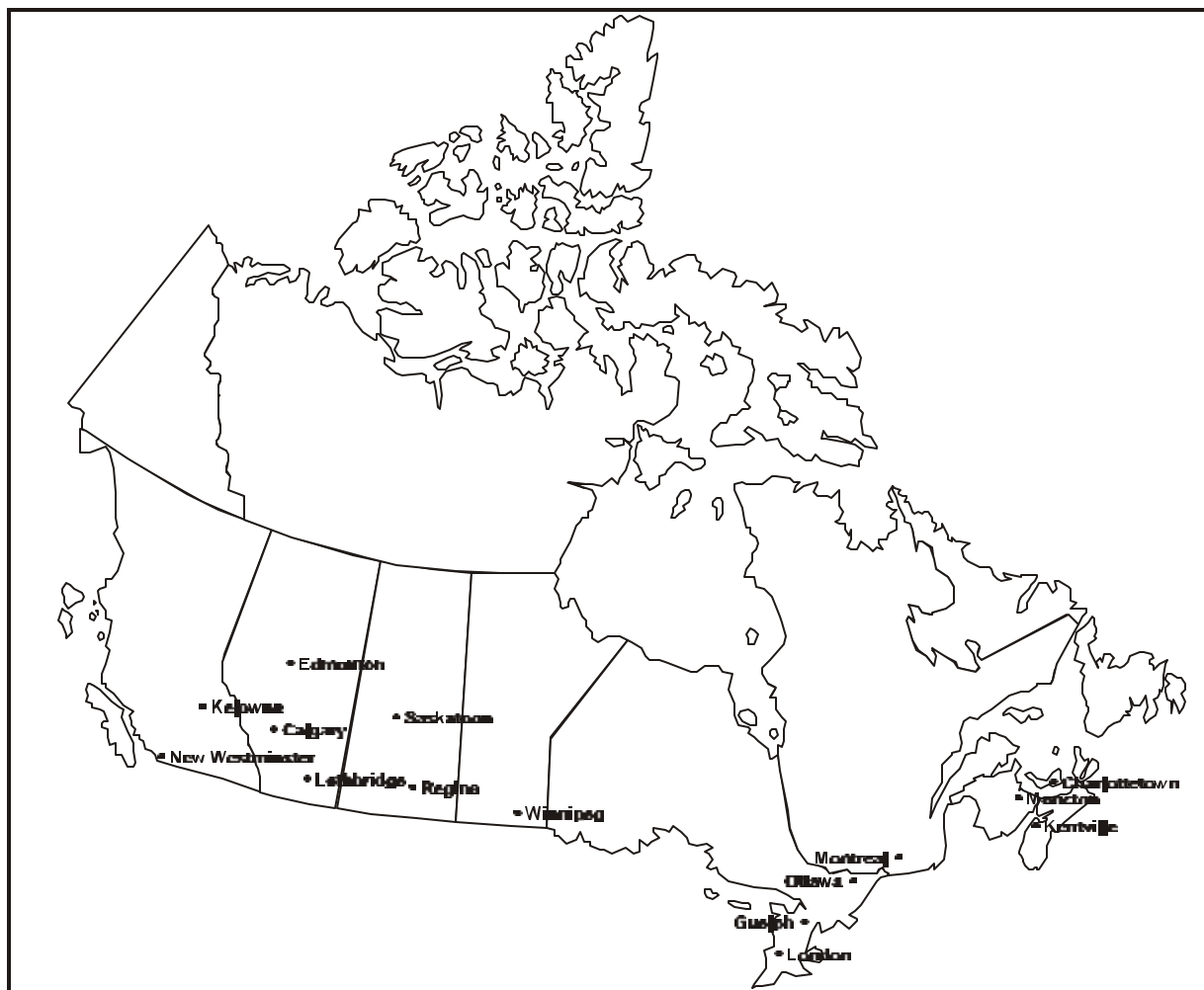


TABLE OF CONTENTS

EXECUTIVE SUMMARY	iii
INTRODUCTION	1
OVERVIEW OF THE ENVIRONMENT	2
STRATEGIC MANAGEMENT FRAMEWORK	2
ACHIEVING OUR STRATEGIC OBJECTIVES	4
Strategic Objective I	4
Strategic Objective II	6
Strategic Objective III	7
Key Initiatives to 2003 Supporting Strategic Objective I	9
Key Initiatives to 2003 Supporting Strategic Objective II	11
Key Initiatives to 2003 Supporting Strategic Objective III	11
PROGRESS ON IMPLEMENTING THE COMMITMENTS BY GOVERNMENT FOR REFORM OF THE PEST MANAGEMENT REGULATORY SYSTEM	13
APPENDIX I	
ROLES OF THE PEST MANAGEMENT REGULATORY AGENCY	31

Pest Management Regulatory Agency Regional Offices and Laboratory Services



EXECUTIVE SUMMARY

The Strategic Plan outlines the direction the Pest Management Regulatory Agency (PMRA) intends to take as it continues to implement the recommendations of the Pesticide Registration Review (PRR) as directed by Cabinet. The Agency has many accomplishments to its credit and is committed to finalize the implementation of these significant reforms by 2003. The key initiatives that the PMRA will pursue in the next five years are grouped under three objectives:

To protect health, safety and the environment from the risks of pesticides through the use of sound, progressive science, including innovative approaches to sustainable pest management.

By strengthening the risk management framework using the best science and incorporating consideration of sustainability; re-evaluating products to ensure that they meet current safety standards; ensuring that products are used legally, according to label instructions; developing innovative approaches to sustainable pest management through partnerships with user groups, provinces, territories and other stakeholders; developing risk reduction strategies in consultation with stakeholders; and implementing a national sales data base.

To meet the needs of Canadians for an open, transparent and participatory regulatory process and for timely access to new, safer pest control products.

By establishing a clear regulatory framework with comprehensive legislation, regulations and guidelines; soliciting public input on major regulatory decisions and inviting stakeholder and provincial and territorial participation in regulatory development; establishing performance indicators and standards for the approval process; facilitating access to minor-use pesticides where there is a need; and achieving a 40% improvement in the efficiency of the process of approving new products by 2003.

To effectively manage human and financial resources.

By providing a supportive work environment for staff that fosters continuous learning; implementing sound financial management practices; establishing an electronic application review environment; and leveraging available resources through collaboration with international partners in harmonizing requirements, work sharing, and other such initiatives.

The Agency has many accomplishments to its credit. It is now essential to take the organization into the next millennium by achieving a high quality, responsive and efficient regulatory system; one in which Canadians can take pride and be confident.

INTRODUCTION

In 1990, the multi-stakeholder Pesticide Registration Review (PRR) team consulted with Canadians across the country to set the direction for major reform, 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 PMRA, reporting to the Minister of Health. Appendix I outlines the roles of the Agency as delineated in the 1995 government response.

Upon its creation the Agency began the task of implementing these reforms and has achieved significant progress. The initial challenges included the organization of the Agency and the collocation of employees from Agriculture and Agri-Food Canada (AAFC), Environment Canada (EC) and Health Canada (HC), the introduction of a cost recovery program, which has had significant implications for both budget management and performance standards, and the development and implementation of legislation to reflect the reforms to the regulatory system recommended by stakeholders and agreed to by Cabinet. Having completed the first two and made substantial progress on the third, it is essential now to take the Agency into the next millennium by achieving a high quality, responsive and efficient regulatory system; one in which Canadians can take pride and be confident.

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 contexts of pesticide regulation.

OVERVIEW OF THE ENVIRONMENT

THE INTERNATIONAL CONTEXT



Many of the Agency activities are international in scope. Harmonization activities through the North American Free Trade Agreement (NAFTA), the European Union (EU) and the Organisation for Economic Co-operation and Development (OECD), work sharing and joint review agreements with the United States Environmental Protection Agency (EPA), and participation in international technology initiatives with the EPA, the EU, and the pesticide industry in Canada, the U.S. and Europe all have an impact on the Agency activities and priorities. These activities are resulting in new processes to meet stakeholder needs. Traditional barriers are being reduced.

This dynamic change process is occurring very rapidly. There is growing recognition within agencies and the pesticide industry that maximum efficiency will be achieved through collaborative efforts by both regulators and industry on an international basis. PMRA must seize the opportunity to influence, shape and aggressively participate in these activities so that they reflect Canadian needs for regulating pest control products.

THE DOMESTIC CONTEXT

At the same time as resources must be expended to work toward harmonization, the Agency must achieve its objectives of reducing the backlog of submissions and meeting performance standards for new submissions. The most significant aspect of the domestic context was the implementation of cost recovery in April 1997. The Agency has made a commitment to implement the reforms to the pesticide regulatory system as directed by Cabinet, maintain the high level of protection of health and the environment expected of the Agency, while at the same time improving performance standards and keeping a cap on expenditures (Regulatory Impact Assessment Statement, Canada Gazette, April 16, 1997).

STRATEGIC MANAGEMENT FRAMEWORK

This framework charts the direction for the PMRA for the period 1998-2003. Guided by its strategic objectives, the Agency will build on positive initiatives already in place and pursue new opportunities so that by 2003, it will have realized major gains in risk reduction and implemented the reform of the regulatory system.

The **Mission** of the PMRA is to protect human health and the environment by minimizing the risks associated with pest control products, while enabling access to pest management tools, namely, these products and sustainable pest management strategies.

The **Vision** is to be a regulatory agency widely respected in Canada and abroad for the quality of its decisions and its commitment to sustainable practices.

The **Strategic Objectives** are:

- I To protect health, safety and the environment from the risks of pesticides through the use of sound, progressive science, including innovative approaches to sustainable pest management.
- II To meet the needs of Canadians for an open, transparent and participatory regulatory process and for timely access to new, safer pest control products.
- III To effectively manage the human and financial resources of the PMRA.

The **Guiding Principles** that will enable the PMRA to meet these strategic objectives are:

- C developing and maintaining a regulatory framework that is responsive to the needs of Canadians;
- C reducing the risks associated with pesticides;
- C fostering sustainable practices;
- C promoting a risk/value assessment and management;
- C maintaining a sound scientific foundation as a basis of regulatory decision making;
- C recognizing the human health and environmental dimension of pest management regulation;
- C creating a work environment that enables us to relate effectively, and in harmony with each other;
- C maintaining timely and open communication within our organization and with diverse stakeholders and the public at large through transparency of our actions and consultation;
- C working in partnership with provincial, territorial, national, and international agencies;
- C providing responsive value-added service to the Minister, the public, industry and others involved in pesticide use and regulation;
- C respecting the public trust in the efficient use of human, financial and information resources; and
- C promoting pesticide risk reduction strategies.

ACHIEVING OUR STRATEGIC OBJECTIVES

STRATEGIC OBJECTIVE I

To protect health, safety and the environment from the risks of pesticides through the use of sound, progressive science, including innovative approaches to sustainable pest management.



Sound science is the cornerstone of our regulatory decision making, and central to the responsibility that Canadians have entrusted us with to safeguard their health and their environment. The makers and the users of pest control products rely on public confidence to successfully market their products. But science is not stagnant, it continuously evolves. We have seen, and will continue to see tremendous strides in the area of environmental assessment. Canada will remain at the forefront in continuously incorporating the best

science in its regulatory activities so that Canadians can be assured that pest control products are safe, and that risk is 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, while conserving or enhancing natural resources and the quality of the environment for future generations.

The PMRA will achieve this objective by:

- a. Incorporating risk management in regulatory decision-making on applications for new products and changes to existing products:
 - C Continuing to make high quality regulatory decisions, while incorporating consideration of sustainability in decision-making.
 - C Facilitating the registration of pest control products that reduce risk.

- b. Ensuring that registered pest control products meet current safety standards through re-evaluation and special review:
 - C Developing and implementing a re-evaluation program for older pesticides through a multilateral approach with the EPA and the EU to make possible, long-term, cost-effective re-evaluation based on cooperative sharing of reviews.
 - C Re-evaluating registered products, and reviewing associated maximum residue limits (MRLs) to ensure that they meet current safety standards and to ensure that users have access to concurrent updates in the regulatory status, labelling and classification of the products.
 - C Conducting special reviews of emerging issues on an ongoing basis.
 - C Developing an adverse effects reporting system for early detection of health and environmental issues.
- c. Developing innovative approaches to sustainable pest management:
 - C Establishing strong linkages in research and monitoring related to pest management with federal departments such as AAFC, EC, Fisheries and Oceans and HC.
 - C Developing a risk reduction policy and strategies in consultation with federal government departments, provinces and territories, the EPA and international organizations. Integrated pest management projects should be used to expedite these.
 - C Developing the capacity to measure risk to health and the environment so that we know we are achieving our goal, and continuously identify sustainability needs and priorities.
 - C Developing and maintaining a national pesticide sales data base to meet requirements both inside and outside of the Agency for comprehensive, accurate and up-to-date information on pesticide usage provincially and nationally. This is contingent on the pesticide industry providing information to the Agency.
- d. Ensuring that pest control products are used legally, according to label instructions:
 - C Continuing to audit compliance and enforce the legislation through regular inspections and the investigation of suspected violations.
 - C Expanding the capability at minimal cost, by relying on improved communication and cost effective methods such as applicator training, and implementation of *Agriculture and Agri-Food Administrative Monetary Penalties Act* (AMPs).

STRATEGIC OBJECTIVE II

To meet the needs of Canadians for an open, transparent and participatory regulatory process and for timely access to new, safer pest control products.

PMRA will achieve this objective by:

- a. Establishing a transparent regulatory framework; clear, comprehensive legislation, regulations, and guidelines communicated in a timely, efficient and effective manner:



- C Developing and implementing legislation to reflect the reforms to the regulatory system recommended by stakeholders.
- C Timely development of regulations that support the legislation.
- C Working with industry to ensure that their need for clear guidance on regulatory requirements is met, using appropriate means such as regulatory directives, industry training, and the PMRA Web Site.

- b. Developing an open and transparent decision-making process:

- C Soliciting public input and comment to major regulatory decisions using Proposed Regulatory Decision Documents (PRDDs). This requires development of a PRDD format and process that meets public need. Implementation of the process involves preparation of the PRDD as part of the review process, publication, assessing comments, and incorporating comments in decisions in a timely, efficient manner.
- C Providing public access to information used to approve applications for registration for new technical active ingredients.
- C Providing information to interested parties regarding proposed and final regulatory decisions.

- c. Inviting participation in regulatory development:
 - C A multi-stakeholder Pest Management Advisory Council to advise the Minister and the PMRA and to serve as a forum to raise issues and develop proposed solutions.
 - C An Economic Management Advisory Committee, comprising of manufacturers and users, to provide strategic advice on streamlining operations and reducing costs.
- d. Providing timely access to new products for all users:
 - C Establishing a submission review process that enables the Agency to achieve its performance targets.
 - C Establishing measurable performance indicators and achievable performance standards, and measuring and reporting performance.
 - C Clearing the backlog of submissions for new products (eliminate type 1, type 2 submissions).
 - C Pursuing opportunities for international cooperation (see Strategic Objective III).
- e. Providing access to minor-use pesticides where there is a need:
 - C User Requested Minor Use Registration (URMUR) Program.
 - C User Requested Minor Use Label Expansion (URMULE) Program.

STRATEGIC OBJECTIVE III

1 To effectively manage the human and financial resources of the PMRA.



Canadians who indirectly fund the program through taxes, and Canadian industries that pay user fees for our services, have the right to expect good quality decisions and value for their money.

The Agency will see increased efficiency as a result of harmonization, work sharing, joint reviews and the implementation of enabling technologies. The pesticide industry will benefit from faster and broader access to international markets. Growers will have more prompt access to a wider range of more effective pest control products, and the public will see health risks reduced as newer and safer pest control products are introduced.

Our staff is composed of highly trained and experienced people who are committed to the task. We are committed to the integration and recognition of all who make up the Agency.

The PMRA will achieve this strategic objective by:

- a. Harmonizing through the NAFTA TWG and the OECD Forum to standardize:
 - ⌄ the type and scope of studies required to register a pesticide;
 - ⌄ the protocol followed in carrying out these required studies;
 - ⌄ the format and presentation of manufacturers' submissions for registration (dossier);
 - ⌄ the methods used to evaluate submissions and prepare country reports (monograph); and
 - ⌄ work sharing and joint reviews.
- b. A re-engineered, electronic environment for the Agency that supports the efficient and effective delivery, storing, accessing and retrieving, distribution, exchange, and functional use of information.
- c. Providing a supportive work environment for our staff through:
 - ⌄ communication amongst staff and between staff and management;
 - ⌄ a strengthened team approach within and between divisions;
 - ⌄ implementation of a staff recognition program; and
 - ⌄ the creation of a Continuous Learning Program to ensure continuous employee training in the latest scientific methods as well as other 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 or management positions.
- d. Implementing sound financial management practices for both appropriations and revenues through:
 - ⌄ implementation and continuous monitoring of user fees to ensure that they are fair and that they generate the required revenue; and
 - ⌄ development of business lines for planning and managing the Agency resources.

KEY INITIATIVES TO 2003 SUPPORTING STRATEGIC OBJECTIVE I

The PMRA and the EPA introduced a joint-review process for reduced-risk chemical pesticides in 1996 and for biological pesticides in 1997. Under this process, products are screened for eligibility as reduced-risk products by the EPA and applications are screened for completeness by the PMRA. Once these screens have been done, successful candidates are reviewed by the joint PMRA-EPA review team. A comprehensive reduced-risk program will be in place in the PMRA by 2000.

Re-evaluation is the term applied to assessment and reconfirmation of acceptability of older compounds in the light of modern technology and scientific standards. Industry recognizes that trade barriers could be introduced if Canada does not coordinate its re-evaluation program with other countries, particularly the U.S. The current Agency resource allocation to re-evaluation is scheduled to increase over the next five years, as resources become available from new product evaluation because of efficiency gains. The PMRA will coordinate its re-evaluation program with the EPA and will also coordinate with their *Food Quality Protection Act* (FQPA) reassessment of MRLs to maximize health protection and to minimize the potential for trade barriers.

The Alternative Strategies and Regulatory Affairs Division within the PMRA was established to provide focus, lead and support for policies, programs and projects related to sustainability. Programs have been developed to facilitate access to new technology, including registration of reduced-risk chemical and biopesticide products. Risk reduction strategies are being developed in consultation with stakeholders to facilitate continuous improvement in the handling and use of pest control products.

The Agency is working with stakeholders (including other federal government departments, provinces, research establishments, grower organizations, manufacturers, and other non-governmental organizations) to coordinate and facilitate development of implementable national strategies for sustainable pest management in a variety of specific commodities and sectors. These strategies will be adaptable to regional situations, and will incorporate the broad range of tools available for use in pest management programs. The following projects have been completed, or are in progress: late blight in potatoes; Colorado potato beetle; food processing sectors (alternatives to methyl bromide); orchards (apple); Canola; sea lice (in salmon aquaculture); urban landscapes; cranberries and forestry (Eastern spruce budworm).

International risk-reduction projects are underway under the NAFTA and the OECD. These projects include development of performance indicators, harmonized data requirements and work sharing for registration of biopesticides, and bilateral and multilateral sustainable pest management projects.

The Canadian Government, under the *Auditor General Act*, required departments to report on progress toward sustainable development in December 1997, and every three years thereafter. The ongoing activities described above are part of the PMRA's contribution to HC's Sustainable Development Strategy.

The federal government committed the PMRA to the development of a national data base on pesticides. As a first step in building the database, the PMRA has proposed collecting pesticide sales information from the registrant. A subsequent or parallel step could include incorporating information from provincial use surveys or integrating information on crop hectareage. The PMRA is currently working with stakeholders through a Federal/Provincial/Territorial (F/P/T) Working Group to determine cost-effective inputs and outputs for the data base. The Working Group is to complete its tasks in early 1999. Concurrently, the PMRA is ensuring that the database can be fully and easily integrated into the future PMRA electronic environment. The pilot data base will be implemented within two years.

Compliance is an important aspect in the protection of the health of Canadians and their environment. It is also important in monitoring the quality of the products sold to users. A more efficient capacity for compiling and monitoring information needed for investigations and inspections will be implemented in the PMRA by 1999. The utilization of the new AMPs will be implemented by 1999.

KEY INITIATIVES TO 2003 SUPPORTING STRATEGIC OBJECTIVE II

Our aim is to meet or exceed the turnaround time for submission review achieved by other major pesticide regulatory agencies. The internal processes of the Agency that have been introduced to date have already had an impact on the capacity to implement the reforms. A streamlined process for screening and management of the review of submissions has been an essential component of the successful implementation of the government commitment of an 18-month performance standard for review of new active ingredients and major new uses (Category A submissions). In addition, the availability of some reviews from EPA has contributed to the continuing reduction in the total work-on-hand from over 3000 submissions inherited by the PMRA to the current 1800, taking into consideration that approximately 2000 submissions are received annually. One of the first priorities of the PMRA was to reduce the backlog. The result has been a reduction of the number of old, complex submissions from nearly 1000 to 200. The target to eliminate this backlog is 1998-99. There has been a 100% increase in the number of minor use registrations and it is targeted that a minor use program, integrated with the U.S. and Mexico through the NAFTA Technical Working Group (TWG) will be in place in 1999.

KEY INITIATIVES TO 2003 SUPPORTING STRATEGIC OBJECTIVE III

The Agency is targeting a 40% efficiency improvement in the review of complex submissions by 2003, through international harmonization, process improvements, and an efficient, effective electronic environment. It is expected to take until 1999 to put the necessary infrastructure in place.

When the PMRA was established in April 1995, the Government made a commitment to pursue harmonization as one of the key means of achieving efficiencies. In order to assess the risks and value associated with the use of a pesticide, extensive data sets must be evaluated. The differences due to climate, agricultural practices, pest and disease complexes or pressures mean that regional or country specific data are required for certain endpoints. For this reason, countries maintain pesticide registration systems that reflect their specific needs. But there are many aspects of the required data that are common amongst countries, especially those that relate to chemistry, characterization and toxicology, and that are amenable to harmonization. By sharing reviews with international partners, particularly the EPA, the PMRA is fostering a streamlined and more efficient approach to making pest control products available to the consumer. The Agency is also aware of the need to maintain the high standards of decision-making that Canadians expect from a regulatory agency.

The PMRA has been actively involved in pursuing harmonization through:

- C The NAFTA TWG on Pesticides, which facilitates cost-effective pesticide regulation and trade among the three countries through harmonization and work sharing while recognizing the broader NAFTA objectives of environmental protection and sustainable development. The TWG ensures that the work corresponds to the priorities of the three countries and that such priorities are identified and addressed in an efficient manner. The TWG holds an annual meeting in the spring and an Executive Board meeting in December. The members are devoting their energy to creating a more consistent basis for pesticide registration by 2002. Within five years, the NAFTA TWG aims to have work sharing become routine amongst Canada, the U.S. and Mexico (North American Initiative). This will build on the work sharing that has already started within NAFTA TWG projects. Joint-review procedures were announced in 1996 for reduced-risk chemicals and in 1997 for biological products.
- C The OECD Pesticides Programme in which twenty-nine Member Countries meet through the Pesticide Forum to improve the efficiency of pesticide assessment and control procedures, minimize non-tariff trade barriers, and reduce risks to human health and the environment from the use of pesticides amongst Member Countries. These activities include promoting harmonization of data requirements, testing methods, and hazard assessment procedures amongst Member Countries, facilitating sharing of the work and enhancing information sharing on approaches to pesticide risk reduction. Through the Forum, common formats for company submissions and country data reviews have been developed. There are frequent opportunities for projects initiated in the NAFTA TWG to be pursued with a broader range of countries through the OECD Pesticide Forum.

The Continuous Learning Program became operational in 1998, and it will be fully integrated with the annual Performance Discussion Review. Internal communication tools and a staff recognition program were implemented in 1998. Professional development and management development opportunities were initiated in 1998 and will be implemented in 1999.

A business line framework has been established and has been used for the annual planning effective fiscal year 1998-99.

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE I.a

Incorporating risk management in regulatory decision-making on applications for new products and changes to existing products

Blue Book Recommendations	Purple Book Commitments	Progress
<p>Evaluation and Decision-Making</p> <p>Regulatory decisions will be made using a risk management approach that will involve an evaluation of efficacy, risk assessment and, when appropriate, value assessment.</p> <p>Products that either pose an unacceptable risk of harm to human health, safety or the environment or are not sufficiently efficacious for their intended use will not be registered.</p> <p>Products that pose negligible risk of harm to human health, safety and the environment will be registered.</p> <p>For products that pose neither negligible nor unacceptable risk, the regulatory decision will be based on a consideration of the totality of the evidence provided by both the risk and value assessments.</p>	<p>Evaluation and Decision-Making</p> <p>The legislation would establish the principle that products posing unacceptable risk would not be registered. The concept of <i>negligible risk</i> would not be included as it is indistinguishable from <i>acceptable risk</i>. If the risk were acceptable, only products that were effective and had value would be registered.</p>	<p>Evaluation and Decision-Making</p> <p>Risk management principles had been implemented operationally prior to 1995. Proposed new legislation incorporates these principles.</p> <p>The PMRA is currently documenting its risk management decision process.</p>
Blue Book:	Final Report of the Pesticide Registration Review, <i>Recommendations for a Revised Federal Pest Management Regulatory System</i> , December 1990	
Purple Book:	Government Proposal for the Pest Management Regulatory System, October 1994	

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE I.b

Ensuring that registered pest control products meet current safety standards through re-evaluation and special review

Blue Book Recommendations	Purple Book Commitments	Progress
Special Reviews <p>The legislation will provide for special reviews of registered or scheduled products. Special reviews may result from new information that indicates that there may be significant risk of harm to human health, safety or the environment, or that the product is no longer efficacious. These reviews may result in the cancellation or suspension of the product, or the maintenance of the registration status of the product, with or without further restrictions.</p>	Special Reviews <p>Would be included in proposed legislative amendments.</p>	Special Reviews <p>Proposed new legislation incorporates provisions for special reviews.</p>
Re-evaluation <p>The legislation will provide for a comprehensive re-evaluation policy for older pesticides.</p>	Re-evaluation <p>The legislation would include a risk-management approach to decision-making in re-evaluation as recommended. However, operational aspects of the re-evaluation regime would encompass a multilateral approach in addition to a bilateral one with the EPA. Major developments in international cooperation since the PRR provide long-term avenues for cost-effective re-evaluation based on cooperation amongst the U.S., Canada and other OECD countries. This is important because re-evaluation is costly and time consuming. The EPA has fallen far behind its schedule for re-evaluation despite the addition of \$250M for this project alone.</p>	Re-evaluation <p>Proposed new legislation incorporates provisions for re-evaluation. Pending new legislation, a re-evaluation program is being developed as a policy matter. The current allocation to re-evaluation is scheduled to increase over six years, funded by resource shifts from new product evaluation emerging from efficiencies and cost savings. In order to reduce costs, the program will rely heavily on foreign data reviews, particularly from the U.S. Coordination of the Canadian re-evaluation program with the U.S. will also minimize the loss of products critical to Canadian growers that might result from the introduction of the FQPA of 1996.</p>



PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE I.b

Ensuring that registered pest control products meet current safety standards through re-evaluation and special review

Mandatory Reporting of Adverse Effects Registrants will be required to report factual information that indicates that a particular pest control product may be causing unreasonable adverse effects on human health, safety or the environment.	Mandatory Reporting of Adverse Effects Would be included in proposed legislative amendments.	Mandatory Reporting of Adverse Effects Proposed new legislation incorporates provisions for mandatory reporting of adverse effects.
Policy on Formulants The system will include a policy on formulant ingredients. The Agency will develop an up to date list of formulants used in Canada and categorize formulants in accordance with a specified classification scheme. The policy includes options for regulatory actions on these formulants.	Policy on Formulants Agency would develop a formulant policy.	Policy on Formulants Under the auspices of the NAFTA TWG on Pesticides, a working group has been charged with developing a harmonized formulant policy.

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE I.b

Ensuring that registered pest control products meet current safety standards through re-evaluation and special review

<p>Export Policy</p> <p>The legislation will include a policy relating to the export of pest control products. Subject to an appeal provision, the international shipment of pest control products that are cancelled or suspended in order to protect human health, safety or the environment is prohibited.</p> <p>Subject to the Export Policy above, allow for the manufacture, import or formulation of an unregistered pest control product for sale in other countries, under certain conditions.</p>	<p>Export Policy</p> <p>Proposed legislative amendments would permit the Minister to issue an export permit for these products providing certain criteria (e.g., consent of the importing country) were met, rather than referring the matter to a Board of Review. This is considered a more cost-effective way of dealing with this matter.</p> <p>Import of Pest Control Products Solely for Manufacture and Export</p> <p>Rather than allowing for the import and manufacture of an unregistered product, products imported for manufacture and export would be registered in accordance with defined criteria.</p>	<p>Export Policy</p> <p>Proposed new legislation would implement the international Prior Informed Consent Convention, by prohibiting the export of products of concern unless a permit has been issued.</p> <p>Import of Pest Control Products Solely for Manufacture and Export</p> <p>Implemented for chemical pest control products.</p>
---	---	---

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE I.c

Developing innovative approaches to sustainable pest management

Blue Book Recommendations	Purple Book Commitments	Progress
<p>The Pest Management Promotion Office</p> <p>The legislation will establish the Pest Management Promotion Office (PMPO), to be administered by the Minister of Agriculture. The mandate of the PMPO is to support the integration of pest management with the broader goals of environmental sustainability, including the role to set targets and establish work plans for the reduction of use of pesticides in all sectors, taking into consideration available and potential pest management strategies that are viable, and to fund research, as appropriate.</p>	<p>Alternatives Office</p> <p>An Alternatives Office would be established within the Agency to perform the roles recommended by the PRR except for the funding and promotion of research into alternative pest management strategies, which would be carried out primarily by AAFC and Natural Resources Canada. Strong linkages would be developed to ensure effective transmittal of information and influence on priorities between the Agency and these departments. A key advantage of having an alternatives office within the Agency is to ensure that the registration process is informed by an alternatives perspective within the broader goals of environmental sustainability. Among the specific roles envisaged for the Alternatives Office is the formulation of a risk reduction policy in cooperation with federal government departments, the provinces, territories and stakeholders.</p>	<p>Alternative Strategies and Regulatory Affairs Division</p> <p>An Alternatives Division was established within the PMRA to find efficient and effective approaches to integrating sustainability into PMRA and user sector functions by encouraging the development and adoption of sustainable pest management systems. The former Alternatives Division is now part of the Alternative Strategies and Regulatory Affairs Division.</p> <p>Risk Reduction</p> <p>The PMRA is developing and implementing policies and programs that help make measurable progress in sustainable pest management in Canada by facilitating step-by-step, continuous improvement towards sustainable pest management, moving from a product-by-product approach to a systems approach that incorporates risk reduction, integrated pest management and support for the use of reduced-risk chemical and biopesticide products. Risk reduction activities are aimed at continuous improvement in the handling and use of pesticides, bringing the acceptable risks associated with pesticide use to the lowest level compatible with optimal management of pest problems. In order to realize the full potential of available risk reduction tools, the PMRA collaborates with other federal, provincial and international partners. A Risk Reduction Policy has not yet been developed.</p>



PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE I.c

Developing innovative approaches to sustainable pest management

Blue Book Recommendations	Purple Book Commitments	Progress
<p>Federal-Provincial Initiatives</p> <p>The legislation will provide that the Agency will take a strong leadership role in establishing minimum national guidelines in cooperation with the provinces concerning matters of national interest and in promoting the implementation of these guidelines. These matters include training and licensing programs, reuse and recycling of containers, action levels for pesticides in ground water and drinking water and product classification systems which dictates sales, packaging sizes and application restrictions. A national database will be established to coordinate record keeping on a national basis.</p>	<p>Minimum National Guidelines</p> <p>Agency would develop minimum national guidelines through the F/P/T Committee.</p> <p>National Database on Pesticide Use</p> <p>The Agency would develop a national database on pesticide use.</p>	<p>F/P/T Initiatives</p> <p>See F/P/T Committee on Pest Management and Pesticides, II.c, below. Working groups have been established on Classification Criteria, Education and Training, National Pesticide Sales Database, Registered Products Database, and Post Registration Monitoring and Incident Reporting.</p> <p>Minimum National Guidelines</p> <p><i>The Standard for Pesticide Education, Training and Certification in Canada</i>, developed jointly by the federal, provincial and territorial governments, was released in 1995 and is being implemented by the provinces and territories.</p> <p>National Pesticide Sales Database</p> <p>The PMRA is developing this database in collaboration with provinces, territories and stakeholders.</p>

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE 1.d

Ensuring that pest control products are used legally, according to label directions

Blue Book Recommendations	Purple Book Commitments	Progress
<p>Enforcement and Compliance</p> <p>The legislation will include a comprehensive compliance strategy, with appropriate enforcement provisions.</p>	<p>National Compliance Policy</p> <p>Strengthened enforcement provisions would be included in proposed legislative amendments. The Agency would develop a national compliance policy through the F/P/T Committee.</p>	<p>Enforcement and Compliance</p> <p>Preparations are complete for implementation of the AMPs process in order to enforce compliance more cost-effectively. Discussions are under way to transfer authority for pest control products in the AMPs Act to the Minister of Health. In addition, the proposed new legislation incorporates enhanced enforcement capability through clearly defined offences, increased powers of inspectors and higher maximum penalties.</p> <p>National Compliance Policy</p> <p>A Compliance and Enforcement Policy Guideline has been prepared by the PMRA and will be issued shortly. The F/P/T Committee on Pest Management and Pesticides has approved an approach whereby a working agreement will be developed between the PMRA and each province in order to ensure effective enforcement and efficient use of resources. These agreements are targeted for</p>

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE II.a

Establishing a transparent regulatory framework

Blue Book Recommendations	Purple Book Commitments	Progress
Legislation The <i>Pest Control Products Act</i> and the Pest Control Products Regulations will be rewritten and entitled the <i>Pest Management Act</i> and the Pest Management Regulations.	Legislation Based on advice from the Department of Justice, the title of the new legislation may need to be modified so that it does not appear to encroach on provincial jurisdiction in pest management.	Legislation A Bill has been prepared and is awaiting direction from the Minister of Health regarding timing of introduction into Parliament.
Data Protection Policy There will be a new data protection policy incorporated into the legislation. The policy will include an exclusive use period, and will allow a generic manufacturer to enter the market by paying compensation according to a predetermined formula to existing registrants.	Data Protection Policy Would be included in proposed legislative amendments.	Data Protection Policy Proposed new legislation incorporates authority to make regulations providing data protection.

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE II.a

Establishing a transparent regulatory framework

Blue Book Recommendations	Purple Book Commitments	Progress
<p>Registration Criteria and Data Requirements</p> <p>The regulations will list the criteria that have to be met by all products prior to registration, as well as the data requirements that registrants must submit to support an application for registration. The data requirements will be specific to product types.</p>	<p>Registration Criteria and Data Requirements</p> <p>General registration criteria are already prescribed in regulation and would be updated as necessary. Guidelines which relate these registration criteria to data requirements would be developed for particular types of registrations and products. These would not be prescribed in detail in statute or in regulations because this would limit capacity to deal with new technologies and could lead to unnecessary inefficiencies in the registration process.</p>	<p>Registration Criteria and Data Requirements</p> <p>The current hierarchy of requirements in the Act, regulations and guidelines is being maintained. Regulatory amendments, to ensure that the general information requirements in the Pest Control Products Regulations are comprehensive, will be made once a new Act is enacted.</p> <p>The PMRA is actively working with other countries to harmonize data requirements, primarily through the NAFTA TWG on Pesticides and the OECD.</p>

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE II.a

Establishing a transparent regulatory framework

Blue Book Recommendations	Purple Book Commitments	Progress
<p>Registration Criteria and Data Requirements</p> <p>The regulations will list the criteria that have to be met by all products prior to registration, as well as the data requirements that registrants must submit to support an application for registration. The data requirements will be specific to product types.</p>	<p>Registration Criteria and Data Requirements</p> <p>General registration criteria are already prescribed in regulation and would be updated as necessary. Guidelines which relate these registration criteria to data requirements would be developed for particular types of registrations and products. These would not be prescribed in detail in statute or in regulations because this would limit capacity to deal with new technologies and could lead to unnecessary inefficiencies in the registration process.</p>	<p>Registration Criteria and Data Requirements</p> <p>The current hierarchy of requirements in the Act, regulations and guidelines is being maintained. Regulatory amendments, to ensure that the general information requirements in the Pest Control Products Regulations are comprehensive, will be made once a new Act is enacted.</p> <p>The PMRA is actively working with other countries to harmonize data requirements, primarily through the NAFTA TWG on Pesticides and the OECD.</p>

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE II.a

Establishing a transparent regulatory framework

Blue Book Recommendations	Purple Book Commitments	Progress
<p>Registration Types</p> <p>The system will include a variety of permit and registration types. Active ingredients, manufacturing concentrates and end-use products that have satisfied the legislated criteria will be granted full registration. End-use products will be classified as domestic or commercial products. Some commercial products will be given a restricted class designation.</p>	<p>Registration Types</p> <p>Agency would implement policies/regulations for registration types, based on the PRR recommendation.</p>	<p>Registration Types</p> <p>Proposed new legislation incorporates authority to make regulations prescribing registration types.</p> <p>The PMRA is working with the F/P/T Committee and various international fora to harmonize pesticide classification systems.</p>

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE II.a

Establishing a transparent regulatory framework

Blue Book Recommendations	Purple Book Commitments	Progress
<p>Appeals</p> <p>The legislation will include a provision for an appeal from a decision to accept or refuse an application to register, or to cancel, suspend or maintain the registration of a pest control product.</p> <p>(The Minister could reject any application for appeal that is frivolous or vexatious.)</p>	<p>Appeal Process</p> <p>The proposed legislation would include appeal provisions, as recommended, but would allow for broader Ministerial discretion regarding the establishment of a Board of Review when requested. This would provide a more satisfactory basis for dealing with frivolous and vexatious appeals and would help to reduce anticipated pressure on resources.</p>	<p>Reconsideration of Decisions</p> <p>Proposed new legislation incorporates provisions for reconsideration of major registration decisions and decisions regarding export permits by a review panel at the discretion of the Minister. The review process would be open to the public with many opportunities for public participation during the review, and access to much of the information received by the review panel.</p>

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE II.a

Establishing a transparent regulatory framework

Blue Book Recommendations	Purple Book Commitments	Progress
<p>Labelling</p> <p>Labelling provisions will ensure that information necessary to ensure safe use is prominently displayed. The legislation will include appropriate aspects of the Workplace Hazardous Materials Information System.</p> <p>The Agency will ensure the establishment of an Information Centre that would provide rapid information on the health, safety and environmental impacts of a particular product. The legislation will then provide that the appropriate phone number(s) for this service will be placed on the label.</p>	<p>Labelling</p> <p>Policies/regulations on labelling would be consistent with the PRR except for the recommendation to register products on the basis of a draft label. A review of errors on proposed final labels submitted by registrants revealed that failure to require approval of a final label could lead to serious problems once the product was on the market.</p> <p>Information Centre</p> <p>The Agency would establish an information centre, as recommended.</p>	<p>Labelling</p> <p>As recommended by a PMRA/industry working group, an 18-month pilot project to assess the feasibility of issuing the certificate of registration based on the version of the final label (i.e., draft label, printers' proofs, final printed labels) presented by the company was implemented on April 1, 1998.</p> <p>The PMRA is working with the F/P/T Committee and various international fora to harmonize pesticide classification and labelling systems.</p> <p>The policy on bilingual labelling is under active review.</p> <p>Information Centre</p> <p>This is not being implemented. Specific labelling provisions could be included in regulations. The Register of Pest Control Products would provide access to the information that would have been furnished through an Information Centre.</p>

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE II.b

Developing an open and transparent decision-making process

Blue Book Recommendations	Purple Book Commitments	Progress
<p>Public Information and Participation</p> <p>The system will incorporate extensive public access to information relating to all aspects of the regulatory system. The public will be given notification of, and opportunity for, involvement in the development of new aspects of the regulatory system.</p> <p>The legislation will establish conditions that will allow for pre- and post- decision access to health, safety and environmental data. The conditions will include provisions that will ensure confidentiality of the data.</p> <p>Proposed Regulatory Decision Document</p> <p>The PRDD will be prepared for all proposed registrations of new active ingredients, and for registrations that may result in substantially increased use or exposure. Certain other proposed regulatory decisions may result in the publication of a PRDD. These documents will be distributed to interested parties and will allow a 60-day comment period.</p>	<p>Public Participation and Access to Data</p> <p>Opportunities for public participation would be provided as recommended, except that access to test data would only be provided post-registration. The public would be invited to contribute to improving registration decisions through comment on PRDDs, which would include the risk and value assessments upon which registration decisions were based. PRDDs would be made available for proposed registration decisions, as recommended by the PRR, and for proposed decisions following special reviews and re-evaluations.</p> <p>If the public were provided access to test data for the purpose of providing comments on proposed registration decisions, sufficient time would have to be provided for review of these data. This would necessitate extending the comment period well beyond the 60 days currently proposed. Other factors that make pre-decision access to test data problematic include: (1) since no other country permits such access, companies might delay applying for registration in Canada until after registration in another country leads to access to the data; (2) General Agreement on Tariffs and Trade and NAFTA permit access to test data only when necessary to protect the public; this need would be difficult to demonstrate before registration results in potential exposure of the public.</p>	<p>Public Participation and Access to Data</p> <p>The PMRA has implemented a policy to consult on proposed decisions to register new active ingredients if the application was received after April 1, 1995. Consultation is through PRDDs. Proposed new legislation incorporates this policy, as well as a requirement to consult on applications that might significantly increase health or environmental risks, re-evaluations and special reviews.</p> <p>The new legislation would also establish a public register containing information about registrations, permits, applications, re-evaluations and special reviews. Except for confidential business information, all information in the register, including test data, would be open to public scrutiny, in a manner designed to prevent "unfair commercial use" of the information.</p> <p>Existing non-legislated public participation mechanisms, such as consultation on proposed policies and guidelines, are being continued by the PMRA.</p>

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE II.c

Inviting stakeholder participation in regulatory development

Blue Book Recommendations	Purple Book Commitments	Progress
<p>Canadian Pest Management Advisory Council</p> <p>The legislation will provide for the establishment of a multi-stakeholder advisory council to advise the Ministers of Agriculture and Health and Welfare on an ongoing basis, on policies and issues relating to the federal pest management regulatory system, and to monitor the system for efficiency and performance.</p>	<p>Consultation with Stakeholders</p> <p>Can proceed as recommended, but Council would formally advise only the Minister of Health.</p>	<p>Pest Management Advisory Council</p> <p>The proposed new legislation would provide the authority for establishment of an advisory council. In the meantime, a council is being formally established as a policy matter.</p>
<p>Linkages with the Provinces</p> <p>Each province will be invited to appoint a Designated Provincial Representative (DPR) through whom all consultations will be made. These DPRs will be invited to sit on a Standing F/P/T Committee. The Committee will be responsible for addressing all matters that affect federal-provincial relations on pest management regulation.</p>	<p>Standing F/P/T Committee on Pest Management</p> <p>Implemented.</p>	<p>F/P/T Committee on Pest Management and Pesticides</p> <p>A new F/P/T Committee on Pest Management and Pesticides held its first meeting in November 1997. The Committee will strengthen federal/provincial/territorial relationships with the aim of enhancing sustainable pest control practices and seeking harmonization where applicable in programs and policies. It will also provide additional opportunities for jurisdictions to work cooperatively in relation to pest management and pesticides.</p>



PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE II.d

Providing timely access to new products for all users

Blue Book Recommendations	Purple Book Commitments	Progress
<p>Timelines</p> <p>Legislation will establish that the Agency must complete its review and make a decision on the regulatory status of a product within specified timelines. Timelines will be based on an 18-month target for new active ingredients.</p>	<p>Service Standards</p> <p>Service standards would be developed in consultation with stakeholders and published in guidelines. An 18-month timeline for the review of “complex” applications, including the preparation of a PRDD, could be met provided a complete data package were submitted and the resources needed for the system were made available.</p>	<p>Performance Standards</p> <p>The PMRA released its draft Management of Submissions Policy in June 1996. The policy presents proposed performance standards for all submission types and the submission review process that will be used to achieve these standards. The PMRA has announced its commitment to meeting the 18-month performance standard for the review of complex submissions for all applications received after July 1, 1996, subject to adequate resources, and is on track with meeting this commitment. One-year performance standards for joint reviews conducted with the EPA and for the review of URMUR submissions have also been implemented.</p>

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE II.e

Access to minor use products where there is a need

Blue Book Recommendations	Purple Book Commitments	Progress
<p>Support Program for User-requested Registrations</p> <p>The Minister of Agriculture will set up a support program to assist in the development of data for URMULE, URMUR and User-requested Registrations (URR) in the agricultural sector.</p>	<p>Support Program for User-requested Registrations</p> <p>URMULE: Implemented.</p> <p>URMUR: Pilot program implemented.</p> <p>URR: Implement once URMUR established.</p> <p>Due to budgetary constraints, funding provided through AAFC and Natural Resources Canada for generating data to support URMULE and URMUR would be lower than the PRR recommendation.</p>	<p>Minor-Use Programs</p> <p>URMULE and URMUR programs have been developed by the PMRA to permit users to encourage pesticide manufacturers to apply for the registration of products, or specific uses of products, for which manufacturers would not otherwise be prepared to apply; ensure that registration requirements are appropriate recognizing the relatively small volumes and areas of use as well as the need to maintain Canadian standards of health and environmental protection; and ensure that the review of minor use applications is as efficient as possible, for example, by using data reviews prepared by reliable regulators in other countries (foreign data reviews). Any financial assistance to users is provided by the sectoral departments, with the user associations and provincial governments playing a role in establishing priorities.</p> <p>The improved URMULE program is fully operational and has resulted in a 100% increase in the number of approved minor use label expansions in 1996/97. A Regulatory Proposal was published in September 1997 to describe the proposed URMUR program, which has been implemented operationally in the meantime. The PMRA intends to work with stakeholders to resolve any remaining concerns.</p>

PROGRESS ON GOVERNMENT COMMITMENT AS RELATED TO STRATEGIC OBJECTIVE III.e

Implementing sound financial management practices for both appropriations and revenues

Blue Book Recommendations	Purple Book Commitments	Progress
The PMRA <p>The legislation will establish a self-contained PMRA. It will report directly to the Minister of Health and Welfare, but will be separate from the Department of Health and Welfare as well as from any other federal department or agency. The Agency will be responsible for all regulatory functions in the legislation, except for those assigned to the PMPO, and for developing and implementing policies related to the regulation of pest control products.</p>	PMRA <p>In order to ensure Ministerial accountability, the Agency would be within the Department of Health rather than being an arms-length agency. However, the characteristics of the Agency would be largely the same as those of an arms-length agency.</p>	PMRA <p>The Agency was established effective April 1, 1995. The Executive Director of the PMRA reports to the Deputy Minister of Health. A submission to seek Single Operating Agency status is in preparation.</p>
Cost Recovery <p>The Agency will develop a cost recovery scheme, including a comprehensive list of fees payable for various submission types.</p>	Cost Recovery <p>Agency would implement a cost recovery regime in consultation with industry and other stakeholders.</p>	Cost Recovery <p>New registration application and maintenance fees became effective April 1, 1997. The revenue target of the new fees was \$12M or 44% of the PMRA's \$27M budget.</p> <p>The PMRA is forecasting a \$4 million shortfall in revenue. Health Canada has commissioned an independent assessment and analysis of the PMRA's performance, program cost, and cost recovery regime. The study has been completed. Results of the study will be considered in deciding on the best means to address the revenue shortfall.</p>

Appendix I: Roles of the Pest Management Regulatory Agency

In 1995, the Government provided a detailed response on how it would implement the recommendations of the 1990 PRR and delineated the roles of the Agency as follows:

- a. Process applications for registration and determine the regulatory status of pest control products in an efficient and timely manner.
- b. Conduct human health, safety and environmental risk assessments, efficacy assessments, value assessments and establish MRLs for pest control products.
- c. Ensure the development of policies, guidelines, codes of practice and legislative amendments that relate to the regulatory process through appropriate consultations and through coordination with other national governments and international coordinating bodies.
- d. Develop effective information and communications by:
 - ☐ notifying interested parties of applications;
 - ☐ providing information to interested parties regarding proposed and final regulatory decisions;
 - ☐ notifying interested parties of proposed amendments to policies, guidelines, legislation and codes of practice;
 - ☐ maintaining the national Pest Management Information Service; and
 - ☐ maintaining a database of submissions and product regulatory status.
- e. Review public comments received as a result of notification of proposed amendments to policies, guidelines, legislation, codes of practice and proposed regulatory decisions.
- f. Audit compliance and enforce the legislation.
- g. Coordinate and monitor implementation of policies.
- h. Consult and liaise with federal departments, provincial and territorial governments, other national governments and international coordinating bodies.
- i. Examine mechanisms to encourage registrants to submit applications for new active ingredients simultaneously in Canada and the U.S. or the EU.
- j. Promote measures that discourage the non-judicious use of pest control products through appropriate mechanisms such as enforcement and education.



Appendix I: Roles of the Pest Management Regulatory Agency

- k. Develop a risk-reduction policy for all use sectors, including agriculture, forestry, industrial, commercial and domestic sectors, following appropriate consultations and taking into consideration available and potential pest management strategies that are viable.
- l. Maintain an information base on research projects and monitoring trends in research both nationally and internationally and identify and prioritize areas where research is needed through consultation and liaison with organizations involved in research into alternatives and integrated pest management, such as federal and provincial departments, industry, users, non-governmental organizations and international partners.
- m. Heighten awareness of alternative pest management strategies by, among other things:
 - C developing an information base on ecologically sound pest management strategies;
 - C publishing a newsletter on alternative pest management strategies; and
 - C publishing and updating, on a regular basis, an overview on Canadian pest problems and on preventive and alternative control strategies.