regulatory agencies in other countries, as provided for in the new Act.

- c) Inviting participation in regulatory development:
 - Continuing to support the multi-stakeholder Pest Management Advisory Council to advise the Minister and to serve as a forum to raise policy issues and develop proposed solutions;
 - Continuing to support an Economic Management Advisory Committee, comprising manufacturers and users, to provide strategic advice on streamlining operations and reducing costs;
 - Maintaining the involvement with, and the support of, the Federal/Provincial/Territorial Committee on Pest Management and Pesticides; and
 - Identifying and acting on new and innovative ways to obtain stakeholder participation in the regulation of pest control products.



- d) Providing timely access to new pest control products that have value and do not present unacceptable risks to health or the environment:
- Maintaining a submission review process that enables the Agency to achieve its performance targets;
 - Continuing to meet performance standards, and measuring and reporting performance; and
 - Pursuing opportunities for international cooperation, including joint reviews and increased ability to workshare globally.
- e) Meeting commitments to re-evaluate and make timely decisions regarding older pest control products, according to the Re-evaluation Program:
- Continuing to implement a re-evaluation program for older pest control products through a multilateral approach with the USEPA, the EU and other OECD member countries to make possible, long-term, cost-effective re-evaluation based on cooperative sharing of reviews;
 - Establishing workplans, taking into account opportunities for joint work with OECD member countries and, in particular, the United States, and reporting regularly on accomplishments;
 - Continuing to develop and implement a business process for the re-evaluation of older pest control products; and
 - Taking timely action on reports of adverse effects or other findings that necessitate a special review, and reporting on the results.
- f) Providing access to pest control products for minor crops, especially those that are reduced risk products:
- Continuing to support the User Requested Minor Use Registration Program, and the User Requested Minor Use Label Expansion Program and other programs that are relevant to minor crop registration;
 - Cooperating with Agriculture and Agri-Food Canada in the implementation of the government's minor use initiative, including undertaking joint reviews with the USEPA Environmental Protection Agency of cooperative submissions prepared by Agriculture and Agri-Food Canada and the United States Department of Agriculture under Inter-regional Project Number 4;
 - Incorporating science-based refinements in the data requirements for, and review of, submissions for minor crops, including increased use of crop groups; and
 - Promoting joint submissions to the United States and Canada, the use of crop groups in submissions and the submission of uses on minor crops when a pest control product is initially submitted for registration.
- g) Continuing to harmonize pest control product regulation through the NAFTA Technical Working Group on Pesticides and the OECD Working Group on Pesticides:
- Continuing to resolve differences in approaches to registering and re-evaluating pest control products;
 - Increasing the ability to share work with the United States in regulating agricultural pest control products;

- Implementing a joint review program for biocides with the United States;
 - Increasing global worksharing including joint reviews with the EU and with other countries and regions through the OECD, through, for example, the use of harmonized templates and compatible information technology approaches;
 - Encouraging the pest control products industry to continue their participation in joint reviews and other global worksharing initiatives;
 - Developing processes to promulgate maximum residue levels more quickly while continuing to provide for public consultation.
- h) Meeting the commitment for accountability consistent with government policy and as required by the new *Pest Control Products Act*:
- Providing Parliament with annual reports concerning the administration and enforcement of the new Act, which include a status report respecting registrations, including the registration of pest control products that pose lower risks, re-evaluations and special reviews; and a report on significant developments relating to the evaluation of the health and environmental risks and the value of pest control products and the integration of those developments into decision-making under this Act;
 - Working with stakeholders to improve the availability and nature of information concerning the accomplishments and performance of the Agency and of pest control product regulation; and
 - Implementing commitments made as a result of reports and audits, including those undertaken by the Commissioner of the Environment and Sustainable Development.

3 *To create a workplace of choice in which employees can make an effective contribution to the mandate of the Agency and in which financial resources are effectively managed.*

Canadians indirectly fund the pest control programs through taxes and Canadian industries pay cost recovery fees to support PMRA operations. Both have the right to expect good quality decisions and value for their money, and to be assured that we practice sound financial management for both appropriations and revenues. The Agency will see increased efficiency and improved decision making as a result of the continued implementation of enabling technologies.

Our staff is composed of highly trained and experienced people who are committed to the task. We are committed to the support and recognition of all who make up the Agency, and to providing a workplace that encourages excellence in performance.

The PMRA will achieve this objective by:

- a) Continuing to improve the re-engineered electronic environment for the Agency that allows information to be delivered, stored, accessed, retrieved, exchanged and used effectively and efficiently:
- Continuously reassessing the adequacy of procedures and processes for submission review and making necessary changes;



- Implementing, through information technology, the capacity for applicants and registrants to interact with PMRA using web-based technology, in a manner that will facilitate transparency of the regulatory process as required by the new Act; and
 - Regularly reviewing and, if necessary, enhancing the Management of Submissions Policy;
 - Leveraging innovations in information technology to support PMRA staff in carrying out their responsibilities nationally and internationally.
- b) Providing a supportive, motivating and engaging work environment for PMRA staff:
- Continuing to encourage communication among staff as well as between staff and management;
 - Continuing to strengthen team approaches within and between divisions;
 - Maintaining the recognition of accomplishments of Agency staff through a staff recognition program;
 - Maintaining the Continuous Learning Program to ensure continuous employee training in the latest scientific methods as well as additional operational skills required to meet the new and evolving challenges of their jobs, and to prepare staff to move laterally into new jobs or progress to more senior positions;
 - Through the PMRA Human Resources Strategy, focusing on recruitment and retention of staff, for example, through the Biologist/Chemist Development Program; and
 - Supporting a workplace that is committed to functioning in an ethical manner, that respects and values diversity and official language requirements, and that actively promotes employees' health and well-being and supports their ability to fulfill the organization's mandate.
- c) Continuing to practice sound financial management for both appropriations and revenues:
- Completing the evaluation of the PMRA's cost recovery initiative and implementing the recommended changes to ensure that cost recovery fees are fair and that they generate the required revenue;
 - Maintaining support for business line based planning and management of the Agency resources with a focus on results and performance measurement, and on Modern Comptrollership; and
 - Incorporating the Treasury Board framework (Managing for Results), including Integrated Risk Management, into PMRA practices.