Health Canada Santé Canada

Evaluation of the Pest Management Regulatory Agency's Cost Recovery Initiative

Presented to

Health Canada
Departmental Audit and Evaluation Committee

April 2006

Canada

COST RECOVERY INITIATIVE EVALUATION

MANAGEMENT RESPONSE ACTION PLAN

PEST MANAGEMENT REGULATORY AGENCY

MARCH 20, 2006

COST RECOVERY INITIATIVE

RECOMMENDATION	PMRA'S MANAGEMENT RESPONSE	PMRA AREA OF RESPONSIBILITY	PROPOSED TIMEFRAME
1. Seek clear guidance from the Minister of Health, in consultation with the Minister's colleagues on the Treasury Board, regarding an appropriate level of cost recovery for the regulation of pest control products, and to set the Agency's A-base to reflect the difference between the level of cost recovery so realized and total costs incurred to satisfy PMRA's mandate. Input from external stakeholders and such information as the findings from the business impact survey conducted for the CRI evaluation will need to be considered in reaching such a decision, as would potential implications for submission examination timelines.	**Agreed** -- PMRA will conduct analysis and costing of outputs and will develop options for appropriate levels of cost recovery for presentation to and approval by the Minister of Health. Consultations with internal and external stakeholders will be conducted and the results incorporated in the development of options for the Minister. The *User Fees Act*, will guide the process. Levels of cost recovery are incorporated in the Agency's appropriations, and any adjustments would be included.	**Lead**: SPFBOD **Support**: CRO/SCD	12 to 18 months following the submission of this action plan to Treasury Board Secretariat (TBS) in August 2006.
2. Update its fees to reflect changes in its costs and activities since the introduction of the current fees in FY 1997/98, taking into account the outcome from Recommendation 1.	**Agreed** -- A revised fee structure would be proposed following a decision on an appropriate level of cost recovery (Recommendation 1) and an update of service performance standards (Recommendation 6).	**Co-leads**: SPFBOD and CRO/SCD	Up to 2 years following approval from Minister to proceed.
3a). Investigate the feasibility of applying alternative approaches to structuring its application fees to provide greater flexibility to more closely match submission examination costs to fees charged, for example, by using the suggested modular fee structure option. **3b).** Investigate the feasibility of adopting a system to measure the actual time spent by staff on the conduct of submission examination and other PMRA activities – for example, through the use of a time tracking system or periodic activity surveys – to provide the detailed time and cost information required to more closely match costs and fees.	a) **Agreed** -- When producing a proposed revised fee structure, applying alternative approaches to provide greater flexibility will be considered and incorporated where feasible. b) **Agreed** -- PMRA is committed to time tracking/activity and will investigate options for time tracking/activity costing. This information will be used in producing a proposed revised fee structure.	**Lead**: SPFBOD **Support**: CRO/SCD	Up to 2 years following approval from Minister to proceed.

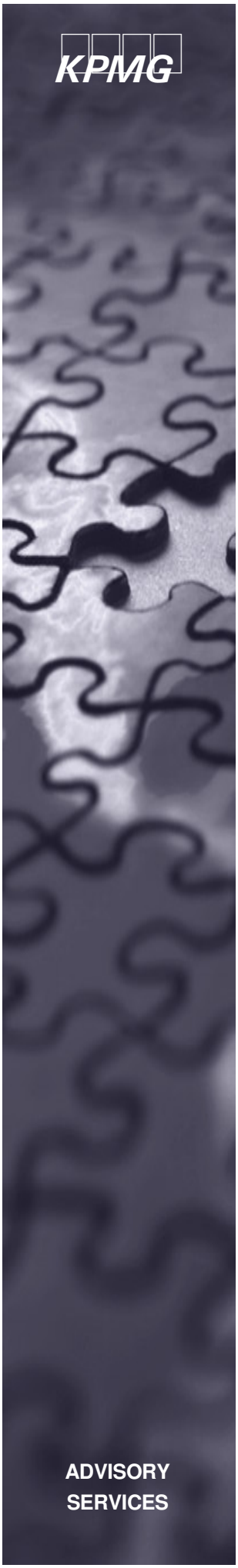
RECOMMENDATION	PMRA'S MANAGEMENT RESPONSE	PMRA AREA OF RESPONSIBILITY	PROPOSED TIMEFRAME
4. Periodically review the alignment of fee levels and structures with underlying costs and changes in cost structures, and make changes where necessary. We recommend that such reviews be conducted at least every five years, and more frequently, if time and cost information demonstrates that costs and fees are diverging. Consideration should be given to establishing a formula basis for adjusting fee elements, for example, to accommodate changes in labour costs that account for close to 80% of PMRA's total costs, subject to satisfactory performance by the Agency against performance standards.	**Agreed** – PMRA will conduct periodic reviews of the fees level and structure as required by federal government policy and when resources are available. *User Fees Act* will guide the process and industry consultations will form part of the process.	**Co-leads**: SPFBOD and SCD	Up to 2 years following approval from Minister to proceed.
5. PMRA should consult with EPA, and potential participants in future joint reviews, to determine how fees could be assessed for joint review submissions without creating disincentives for simultaneous application and registration of new products, and how such a mechanism could be incorporated into PMRA's, and EPA's, future fee schedules.	**Agreed** – PMRA will consult with EPA and with potential participants in future joint reviews and other stakeholders as required by the *User Fees Act*. Next steps would be derived from the result of this consultation, the Minister's decision regarding the level of cost recovery (Recommendation 1), and the outcome of any fee review that may be undertaken.	**Lead**: CRO/SCD	Current and as required.
6. Issue an updated Management of Submissions Policy incorporating revisions and additions made to the performance standards for examining submissions and other elements of the submission management processes since the Policy was first issued in June 1996.	**Agreed** – The Evaluation Steering Committee for PMRA's Cost Recovery Initiative expressed sn interest in an updated policy A revised Management of Submissions Policy will be developed as part of any proposed revised fee structure. Industry stakeholders will also be consulted on the revised policy.	**Lead**: CRO/SCD	Up to 2 years following approval from Minister to proceed.

RECOMMENDATION	PMRA'S MANAGEMENT RESPONSE	PMRA AREA OF RESPONSIBILITY	PROPOSED TIMEFRAME
7. Continue to aggressively pursue current initiatives to improve the efficiency of service delivery by such means as: **a)** International harmonization of review elements and standardization of templates and work sharing, especially with the U.S. EPA. **b)** Working with applicants to encourage their participation in joint reviews and work sharing. **c)** Use of review monographs prepared by equivalent pesticide regulatory agencies in other jurisdictions. **d)** The introduction of electronic submissions and their adoption by industry.	**Agreed** – PMRA will: Continue to actively pursue current initiatives and to look for other means to improve efficiency such as best practices in other regulatory jurisdictions and technology improvements. Continue to actively work with industry and other stakeholders to encourage their full participation regarding IT initiatives such as electronic submissions, sharing of reviews, joint reviews within the NAFTA context, as well as, more global coordination of submissions in the OECD context.	**Lead**: CRO/SCD	Current and ongoing.
8. Conduct detailed reviews of performance and possible fee-related issues that may be limiting: **a)** The rate of introduction of new products (Category A submissions), as identified in the business impact survey conducted as part of this evaluation. The performance of the AAFC-PMRA Minor Use program to facilitate the introduction of new products for minor use applications, and the extent to which current cost recovery fees and their application may be limiting the broader introduction of pest control products for minor use applications. **b)** Based on the findings from these investigations, determine how any limiting factors attributable to the CRI or other aspects of PMRA's performance may be modified to minimize future barriers to the provision of suitable pest control products to Canadian users. (It is likely that these two aspects of the supply and demand for pest control products will overlap and a joint, or parallel, study would likely afford opportunities for common lines of enquiry and data gathering).	a) The rate of introduction of new products in Canada continues to be an issue, and PMRA will continue to work with industry including individual companies, growers and other stakeholders to encourage manufactures to make submissions to Canada. PMRA will continue to monitor and report on performance against established standards. Analysis of the fee structure will consider the implications for new products in Canada. b) The work outlined in Recommendation 7 will continue with industry's participation, and will facilitate the entry of new actives into Canada. This will support the extension of minor uses on these new actives. In addition, the minor use joint review program, now underway, also facilitate minor use accessibility in Canada. Under this program, Agriculture and Agri-Food Canada and the United States Department of Agriculture (IR-4) develop the supporting data and the submissions jointly for minor uses. PMRA and US EPA review the applications and make decisions jointly.	**Lead**: CRO/SCD **Support**: SPFBOD	Current and ongoing.

RECOMMENDATION	PMRA'S MANAGEMENT RESPONSE	PMRA AREA OF RESPONSIBILITY	PROPOSED TIMEFRAME
9. We strongly endorse the inclusion of performance expectations linked to the Agency's 2003-2008 Strategic Objective - to provide timely access to new, safer and effective pest control products - in the performance agreements of the Agency's senior management. We recommend that PMRA review the alignment of the performance expectations in senior managers' performance agreements relating to this Strategic Objective to ensure due attention is paid to the timely and efficient conduct of product evaluations and re-evaluations. This element of the performance agreements should have equal weight with performance expectations relating to applicable elements of the Agency's other two 2003-2008 Strategic Objectives, regarding protection of human health and the environment from unacceptable risks associated with pest control products, and to provide a workplace of choice.	**Agreed** - The performance agreements and evaluations of the Agency's senior managers will continue to contain performance expectations related to timely and effective product evaluations and re-evaluations, as well as other policy and administrative measures.	**Lead**: Executive Director	Current and ongoing.

RECOMMENDATION	PMRA'S MANAGEMENT RESPONSE	PMRA AREA OF RESPONSIBILITY	PROPOSED TIMEFRAME
10. PMRA introduce a more formal system of regular performance reports to registrants, users and other stakeholders that build upon the recommendations of the recent report on performance standards and results presented in the 2003 Agency's Progress Report. Aspects of performance that should be considered in the design of the system include, as a minimum: **a)** Numbers of products registered, withdrawn or rejected, by category; average and median times to decision; distributions of times to decision around the applicable performance standards; and the relative incidence of ideal and non-ideal submissions; and significance of different contributions to these outcomes (for example, screening, review, applicant, deficiency, and consultation times). **b)** Periodic surveys of satisfaction among registrants and other key stakeholder groups regarding PMRA's performance, similar to the surveys conducted by the U.K. Pesticides Safety Directorate. **c)** Performance in examining and registering products of particular interest to stakeholders, such as joint reviews with the EPA, reduced risk products, minor use products. **d)** Progress in achieving process efficiency improvements, and their impacts. **e)** Progress in the conduct of re-evaluation of existing pesticide products. **f)** Compliance performance, and compliance issues encountered.	PMRA will continue to improve and evolve the reporting system and the format and content of the Annual Report in consultation with stakeholders. a) PMRA will consider these elements in its reporting. b) PMRA will consult with stakeholders regarding its performance, will identify areas for improvement, and implement corrective measures, where feasible. PMRA will continue to report at meetings of Economic Management Advisory Committee and Pesticide Manafactures Advisory Council, and on its website regarding its performance and progress for items outlined in ©) through (f). The Annual Report also includes some of this information.	**Lead**: CRO/SCD **Support**: ASRAD	Current and ongoing.
11. The Economic Management Advisory Committee (EMAC) develop a new strategy and work plan to proactively guide its work on advising the Executive Director on specific ways to improve the efficiency of the submission examination process and timeliness of submission decisions.	EMAC was established 9 years ago and a review of its mandate and structure are needed to ensure its continued effectiveness. PMRA will take into consideration the role of EMAC when considering improvements to the submission examination process and the timeliness of submission decisions. The role of EMAC will also be considered during consultations related to cost recovery.	**Lead**: AMC	Up to 2 years following approval from Minister to proceed.

RECOMMENDATION	PMRA'S MANAGEMENT RESPONSE	PMRA AREA OF RESPONSIBILITY	PROPOSED TIMEFRAME
12. Notwithstanding the fact that PMRA's fee dispute process has functioned as intended, PMRA should establish a second level of independent appeal for fee disputes. In this regard, PMRA should consider a similar approach to the approach used for fee disputes regarding cost recovery for therapeutic products elsewhere in Health Canada. As with the current mechanism, the mandate of this appeal level should be to review the interpretation and application of the fee regulations, not the philosophical basis and structure of the fee regulations.	The Office of Revenue and Costing has developed a proposal to implement a Departmental Dispute Management Process and received approval from the Departmental Executive Committee - Operations to conduct internal and external consultations on Health Canada's Resolution and Dispute Management Process. The goal of this process will be to address disputes regarding existing and proposed new fees, and will be used for all cost recovery activities at Health Canada. PMRA has been a participant in the development of the proposal.	**Lead**: Office of Revenue and Costing	Ongoing - PMRA will continue to participate in this process.



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ADVISORY SERVICES

FINAL REPORT
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Evaluation Of The Pest Management Regulatory Agency's Cost Recovery Initiative

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I. Introduction

This chapter summarizes the objectives and context for the conduct of an evaluation of the Pest Management Regulatory Agency's Cost Recovery Initiative (PMRA CRI), implemented in April 1997. The evaluation is in keeping with good management practices and also responds to a commitment in the CRI *Regulatory Impact Analysis Statement* (RIAS) published in April, 1997, to periodically review its fee structure (albeit not at the end of the initial two-year period of the CRI envisaged in the RIAS), and a requirement in the Treasury Board's *Cost Recovery and Charging Policy* (1997) to conduct periodic reviews of their user charges and needs in response to changes in cost structures and levels and/or changes in service levels.

The following sections summarize the objectives of the evaluation, the definition and scope of the CRI, and the requirements of the underlying government policies relating to cost recovery by regulatory agencies. The final section provides a brief overview of the mission, strategic objectives, and business line structure and resources of PMRA.

A. Evaluation objectives

The Statement of Work for this evaluation required us to:

> *… provide a value-added analysis for the PMRA, including substantiated recommendations, in order for the PMRA to make informed decisions regarding any alternatives and/or modifications which may be required to the application and maintenance fees charged and activities, including (but not limited to) fee levels, structure and/or other related cost recovery parameters. (p.2)*

In meeting this overall objective we were asked to consider specific aspects of:

- ***The effectiveness of the costing model used by PMRA*** (Task 1), including:
  - a) Identify PMRA activities performed related to pesticide regulation for the last complete fiscal year (i.e., FY 2002-03).
  - b) Review all current PMRA costs related to pesticide regulation; refer to PMRA's costing by business line.
  - c) Assess the PMRA costing model for activities and cost recovery fees and determine the degree to which the costs are indicative.
  - d) Determine how sensitive the costs identified above are to the underlying assumptions of the costing model.
  - e) Examine the relationship between fees charged, PMRA costs incurred and regulatory activities performed/provided, broken down by sectors within the pesticide industry (i.e., what costs are included and excluded, and the appropriateness of these assignments).
  - f) Compare ratios of fees to costs for PMRA services.

g) Identify any gaps in the current fee structures or in the existing collection, compliance and enforcement systems.

h) Present options concerning the fee schedules in light of the PMRA's regulatory activities and the objectives of the Cost Recovery Initiative and identify any constraints to their implementation.

- ***The impact of the CRI on PMRA's performance*** (Task 2), including:

  a) Analyze all PMRA activities in terms of the timeliness of decisions, service standards, actual performance, PMRA's responsibilities under the regulations, workflow and communications with stakeholders.

  b) As a means of assessing the impact of the introduction of the CRI on the PMRA's processes and organization, develop a model to evaluate the impact of the introduction of the CRI on the Agency's five business lines to isolate cost recovery as a factor with clear identification of confounding variables in the analysis.

  c) Determine whether the CRI has contributed to the delivery of an efficient service (i.e., at the least cost, while meeting the Agency's regulatory responsibilities and quality and time specifications). Identify areas, (including the two below) where the CRI led to more efficient service delivery and why; and provide suggestions for improvement, where applicable.

     1. Performance standards and timelines of registration decisions;
     2. Effectiveness of consultation, feedback and dispute resolution mechanisms.

- ***The impact of the CRI on registrants, users of pest control products and other stakeholders*** (Task 3), including:

  a) Identify, describe and assess the impacts (positive and negative) of the PMRA's CRI on each of the stakeholder groups listed below:

     - Large, medium and small registrants, distributors, wholesalers and retailers.
     - Consumers, growers, and other users, the Canadian public, and provincial ministries of Agriculture and Environment.

  b) As part of the overall impact assessment, provide conclusions with regard to the total impact of the PMRA's CRI on the various stakeholders.

PMRA's Management Planning and Coordination Division was responsible for managing the evaluation process. Two review committees—the Evaluation Steering Committee and the Technical Sub-Committee—composed of internal and external stakeholders, provided input to the formulation of the Terms of Reference for the evaluation and review of the interim and final deliverables. The Terms of Reference for these two committees and their members are provided in Appendix 1 to this report. Details of the methodologies used for each of the three principal lines of enquiry are provided in the introductions to the respective Task chapters and supporting appendices.

B. Definition and scope of the PMRA CRI

The Statement of Work for this evaluation refers to the types of fees charged by the Agency (application and maintenance fees) and a set of objectives abstracted from the Treasury Board *Cost Recovery and Charging Policy* (1997). These objectives refer to promoting more efficient use of government services, introducing business-like and client-oriented practices in service provision, and ensuring that costs that primarily benefit specific subsets of the population are recovered from those beneficiaries (and the costs of other, public benefit services are funded through public appropriations collected via taxes).

The 1996 *Discussion Paper: Cost Recovery Analysis*, which is generally regarded as providing the foundation for the Agency's approach to cost recovery, provided an outline of program costs and an analysis of the Agency's proposed fee structure. The paper also included a section on Cost Avoidance/ Cost Reduction/ Performance Targets, which was referred to as an element of the cost recovery initiative, a brief discussion of avenues for achieving operational efficiencies and cost reductions, and a commitment to introduce a *Management of Submissions Policy (MOSP) aimed at reducing elapsed time for review* and establishing *performance targets for all submission types*.[1] The MOSP was subsequently issued in June 1996 and established performance standards for Category A through to E, which were progressively implemented from July 1, 1996 (Category A) to April 1, 2000 (Category D URMULEs and Category E). Additional performance standards were added, effective June 1, 2002, for reduced risk products, such as joint reviews, reduced risk chemicals, microbial products, pheromones, and other biopesticides.

The RIAS prepared by the Minister of Health in April 1997, which was an outcome from the Agency's consultations on cost recovery, presented an analysis of the expected impacts of the PMRA cost recovery fees. It re-affirmed the linkage of the cost recovery program to the MOSP and its interim performance standards and the re-engineered submission review process. The accompanying fee regulations and *Guidance Document on Pest Control Product Cost Recovery Fees* established the current fee structure, which was developed within the guidelines set by the 1989 Treasury Board Policy on external user charges.

The RIAS noted that some registrants had suggested that application fees be linked to performance standards, as a way of motivating the Agency to consistently meet the standards. The Minister of Health warned against the use of such a linkage, which had traditionally only been used in contractual situations where a higher fee could also be applied for superior performance, due to *potential crown liability, perception of conflict of interest, and operational implications*. The RIAS also went on to note that *(t)he imposition of penalties may lead to unnecessarily conservative decision making on the part of the regulator by providing an incentive to make a hasty negative decision rather than seeking creative ways to strike the often elusive balance between risks and benefits*.[2]

The discussion in the RIAS also included commitments by PMRA to create an economic stakeholder advisory committee to the Executive Director; to publish an annual report on costs, activities and performance; and, to establish a complaint and redress mechanism that meets the

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1 PMRA, *Discussion Paper: Cost Recovery Analysis*, Pest Management Regulatory Agency, Health Canada, April, 1996.

2 Minister of Health, *Regulatory Impact Analysis Statement: Fees for the Right and Privilege to Manufacture or Sell Pest Control Products and for the Registration Application Examination Service*, HC/96-38-M, April 16, 1997, p.9.

requirements of the Treasury Board service standard initiative for applicants that wish to dispute the fees assessed.

These various sources of information suggest that the core structure and content of the PMRA CRI is a "package" consisting of:

- A set of fees based on PMRA's best estimates of the cost of operating the Agency in FY 1997/98 (remembering that the PMRA was a start-up operation formed from the separate pesticide regulation activities undertaken by Agriculture and Agri-Food Canada, Health Canada, Natural Resources Canada and Environment Canada) and a negotiated agreement between the government, industry and other stakeholders regarding the amount of funding expected to be generated through cost recovery. The agreed amount of revenue to be collected via cost recovery fees was $12.3 million, which represented 45% of the estimated FY 1997/98 PMRA budget, of $27.6 million.
- A set of interim performance standards that PMRA has aimed to hold itself to, and measured its performance against.
- A mechanism for consultation and communication with economic stakeholders—the Economic Management Advisory Committee—with a mandate to *provide strategic advice to the PMRA on ways to improve efficiency and cost effectiveness without compromising the mandate of the agency*.
- A commitment to publish an annual report on performance, which currently takes the form of briefings on performance results to EMAC and publication of those presentations on the EMAC section of the PMRA web site.
- A fee dispute resolution process.

C. Policy framework for cost recovery

Guidance to departments regarding cost recovery is provided in Treasury Board cost recovery policies. At the time of PMRA's consultations on the introduction of a CRI and subsequent formulation of PMRA fees the policy context and guidance was provided by the 1989 Treasury Board policy. In April, 1997, an updated version of the policy, the *Cost Recovery and Charging Policy* was introduced. In turn, the 1997 policy requirement for the conduct of periodic reviews to ensure user-charge policy provided the context for this evaluation of the CRI. Accordingly, we have used the 1997 policy as the principal frame of reference for assessing elements of the CRI and their impacts.

In introducing this update to the original 1989 cost recovery policy, Treasury Board noted that departments should *implement user charges for services that provide identifiable recipients with direct benefits beyond those received by the general public, unless overriding policy objectives would be compromised*. The Board also noted that external charges *cannot be used simply as a means of generating revenue to meet the funding requirements of a department or agency,* and that *there must be a relationship between the fee charged and the cost of the good or service, or the value of the privilege provided to clients*. The principal objectives of the Policy were to:

- *Promote the efficient allocation of resources (i.e., to eliminate the excess demand that often exists with "free goods", by subjecting programs to a market test of supply and demand).*
- *Promote an equitable approach to financing government programs, mandatory or otherwise, by fairly charging clients or beneficiaries who benefit from services beyond those enjoyed by the general public. …*
- *Earn a fair return for the Canadian public for access to, or exploitation of, publicly-owned or controlled resources.*[1]

The policy requires departments to follow appropriate costing and pricing practices; to set fees on the basis of clear, and preferably agreed, service standards and performance measures unless it can be demonstrated that it is not practical or reasonable; to establish a fee dispute resolution process; and, to conduct periodic reviews to ensure user-charge requirements are being met. The structure of the PMRA CRI is broadly consistent with the expectations of the 1997 Treasury Board *Cost Recovery and Charging Policy*.

In developing our recommendations—that is, looking forward to the future application of cost recovery by the Agency—it was necessary to take into account two more recent cost recovery requirements:

- ***2003 update to the Treasury Board Cost Recovery Policy.*** In August 2003, Treasury Board issued a new version of its policy—now called the *External Charging Policy*. This new policy strengthens or clarifies many aspects of the prior version, such as provisions relating to the establishment of performance standards, performance reporting, the resolution of fee disputes, and removes the requirement for departments to work with program beneficiaries (clients) to determine an appropriate allocation of private and public benefits.
- ***User Fees Act, an act providing for parliamentary scrutiny and approval of user fees set by regulating authorities (formerly Bill C-212).*** This Bill, passed in March 2004, shares many of the same requirements for establishing and consulting on proposed new fees and fee changes with the Treasury Board policy on external charges. Beyond these requirements, it provides for Parliamentary review and approval of proposed new and amended fees, establishment of independent advisory panels to adjudicate fee disputes, fee reductions if a regulatory agency fails to meet performance standards, and requires Ministers to report to Parliament on fees in effect in their portfolios and the operation of their fee dispute panels.

Treasury Board is currently considering whether to modify or revoke the 2003 cost recovery policy and how to implement the requirements of the *User Fees Act*.

D. About PMRA

PMRA defines its Mission as being to *protect human health and the environment by minimizing the risks associated with pest control products in an open and transparent manner, while enabling*

[1] Treasury Board of Canada Secretariat, *Cost Recovery and Charging Policy*, 1997. (Accessed at: www.tbs-sct.gc.ca/archives/opepubs/tb_h/crp_e.asp.)

access to pest management tools, namely, these products and sustainable pest management strategies. Legislative authority for the Agency's functioning is provided by the *Pest Control Products Act* and Regulations. The Act *provides the authority for decision making on the basis of risk assessment and risk management; it requires a risk based, proactive approach for new products which are subject to premarket approval, and it requires a continued regulatory vigilance to ensure that registered products remain acceptable*.[1]

According to Health Canada's 2002-03 *Departmental Performance Report* and 2003-04 *Report on Plans and Priorities*, PMRA has three priorities for its work in support of this Mission:

- Ensure safe and effective pest control products.
- Ensure compliance with the *Pest Control Products Act*.
- Ensure sustainable pest management practices that reduce reliance on the use of pesticides.

Business planning and budgeting for the Agency is based on five business lines, each of which involves varying combinations of resources from the Agency's ten divisions:

Business Lines	Organization Divisions
BL 1 – New Product Evaluation—Makes regulatory decisions within specified performance standards on applications for the registration of new pest control products through the conduct of human health, safety and environmental risk assessments, efficacy assessments, value assessments and the establishment of Maximum Residue Limits (MRLs) for pest control products. **BL 2 – Registered Product Evaluation**—Ensures that registered products meet current standards by periodically re-evaluating the data supporting the registered technical active ingredients and end-use products and reflecting the necessary changes in the regulatory status and labeling of the products. **BL 3 – Compliance**—Promote, maintain and enforce compliance with the *Pest Control Products Act* through investigations, inspections and consultations that are coordinated with provincial and territorial governments and other federal departments. **BL 4 – Sustainable Pest Management**—Contribute to sustainable pest management (SPM), focusing on development of risk reduction strategies, working in partnership with other government departments, provincial/territorial governments and stakeholders to reduce risks from pesticides in major pesticide use sectors, measuring and reporting on risk reduction trends, facilitating the registration of reduced risk products, and informing and advising on SPM. **BL 5 – Business Line Improvement**—Develop Agency strategic initiatives for information technology, cost recovery, legislative changes, and all development projects that cross divisional lines in support of Agency commitments to improve performance and reduce costs while maintaining a high level of protection of health and the environment.	▪ Executive Director's Office (EDO) ▪ Chief Registrar's Office (CRO) ▪ Submission Coordination Division (SCD) ▪ Efficacy and Sustainability Assessment Division (ESAD) ▪ Health Evaluation Division (HED) ▪ Environmental Assessment Division (EAD) ▪ Compliance, Lab Services and Regional Operations Division (CLSROD) ▪ Alternative Strategies and Regulatory Affairs Division (ASRAD) ▪ Management Planning and Coordination Division (MPCD) ▪ Business Line Improvement and Technology Development Division (BLITDD)

[1] PMRA, *Technical Paper: A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency*, Science Policy Notice: SPN2000-01, Ottawa, December 22, 2000, p.3. (Accessed at: www.hc-sc.gc.ca/pmra-arla/english/pdf/spn/spn2000-01-e.pdf.)

PMRA's total operating budget for FY 2002-03 was $38.7 million, and the total number of FTE's utilized was 424.2 of which 51% were engaged in New Product Evaluation (BL 1) work, 21% in Registered Product Evaluation (BL2) work, 20% in Compliance (BL 3) work, 5% in Sustainable Pest Management (BL 4), and 3% in Business Line Improvement (BL 5) work.

II. Task 1 — Effectiveness Of The PMRA Costing Model

This section provides a summary of the scope of Task I, the methodology used in completing Task I and the resulting analysis and conclusions. Appendix 2 provides a glossary of terms and acronyms used throughout the report to describe aspects of the CRI, other aspects of PMRA performance and operations, and the analysis undertaken in Task I.

A. Scope of Task I

In Task I we assess the effectiveness of the CRI costing model and its application in the development of a fee structure and pricing model. As set out in the Terms of Reference for the evaluation, the sub-tasks in Task I were to:

a) Identify PMRA activities performed related to pesticide regulation for the last fiscal year (i.e., FY 2002-03).

b) Review all current PMRA costs related to pesticide regulation.

c) Assess the PMRA costing model for activities and cost recovery fees and determine the degree to which the costs are indicative.

d) Determine how sensitive the costs identified above are to the underlying assumptions of the costing model.

e) Examine the relationships between fees charged, PMRA costs incurred and regulatory activities performed/provided, broken down by sectors within the pesticide industry. (That is, what costs are included and excluded, and the appropriateness of these assignments?)

f) Compare ratios of fees to costs for PMRA services.

g) Identify any gaps in the current fee structures or in the existing collection, compliance, and enforcement systems.

h) Present options concerning the fee schedules for pesticides in light of the PMRA's regulatory activities and the objectives of the Cost Recovery Initiative and identify any constraints to their implementation. Examples of constraints are costs, timelines and technological changes.

B. Methodology - time period of analysis

We believe that the focus of the evaluation is not on the implementation of the CRI for pesticides, but on its impacts and effectiveness as an operating and relatively mature program. Accordingly, in Task I we focus on an analysis of the CRI for pesticides in FY 2002/03 (the most recent fiscal year for which data were available when the evaluation began in the fall of 2003).

To confirm that our focus on FY 2002/03 is appropriate and does not bias the cost analysis, we undertook two lines of enquiry. We:

- Asked line managers at PMRA to identify any out-of-the-ordinary events that occurred during FY 2002/03 and the extent to which these events may have had an impact on PMRA costs and revenue in that year;
- Analyzed, at a high level, costs and fee revenue over a multi-year period to confirm FY 2002/03 costs and fees are consistent with previous years.

The remainder of this section describes each of these lines of enquiry. Based on this analysis we conclude that the focus on FY 2002/03 is appropriate and does not bias the results of the evaluation.

1. Insight from PMRA management

PMRA managers identified the following events and activities that may have caused FY 2002/03 costs and revenue patterns to differ from prior years:

- An updated program for minor use products was introduced, with the intention of improving PMRA's capacity to perform examinations of minor use submissions[1], and linked to the creation of a minor use initiative at AAFC to increase data generation capacity for priority minor use products. Initial work was done to add new capacity for agreed activities.
- An enhanced re-evaluation program was introduced in FY 2001/02 with links to the U.S. Environmental Protection Agency's reregistration program, and involved substantial work during FY2002/03 to get the program up and running. The enhanced program is designed to enable the re-evaluation of pest control products registered prior to January 1, 1995.
- A relatively large number of new employees were added to the Review Submissions sub-element of the New Product Evaluation business line during FY2002/03 (for a net increase of 27 FTEs) to enable the Agency to meet requirements related to the new *Pest Control Products Act* and associated activities. Requirements for existing staff members performing review activities to provide orientation, training and guidance for these new employees may have placed an additional demand on the time of the review staff, compared to earlier years.

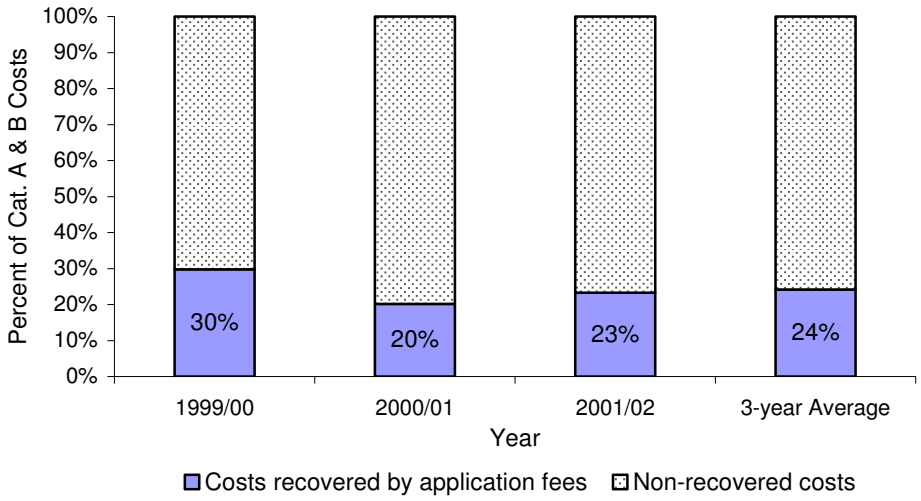
PMRA managers indicate that, on balance, they believe that the use of FY 2002/03 as a primary focus for our revenue and cost analysis would not create a bias. They indicated that every year is somewhat different and that the use of FY 2002/03 provides an appropriate basis for the review of the effectiveness of the CRI costing model used by PMRA.

[1] We have used the term "submission examination" throughout the report to refer to the process used by PMRA to reach decisions for applications to register new products, amend details of existing registrations, establish import MRLs and approve research permits. The term "review *process*" is used to refer to an element of the submission examination process: the detailed evaluation of complete submissions and formulation of proposed regulatory decisions.

2. Historical costs and fee revenues

To supplement our own investigation, we have drawn upon an analysis prepared by PMRA staff that is based on FY 1999/00 to FY 2001/02. Exhibit II-1 shows annual revenues and operating costs for that period to examine Category A and B submissions.

Exhibit II-1
Percentage of PMRA operating costs recovered through application fee revenues (New Product Evaluations, Categories A and B)[1]



Source: PMRA Cost and Revenue Analysis: Business Lines 1.1-Review, 2-Re-evaluation, and 3-Compliance.

Exhibit II-1 suggests that for Category A and Category B new product evaluations, the percentage of evaluation costs that are recovered through application fees vary somewhat from year to year, however these variations do not appear to be unduly large, and accordingly while year to year swings occur these variances do not in our opinion affect the relevance of FY 2002/03 as the primary focus for Task I of the evaluation.

C. Activities

The Terms of Reference for the evaluation required identification of PMRA activities performed related to pesticide regulation for the last fiscal year (that is, FY 2002/03).

According to the PMRA website and management, the principle activities of PMRA are to:

- Review applications for the registration of pest control products.
- Conduct science-based health, environmental and value (including efficacy) assessments of new pesticides before deciding if they should be approved for use in

[1] We understand from PMRA management that the methodology used by PMRA to allocate costs among submission categories in this analysis may result in a slight overstatement of the cost of Category A and Category B submissions and an understatement of costs to other submissions.

Canada, including the setting of Maximum Residue Limits for pesticides in domestic and imported food commodities.

- Conduct science-based health, environmental and value (including efficacy) assessments of registered pesticides according to current standards to determine acceptability for continued registration.
- Develop and implement policies and guidelines related to pesticide regulation.
- Support sustainable pest management.
- Seek efficiencies in the processing of registration applications through such means as international harmonization and electronic submission and review of pesticide registration data.
- Enforce compliance with the *Pest Control Products Act*; and disseminate information on pest management issues to the public.

In the conduct of the evaluation, we considered activities associated with all elements of PMRA. This included activities that are directly related to new product evaluation, post-registration regulation and other direct activities that are not explicitly addressed in the fee schedule, as well as for indirect activities and overhead activities (that is, activities associated with the overall management and support of the agency and a share of the overall management and support of Health Canada and other federal agencies). Exhibit II-2 identifies direct activities undertaken by staff in PMRA in the regulation of pesticides.

The activities, and associated costs, identified in Exhibit II-2 were developed using the Agency's Operations Plan for FY 2002/03. The Agency develops resource allocation estimates at the business line and sub-activity level as part of its annual management planning and accountability cycle, which includes appropriate review and due diligence by senior management.

In essence, the primary activities in the new product evaluation business line (Business Line 1.0) are undertaken to support regulatory decisions on applications for the registration and amendment of new and existing pesticides through the conduct of human health, safety and environmental risk assessments, efficacy assessments, value assessments and the establishment of Maximum Residue Limits (MRLs) for domestic and imported food.

Current approaches to budgeting and cost management in PMRA are not based on breakdowns of the estimated volumes of different submissions and associated amounts of work required to examine the different types of submission categories. Instead, the Agency's annual work plans focus on expected resource requirements for various submission examination elements (for example, chemistry, toxicology, value and effectiveness reviews) across all submissions. Accordingly, the following analysis of costs and fee revenue focuses on more aggregated cost components and the overall fee types (that is, new product evaluation and maintenance fees) because detailed information to support analysis by fee element is not available.

Exhibit II-2
Direct activities undertaken by PMRA in the regulation of pesticides and the associated salary cost, FY 2002/03

Business Line / Activity		Salary Cost[1] ($'000s)	Percent of Salary Cost
1.0	**New Product Evaluation**		
	Labelling	810.6	3%
	Chemistry	500.5	2%
	Toxicology data	2,900.6	11%
	Exposure data	792.9	3%
	Metabolism and residue data	1,518.4	6%
	Environmental fate and toxicology data	1,842.4	7%
	Value and effectiveness data	2,862.1	11%
	Other	1,121.5	4%
2.0	**Registered Product Evaluation**		
	Re-evaluation reviews	4,469.7	17%
	Other	794.5	3%
3.0	**Compliance**		
	Investigation	1,897.1	7%
	Inspection	2,376.4	9%
	Other	483.0	2%
4.0	**Sustainable Pest Management**		
	Develop/adopt of SMP system	1,324.9	5%
	Other	7.8	0%
5.0	**Business Line Improvement**		
	Electronic environment	1,482.4	6%
	Other	419.6	2%
	TOTAL	25,604.4	100%

Source: KPMG Analysis

D. Overview of costs for FY 2002/03

The Terms of Reference for the evaluation required review of all current PMRA costs related to pesticide regulation.

We developed our estimate of PMRA related costs in FY 2002/03 based on expenditures made by PMRA and Health Canada and an estimate of non-cash items such as depreciation and cost of capital. We believe that, overall, this methodology represents a reasonable estimate of full costs as required by the Treasury Board policy for external charging.

The cost estimates are based upon the cost of direct, indirect and overhead activities. Direct costs are incurred by PMRA's operational divisions that participate in activities that are directly related to pesticide regulation and by the Canadian Food Inspection Agency, which through a Memorandum of Understanding provides primary inspectors for monitoring the safety and appropriate use of registered pesticide products. While some overall support is provided by the Corporate Services Branch of Health Canada, a large number of the functions generally provided by Corporate Services are instead provided by PMRA. Corporate Services pays only for a reduced scope of central support. (These services largely relate to central systems and the fit up of new complement and are identified in Exhibit 1, Appendix 3.)

[1] Estimated salary costs are presented with the activity listing to help the reader assess the relative level of effort associated with activities undertaken by PMRA.

We estimate that the total cost to complete PMRA regulatory responsibilities in FY 2002/03 was $43.4 million. (See Exhibit II-3).

Exhibit II-3
PMRA direct, indirect and overhead costs, FY 2002/03 ($000's)

	New Product Evaluation	Post-Registration[1] & Business Line Improvement	Total
Salary	11.227.4	14,376.9	25,604.3
Operating	913.0	1,074.8	1,987.8
Subtotal	12,140.4	15,451.7	27,592.1
Indirect	973.9	961.5	1,935.4
Overhead	6,885.1	6,952.1	13,837.2
Full cost	**19,999.4**	**23,365.3**	**43,364.7**

1. Activities in the Re-evaluation, Compliance, Sustainability business lines

Source: KPMG Analysis

Appendix 3 provides a description of the basis for the estimated cost of PMRA services in FY 2002/03 shown in Exhibit II-3.

E. Costing model

The Terms of Reference for the evaluation required assessment of the PMRA model for activities and cost recovery fees and determination of the degree to which the costs are indicative of the actual cost of recoverable activities.

As outlined in our proposal and in the Project Management Plan, we have developed an independent high-level model of costs in FY 2002/03 (the KPMG model) to use as a basis to assess whether costs developed using the PMRA model are indicative of the actual cost of recoverable activities. To address this requirement, in this section we:

- Review the requirements for a costing model;
- Describe the model developed by KPMG to estimate the cost of recoverable activities in FY 2002/03 (the KPMG model);
- Describe the model that was used by PMRA in 1995-96 to develop preliminary estimates of the anticipated cost of pesticide regulation (the PMRA model). The PMRA model was used as the basis for discussion with stakeholders; and
- Compare FY 2002/03 costs developed using the KPMG model and the PMRA model.

Our comments on the PMRA model are based on our review of the documentation of the original model that was available, supplemented by input from PMRA management, many of whom were involved in the development of inputs to the PMRA model.

1. Costing model requirements

A costing model that is used as the basis for establishing fees for cost recovery is, by necessity, a forecasting model. It estimates future costs and attributes these costs to activities, some or all of which are recoverable from users.

The development of a forecasting model requires consideration of future events that may or may not come to pass. In developing a forecasting model it is necessary to consider the time period over which the fees schedule will be used. The anticipated time period for the fee structure sets the forecast period for the model. For example, if a fee structure is to be used for a five-year period, cost estimates should reflect anticipated costs for that same five-year period.

Once the forecast period has been determined, several additional questions must be considered, for example:

- What efficiency and operating changes are anticipated over the forecast period?
- What capital investments are anticipated over the forecast period?
- What should be the assumptions regarding other direct and overhead activities? (If, for example, non-recoverable activities are expected to increase or decrease, will the level of overhead support provided to recoverable activities be maintained at the same level?)

A forecasting model develops an estimated cost for recoverable services. These costs then form the basis for the development of a fee structure, which reflects anticipated costs per unit volume. The same forecast period should also apply to develop estimates of application volumes for new product evaluation and the number of registered products.

2. FY 2002/03 costs based on the KPMG model

In developing the KPMG model we estimate the cost of PMRA operations that relate to pesticides and attribute them to activities using the best available attribution method. For example, salary, benefits and other staff related costs are assigned to activities based on management's estimate of people usage by business line and business line sub-activity. Most non-staff costs are then allocated based on the staff time.

To the extent that discrete activities that relate to specific business lines are identified in the annual work plans for each PMRA business line, we assigned the cost of these activities to the appropriate fee categories (that is, new product evaluation, and maintenance fee-related re-evaluation, compliance activities)). Where activities are more general in nature, we apportioned these costs across PMRA fee categories based on the proportion of PMRA salary costs consumed by direct and indirect activities. We believe, however, that our approach is unlikely to have fully addressed the possible issue of differing rates of use of PMRA overhead support activities and resources. (For example, if maintenance activities consume a larger share of policy support than

new product evaluation, or if new product evaluation activities consume a larger share of office supplies and mail and courier services than maintenance activities, these differences are not captured in our analysis of FY 2002/03 costs.) Accordingly the cost estimates developed using the KPMG Model and presented in this section are approximate only. While we believe that these estimates are appropriate for an evaluation of this kind, we caution that further analysis would be required if the estimates were to be used for other purposes, such as for example, to develop a new fee schedule.

3. The PMRA model

The PMRA model was developed in 1995-96 based on the anticipated organization, responsibilities and resources that would be put in place in the newly formed agency to regulate pesticides. The cost estimates developed using the PMRA model were one of the inputs to consultation with industry on the establishment of the fee schedule for new product evaluations and registration of pesticides for sale in the Canadian market. The PMRA model was not updated or modified since its development in 1995-96, and accordingly does not reflect any subsequent changes in, for example, the cost of inputs or changes in the level of effort required to fulfill PMRA's mandate.

Although PMRA undertakes many activities that were anticipated in the PMRA model, how or to what extent these services are performed may differ from what was originally anticipated due to many influences including, for example, changes in:

- The size and complexity of submissions (e.g., new test protocols, and numbers of studies and range of proposed uses for a product);
- Approaches to, and the complexity of, risk assessment for regulatory decision making.
- Increased volume of submissions compared to the levels originally forecast in the analysis and development of cost recovery options for the Agency.
- Transfer of responsibility for disinfectants from PMRA to elsewhere within Health Canada, and expansion of Notification/Non-notification as an alternative to submissions for minor administrative changes to product registration details.
- New operating approaches and procedures (e.g., use of joint reviews, pre-submission consultations, electronic submissions); and
- Input prices (e.g., salaries).

Accordingly, costs in FY 2002/03 are likely to vary somewhat from the initial estimates developed using the PMRA model. Exhibit II-4 provides a summary of activities that were used to assign costs to submissions in the PMRA model.

Exhibit II-4
Summary of activities used in the PMRA Model to assign estimated costs to fees

Label:	Information to support new or change to label, new active ingredient or other related labelling, including label.
Chemistry:	Active ingredient, end use product or concentrate.
Toxicology data:	New active ingredient, new use or acute studies only.
Exposure data:	New active ingredient, major new use or other related data.
Metabolism and residue data:	New active ingredient and associated new end use product.
Environmental fate data:	New active ingredient, major new use or other related data.
Environmental toxicology:	New active ingredient
Value and effectiveness data	
User Requested Minor Use Label Expansion	
Research permit	
Own Use Import application	
Import for Manufacture and Export Permit	
Import Maximum Residue Limit	
Renewal of certificate of registration	
Annual product registration	

In the PMRA model, cost estimates were based on the full cost, which is in keeping with the Treasury Board's *Guide to Costing of Service Delivery for Service Standards*, October 1995.

Costs were assigned to activities and fee categories based on the predicted resource usage. Direct and indirect costs were assigned to activities based on the anticipated use of resources. For example, salary, benefits and operating costs were assigned based on the anticipated employee requirements to complete each sub-activity associated with the evaluation of new products. Various costs, such as training, systems support and facilities, were assigned as overhead. Overhead costs were then reallocated to the business lines based on an overall assessment of the number of full time equivalents used by the business line. Overhead includes such things as information technology services and oversight from senior management.

The primary source of resource utilization estimates in the PMRA model was senior management from the four founding departments (Health Canada, Agriculture and Agri-Food Canada, Natural Resources Canada and Environment Canada), which came together to plan the new agency. Accordingly, the exercise was to estimate costs for a new organization, which was in the process of determining procedures and workflows, concurrent with planning for the implementation of cost recovery. As an aside, while the establishment of a new agency complicated the task of estimating the cost of pesticide regulation, it enabled the organization to establish systems and procedures that considered the CRI in the overall design and resulted in a relatively discrete organizational unit that is focused on the regulation of pesticides, rather than on addressing multiple departmental mandates. Accordingly, the financial reporting systems provide relatively "clean" data for estimating the overall cost of pesticide regulation.

Exhibit II-5 presents a summary of the estimated cost of new product evaluation and post-registration regulation developed using the PMRA model. Costs were estimated based on the

estimated demand for each activity and the estimated staff time to complete each activity required in the submission examination and in the reassessment of older products and monitoring of potential impacts of products that are already in use. Other costs and overheads were assigned to each activity based on the percentage of direct resources associated with the activity.

Exhibit II-5
Summary of the PMRA Model cost estimates by type of fee ($'000s)

New Product Evaluation	$17,764.0
Post-Registration Regulation	15,991.6
	33,755.6

Source: PMRA Cost model, developed in 1995-96.

The PMRA model also provides a forecast of annual demand for submission examinations and product registration, which together with the cost estimates outlined above, forms the basis for the development of the new product evaluation fee schedule and maintenance fees. Based on the cost estimates developed using the PMRA model, discussions with industry followed, including the analysis of three fee options providing alternative approaches to the partial recovery of estimated PMRA costs. The PMRA model was used as a starting point for consultation, and was not amended to reflect the final pricing schedule that was implemented.

The user fees introduced in 1997/98 were forecast to recover about $12.3 million annually, based on the forecast volume of submissions for new product evaluations, the number of registered pesticide products derived from the Business Impact Analysis study, and the associated fees and fee reduction provisions.

4. FY 2002/03 costs versus cost estimates developed using the PMRA model

Total cost estimates for regulatory activities are substantially higher in FY 2002/03 than in the PMRA model. The PMRA model estimates the annual cost of products and services for pesticides at $33.8 million (with no provision for inflation) while the KPMG model estimates the cost of PMRA regulatory activities in FY 2002/03 at $43.4 million. (See Exhibit II-6).

Exhibit II-6
Estimated costs new product evaluation and post-registration activities for FY 2002/03 and PMRA Model ($'000s)

	FY 2002/03[1]	PMRA Model[2]	Difference	% Difference
New Product Evaluation	19,999.4	17,764.0	2,235.4	12.6%
Post-Registration Regulation	23,365.3	15,991.6	7,373.7	46.1%
Total	**43,364.7**	**33,755.7**	**9,609.0**	**22%**

1. *Based on KPMG model*
2. *Based on estimated costs developed in 1995-96 using PMRA costing model.*

The PMRA model produced estimated total costs for each new product evaluation activity and activities in support of registered products, based on data available in 1995-96. FY 2002/03 cost estimates (which were developed using the KPMG Model) suggest that, in FY 2002/03, the cost of new product evaluations was higher than the estimated cost using the PMRA model ($2.2 million or 12.6% higher). Costs of post-registration activities for FY 2002/03 (calculated using the KPMG model) are about $7.4 million (46%) higher than estimated using the original model developed by PMRA ($23.4 million versus $16.0 million).

Exhibit II-7 presents a high-level summary of the split among direct, indirect and overhead costs in FY 2002/03 and the PMRA model.

Exhibit II-7
Estimated costs for FY 2002/03 and PMRA Model ($'000s)

	FY 02/03* $'000s	PMRA Model $'000s	FY 02/03* % of Cost	PMRA Model % of Cost
Direct	25,604.3	24,028.1	59%	73%
Indirect	1,935.4	4,585.3	4%	14%
Overhead	15,825.0	5,142.3	36%	13%
Total	43,364.7	33,755.7	100%	100%

** Based on KPMG Model*

As mentioned earlier, the KPMG model estimates costs in FY 2002/03 to be approximately $43.4 million. This amount consists of approximately $26.5 million in direct costs (59% of the estimated total), $1.9 million in indirect costs (4%), and $15.8 million in overhead costs (36%). The PMRA cost model estimated total costs to be $33.8 million, with estimated overhead costs being noticeably lower and indirect costs noticeably higher. Direct costs were not substantially different in absolute terms, but represented a much higher proportion of the total estimated cost compared to the estimates from the KPMG model (73% versus 59%).

5. Sensitivity analysis

The Terms of Reference for the CRI evaluation required us to determine how sensitive the costs of PMRA's regulatory activities are to the underlying assumptions of the PMRA model. To test the sensitivity of the cost of pesticide regulation to changes in the underlying assumptions, we considered the impact on estimated FY 2002/03 costs of changes in submission volumes and the method of allocating overhead costs to direct activities.

Estimated costs varied by $3.6 million (11% of total operating costs) when the volume of submissions changed by 20%. Similarly, estimated costs varied by $0.8 million (2%) when overhead costs attributed to activities varied by 20%. (See Exhibit II-8.)

Exhibit II-8
Estimated Sensitivity of the KPMG Model to Changes in Submission Volumes and Overhead Costs

	Base (PMRA Model)	Change in submission volumes		Change in overhead costs	
		-20%	+20%	-20%	+20%
New Product Evaluation	17,763,950	14,211,160	21,316,740	17,326,154	18,201,746
Post-Registration Regulation	15,991,100	15,991,100	15,991,100	15,596,996	16,385,204
Total	**$33,755,050**	**$30,202,260**	**$37,307,840**	**$32,923,150**	**$34,586,950**

Source: KPMG analysis

F. Overview of fee revenue

The Terms of Reference for the evaluation required examination of the relationships between fees charged, PMRA costs incurred and regulatory activities performed (pre and post-registration), broken down by sectors within the pesticide industry (that is, what costs are included and excluded, and the appropriateness of these assignments). We were unable to assess costs by sector as PMRA does not track this information in its invoice files. Instead, this section includes an overall assessment of fees and fee payers.

Ideally, a review of the effectiveness of the CRI for pesticides should consider revenue as defined by GAAP. GAAP ties revenue to the time period in which a product or service is provided (generally known as the matching principle).

As mentioned previously, Health Canada has moved to an accrual accounting approach, however, no accrual-based revenue records exist for FY 2002/03. Accordingly, the practical alternatives are to use cash receipts or invoices issued as a proxy for revenue. We chose to use cash receipts, as we believe it provides a reasonable match with GAAP.

FY 2002/03 cash receipts differ from revenue as defined by GAAP and by Health Canada. Maintenance fee cash receipts in FY 2002/03 relate to product registration for the FY 2002/03. New product evaluations cash receipts in FY relate to:

- Regulatory activities performed in FY 2002/03; and
- Regulatory activities that will be performed in future years. (For example, the final 65% of a new product fee might be received in March 2003, but the majority of the analysis would be undertaken in the subsequent fiscal year.

For FY 2002/03, Health Canada tied revenue to cash receipts. In other words, PMRA's reported revenue is the cash it received in FY 2002/03. Cash receipts in FY 2002/03 differ from revenues using GAAP in that year because:

- They capture any cash received in FY 2002/03 in settlement of maintenance fee invoices issued in previous years; and

- They exclude maintenance fees invoice amounts that are outstanding at the financial year-end. These outstanding amounts include accounts receivables and any fee reductions that may be documented at a later date. PMRA invoices all products at the full maintenance fee of $2,690. Upon notification of sales below the threshold of $89,667 it credits the product account accordingly. (We understand that many pesticide products meet the criteria for reduced fees, and accordingly, the invoices overstate maintenance fee revenue by a substantial amount.)

1. Overview of PMRA regulatory fees

In FY 2002/03, PMRA collected $7.7 million from fee-payers for a variety of pest management regulatory services and activities. New product evaluation fees accounted for $2.9 million of the total and maintenance fees accounted for $4.7 million.

Fee revenues vary somewhat from year to year. (See Exhibit II-9.) Since FY 1999/00, PMRA has received between $2.8 million and $3.4 million in new product evaluation fee revenue annually. Generally, Category A and Category B fees account for approximately 90% of fee revenues from new product evaluation in a given year. Fee revenues for FY 2002/03 were consistent with the fee revenue distribution pattern for new product evaluations observed in earlier fiscal years.

Over the past four fiscal years, Category A fee revenue has ranged from 55% to 66% of new product evaluation fees and Category B fee revenue has ranged from 26% to 29% of new product evaluation fees. All other new product evaluation categories, (that is, Categories C, D and E), account for between 9% and 13% of fee revenues from new product evaluations over this period, except for FY 2000/01, when they accounted for approximately 18%.

Maintenance fees have declined in each year since FY 1999/00, going from $5.1 million to $4.7 million in FY 2002/03. On a proportionate basis, maintenance fees have accounted for between 59% and 64% of total fee revenue during this period; in FY 2002/03 they accounted for 62%.

Exhibit II-9
Fee Revenues by Fee Category

	FY 1999/00	FY 2000/01	FY 2001/02	FY 2002/03
New Product Evaluation Fees				
Category A	2,171,416	1,566,195	2,044,860	1,760,162
Category B	853,844	751,047	991,838	792,139
Category C	173,192	246,905	206,408	194,783
Category D	112,060	258,552	189,267	175,950
Category E	18,150	15,000	11,400	13,753
Sub-total	3,328,662	2,837,699	3,443,773	2,936,788
Maintenance Fees	5,097,402	5,065,808	4,900,341	4,721,138
Total	**$8,415,064**	**$7,903,507**	**$8,354,114**	**$7,657,926**

Source: PMRA financial reports.

Fees for Category A include new active ingredients and major new uses and have either full or substantial data packages that may include mammalian toxicology, exposure, residue, chemistry, environmental chemistry and fate and environmental toxicology and value data. The fee to evaluate Category A submissions ranges from $262 to $147,551 for a new technical grade active ingredient and from $262 to $81,281 for a new end-use product, giving a maximum possible fee of $228,832.

Fees for Category B submissions include new formulations, changes in current formulation, new hosts and/or pests added to existing products, renewal or conversion of temporary registration, new source of currently registered active ingredients and changes in rate and method of applications. The fee per Category B submission is generally up to $42,000.

Category C submissions include product registrations and amendments that may have reduced data requirements. The fee for a Category C submission is generally $154 but may be up to $1,161 for a "fast track" Category C submission.

Category D submissions include Import for Manufacture and Export Program (IMEP), Own-Use Import (OUI), master copy, private label and User Requested Minor Use Label Expansion (URMULE). Fees for Category D submissions range from $0 (for an URMULE and OUI) to $4,601 for an IMEP.

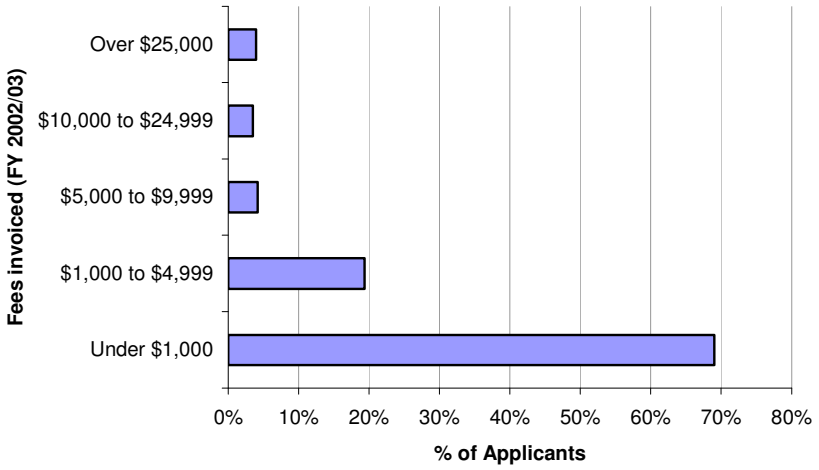
Category E submissions include research permits for new actives, new use of registered actives and notification that are required for field research carried out in Canada. An administrative fee for Category E submissions is charged of $150 per submission.

2. Applications for new product evaluation in FY 2002/03

During FY 2002/03 approximately 455 companies/entities were invoiced for applications for new product evaluations made to PMRA. The majority of application fees invoiced were paid by a relatively small number of applicants. An estimated 13% of applicants (51 companies/entities) accounted for 91% of new product evaluation fees paid to PMRA, while the remaining 87% of applicants (392 companies/entities) accounted for 9% of total revenue.

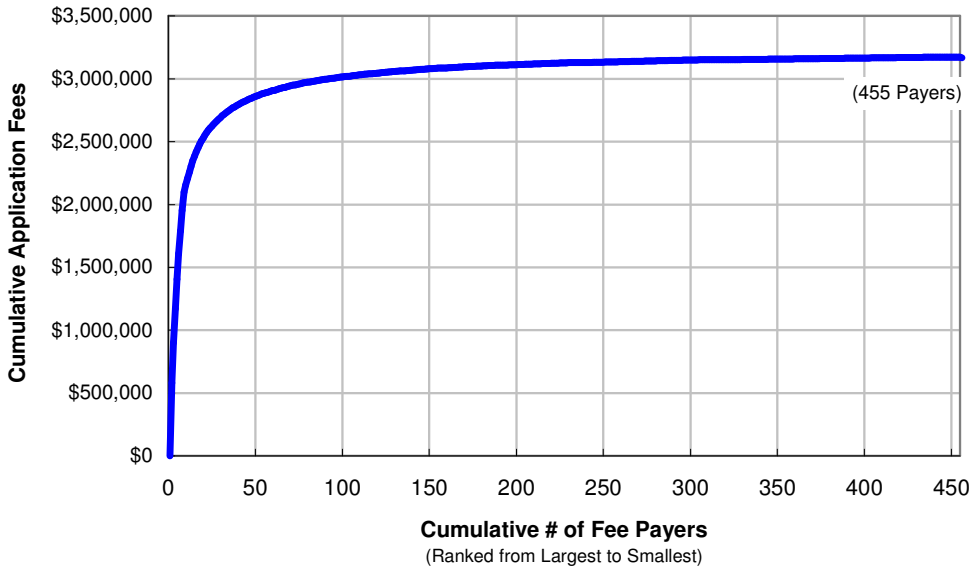
An estimated 4% of applicants paid over $25,000 in fees each, accounting for 79% of application fee revenues in FY 2002/03. In contrast, most applicants (~ 69%) were invoiced for under $1,000 each, together accounting for approximately 3% of total fee revenues from new product evaluations. Invoices in the range of $1,000 to $4,999 accounted for 6% of fees and 19% of applicants. While invoices in the ranges: $5,000 to $9,999, $10,000 to $24,999 and over $25,000 accounted for 4% each of total applicants. (See Exhibit II-10 and Exhibit II-11.)

Exhibit II-10
Profile of new product evaluation fees invoiced, FY 2002/03



Source: KPMG analysis

Exhibit II-11
Cumulative new product evaluation fees invoiced, FY 2002/03



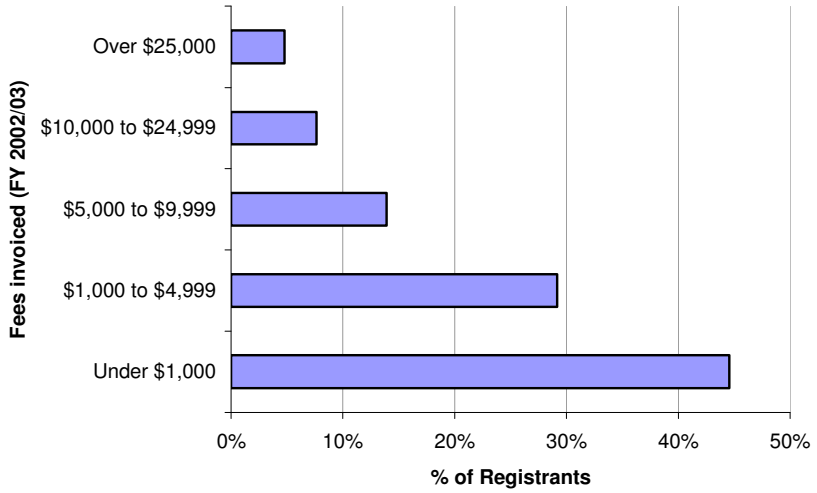
Source: KPMG analysis

3. Maintenance fees for registered pesticide products in FY 2002/03

The breakdown of FY 2002/03 cash receipts from maintenance fees shows that approximately, 5% of registrants were invoiced for over $25 thousand (after credits for sales below the maximum fee threshold) and accounted for $2.3 million (54%) of maintenance fee revenue in FY 2003/03. Invoices in the range $10,000 to $24,999 and $5,000 to $9,999 accounted for 8% or $0.7 million

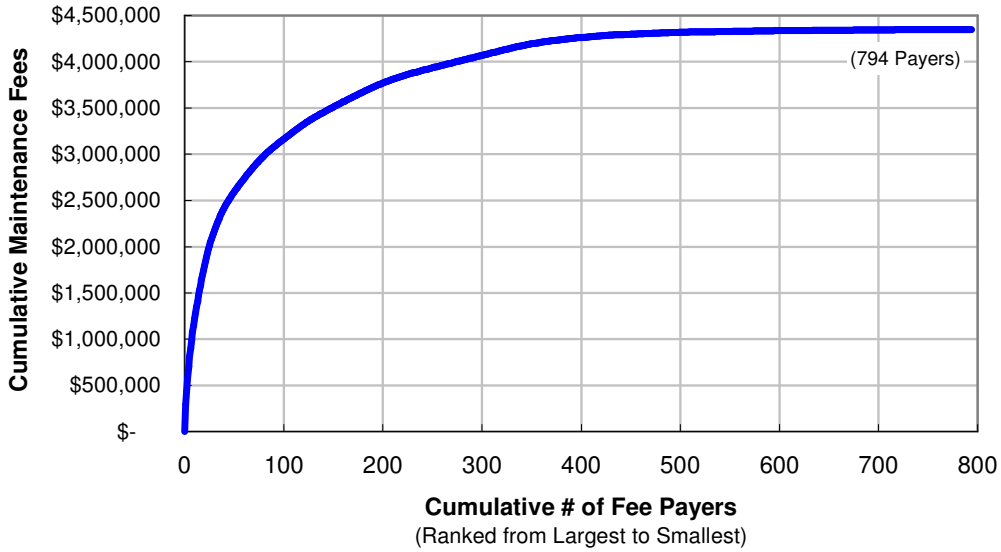
of maintenance fee revenue and 14% and $0.7 million, respectively. Additionally, invoices in the range $1,000 to $4,999 accounted for approximately 29% or $0.56 million of maintenance fee revenue and invoices under $1,000 accounted for 45% or $0.08 million of revenue. (See Exhibit II-12 and Exhibit II-13.)

Exhibit II-12
Profile of maintenance fee payments, by registrants, FY 2002/03



Source: KPMG analysis

Exhibit II-13
Cumulative maintenance fee payments, FY 2002/03



Source: KPMG analysis

PMRA's initial planning for the introduction of cost recovery—as summarized in the 1996 *Discussion Paper: Cost Recovery Analysis*—expected the introduction of maintenance fees to result in a 40% fall in the number of registered products (based on maintenance fee options with a maximum payment equivalent to 10% of products' prior year sales and maximum payments of $1,851, $2,950 and $5,900, respectively). It should be noted that half of this 40% reduction was attributable to the normal 20% reduction in the number of registered products that occurred when registrations came due for renewal every five years, another 8% was attributable to the "scheduling" of pool and spa products in 1995, and thus no longer had to be registered.[1] The remaining 12% of registration reductions were expected to be due to the introduction of maintenance fees.

The subsequent Business Impact Test (BIT) analysis provided prospective estimates that suggested between 21% and 29% of registered products would be discontinued in response to these maintenance fee options. As a result of the BIT findings, PMRA reduced the maximum maintenance fee payable per product to $2,690 and products with prior year sales of less than $89,667 were made eligible for a reduced fee set at 3% of prior year revenues, with a minimum fee of $75. This change had the effect of increasing the number of products eligible for reduced maintenance fees, compared to the closest prior option, (maximum fee set at $2,950 with a reduced fee of 10% of product revenues if prior year sales were below $29,500).

Projected revenues from the revised maintenance fee structure were approximately $8.8 million. However, actual maintenance fee revenues have never exceeded $5.1 million and the proportion of registered products paying the minimum annual fee has progressively increased. Excluding products for which product discontinuation requests were made by registrants and where no response had been received to PMRA's invoice at the applicable year-end, the percentage of registrants paying the minimum fee has risen from 47% in FY 1997/98 to 53% in FY 2002/03. The percentage paying a reduced fee went from 32% to 25%, and the percentage paying the maximum fee went from 20% to 22%.

KPMG's survey of registrants (Chapter IV) produced retrospective estimates of the number of registered products if maintenance fees had not been introduced in 1997, which suggested that the number of registered products was 18% below what it would have been if there were no maintenance fees.[2]

4. Relationship between revenues and pricing structure

To assess the relationship between revenues and the pricing structure we compared fees invoiced (as a proxy for revenue) to the estimated costs for each fee category (based on the PMRA model), which led to the determination of the pricing structure.

We are unable to comment upon the detailed components of the fee structure because invoicing and activity tracking records do not provide the necessary detailed information. Our assessment of fees invoiced is therefore limited to an analysis at the level of the fee categories.

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1 The scheduling of a swimming pool or spa chemical or product indicates the product conforms to a pre-approved standard and meets the PMRA's requirements for safety and efficacy.

2 Note that this was an estimate only, not a comparison of actual numbers. Survey participants also indicated that nearly 90% of the estimated reduction would have been due to dropped registrations (versus decisions to not register new products).

For each fee category, we compared fees invoiced in FY 2002/03 to the estimated cost of undertaking regulatory activities as calculated by the PMRA model in order to assess whether the fee structure recovered the estimated cost of regulating pesticides. The PMRA fee structure was developed from a forecast of costs, activities and projected number of new product evaluation applications and registered products. The PMRA model developed an estimate of costs for each fee category. The fee structure is based upon a further assignment of resources across various fee components representing the range of activities to be undertaken in support of a given fee category.

In FY 2002/03, total fees invoiced were below the estimated total costs for pesticide regulation (as estimated by the PMRA model) by $26.1 million. For maintenance related cost, the PMRA model cost estimate is $16.0 million, versus revenue of $4.7 million. For new product evaluations, the related cost developed using the PMRA model was estimated to be $17.2 million compared to revenues of $2.9 million). (See Exhibit II-14.)

Exhibit II-14
Revenues and PMRA Model cost estimates ($'millions)

	Estimated cost[1]	Estimated revenues[2]	Difference between estimated cost and fees invoiced	Fees as % of estimated costs
New Product Evaluation	17.2	2.9	14.8	17%
Post-Registration Regulation	16.0	4.7	11.3	30%
Total	**33.8**	**7.7**	**26.1**	**23%**

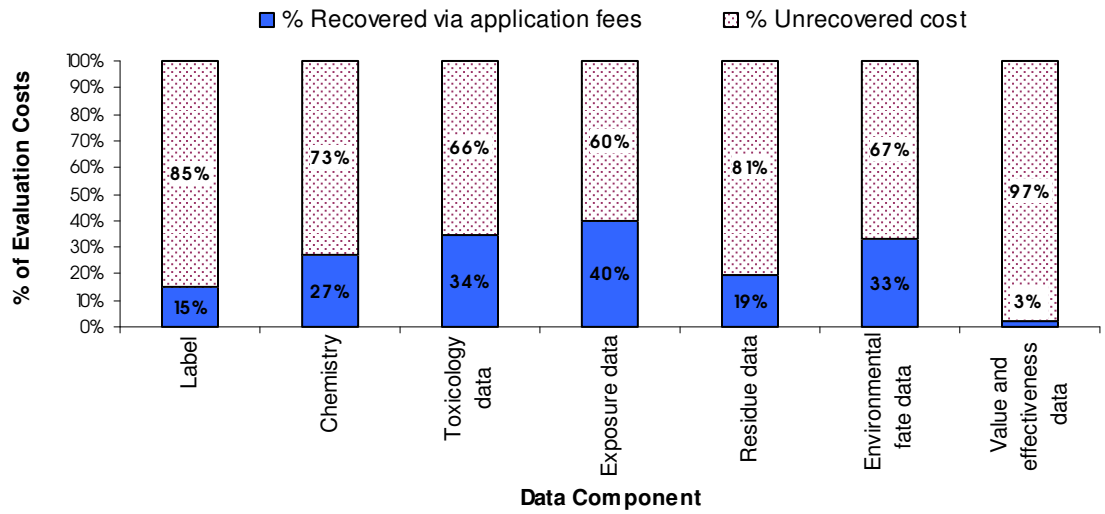
1. *Based on PMRA model*
2. *FY 2002/03*

5. Analysis of previous years

In this section, we provide a high-level summary of the financial performance of previous years prepared by PMRA, to supplement our more focused analysis of FY 2002/03.[1] This analysis showed that, over the past four fiscal years, the average annual cost of PMRA regulatory activities increased by 10%. Each business line showed a steady upward trend in costs with the exception of the business line improvements category, which had an average annual decline of 12% over the review period.

[1] PMRA, Business Lines 1.1-Review, 2-Re-evaluation, and 3-Compliance: Costing and Revenue Analysis, 2002/03(?).

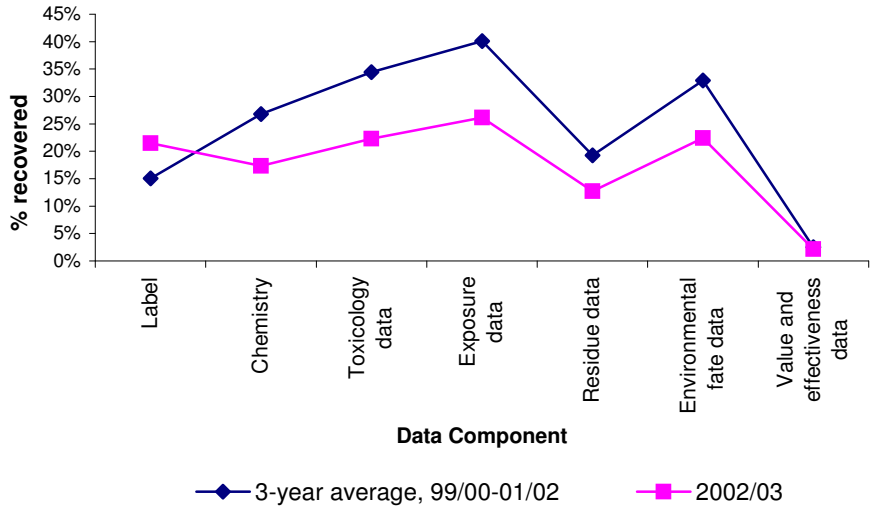
Exhibit II-15
Average total cost recovered by new product application fees, FY 1999/00 to FY 2001/02



Source: PRMA Costing and Revenue Analysis

This same report also analyzed fee revenues and the level of cost recovery for activities subject to cost recovery for the period FY 1999/00 to FY 2001/02. Generally, the proportion of the cost of new product evaluation that was recovered through user fees declined in FY 2002/03 when compared to the average of FY 1999/00 to FY 2000/01. (See Exhibit II-16.)

Exhibit II-16
FY 1999/00-FY2001/02, 3-year Average versus FY 2002/03 Total Cost Recovered by Application Fees



Source: PRMA Costing and Revenue Analysis

G. Potential revenue gaps

The Terms of Reference for the evaluation required identification of any gaps in the current fee structure or in existing collection, compliance and enforcement systems. Gaps between the cost of a regulated activity and the fee revenue it generates may be the result of a policy decision by PMRA or may be inadvertent. Examples of inadvertent gaps include changes in the cost of inputs, or changes in the scope of activities undertaken without an offsetting adjustment to the price schedule.

We interpreted the primary focus in identifying and assessing gaps to be in two areas:

- The extent to which costs may be incurred by PMRA for activities covered by the cost recovery regulations but which are not fully recovered in the existing fees.
- Activities performed by PMRA that may confer benefits to registrants (private benefits) but are subject to exemptions and reductions that form part of PMRA's cost recovery regulations. These exemptions and reductions reflect policy decisions made at the time of fee formulation to obviate potential impacts on the availability of pest control products to Canadian users.

It is also theoretically possible that some user groups may receive private benefits from PMRA but are currently not paying directly for these activities. We understand that PMRA believes the possibility of such an occurrence is extremely low due to the way the product registration and market monitoring activities are conducted. (For example, if the fee schedule is not applied consistently.) The potential for this type of fee gap is discussed briefly in Section 3.

1. Costs not fully recovered by existing fees

As indicated in Exhibit II-12 and II-13, based on estimated revenues and costs for FY 2002/03, there is a substantial gap between the cost of reviewing new product evaluation and monitoring registered products and the fees collected for these regulatory activities. In aggregate only about 18% of the cost of providing these services is recovered.

This level of cost recovery is a function of past decisions regarding the share of total expenditures to be met through cost recovery plus the impacts of such factors as inflation and changes in processes and methods, including process and productivity improvements that result in some elements being effectively overstated in the fees.

One change in the submission evaluation process that was not anticipated in the design of the current fees and which has developed into a significant cost element is that of pre-submission consultations. On request, PMRA will hold a pre-submission consultation with a manufacturer/importer to help the company determine the research and documentation that would be required to support a prospective new product evaluation. As well, pre-submission consultations are a requirement for some types of new product submissions, such as, microbial and other biopesticide products, because data requirements are set based on the nature of the organisms, that is, must be established on a case-by-case basis.

We understand that a pre-submission consultation potentially reduces the elapsed timeframe for completing the evaluation of a submission (because all of the data requirements are more likely to

have been confirmed with the applicant and included in their submission); but does not reduce the work required to evaluate a submission. Additionally, we understand that pre-submission consultations require significant advance preparation by PMRA staff in addition to the time spent in the conference and with follow up communications. PMRA's records show that approximately 157 pre-submission consultations were conducted in FY 2001/02 and another 129 were conducted in 2002/03. PMRA allocated 5.1 FTEs to these FY 2002/03 pre-submission consultation activities.

2. Activities with no or reduced levels of cost recovery

Several activities that confer a benefit to users and are not included in the current fee structure or are not recovered to the same extent as other fee elements were identified through the course of the evaluation and/or by PMRA staff, including:

- URMULE and OUI submissions, which are exempt from fees, and biopesticides, semiochemicals and other products as specified under Section 2(2)(c) of the *Pest Control Product Fee Regulations,* which are only subject to label fees, of either $262 or $154.
- Special treatment of applications for research permits and the establishment of maximum residue limits on unregistered products or uses (import MRLs).
- Reduced maintenance fees for registered products with low sales levels in Canada.
- Reduced application fees for new active ingredients and end-use products with limited Canadian demand and thus low sales revenues.

The following sections briefly describe the characteristics of the main types of exemptions and reductions.

a) Minor use submission examination

PMRA defines a minor use as: *a necessary use of a pest control product for which the anticipated volume of sales is not sufficient to persuade a manufacturer to register and sell the product in Canada*[1]. PMRA has two sub-categories in its categorization structure for new product registration applications for user requested minor use registrations: user requested minor use label expansions (URMULEs – Category D.3), and user requested minor use registrations (URMURs – Category A.3.1).

URMULE applications submitted via provincial minor use coordinators or forestry minor use coordinators are exempt from all application fees. These approvals are sought by user groups when manufacturers of the applicable products consider that the cost to register their products for the required end use outweighs the expected returns on sales for minor use applications. The Agency's URMULE program *considers the expansion of a label for a new minor use or a pesticide for which the active ingredient(s) and the EP (end-use product) are currently registered in Canada*, and, *the product is efficacious and the risks*

[1] *PMRA,* User Requested Minor Use Label Expansion*, Regulatory Directive: DIR2001-01, PMRA, Ottawa, 2001, p.1*

are considered as acceptable.[1] Once an URMULE application has been reviewed and if it is approved, the registrant is required to make a Category C application to add the approved minor use to the label, and pay a fee of $154.

Users may also seek URMUR registrations for products that have been registered in another OECD country within the last five years, and for which PMRA will accept and use acceptable foreign reviews and data. These applications are not eligible for fee exemptions but may be eligible for reduced application fees if the sales revenues in the three years following registration in Canada are less than ten times the applicable application fee.

In FY 2002/03, PMRA conducted 120 URMULE pre-submission consultations, 49 URMULE submission examinations, and 10 URMUR submission examinations (Category A.3.1).

In June 2002, AAFC and PMRA launched a joint Minor Use Pesticide Program to improve access to minor use pesticides, with an emphasis on reduced risk products. Under this initiative, AAFC committed to work with stakeholders (provincial ministries, user groups and manufacturers) to identify priority crops, conduct field trials and prepare the associated submissions for minor use registration. PMRA committed to increasing its capacity to review these URMULE submissions and reduce the time lines to registration for new reduced risk products. PMRA does not apply fees to examine these URMULE submissions.

PMRA began gearing up for its role in this initiative during 2002/03 with an aim of being fully operational by the start of FY2003/04. The reported expenditure by PMRA during FY2002/03 was $800,000. PMRA expenditures in each of the following five years of the initiative are expected to be of the order of $4 million per year, covering pre-submission consultations with AAFC, provincial representatives, grower groups and registrants, and the conduct of submission evaluations for URMULE submissions (Category D.3) and submissions in other categories containing minor uses or reduced risk uses.

b) Biopesticides and semiochemicals

Exemptions from application fees are also provided for microbial, pheromone and other semiochemicals, plant extracts and naturally occurring substances for which data and evaluation requirements differ from conventional chemical products. PMRA provided this exemption to encourage development and registration of these types of products.

c) Research permits and research notifications

A research permit is required to investigate new active ingredients and new use(s) and/or new formulations for currently registered active ingredients. Examination of submissions for research permits (Category E submissions) are subject to a $150 administration fee, and no charge for research notifications. Research permits are not required for small scale research on condition that researchers provide PMRA with summary details of the work by submitting a Pesticide Research Notification. PMRA reviews the notification to confirm that the product meets the criteria for research notification.

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[1] PMRA, User Requested Minor Use Label Expansion, *ibid*, p.1.

Research permits are subject only to an administrative fee. The effort and cost involved in reviewing the data package is recaptured, at least in part, if the permitted research ultimately leads to a new product evaluation submission. However not all research permits result in a new product application. We understand that it is a policy decision was made by PMRA when the Cost Recovery Guidelines were formulated to not charge directly for the review work associated with research permits on the grounds that imposition of cost recovery for research permits could discourage research and development and pest control innovation in Canada.

In FY 2002/03 PRMA processed 127 research permits and notifications.

3. Other potential gaps

Three additional potential gaps in the fee structure were identified:

- Inconsistent application of the fee structure.
- Inadequate identification of the fee components.
- Printing and assembly of file copy (manual copies are still required to support electronic submission).

Each of these potential gaps is reviewed and discussed briefly in the remainder of this section.

a) Application of the fee structure

Generally, based on discussions with PMRA management and a review of the fee structure, we believe that adequate processes are in place to avoid material inconsistencies in the determination of the most appropriate Category for an application, and the resulting fee determination.

We understand that in some instances judgement is required to determine whether a new product application should be evaluated as a Category B or a Category C submission, depending on whether a precedent exists relating to the acceptability (or not) of reduced or no data requirements for a label or formulation review. If PMRA determines that an application is a Category B submission then the applicant is required to submit supporting data for review by PMRA. The difference in workload between reviewing a Category B versus a Category C application (that is, between having to review data in support of the application or not) is significant, as is the potential difference in fee revenues (typically, $154 for a label amendment in Category C versus a typical Category B fee of the order of $42,000).

b) Identification of fee components

Anecdotal evidence from PMRA officers and industry representatives suggests that the amount of work required to evaluate the data submitted in a submission can vary significantly within a submission category, depending on such factors as the numbers of end-uses proposed, numbers of MRLs to be established and numbers of supporting studies, while the fee applied can remain unchanged. This is a function of the fact that the fee

applied was based on an average cost for the applicable activity, calculated from a broad distribution of actual costs. In effect, the cost to review the larger submissions is cross-subsidised by smaller, less complex submissions.

c) Copy and collation of hard copy of submission

In support of an electronic submission filing, PMRA staff have determined that a hard copy of the file is still required to facilitate the review and assessment of an application. Most recently, electronic submissions submitted as part of PMRA's pilot program to test and refine the approach to electronic submissions did not require a supporting, suitably indexed hard copy.

PMRA managers indicated that, if the approach used for the pilot submissions was maintained as a standard practice for electronic submissions, the time and resources required to prepare the paper copy of a submission would be material.

III. Task 2 — Impact Of The CRI On PMRA's Performance

A. Scope

The purpose of Task 2 of the evaluation was to determine whether and how PMRA's performance has been affected by the CRI, where performance is assessed in terms of such factors as time, quality and cost of providing a service. The Terms of Reference for the study called for the evaluation to:

a) Analyze all PMRA activities in terms of the timeliness of decisions, service standards, actual performance, PMRA's responsibilities under the regulations, workflow, and communications with stakeholders.

b) Develop a model to evaluate the impact of the introduction of the CRI on the Agency's five business lines to isolate cost recovery as a factor as well as other contributory or confounding factors.

c) Determine whether the CRI has contributed to the delivery of an efficient service (that is, at the least cost, while meeting the Agency's regulatory responsibilities and quality and time specifications). In doing so, identify areas where the CRI lead to more or less efficient service delivery and why; and provide suggestions for improvement, where applicable.

The following sections of this chapter provide an overview of the approach taken to this analysis, key features of the evaluation and registration process, and our assessments of registration performance versus standards, the impact of the CRI on PMRA's business lines and efficiency, and the effectiveness of its consultation and communication mechanisms. The final section presents our conclusions regarding the impacts of the CRI on PMRA performance.

B. Methodology

Five lines of investigation were used to provide input to the analysis of PMRA's performance and the impacts of the CRI:

- A review of data on the volume of registration submissions and the outcomes from their evaluations. This included performance summaries provided to the Economic Management Advisory Committee (EMAC) as well as the generation of summary data tables from PMRA's submission tracking and management system.
- A review of PMRA management reports and studies regarding registration performance, efficiency and resources.
- Interviews with PMRA directors and officers across PMRA's five business lines.
- Interviews with industry representatives and other stakeholders with a relatively high degree of interaction with PMRA to obtain their perspectives on the CRI's impacts on PMRA. An initial list of over 30 prospective participants in these interviews

(and/or stakeholder interviews investigating observations on the impacts of the CRI on users of pesticides) was developed in consultation with the Evaluation Steering Committee and PMRA, and 10 additional organizations were added during the interviewing program from suggestions made by interviewees. A total of 30 interviews were conducted, of which 17 covered perspectives on the impact of the CRI on PMRA. The organizations in the sample came from the following sectors:

- Associations representing pesticide manufacturers, importers and distributors.
- Associations representing users of pest control products.
- Environmental NGOs (non-government organizations).
- Provincial government departments involved in regulation of pest control product use and support for minor use product submissions (typically ministries of agriculture/forestry and environment).
- A small cross-section of pesticide manufacturers that are based outside of Canada but register products with both the PMRA and EPA. These organizations were included at the request of the Pest Management Sub-Committee that provided guidance for the planning and design of the Task 3 analysis of CRI impacts on registrants.

The majority of interviews were conducted by telephone, with a number of interviews with Ottawa-based participants conducted in person. The complete list of organizations that were interviewed is included in Appendix 4and a copy of the interview guide used in Appendix 5.

- Interviews with representatives of pesticide regulatory agencies and selected industry associations in:
  - United States—Office of Pesticide Programs (OPP) within the Environmental Protection Agency (EPA).
  - United Kingdom—Pesticides Safety Directorate (PSD), the European Commission's DG Health and Consumer Protection (SANCO), and the European Crop Protection Association.
  - Australia—Australian Pesticides and Veterinary Medicines Authority (APVMA), and Avcare.

In reviewing trends in PMRA's submission examination performance, we examined data on the volume of Category A, B and C submissions completed each year from FY 1998/99 to FY 2003/04 rather than looking at a single "snapshot" of 2002/03. However, one must be careful not to make direct comparisons between the outcomes for most recent years and those achieved in FY 1998/99 and FY 1999/00. Outcomes in these two earlier years of Agency operation reflect performance in reaching decisions for submissions that were more complete (limited or no data deficiencies) or straightforward while the results in more recent years show performance across the spectrum of submission quality, sizes and levels of complexity. **Our analysis focused on performance over the period from FY 2000/01 to FY 2003/04; results for FY 1998/99 and FY 1999/00 are included to provide historical context.**

C. Overview of PMRA's registration process

PMRA's New Product Evaluation Business Line (Business Line 1) is responsible for the evaluation of submissions to register new pest control products, amend existing registrations, or carry out research on new uses. The evaluation process for new products involves the conduct of human health, safety and environmental risk assessments; efficacy and value assessments; and establishment of Maximum Residue Limits (MRLs) on domestic and imported food products.

1. Types of applications

Submissions to PMRA are categorized according to the purpose of the submission and level of complexity, which determines the amount of work required to examine the required data, and reach a registration decision. PMRA uses five major submission categories:

- **Category A:** includes submissions to register new technical grade of active ingredient (TGAI) or integrated system products (ISP) (not previously registered in Canada) and their related end-use product(s) (EPs), manufacturing-use products (MAs) or major new use (defined as the addition of a new use–site category to the use pattern for a specific registered TGAI), or to establish an import maximum residue limit for a new active ingredient. These submissions are usually accompanied by a significant amount of data supporting safety and value, and include URMURs (User Requested Minor Use Registrations) and joint reviews.

  Category A applications may be processed on a Priority basis or as Standard applications. Priority submissions involve critical need products containing new active ingredients, URMUR submissions, and Joint Review submissions (PMRA and the Office of Pesticide Programs at the U.S. EPA).

- **Category B:** includes submissions to register new pest control products (must contain an active ingredient that is currently registered for use in Canada) or to amend existing products. These include changes in product chemistry for the TGAI or ISP, changes in product chemistry for the EP or manufacturing concentrate (MA), changes in product labelling, the conversion or extension of temporary registration and the addition of import MRLs for previously assessed TGAIs. Category B submissions may be processed on a Priority basis or as Standard submissions.

- **Category C:** includes submissions with no or reduced data requirements for new or amended registrations requiring minor label or formulation reviews, such as product registrations based on precedent. Category C submissions may also be processed on a Priority basis, for example, "fast track" Category C submissions, or as Standard submissions.

- **Category D:** includes submissions to register or to amend products within particular programs, for example, Import for Manufacture and Export Program (IMEP), own use import (OUI), master copy, private label, user requested minor use label expansion (URMULE), renewals.

- **Category E:** includes submissions for research permits for new TGAIs and new use(s) of registered TGAIs, as well as research notifications carried out in Canada.[1]

2. Major stages in the submission examination process

At the highest (that is, most complex) level—Category A—the PMRA's process for examining submissions for product registration involves the steps described below.

- ***Verification***—to ensure that all required forms and fees are submitted, assign a submission number and create a submission file.
- ***Screening***—to confirm that submission is complete, that is, is properly organized and formatted, contains all the required elements, and each element is of acceptable quality. A submission is normally composed of covering letter, an application form, the fee and supporting information. The supporting information may comprise a product specification form, various letters of support or authorization, draft label, index of supporting scientific data or studies, and the scientific data. Submissions may also include requests for waivers of supporting data requirements along with a scientific rationale for the proposed waiver.
- ***Review***—a major component in the overall examination process, involving:
  - ***Preliminary review***—to determine if conditional data requirements have been properly interpreted, data waiver requests are justified, and any non-standard protocols are acceptable. Chemical data is reviewed to confirm the information about the compound and efficacy data is reviewed to confirm or establish the lowest effective application rate required for the product to provide consistent results under normal use conditions.
  - ***Detailed evaluation***—to evaluate the safety, value and merit of the product by PMRA's science review divisions.
  - ***Risk assessment and proposed registration decision***, including the need, or otherwise, for public consultation on proposed regulatory decisions.
  - Preparation of a ***Regulatory Note*** or ***Proposed Regulatory Decision Document (PRDD)*** summarizing the rationale and evidence for registration decisions or proposed registration decisions for all new active ingredients and some major new uses of currently registered pesticides.
- ***Public consultation*** on proposed regulatory decisions—applications to register new active ingredients and major new uses of currently registered products are subject to public consultation prior to the making of final full registration decisions, as a matter of policy.
- ***Assessment of comments*** received during the public consultation period and ***final decision*** regarding registration, including the publication of a **Registration Decision Document** (RDD).

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[1] These definitions are taken from PMRA's Regulatory Directive DIR 2003-01 (revised), *Organizing and Formatting a Complete Submission for Pest Control Products*, and Regulatory Note REG 2003-01, *Guidance on Selecting the Correct Category for Pest Control Product Submissions*. (Accessed at www.hc-sc.gc.ca/pmra-arla/english/pubs/pubs-e.html on April 21, 2004.)

- ***Verification of final label***—PMRA issues a letter of intent to register a product, at which point the applicant must submit the final label for the product in question. This review is used to check that the label has no errors that could compromise human or environmental health and safety, or product performance.
- Issuance of a ***Certificate of Registration***. Normally, a product registration has a term of five years after which it is subject to a renewal process, and payment of a renewal fee. Temporary registrations may also be issued for products or uses that do not fully meet regular registration requirements for periods of up to a year. Temporary registrations are considered if the risks posed by the product's use are determined to be acceptable. The registration is conditional on the applicant agreeing to produce additional confirmatory scientific or technical information related to the product. Temporary registrations may be converted to a full registration when the specified data requirements have been satisfied, or extended for another year via submission and approval of a Category B4 submission. Other federal departments and provincial ministries may also seek emergency registrations of products to control emergency pest infestations that are detrimental to public health, domestic animals, natural resources or the environment. These registrations usually involve new uses of currently registered products.

The less-complex Category B, C, D and E submissions involve shorter target times for the completion of key elements of the examination process, and registration decisions for Category C, D and E submissions do not require public consultation on proposed registration decisions.

3. Performance standards

The PMRA *Management of Submissions Policy* (MOSP) sets out a series of performance standards for the conduct of the various steps, and calls for PMRA to process at least 90% of submissions in all categories within the MOSP standards. Since the publication of the MOSP in 1996 modified performance standards applicable to certain sub-categories of submissions have been established, leading to the sets of target times ("PMRA Time") for the completion of submission examination tasks by PMRA shown in Exhibit III-1.

Time standards are also provided for applicants to address deficiencies in their submissions and to provide outstanding fees and final labels ("Applicant Time"), and for PMRA to screen and review the revised submissions ("Deficiency Time"). This means that, while PMRA may complete its submission examination and make a registration decision within the applicable performance standard (for example, 737 calendar days for a standard Category A chemical submission) the elapsed, or total life cycle time, may be significantly higher due to requirements for applicants to provide missing data and for PMRA to review this data and integrate it into decision making regarding an application.

As such, the timeliness of decisions is driven by a combination of the applicant's thoroughness when preparing their submissions and timeliness of responses to submission deficiencies as well as the timeliness and efficiency of PMRA's work in examining the initial submissions as well as responses to deficiencies. Ideal submissions are those that do not involve any Applicant or Deficiency Time and are completed in accord with the applicable PMRA time standards.

Exhibit III-1
Performance standards for the conduct of examination tasks by PMRA (calendar days)

Submission Category	Submission Examination Elements						TOTAL (days)
	Verification	Screening	Review/ Decision[1]	Public Consultation	Registration Decision	Final Label Review	
Category A *(Standards for Reduced Risk, NSCLP, Other Bio-pesticide, SCLP, and Microbial submissions effective from June 1, 2002)*							
Standard:							
Chemical	7	45	550	45	45	45	**737**
Reduced Risk/ NSCLP[2], Other Bio-Pesticides	7	45	450	45	45	45	**637**
Microbial	7	45	365	45	45	45	**552**
SCLP[3]	7	45	180	45	45	45	**367**
Priority:							
Chemical	7	45	365 (or negotiated)[4]	45	45	45	**552**[4]
Reduced Risk/ NSCLP[2], Other Bio-Pesticides	7	45	365	45	45	45	**552**
Microbial	7	45	365	45	45	45	**552**
SCLP[3]	7	45	180	45	45	45	**367**
Category B—Standard and Priority *(Standards for Reduced Risk, NSCLP, Other Bio-pesticide, SCLP, and Microbial submissions effective from June 1, 2002)*							
Chemical	7	45	365	45	45	45	**552**
Reduced Risk/ NSCLP[2], Other Bio-Pesticides	7	45	300	45	45	45	**487**
Microbial	7	45	180	45	45	45	**367**
SCLP[3]	7	45	180	45	45	45	**367**
Category C							
Standard							
(Complex submission)	7	45	180			45	**277**
(Simpler submissions)	7	225				45	**277**
Priority	7	45	98			45	**195**
Category D							
IMEP	7	14	32			45	**98**
OUI (Own Use Import)	7	14	56			45	**122**
Master Copy	7	21				21	**49**
Private Label	7	10				(Incl. in Review)	**17**
URMULE							
Pre-submission	7	21	69				**97**
Submission Exam.	7	21	219				**247**
Reduced Risk Sub.	7	21	189				**217**

Submission Category	Submission Examination Elements						TOTAL (days)
	Verification	Screening	Review/ Decision[1]	Public Consultation	Registration Decision	Final Label Review	
AAFC URMULE *(Effective 31/03/04)*	(Program includes target dates for receiving & examining submissions. Target dates for completing submission examinations: Pre-submissions – Feb. 28th; Submissions: Sept. 30th.)						
Renewal *(Effective 01/06/02)*	(Target date for completion of processing is March 15th.)						
Discontinuation	7	45					**52**
Category E							
New Active - Food	7	14	152			7	**180**
New Active – Non-Food Use	7	14	152			7	**180**
Other	7	14	62			7	**90**
Notification	23					7	**30**

Notes: 1. Preliminary review, evaluation, review decision and PRDD (if applicable).
2. NSCLP — Non-Straight Chain Lepidopteran Pheromones
3. SCLP — Straight Chain Lepidopteran Pheromones
4. For joint reviews (conducted with the U.S. EPA) the review time can be 365 days, 550 days, 730 days or negotiated time lines.

Sources: *Management of Submissions Policy* (MOSP), 1996; *Draft Response to the Blair Consulting Report*, May 2003.

Exhibit III-2 presents a summary of the points at which deficiencies in Category A submission examinations may be identified and the performance standards for the associated Applicant Time and Deficiency Time. Applications may be withdrawn by applicants instead of responding to deficiencies and PMRA may reject applications if deficiencies are not remedied or the Agency's risk assessment process determines that a proposed product poses unacceptable risks.

Exhibit III-2
Performance standards for applicants and PMRA to address submission deficiencies (calendar days)

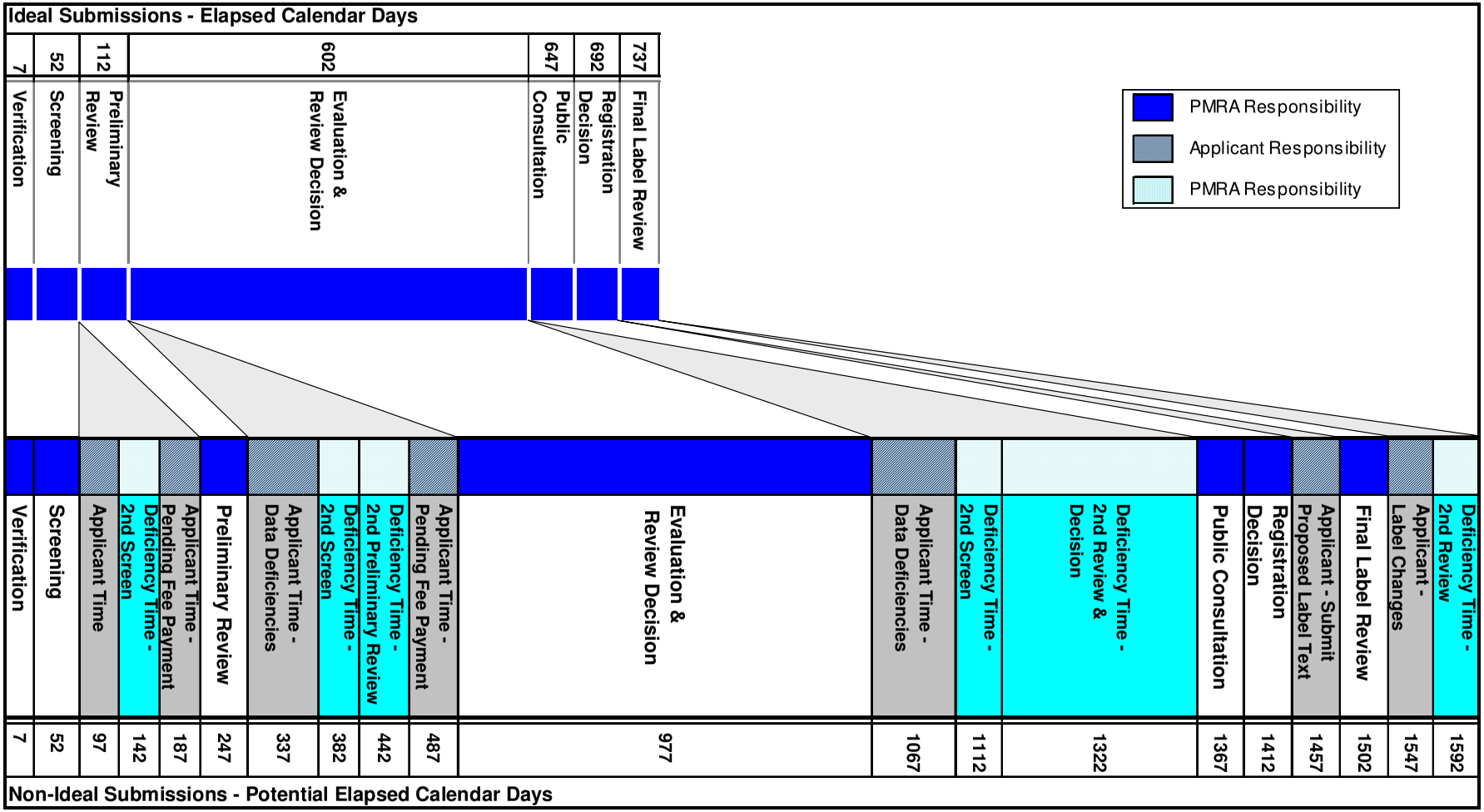
Examination Stage	Basis For Deficiency	Applicant Time	Deficiency Time	
			2nd Screen	2nd Review
Verification	Submission returned if required forms, fees and information not provided	(Not Applicable)	(Not Applicable)	(Not Applicable)
Screening[1]	Incomplete and/or incorrectly formatted data and non-data elements	45	45	-
Preliminary Review[1] (First 60 days of Review period)	Fee payment not received[2]	45	-	-
	Deficiencies in one or more review streams	90	45	60
Evaluation/Decision[1]	Fee payment not received[2]	45	-	-
	Deficiencies in data submitted for evaluation	90	45	180 (Review) 30 (Decision)
Final Label Review[3]	Deficiencies in proposed final label	45 (Submit proposed label text) 45 (Label changes)	-	45

Notes:
1. PMRA may also issue "Clarifaxes" (requests for clarification of submitted information), for which applicants have 10 days to respond. The PMRA clock is not stopped during the Clarifax response period.
2. Notifications that required fees have not been received are sent via a Deficiency Letter along with the notification of any data deficiencies. Typically, applicants would make the necessary payments at the same time as they address and data deficiencies. However, it does happen that applicants do not make the required payments within the time allowed for data deficiencies to be addressed, and these applications would then remain on-hold until the fees are paid or 45 days passes.
3. Effective July 1, 2003, PMRA required applicants to submit an electronic copy of their proposed label text (in both English and French) rather than a printer's proof or marketplace label. As part of this change, the time for applicants to respond to any label deficiencies was modified. Submissions received prior to the effective date were subject to a 365-day period in which the applicant was required to provide the printer's proof or marketplace label (i.e., a proposed final label).

Sources: *Management of Submissions Policy*, 1996; *Registration Handbook*, Part 5, 1998; *Draft Response to Blair Report*, May 2003; *Label Process Changes, Part 1: Overview,* LPS 2003-01.

Exhibit III-3 provides a schematic illustration of the potential impact of the provisions for applicants to remedy data deficiencies on the time standard for completing standard Category A submissions, and the points at which the PMRA clock may stop during the submission examination process.

Exhibit III-3
Schematic illustration of the range of possible time standards for standard Category A submissions (applicable to submissions received after July 1, 2003)



D. Performance trends

In order to gain a good understanding of PMRA's performance in examining and registering new pest control products it is necessary to look at several different attributes of the Agency's activities and outputs, focusing on:

- The number and mix of applications received.
- The number and mix of outcomes from the submission examination process—registrations, withdrawals and rejections.
- The characteristics of the total elapsed time required to examine submissions and register products.
- PMRA's performance against its performance standards.

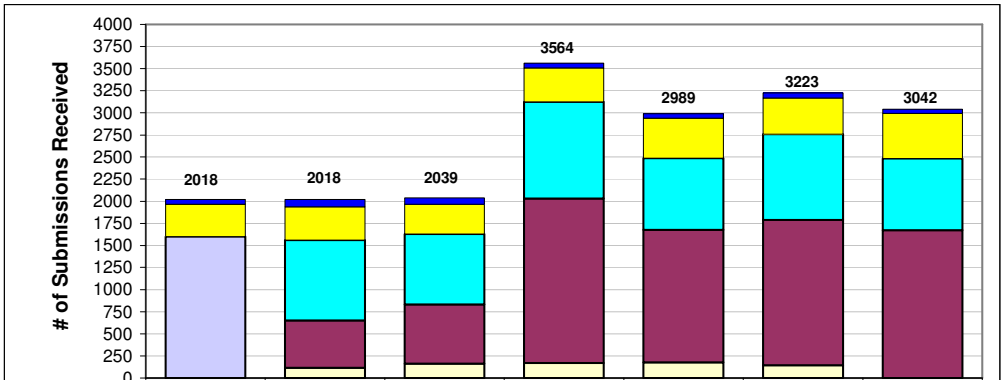
1. Number and mix of applications received

Application of the MOSP requirements for the preparation and examination of submissions was phased in over a period of approximately four years. As such, MOSP requirements were initially applied for Category A submissions from July 1, 1996, and extended to Category B submissions on April 1, 1997, Category C and D (excluding URMULE applications (User Requested Minor Use Label Expansion)) on April 1, 1998, and Category D-URMULE and Category E submissions on April 1, 2000. This means that over this phase-in period PMRA was receiving and/or examining a combination of submissions subject to MOSP plus Type 1, 2 and 3 submissions subject to pre-MOSP requirements. These Type 1-3 submissions were not subject to the MOSP performance standards. It also meant that starting on July 1, 1996, PMRA had a stock of approximately 1000 older Type 1, 2 and 3 submissions in hand, and which continued to work their way through the submission examination system in subsequent years. PMRA also developed its processes for examining submissions in each of the different categories and sub-categories during this phase-in period, defined the structure and content of its DACO (Data Code) tables, and provided training for staff and applicants.

Exhibit III-4 summarizes the trends in the numbers of submissions received over the period from FY 1997/98 to FY 2003/04. As can be seen from the chart, the number of submissions received was quite stable to FY 1999/00, and then jumped to a new level ranging between ~3,000 and 3,500 per year, primarily due to a sustained rise in the volume of Category D and, to a lesser extent, B and C submissions. The number of Category A submissions received exhibited an initial surge during FY 1998/99 and FY 2000/01 and thereafter fell to a level of around 50 per year.

The growth in submissions received is contrary to estimates of future application volumes prepared in 1996. For instance, the 1996 *Discussion Paper: Cost Recovery Analysis* estimated that the introduction of the CRI would result in a 10% drop in the number of Category A submissions and 20% in other submissions. The findings of the subsequent Business Impact Test (BIT) Analysis suggested that between 15% and 17% of the new applications in 1994 and 1995 would not have happened if they had been subject to the proposed CRI application fees.

Exhibit III-4
Trends in the number and mix of new product applications received by PMRA



	1997/98	1998/99	1999/00	2000/01	2001/02	2002/03	2003/04
Cat. A	55	82	73	55	49	53	51
Cat. B	364	375	334	384	455	413	509
Cat. C	0	910	797	1095	809	966	809
Cat. D	0	536	672	1860	1499	1647	1673
Cat. E, Misc.	0	115	163	170	177	144	0
Pre-MOSP	1599						

(Note: Numbers for 97/98 to 00/01 exclude URMULE submissions.)
2003/04 Category D figure includes Category E and Miscellaneous submissions.)

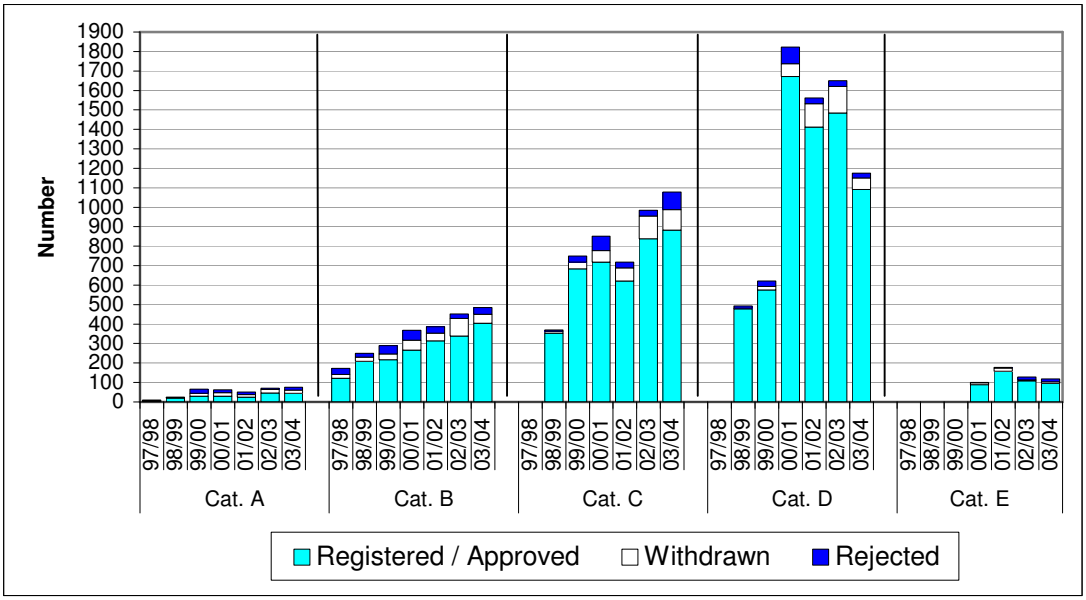
2. Number and mix of submission examination outcomes

Applications to register pest control products, amend details of existing registrations, establish import MRLs, and approve research permits have three possible outcomes:

- Registration or approval (that is, acceptance of the submission);
- Withdrawal of the submission by the applicant; or
- Rejection of the submission by PMRA due to unacceptable risks or incomplete supporting data.

Exhibit III-5 summarizes the trends in the number of registrations (for products subject to MOSP), withdrawals and rejections since FY 1998/99.

Exhibit III-5
Trends in outcomes from the submissions subject to the MOSP



	FY 1997/98	FY 1998/99	FY 1999/00	FY 2000/01	FY 2001/02	FY 2002/03	FY 2003/04
Category A							
Registered	2	19	29	29	25	46	45
Withdrawn	2	4	16	19	12	18	15
Rejected	5	2	20	15	14	7	15
Total	*10*	*25*	*65*	*63*	*51*	*71*	*75*
Category B							
Registered	122	208	217	267	314	338	405
Withdrawn	19	22	29	51	40	91	46
Rejected	32	20	44	50	33	23	34
Total	*173*	*250*	*290*	*368*	*387*	*452*	*485*
Category C (MOSP applicable from April 1, 1998)							
Registered		353	683	718	622	838	882
Withdrawn		10	35	60	66	117	106
Rejected		6	31	73	31	30	90
Total		*369*	*749*	*851*	*719*	*985*	*1078*
Category D (MOSP applicable from April 1, 1998; URMULEs from April 1, 2000)							
Registered		479	576	1672	1412	1484	1092
Withdrawn		3	17	65	120	137	58
Rejected		11	28	86	29	29	25
Total		*493*	*621*	*1823*	*1561*	*1650*	*1175*
Category E (MOSP applicable from April 1, 1998, except for URMULEs)							
Registered				88	158	108	95
Withdrawn				10	16	6	9
Rejected				2	3	15	15
Total				*100*	*177*	*129*	*119*

As might be expected, the rate of withdrawal or rejection is higher for submissions to register new active ingredients and major new uses or to make significant amendments to existing product registrations, compared to more minor changes to registrations covered in Category C, due to the

greater complexity and size of these submissions. Since the main transition to the MOSP examination process from FY 1996/97 to FY 1998/99, the percentage of submission examinations that resulted in a registration decision (versus withdrawal or rejection) has:

- Generally increased for Category A submissions—rising from 46% in FY 2000/01 to 65% in FY 2003/03 and 60% in FY 2003/04.
- Remained relatively stable for Category B, C and D submissions—in the range of 73 – 84% for Category B submissions, 82 – 87% for Category C submissions, and 90 – 93% for Category D.
- Decreased for Category E submissions, from 88% in FY 2000/01 to 80% in FY 2003/04.

3. Trends in the total time to register new products

Timely completion of submission examinations is a shared responsibility, in which the total elapsed time to a new or amended registration depends on both completeness and quality of applicants' submissions, and the efficiency of PMRA's management of submissions through the examination process. The total elapsed time to complete examinations of submissions and register pest control products has, as was noted earlier in this chapter, three main components: PMRA Time, Applicant Time, Deficiency Time plus, in the case of major new ingredients and uses requiring a PRDD, Public Consultation Time. Applicant Time and Deficiency Time are only incurred when the PMRA screening and/or review processes determine that submissions have deficiencies and requests for information to fill these gaps are issued to applicants. The PMRA "clock" is stopped when a request to address a deficiency is issued and restarts after the applicant prepares and submits their response (Applicant Time) and PMRA screens and reviews the new data (Deficiency Time).

Individual submissions may also have target performance standards that deviate from the published standard. These deviations are due to such factors as requests for extensions to time periods by applicants, needs for extended times to conduct data reviews, additional deficiency loops to address data deficiencies, and submissions following the process required by the Product Specific Registration II Policy on data protection (which pre-dates the MOSP). The number of deviations approved by the Agency Management Committee has exhibited an increasing trend in recent years, as shown in Exhibit III-6. The presence of these submissions then influences the distribution of times taken to complete submission examinations, particularly for Category A submissions.

Exhibit III-6
Numbers of completed submissions with deviations approved by the Agency Management Committee

Submission Categories	Fiscal Years				
	99/00	00/01	01/02	02/03	03/04
Category A	2	11	16	18	36
Category B	2	15	8	10	17
Category C	0	0	2	2	1

Source: PMRA data.

The scope for branching and looping in the examination process means that it is not a simple process to understand and assess PMRA's effectiveness and efficiency in examining submissions and making registration decisions, and requires consideration of such questions as:

- What are the trends in total elapsed time (that is, the sum of PMRA, Applicant, Deficiency and Consultation Times) for new registrations, and for withdrawn/rejected submissions?
- What is the incidence of ideal submissions?
- How does PMRA's performance on those elements of the process over which it has control compare to its performance standards?

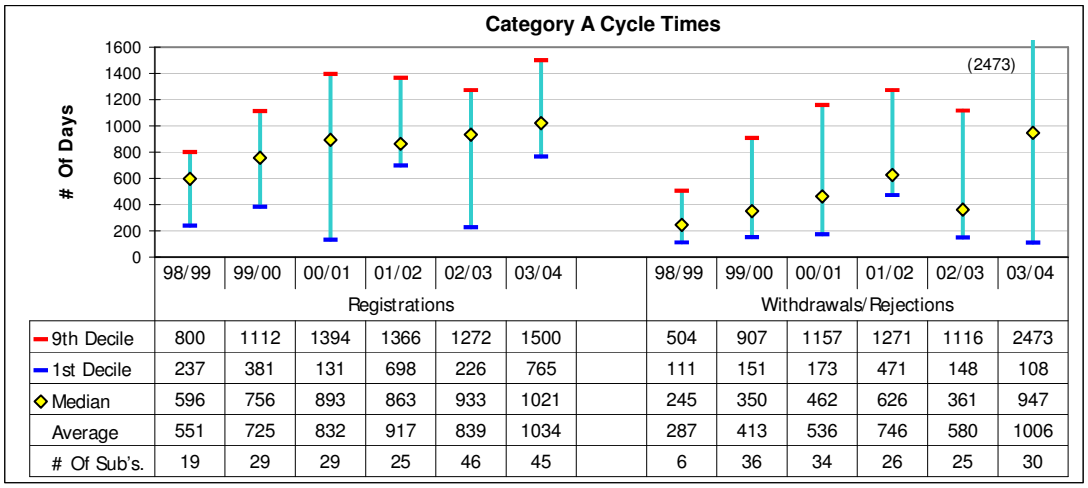
The following sections present findings relating to these questions. The information presented is drawn from an analysis by KPMG of data from PMRA's submission tracking system for Category A, B and C submissions completed during the FY 1998/99 to FY 2003/04 period. These submission Categories were chosen because they account for the majority of the time expended by the New Product Evaluation Business Line on the "1.1 Review Submissions" activity. (The following section examines PMRA's performance against its published standards.)

a) Trends in total elapsed time for new product registrations

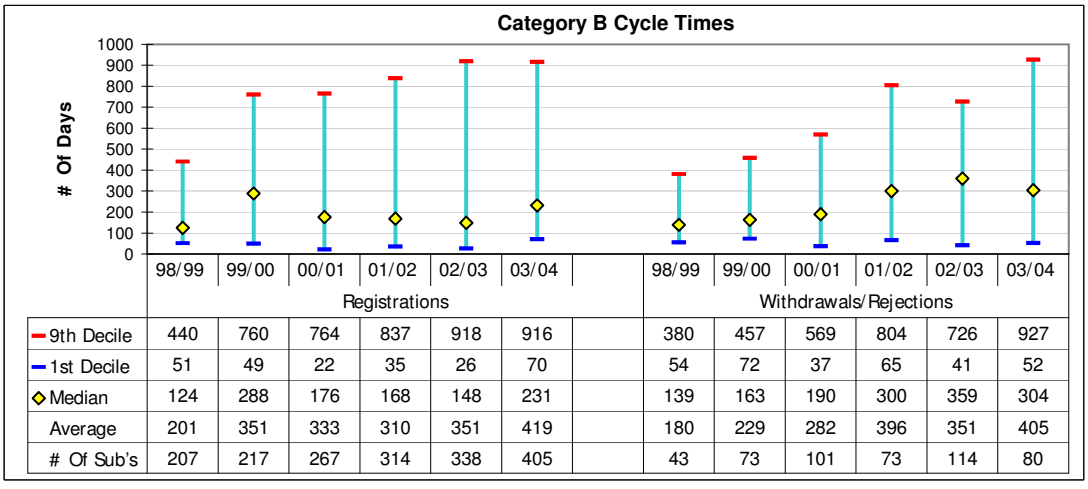
Information on total elapsed times ("cycle times") for standard and priority Category A, B and C submissions from PMRA's tracking system for the period from FY 1998/99 to FY 2003/04 is shown in Exhibit III-7. In reviewing this information, one must be careful in making comparisons between outcomes in the early years of the Agency's operations and those achieved in the latter years. Outcomes in the early years of Agency operation reflect performance in reaching decisions for the better (that is, quicker to be examined) submissions rather than performance across the full spectrum of submission quality and complexity. Category A submissions, for example, can take up to about five years to reach an outcome and still be within standard. As a result, we have focused our examination of trends in performance on the period from FY 2000/01 to FY 2003/04.

- ***For Category A submissions***, the median cycle times for registered products for the period from FY 2000/01 to FY 2003/04 exhibit an increasing trend, going from 893 days (29.3 months) in FY 2000/01 to 1,021 days (33.6 months) in FY 2003/04—a 14% increase. The distribution of cycle time around the median has varied, with the range between the 1st and 9th deciles varying between 1263 days (FY 2000/01) and 668 days (FY 2001/02). A large part of this variation is due to marked variations in the incidence of submissions with short cycle times. It should also be noted that these times include cycle times for submissions where the target performance time was negotiated with applicants and deviated from the applicable performance standards. The trend for withdrawn or rejected submissions since FY 2000/01 is similar, although not as strong.

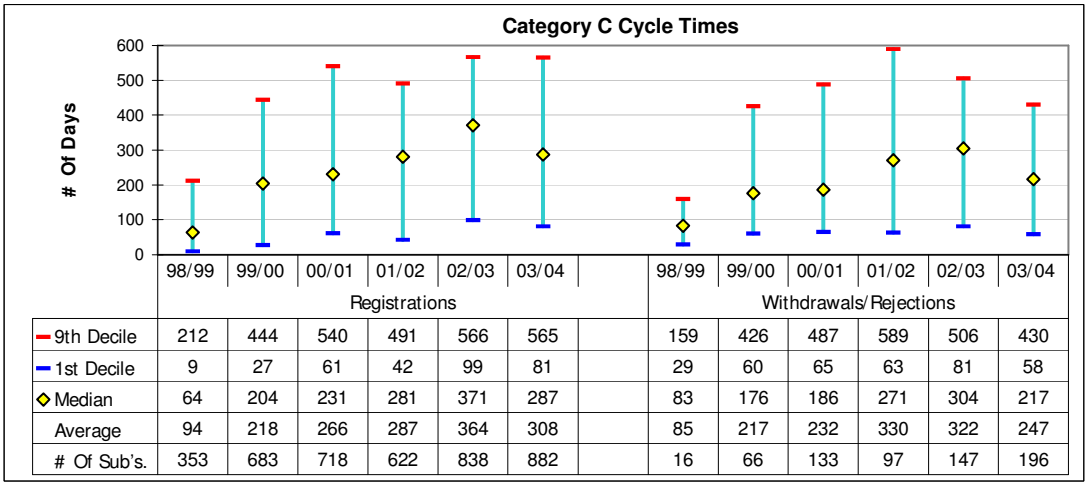
Exhibit III-7
Trends in Total Elapsed Times for Category A, B and C submissions



	Registrations							Withdrawals/Rejections					
	98/99	99/00	00/01	01/02	02/03	03/04		98/99	99/00	00/01	01/02	02/03	03/04
9th Decile	800	1112	1394	1366	1272	1500		504	907	1157	1271	1116	2473
1st Decile	237	381	131	698	226	765		111	151	173	471	148	108
Median	596	756	893	863	933	1021		245	350	462	626	361	947
Average	551	725	832	917	839	1034		287	413	536	746	580	1006
# Of Sub's.	19	29	29	25	46	45		6	36	34	26	25	30



	Registrations							Withdrawals/Rejections					
	98/99	99/00	00/01	01/02	02/03	03/04		98/99	99/00	00/01	01/02	02/03	03/04
9th Decile	440	760	764	837	918	916		380	457	569	804	726	927
1st Decile	51	49	22	35	26	70		54	72	37	65	41	52
Median	124	288	176	168	148	231		139	163	190	300	359	304
Average	201	351	333	310	351	419		180	229	282	396	351	405
# Of Sub's	207	217	267	314	338	405		43	73	101	73	114	80



	Registrations							Withdrawals/Rejections					
	98/99	99/00	00/01	01/02	02/03	03/04		98/99	99/00	00/01	01/02	02/03	03/04
9th Decile	212	444	540	491	566	565		159	426	487	589	506	430
1st Decile	9	27	61	42	99	81		29	60	65	63	81	58
Median	64	204	231	281	371	287		83	176	186	271	304	217
Average	94	218	266	287	364	308		85	217	232	330	322	247
# Of Sub's.	353	683	718	622	838	882		16	66	133	97	147	196

Includes cycle times for standard and priority submissions, and submissions where deviations from the MOSP standards were negotiated with applicants.

Source: PMRA submission tracking system data.

- ***For Category B submissions***, the median cycle time for registered products dropped from 176 days (5.8 months) in FY 2000/01 to 148 days (4.9 months) in FY 2002/03, and then jumped to 231 days (7.6 months) in FY 2003/04. For withdrawn and rejected products, the median cycle time rose steadily over the period to FY 2002/03—to 359 days (11.8 months)—before dropping to 304 days (10 months) in FY 2003/04.

  The distribution of cycle times for Category B registrations and, to a lesser extent, withdrawals/rejections is quite asymmetric, with a high incidence of times at the lower end of the range and a relatively small proportion of submissions incurring significantly higher elapsed times.

- **For Category C submissions**, median cycle times for both registrations and withdrawals/rejections exhibited steady growth from FY 2000/01 to FY 2002/03, followed by a drop in FY 2003/04:

  - From 231 days (7.6 months) in FY 2000/01 to 371 days (12.2 months) in FY 2002/03, and back to 288 days (9.5 months) in FY 2003/04 for product registrations.
  - From 186 days (6.1 months) in FY 2000/01 to 304 days (10.0 months) FY 2002/03 and back to 217 days (7.1 months) in FY 2003/04, for withdrawals/rejections.

  The range between the 1st and 9th deciles for registered products was relatively stable over the 2000/01 to 2003/04 period, varying between 449 days (FY 2001/02) and 484 days (FY 2003/04).

The data in Exhibit III-7 on median cycle times (sum of PMRA, Applicant, Deficiency and, as applicable, Consultation Time) to register new products and amend the registrations of existing products show a generally increasing trend in the overall time to registration for Category A and C products during the FY 2000/01 – 2003/04 period, and a more stable pattern for Category B registrations until FY 2003/04, when it rose sharply. The absolute increases in median times, and the average annual rates of change were as follows:

Submission Types	% Change in Median Cycle Time 00/01 to 03/04	Average Annual Rate of Increase 00/01 to 03/04
Category A:		
Registrations	14.3%	4.7%
Withdrawals/Rejections	105.0%	51.8%
Category B:		
Registrations	31.3%	13.2%
Withdrawals/Rejections	60.0%	20.7%
Category C:		
Registrations	24.5%	10.4%
Withdrawals/Rejections	16.4%	9.7%

b) Incidence of ideal submissions

Ideal submissions are complete, high quality submissions that incur neither Applicant Time nor Deficiency Time[1], that is, where applicants do not have to fill gaps in the data submitted and PMRA does not spend additional time examining data submitted by applicants to address deficiencies in their submissions. The ability of applicants to submit high quality submissions with low likelihoods of deficiencies, and the ability of PMRA to complete the examination of submissions in an expeditious manner is a function of such factors as the complexity of data requirements and their review, uniqueness of a product and the associated science, clarity of the PMRA requirements, and the level of understanding of PMRA's requirements and the examination process among applicants. As can be seen from the data in Exhibit III-8, very few Category A registrations, fewer than half of the Category C submissions, and just over half of the Category B registrations are ideal in any one year.

Comparisons of the amount of PMRA Time for ideal and non-ideal submissions for registered products, (Exhibit III-8), show that ideal submissions frequently have faster examination periods. Non-ideal submissions also involve Applicant Time and Deficiency Time over and above the PMRA Time, leading to significantly longer elapsed times from application lodgement to registration. For example:

- PMRA Time for the two ideal Category A submissions since FY 2000/01 was 46 and 237 days, respectively, whereas the median PMRA Time for the non-ideal Category A registrations varied from 549 days in FY 2000/01 up to 664 days in FY 2003/04. Median Applicant Time amounted to another 107 to 159 days, and median Deficiency Time another 90 to 222 days.

- Ideal Category B submissions had median PMRA times of between 64 and 129 days between FY 2000/01 and FY2003/04, while median PMRA Times for the non-ideal submissions, ranged from 396 to 497 days, plus median Applicant Times of 57 to 108 days, and median Deficiency Times of 5 to 90 days.

- Category C patterns were similar. The ideal submissions had median PMRA Times of between 67 and 168 days whereas the non-ideal submissions had PMRA Times of 128 to 265 days, plus median Applicant Times of 35 to 82 days. However, the majority of the non-ideal submissions had no Deficiency Time.

[1] Applicant Time—Defined by PMRA as the time taken by the applicant to respond to deficiency letters and to provide outstanding fees and final labels.
Deficiency Time—Additional time taken by PMRA to examine applicant responses to deficiency letters. This may happen at screening, review or final label review.
PMRA Time—Time taken by the PMRA on a submission that has no deficiencies or applicant time. It includes the time at verification, the first screen, review time, final decision time after public consultation and final label review time.

Exhibit III-8
Registered products — characteristics of ideal and non-ideal submissions

	Ideal Submissions							
	# of Regis-trations	# of Ideal Sub-missions[1]	% Ideal	PMRA Time (days)[2]		Ideal Time Standards (days)[3]		
				Range	Median	Priority Submissions		Standard Submissions
						Standard	Deviations	
Category A				(Actual)				
FY 1998/99	19	1	5%	14		552	-	737
FY 1999/00	29	2	7%	8, 16		552	-	737
FY 2000/01	29	2	7%	237		552	-	737
FY 2001/02	25	1	4%	46		552	577	737
FY 2002/03	46	0	0%	-		552	681	737
FY 2003/04	45	0	0%	-		552	367 – 1032	737
Category B						(Priority and Standard Submissions)		
FY 1998/99	207	114	55%	7-370	98	552	-	
FY 1999/00	217	80	37%	6-336	85	552	-	
FY 2000/01	267	136	51%	2-1010	64	552	-	
FY 2001/02	314	207	66%	0-542	114	552	-	
FY 2002/03	338	196	58%	7-541	110	367 – 552	-	
FY 2003/04	405	194	48%	8-367	129	367 – 552	-	
Category C								
FY 1998/99	353	174	49%	2-189	41	195	-	277
FY 1999/00	683	246	36%	1-265	66	195	-	277
FY 2000/01	718	162	23%	1-729	67	195	-	277
FY 2001/02	622	184	30%	1-537	96	195	-	277
FY 2002/03	838	212	25%	2-643	172	195	-	277
FY 2003/04	882	195	22%	3-565	168	195	-	277

	Non-Ideal Submissions							
	# of Non-Ideal Sub's.	% of Regis-trations	PMRA Time (days)		Applicant Time (days)		Deficiency Time (days)	
			Range	Median	Range	Median	Range	Median
Category A								
FY 1998/99	18	95%	96-590	375	14-221	106	0-211	65
FY 1999/00	27	93%	175-674	493	29-291	159	0-336	132
FY 2000/01	27	93%	78-740	549	5-565	108	0-550	90
FY 2001/02	24	96%	449-684	615	34-644	107	1-340	178
FY 2002/03	46	100%	32-1138	556	7-595	107	0-1017	182
FY 2003/04	45	100%	139-951	664	25-764	159	0-973	222
Category B								
FY 1998/99	93	45%	1-490	151	0-350	60	0-399	38
FY 1999/00	137	63%	40-623	318	1-561	70	0-424	35
FY 2000/01	131	49%	22-634	396	2-531	108	0-379	91
FY 2001/02	107	34%	14-843	458	8-504	124	0-512	70
FY 2002/03	142	42%	1-1167	485	1-641	88	0-823	43
FY 2003/04	211	52%	62-1154	497	2-565	57	0-1216	5
Category C								
FY 1998/99	179	51%	0-227	64	0-282	37	0-245	0
FY 1999/00	437	64%	1-548	140	1-494	73	0-231	0
FY 2000/01	556	77%	17-723	128	3-492	82	0-413	0
FY 2001/02	438	70%	23-644	185	2-724	63	0-483	0
FY 2002/03	626	75%	7-963	273	2-658	67	0-597	0
FY 2003/04	687	78%	19-727	265	1-650	35	0-281	0

1. Ideal Submission: one where no Applicant Time incurred by the applicant nor any Deficiency Time by PMRA.
2. PMRA Time (verification, first screen, review time, final decision time after public consultation & final label review time) plus, where applicable, Consultation Time.
3. Ideal times shown are for chemical product submissions. Ideal times for reduced risk and biopesticide products are shorter. See Exhibit III-1 for a complete breakdown. Deviations are negotiated with applicants on an exception basis.

Source: PMRA submission tracking system data.

The distribution of cycle times for ideal and non-ideal submissions shown in Exhibit III-9, further illustrates these differences between ideal and non-ideal submissions:

- Times to registration for ideal submissions have been generally increasing but have typically stayed within the applicable Ideal Time standards.

- Non-ideal submissions have exhibited a more rapid rate of increase in times to registration.

Note that cycle times for non-ideal submissions cannot be compared to the applicable Ideal Time standard alone. For these submissions, the applicable target times may differ from submission to submission depending on the point(s) within the submission examination process at which deficiencies are identified, the nature of these deficiencies and the applicable standards for Applicant Time and PMRA's Deficiency Time. As a result, the target time standards for non-ideal submissions can fall within a range of times involving varying combinations of Applicant Time to remedy deficiencies and additional screening and review loops (Deficiency Time) by PMRA. Responsibility for achieving the applicable time standard is thus shared between the applicant and PMRA. (Exhibit III-3 illustrated the trigger points for deficiency loops and the associated impacts on time standards.)

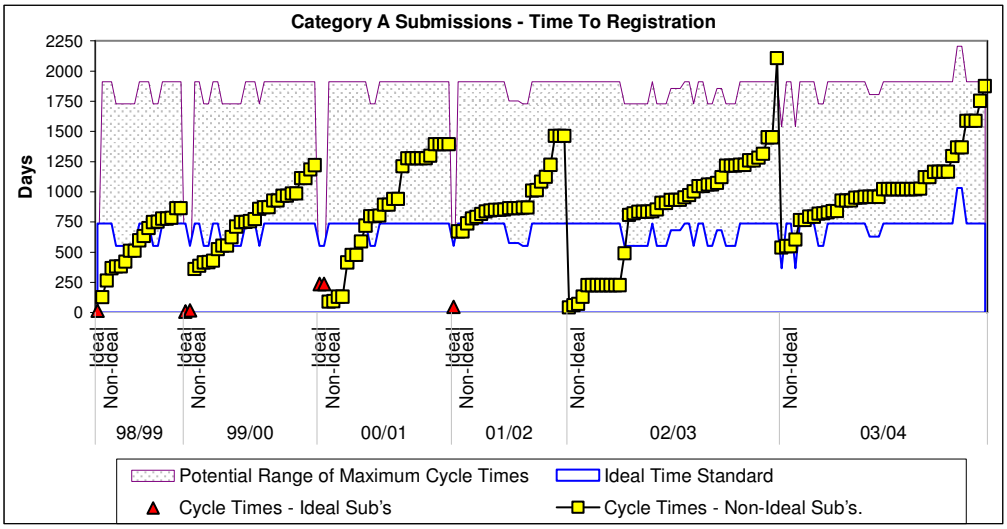
This effect is illustrated in the Category A graph in Exhibit III-9, which compares actual cycle times to the applicable potential maximum target times. In the worst case scenario for Category A submissions, the target cycle time would be equal to the sum of:

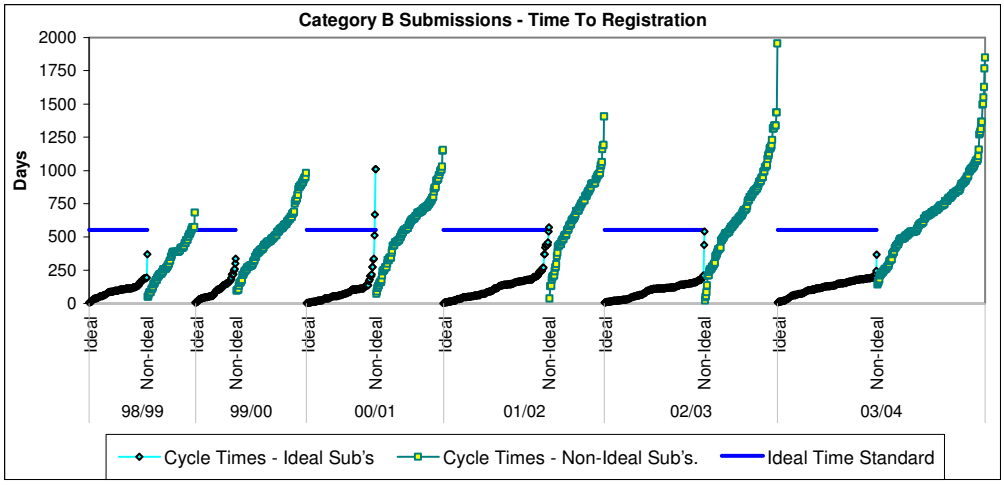
- PMRA Time of 737 days to screen and evaluate the submission, make a registration decision, and review and approve the final label.
- Applicant Time of up to 725 days, composed of:
  - Up to 225 days to prepare and submit additional data in response to submission deficiencies identified during screening, preliminary review and/or detailed evaluation.
  - Up to 90 days to respond to outstanding fee payments due prior to preliminary review and prior to detailed evaluation.
  - 365 days in which to submit the proposed final label plus 45 days to submit any required label changes.[1]
- Deficiency Time of up to 450 days for PMRA to review the additional data submitted by applicants to remedy data deficiencies and required label changes.

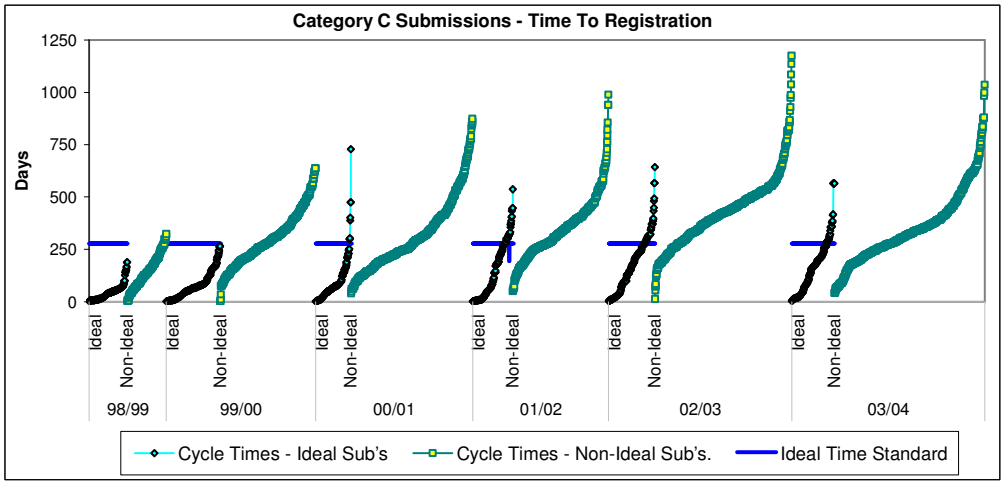
Similar upper boundaries also apply to the time standards for non-ideal Category B and C submissions but are not shown in Exhibit III-9.

[1] Note that the process for reviewing proposed labels was revised, effective July 1, 2003. These changes meant that, instead of having 365 days in which to submit a printer's proof of the marketplace label, applicants have 45 days to submit electronic copies of the proposed English and French label text. Some of the registrations included in Exhibit III-9 may have been subject to this revision and thus would have had a lower maximum potential time target.

Exhibit III-9
Distribution of cycle times for registered products







Source: PMRA submission tracking system data. Graphs include data for submissions with agreed deviations from the MOSP standards.

c) Extent to which PMRA has met its performance standards

PMRA's published target performance standard is to process 90% of submissions in all categories within published times. In practice, PMRA evaluates its performance by:

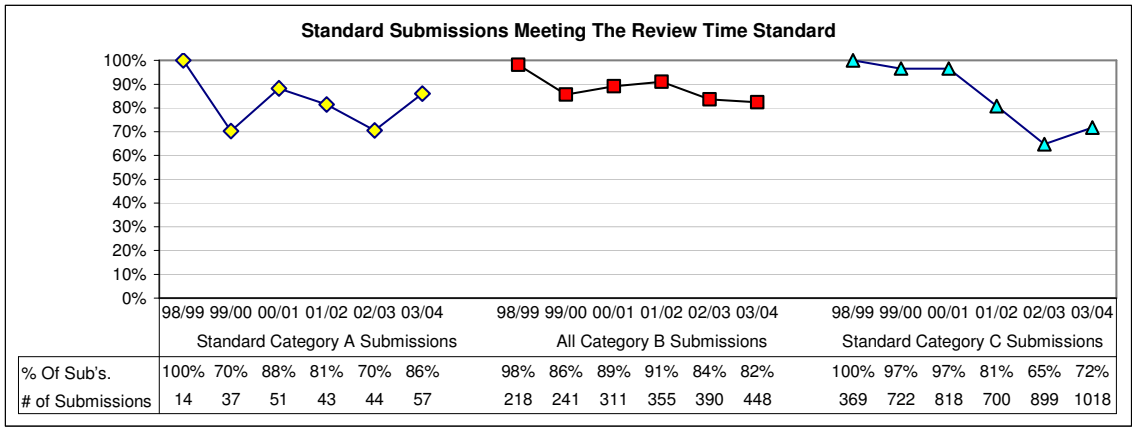
- Comparing the amount of Review Time (elapsed time by PMRA on the review component of the submission examination process) to the applicable review standard. For example, the Review Time for a standard Category A chemical submission is 550 calendar days or approximately 18 months.
- Comparing the PMRA Time (spanning all elements of the examination process, from verification to final label review, and excluding time spent responding to deficiencies by applicants and PMRA) plus Consultation Time to the Ideal Time. For example, the Ideal Time for a standard Category A chemical submission is 737 days or approximately 24 months.

Exhibit III-10 summarizes trends in PMRA's actual Review Time for priority and standard submissions (including submissions where time deviations from the MOSP have been negotiated with applicants) compared to the applicable performance standards. (As such, it differs from the breakdowns in the submission statistics that presented to EMAC, which summarize PMRA's Review Time performance for standard submissions only.)

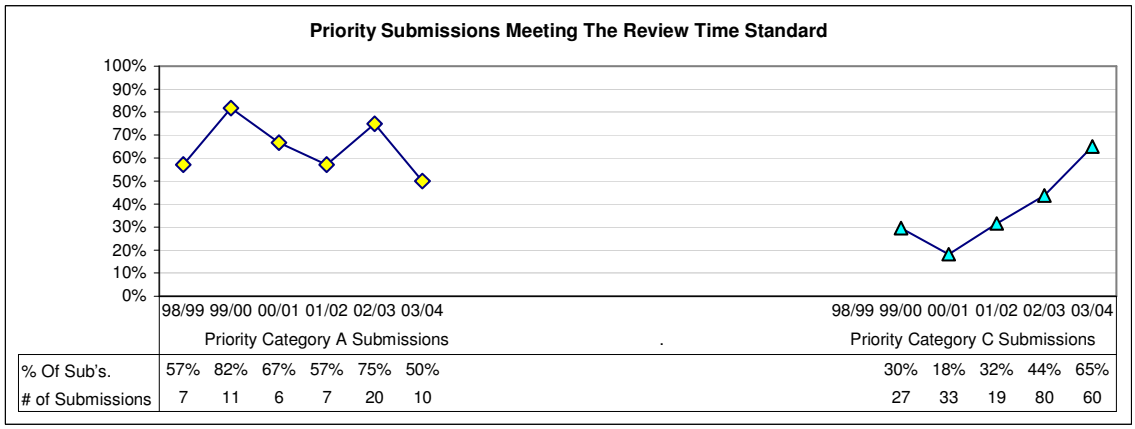
Our review of this data on PMRA's Review Times for submissions that reach the Review element of the submission examination process (that is, excluding submissions that were withdrawn or rejected during the initial Verification and Screening levels) suggests that:

- PMRA has experienced an increasing level of difficulty in completing submission examinations within applicable Review standards, with Category A, B and standard Category C submissions all exhibiting generally declining trends in compliance rates. (It should be noted that the outcome results for Category A and priority Category C submissions are calculated on small bases, and thus more likely to exhibit variability in response to small changes in the numbers of submissions that exceed the applicable Review standards.)
- Priority Category C submissions have exhibited a contrary trend, going from a low compliance level, of 18% in FY 2000/01, to 65% in 2003/04. We understand that PMRA encountered difficulties in matching resources to demand for Category C submission reviews during the period from FY 2000/01 to FY 2002/03, but changes made towards the end of this period appear to have resulted in improved performance in FY 2003/04 (and are continuing into 2004/05).

Exhibit III-10
Breakdowns of PMRA Review Time performance versus review standards—registered products plus withdrawn/rejected submissions that reached Review



	98/99	99/00	00/01	01/02	02/03	03/04	98/99	99/00	00/01	01/02	02/03	03/04	98/99	99/00	00/01	01/02	02/03	03/04
	Standard Category A Submissions						All Category B Submissions						Standard Category C Submissions					
% Of Sub's.	100%	70%	88%	81%	70%	86%	98%	86%	89%	91%	84%	82%	100%	97%	97%	81%	65%	72%
# of Submissions	14	37	51	43	44	57	218	241	311	355	390	448	369	722	818	700	899	1018

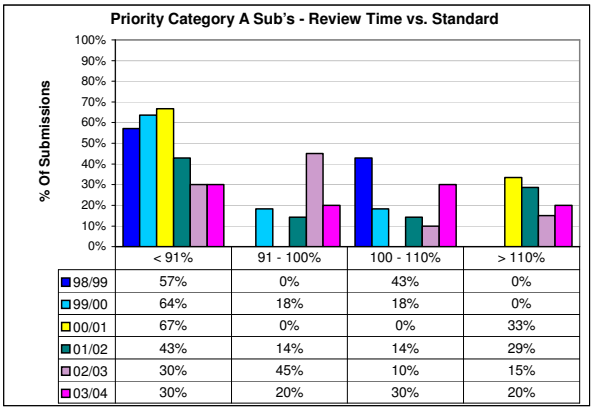


	98/99	99/00	00/01	01/02	02/03	03/04							98/99	99/00	00/01	01/02	02/03	03/04
	Priority Category A Submissions												Priority Category C Submissions					
% Of Sub's.	57%	82%	67%	57%	75%	50%							30%	18%	32%	44%	65%	
# of Submissions	7	11	6	7	20	10							27	33	19	80	60	

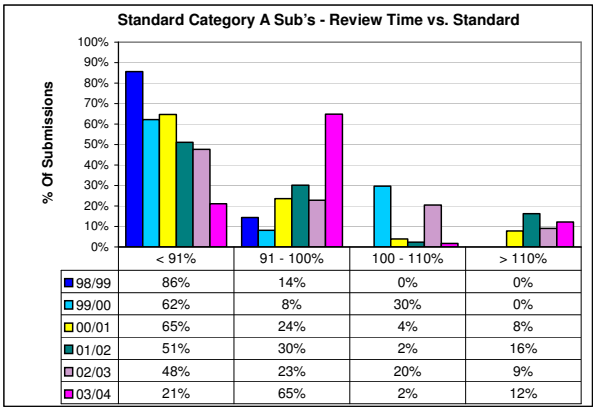
Source: PMRA submission tracking system data. Based on numbers of submissions that result in a product registration plus Withdrawn/Rejected submissions that reached the Review stage of the submission examination process. Data includes submissions with agreed deviations from MOSP standards.

Breakdowns of the distribution of Review Times around applicable performance standards shown in Exhibit III-11 also support the conclusion that PMRA has experienced increasing difficulty in completing the Review element of submission examinations within published performance standards. In particular, increasing proportions of completed submissions involve elapsed review times that were close to the performance standards, and fewer have Review Times that were comfortably below the standards. For example, in FY 2000/01, 88% of standard Category A submissions were completed within standard, and 27% of these submissions had Review Times that were between 90% and 100% of the applicable standard, that is, close to the target maximum. In FY 2003/04, 86% were completed within standard, but 76% of these submissions were within 90% - 100% of the applicable standards, and only 24% had Review Times below 90% of standard. Generally similar patterns are apparent in the distributions of Review Times for priority Category A submissions, and for Category B and standard Category C submissions.

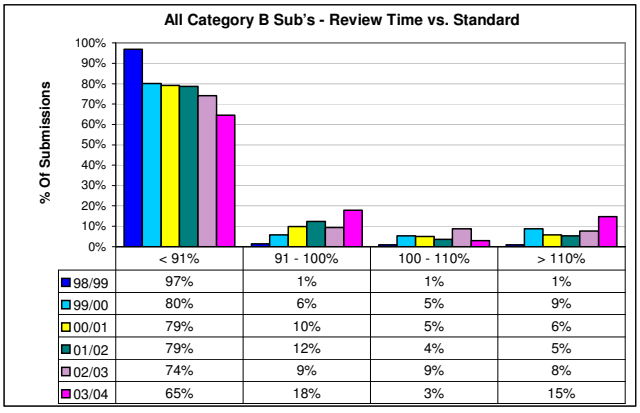
Exhibit III-11
Distribution of submission Review Times around applicable Review Time standards



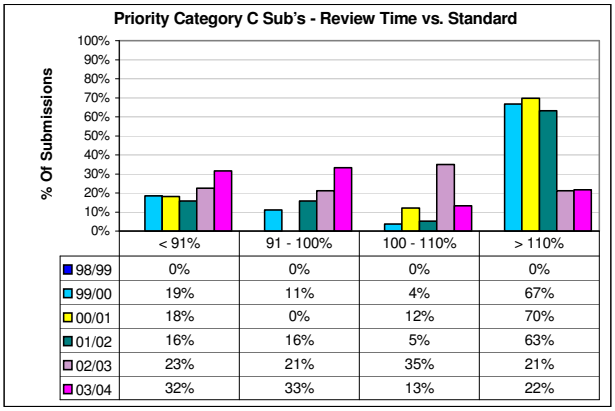
	< 91%	91 - 100%	100 - 110%	> 110%
98/99	57%	0%	43%	0%
99/00	64%	18%	18%	0%
00/01	67%	0%	0%	33%
01/02	43%	14%	14%	29%
02/03	30%	45%	10%	15%
03/04	30%	20%	30%	20%



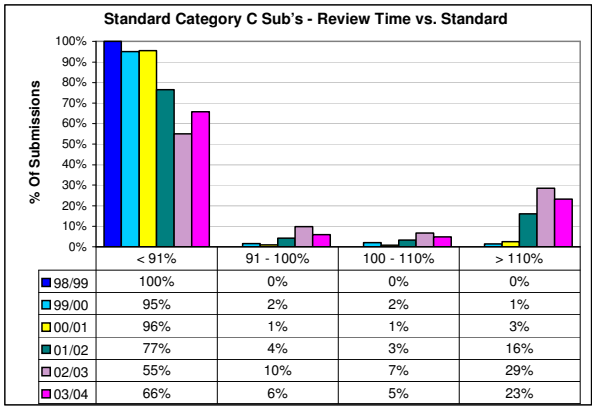
	< 91%	91 - 100%	100 - 110%	> 110%
98/99	86%	14%	0%	0%
99/00	62%	8%	30%	0%
00/01	65%	24%	4%	8%
01/02	51%	30%	2%	16%
02/03	48%	23%	20%	9%
03/04	21%	65%	2%	12%



	< 91%	91 - 100%	100 - 110%	> 110%
98/99	97%	1%	1%	1%
99/00	80%	6%	5%	9%
00/01	79%	10%	5%	6%
01/02	79%	12%	4%	5%
02/03	74%	9%	9%	8%
03/04	65%	18%	3%	15%



	< 91%	91 - 100%	100 - 110%	> 110%
98/99	0%	0%	0%	0%
99/00	19%	11%	4%	67%
00/01	18%	0%	12%	70%
01/02	16%	16%	5%	63%
02/03	23%	21%	35%	21%
03/04	32%	33%	13%	22%



	< 91%	91 - 100%	100 - 110%	> 110%
98/99	100%	0%	0%	0%
99/00	95%	2%	2%	1%
00/01	96%	1%	1%	3%
01/02	77%	4%	3%	16%
02/03	55%	10%	7%	29%
03/04	66%	6%	5%	23%

Source: PMRA submission tracking system data.

Exhibit III-12 summarizes trends in the actual amount of PMRA and Consultation Time compared to the applicable Ideal Times. This comparison is similar to that shown earlier in Exhibit III-10 except that it incorporates all elements of primary submission examination process over which PMRA has control, excluding time spent by PMRA screening and reviewing data provided by applicants to address any deficiencies. In other words, the Ideal Time is the maximum time that an applicant could expect submission examination to take if their submission is free of deficiencies. Exhibit III-12 shows that:

- Performance in completing standard Category A submissions and all Category B within applicable Ideal Time standards has exhibited a slight downwards trend over the period from FY 2000/01 to FY 2003/04, and dipped below the PMRA target of processing at least 90% of submissions within applicable time standards in 2003/04.

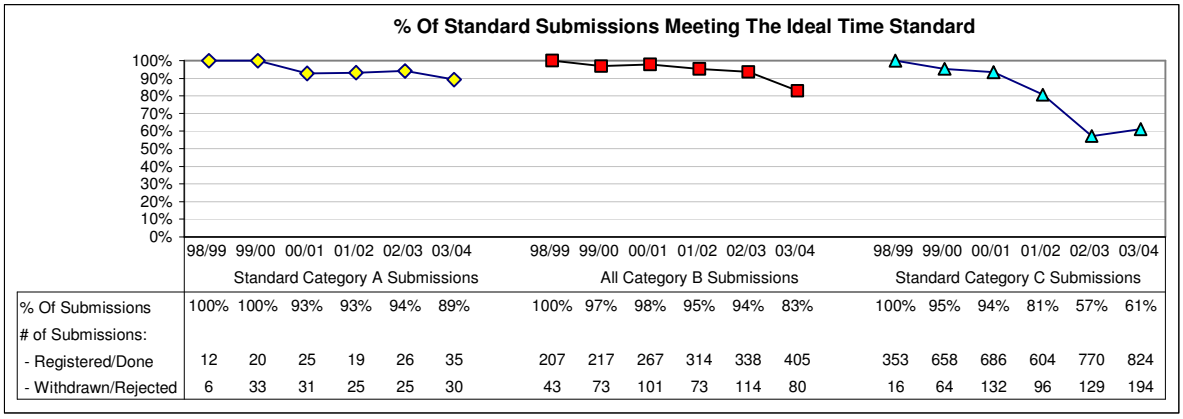
- Performance on priority Category A submissions went from 100% completed within standard in FY 2000/01 to 71% and 75% in FYs 2001/02 and 2002/03, respectively, before recovering to 100% in FY 2003/04. (Note that percentages for priority submissions are calculated on small bases.)

- Performance on standard Category C submissions consistently fell in each year from FY 2000/01 to FY 2002/03—from 94% completed within standard to 57%—before recovering slightly in FY 2003/04, to 61%.

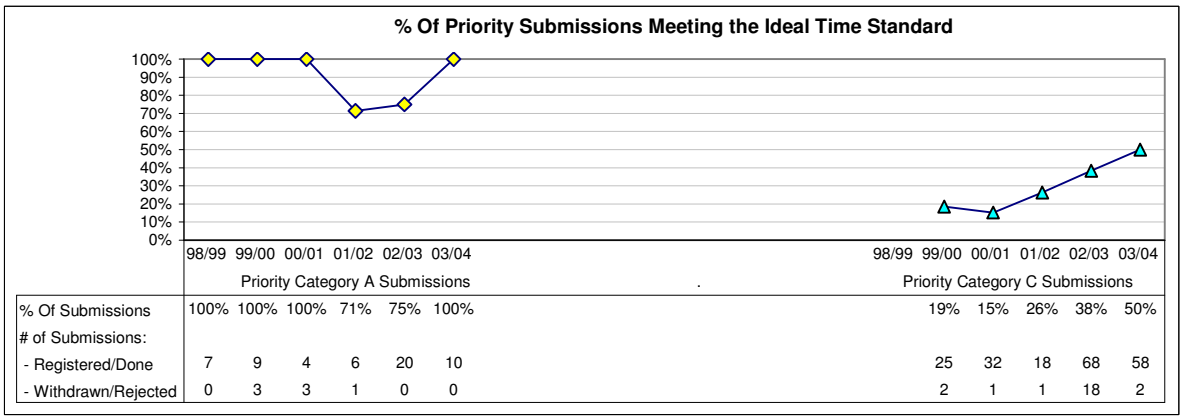
- Performance on priority Category C submissions has improved consistently in each year since FY 2000/01, albeit from a low base of 15% completed within standard.

These outcomes results suggest that PMRA has a better record in completing the full range of submission examination elements included in Ideal Time than it has in completing the Review element only for Category A and B submissions. For example, in FY 2002/03, 94% of standard Category A submissions were completed within the applicable Ideal Time standard, whereas only 70% of these submissions had Review Times that met the applicable Review standard. This pattern suggests that PMRA has been able to compensate for Review Times in excess of standard for Category A and B submissions by "catching up" time in other elements of the submission examination process. Performance patterns on completing Category C submissions has differed from that of Category A and B submissions, with performance on the review stage of the examination process consistently better than performance on the overall process.

Exhibit III-12
Breakdowns of PMRA Time versus Ideal Times for completed submissions



	98/99	99/00	00/01	01/02	02/03	03/04	98/99	99/00	00/01	01/02	02/03	03/04	98/99	99/00	00/01	01/02	02/03	03/04
	Standard Category A Submissions						All Category B Submissions						Standard Category C Submissions					
% Of Submissions	100%	100%	93%	93%	94%	89%	100%	97%	98%	95%	94%	83%	100%	95%	94%	81%	57%	61%
# of Submissions:																		
- Registered/Done	12	20	25	19	26	35	207	217	267	314	338	405	353	658	686	604	770	824
- Withdrawn/Rejected	6	33	31	25	25	30	43	73	101	73	114	80	16	64	132	96	129	194



	98/99	99/00	00/01	01/02	02/03	03/04	98/99	99/00	00/01	01/02	02/03	03/04
	Priority Category A Submissions						Priority Category C Submissions					
% Of Submissions	100%	100%	100%	71%	75%	100%	19%	15%	26%	38%	50%	
# of Submissions:												
- Registered/Done	7	9	4	6	20	10	25	32	18	68	58	
- Withdrawn/Rejected	0	3	3	1	0	0	2	1	1	18	2	

Source: PMRA submission tracking system data, including data for submissions with deviations from MOSP standards.

4. Trends in the quality of submissions received

A key determinant of the overall cycle time for examining submissions is the extent to which submissions are of high quality and without deficiencies to begin with, and thus are less likely to incur delays in screening. Efforts by both PMRA and applicants to improve the completeness of the more complex Category A and B submissions and reduce the incidence of deficiencies at the screening stage (that is, prior to review) appear to have been relatively successful. Data reported to the Agency's Economic Management Advisory Committee (EMAC) on the proportion of submissions that pass screening on the first try shows the following trends:

Fiscal Year	% Of Submissions That Passed Screening On The First Try				
	Cat. A	Cat. B	Cat. C	Cat. D	Cat. E
FY 2000/01	38%	58%	60%	92%	97%
FY 2001/02	84%	81%	77%	89%	94%
FY 2002/03	64%	78%	76%	92%	98%
FY 2003/04	70%	76%	73%	95%	89%

Source: Annual Submission Statistics reported to EMAC, *Submission Statistics – 2003-2004, Q1–Q2*, Nov. 26, 2003

* * *

In summary, the key trends in PMRA's submission examination process performance since FY 2000/01 are:

- PMRA's MOSP requirements were progressively implemented over the period from July, 1996, to April, 2000. Elements of the submission examination process were developed, or refined, in parallel.

- The MOSP also established interim performance standards for the examination of each submission category and sub-categories. A number of modifications to standards were subsequently introduced, resulting in reduced performance timelines for various submission sub-categories, for example, for reduced risk and microbial products.

- The number of submissions subject to MOSP was quite stable—at about 2000 per year—over the period from FY 1997/98 to FY 1999/00, and then jumped to a new level of between 3,000 and 3,500, primarily due to a sustained rise in the volume of Category D and, to a lesser extent, B and C submissions. Category A submissions peaked at 82 in FY 1998/99 and have run at a rate of about 50 per year since FY 2000/01. The growth in submissions received is contrary to the estimates that underpinned the forecast of costs used in the 1996 *Discussion Paper: Cost Recovery Analysis* and the findings of the subsequent Business Impact Test (BIT). For example, the BIT findings suggested that between 15% and 17% of the new applications in 1994 and 1995 would not have happened if they had been subject to the proposed CRI application fees.

- Since the main transition to the MOSP examination process from FY 1996/97 to FY 1998/99, the percentage of submission examinations that resulted in a registration decision (versus withdrawal or rejection) has:
  - Generally increased for Category A submissions—rising from 46% in FY 2000/01 to 65% in FY 2002/03 and 60% in FY 2003/04.
  - Remained relatively stable for Category B, C and D submissions—in the range of 73-84% for Category B submissions, 82-87% for Category C submissions, and 90-93% for Category D.
  - Decreased for Category E submissions, from 88% in FY 2000/01 to 80% in FY 2003/04.

- In FY 2002/03, outcomes were determined for 3,287 submissions—2814 resulted in a registration (86%), 104 were rejected (3%) and 360 (11%) were withdrawn by applicants. In FY 2003/04, the total number of outcome determinations dropped to 2,932—2,519 registrations (86%), 179 rejections (6%) and 234 withdrawals (8%).

- Data on median cycle times (sum of PMRA, Applicant, Deficiency and, as applicable, Consultation Time) to register new products and amend the registrations of existing products show a generally increasing trend in the overall time to registration for Category A and C products over the FY 2000/01 – 2003/04 period, and a more stable pattern for Category B registrations until FY 2003/04, when it rose sharply:

Submission Types (Subject to MOSP)	Median Cycle Times 00/01 (days)	01/02 (days)	02/03 (days)	03/04 (days)	Average Annual Rate of Increase (00/01 to 03/04)
Category A:					
Registrations	893	863	933	1021	4.7%
Withdrawals/Rejections	462	626	361	947	51.8%
Category B:					
Registrations	176	168	148	231	13.2%
Withdrawals/Rejections	190	300	359	304	20.7%
Category C:					
Registrations	231	281	371	287	10.4%
Withdrawals/Rejections	186	271	304	217	9.7%

Source: PMRA submission tracking system data.

- Very few Category A registrations in any one year are ideal (that is, for complete submissions that incur neither Applicant Time nor Deficiency Time), with one each in FYs 2000/01 and 2001/02, and none at all in FYs 2002/03 and 2003/04.

- The incidence of ideal Category B registrations has varied between 66% (FY 2001/02) and 48% (FY 2003/04), and the incidence of ideal Category C registrations between 30% (FY 2001/02) and 22% (FY 2003/04). PMRA Time is also more likely to be lower for ideal submissions than non-ideal submissions, in all categories.

- PMRA evaluates its review performance on two dimensions:

  - By comparing the amount of Review Time (elapsed time for the last preliminary review for deficiencies, evaluation time, first decision time, and PRDD preparation time (as applicable) by PMRA) to published standards for the Review element of its MOSP processes. This Review Time data (and including any submissions with prior agreed deviations), indicates that PMRA has encountered increased difficulty in meeting its target of completing 90% of submissions within the published standards, as shown below:

Submission Types	% of Submissions Meeting Review Time Standards 00/01	01/02	02/03	03/04
Category A				
Priority	67%	57%	75%	50%
Standard	88%	81%	70%	86%
Category B	89%	91%	84%	82%
Category C				
Priority	18%	32%	44%	65%
Standard	97%	81%	64%	72%

Source: PMRA submission tracking system data.

  - By comparing the amount of PMRA Time (spanning all elements of the submission examination process, and excluding Deficiency Time) plus Consultation Time to the applicable Ideal Time. On this measure of performance:

- The Agency has a better record in completing the submission examination elements included in Ideal Time than it does on completing the Review Time elements for Category A and Category B submissions.
- On Category C submissions, the Agency's performance on the review stage of the examination process has been consistently better than its performance in meeting standards for the overall submission examination process.
- Overall performance against Ideal Time standards has mirrored the downwards sloping trends for Review Time performance, except for priority Category A submissions.

- In addition, those submissions that meet the performance standards are more likely to be closer to the maximum target elapsed times for submission examination now compared to four years ago.
- Efforts by PMRA and applicants to reduce the incidence of deficiencies in screening (that is, prior to review) have had some success, leading to generally higher rates of submissions passing screening on the first try over the last three years compared to levels reported for FY 2000/01.

E. CRI contribution to efficient service delivery

This section reviews the extent to which steps have been taken to improve the delivery of an efficient service and extent to which such changes can be attributed to the CRI. It also summarizes external stakeholders' views on the extent to which the CRI has influenced the efficiency and effectiveness of PMRA's processes and performance.

The Statement of Work for this evaluation defined "delivery of an efficient service" as being "at the least cost, while meeting the Agency's regulatory responsibilities and quality and time specifications". Our review also took into account proposals made in the 1996 *Cost Recovery Discussion Paper* regarding the pursuit of operating efficiencies through changes in internal operations and collaboration with industry on improvements to the management and processing of submissions.

For applicants, and users of pesticide products, efficiency is perceived to be a function of the ability of the Agency's submission examination resources to complete examinations and decide on registration outcomes within the targeted time standards. On this basis, the extent to which PMRA has delivered an efficient service needs to be assessed in terms of the interplay between process efficiency, submission volumes, the resources available for submission examination and the quality of submissions received.

1. CRI attribution issues

The Statement of Work called for the contractor to evaluate the impact of the CRI on PMRA's processes and organization, ideally using multivariate analysis to isolate the impact of the CRI from other factors, and determine whether it has contributed to the delivery of an efficient service.

We noted, however, that in prior cost recovery reviews performed for Health Canada, KPMG and TNS found that consistent, comprehensive data (both quantitative and qualitative) regarding the impact of cost recovery on internal performance was difficult to develop and interpret, and was insufficient to permit any structured statistical analysis. This is also the case with PMRA, and our analysis of changes and impacts attributable to the CRI largely relied on a qualitative analysis of performance and the contribution of the CRI.

Two principal reasons underpin this inability to breakdown the driving forces underpinning decisions and actions to improve the efficiency of service delivery:

- ***Continuous performance improvement is generally regarded as being a core element of good management practice.*** Efficient service delivery, and continuous performance improvement, is generally accepted as being a required outcome of good management practice in both the public and private sectors. In PMRA's case, efficient allocation of resources and process management has been a necessity as Agency managers have sought to achieve required performance outcomes within resource limits created as function of such factors as lower than forecast revenues from cost recovery, faster growth in the number of submissions received relative to growth in budgets and resource allocations.

- ***Limits on PMRA's ability to monitor performance activities and their costs.*** PMRA has implemented an effective system to track the progress of submissions through the examination process and generate management reports. However, PMRA does not have, as part of this system, a means of collecting and tracking information on the actual time (and thus, a basis for costing) spent on different elements and tasks involved in submission examinations, and relies upon consensus estimates of time required for these activities. The lack of such information limits the extent to which performance can be tracked and the impacts of new requirements or process improvement initiatives to be accurately assessed, for example, to understand the relative significance of actual examination time versus queue or waiting time contributions to the elapsed time to examine submissions and register/amend products. In our international interviews we found that the U.S. Office of Pesticide Programs and the U.K. Pesticides Safety Directorate use time recording systems to track examination activities, and the Australian Pesticides and Veterinary Medicines Agency has conducted a number of periodic activity based costing surveys of its operations, with all three agencies using this information to develop and justify fees, and inform resource planning and allocation processes.

  In this context, the justification for introducing many performance improvement initiatives included consideration of the potential for improvements in operational efficiency at the same time as changes to meet new regulatory requirements or improve the effectiveness of examination and other regulatory processes are developed. In some cases, the initial impetus for business performance improvement initiatives was advocated or strongly supported by external stakeholders, such as the upgraded minor use initiative announced by AAFC and PMRA in FY 2002/03. In other cases—such as the development of the electronic submissions process, introduction of pre-submission consultations, steps to streamline the screening and review of submissions, or enable work sharing and international harmonization—there is clear evidence that efficiency improvements could be achieved but it is not

possible, nor practicable, to determine what specific impact could be attributed to the CRI. We understand that formal analyses of the expected impacts of major process changes on submission examination performance (that is, business case analyses) were not prepared as part of the planning for such initiatives.

2. Major changes to PMRA processes since 1997

PMRA's establishment in 1995 represented the outcome from an extended process designed to improve the federal pesticide regulatory system by consolidating all responsibilities and resources for the regulation of pest control products in a single organization within Health Canada. Since that time, PMRA has developed and implemented a wide range of process improvements and re-designed examination activities to improve the efficiency of its regulatory processes, which are summarized below. At the same time, however, other changes and developments have offset at least part of the gains made in streamlining the processing and examination of submissions. These offsetting factors are also summarized in this section.

a) Actions taken to improve process efficiency and/or effectiveness

The following list of steps taken to improve the efficiency of PMRA's submission examination activities is based upon information from PMRA documents and provided to KPMG during interviews with PMRA officers.

- ***Pre-submission consultations***. A means of providing advice and guidance to potential applicants seeking guidance on the required structure and content of proposed Category A, B and priority C submissions to maximize the likelihood of a complete submission and minimize the incidence of data deficiencies leading to the submission being placed on "hold" during the review process. PMRA has appointed a pre-submission coordinator to liaise with potential applicants, obtain pertinent background information, and arrange for officers from the relevant PMRA science divisions to review the applicant's information and provide advice to the potential applicant via a consultation meeting or conference call. Pre-submission consultations are strongly encouraged for new applicants, applicants with submissions involving potentially problematic active ingredients, and applicants proposing to seek registration of biopesticides. We understand that there were 157 pre-submission consultations in FY 2002/03 and approximately 129 in FY 2002/03.

- ***Submission tracking and management system.*** PMRA has implemented a well-developed system to log the receipt of submissions, track their progress through the submission examination process, and support the overall management and coordination of submission examinations. Data captured by the system regarding the status of submissions and time taken to move through various review levels provides the basis for the Agency's reporting on performance in examining submissions.

- ***Submission screening prior to detailed review to identify deficiencies.*** PMRA established a submission verification, screening and preliminary review process as the first steps in its MOSP to identify omissions in submissions prior to the detailed evaluation of a submission, and as early as possible in the overall submission examination process.

- ***Development and introduction of standardized templates and workbooks to facilitate consistent examination of submissions and preparation of monographs by PMRA's evaluators.*** Standardized templates for the evaluation of data submitted in support of applications for registration and preparation of data evaluation reports by PMRA (and EPA) evaluators have been developed to facilitate preparation of submissions and consistency in the evaluation of submissions. These templates draw upon standardized Use-Site Categories (USC) that group use-sites with common data requirements into specific categories and associated DACO tables (Data Code tables) that list data requirements for product registrations for USCs. According to DIR2003-01, the templates used to evaluate the information specified in DACO tables are used to:

  - *Review the scientific studies that are submitted to support applications to register pest control products.*
  - *Capture specific data components and record the reviewer's conclusions and rationales that are based on each data set.*
  - (Provide the basis to) *create an overall science monograph (a review document) on which the regulatory decision is based.*[1]

  The templates can also serve as guides for the preparation of submissions by applicants and are a key element in the structure of the approach to electronic submissions promoted by PMRA and the EPA.

- ***Development of standards and processes for electronic submissions, and conduct of e-filing pilot projects.*** PMRA has been working on the development of its secure Electronic Dossier, Delivery and Evaluation (EDDE) System for a number of years and is now at a point where a number of full electronic submission pilot projects have been conducted or are in progress, and many submissions include elements of the full submission in electronic format. Electronic submissions will be encouraged, but not mandatory, as full adoption and use will rely on development of the necessary capacity and skills at both PMRA and among registrants.

  Initial assessments of the benefits of electronic submissions by PMRA and the EPA indicate that such systems have the potential to streamline critical administrative and production activities involved in the screening and review of submissions, and preparation of data evaluations. For example, PMRA's pilot projects achieved a 25-50% gain in evaluation efficiency compared to paper submissions due to the application of electronic templates and workbooks, and the ability to readily transfer and/or analyze submission data. EPA has also reported a similar experience, achieving a 33-50% reduction in the time needed to review, analyze, and write DER (Data Evaluation Records) due to elimination of the need to re-key data arrays, potential to allow excerpting of information and preparation of review documents, and streamlined assembly of material for peer reviews.[2] It should be noted that these

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1 PMRA, *Organizing and Formatting a Complete Submission for Pest Control Products*, DIR2003-01 (revised), April 11, 2003. Accessed at: www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir2003-01-e.pdf.

2 *OECD Workshop on Electronic Tools for Data Submission, Evaluation and exchange for the Regulation of Agricultural Pesticides and Biocides*, Plenary Session presentation, Ottawa, October 2002. (Accessed at: www.oecd.org/dataoecd/55/2/28911346.pdf.)

estimates of time savings do not apply to the entire submission examination process for a submission, that is, it is still necessary to review data provided in support of a submission and the time involved in doing so is not expected differ substantially between electronic and paper submissions.

- ***Minor Use program with AAFC.*** In FY 2002/03, AAFC and PMRA launched an updated Minor Use and Reduced Risk Pesticide Program to enable improved access to minor use pesticides for growers. Under this program, which is integrated with the long-standing U.S. IR-4 program for minor use pesticides:
  - AAFC coordinates priority setting with grower groups, the provinces and territories, and registrants; performs field trials, and will prepare and submit registration submissions.
  - PMRA has appointed a minor use advisor and increased its capacity to examine minor use submissions; provides guidance to AAFC on data requirements and preparation of minor use submissions; and, implemented a joint review program for minor use products as part of the broader joint review initiative with the U.S. EPA. Maximum use will be made of U.S. IR-4 and EPA data in submissions and their review, to minimize the cost and data preparation requirements on AAFC and grower groups.

  The Minor Use Program was initiated in response to widespread concerns among grower organizations, provincial minor use coordinators, provincial extension services, and researchers regarding the effectiveness of Canada's approach to facilitating minor use registrations. These concerns related to the level of resources and funding available to support minor use work, the scale of data requirements for URMULE submissions relative to the significance of the target plant products and associated pest control needs, impacts on relative competitiveness of Canadian products, needs to improve access to reduced risk pest control products, and weaknesses in the communications and coordination between the various players.

- ***Shortening of performance standards for certain types of submissions.*** Performance standards for a number of different types of submissions have been shortened. For example, proposed label changes (application rate increases, level of control claims, changes to tank mixes, addition of new pests) that require efficacy data reviews only were transferred from Category B to C with concomitant reductions in review time, and new standards were established for reduced risk and biopesticide products.

- ***Revisions to PMRA's Notification/Non-Notification requirements*** leading to an expanded number of changes to the status of product registrations that either do not require PMRA to be notified (for example, correction of typographical errors on labels) or where a letter of notification can be used rather than a submission applying for a registration amendment (for example, a product name change or deletion of a pest from a product label). PMRA's changes also took EPA's notification and non-notification procedures into account.

- ***Transfer of the regulatory jurisdiction for hard surface disinfectants and disinfectant/sanitizers to the Therapeutic Products Directorate, Health Canada.***

Authority for the regulation of disinfectant and disinfectant/sanitizer products was transferred to simplify the application and evaluation process for companies and eliminate duplication of effort.

- ***Changes to the final label review process***, to require electronic submission of proposed label text (in English and French) for review, rather than a final version (or printer's proof), within 45 days of a registration decision. This change means that PMRA can more readily review the proposed text and ensure label is correct prior to certificate issue, and registrants do not incur additional time and cost if they have to make revisions to the label during the final stages of printing.

- ***Sharing of assessment reports, harmonization of approaches to the evaluation of submissions and work sharing among pesticide regulatory agencies.*** Harmonized requirements for submissions, joint reviews and work sharing, information sharing, and acceptance of other agencies' assessment findings have been identified by pesticide regulatory agencies, registrants and other stakeholders as a key means of improving the effectiveness and timeliness of the labour-intensive review process. PMRA is an active participant in two international harmonization initiatives:

    - *NAFTA Technical Working Group on Pesticides* (TWG), which has an objective of facilitating cost-effective pesticide regulation and trade between Canada, the U.S., and Mexico through harmonization and work sharing, while maintaining high levels of protection of public health and the environment. Outputs from the TWG's work with implications for the management and operation of PMRA's review process include:

        - Development of guidance and protocols for electronic lodging of submissions.
        - Substantially harmonized data requirements for agricultural pesticides, microbials and pheromones.
        - Efforts to increase use of work sharing (sharing of review reports and risk assessments for pesticides that have not been simultaneously submitted for examination and may be at different stages in the examination process in different countries) to increase the efficiency of the process and facilitate simultaneous, or more rapid, registration of products in the collaborating countries.
        - Creation of the joint review process for simultaneous registration of conventional chemical pesticides, microbials and semiochemicals based on new active ingredients and end-use products in Canada and the U.S., as a means of improving access to new products for Canadian users and sharing review tasks between the PMRA and EPA. As at December 31, 2003, 50 registrations (20 traditional chemicals, 24 reduced risk chemicals, 4 microbials and 2 pheromones) have been granted as a result of joint reviews and work sharing between PMRA and the EPA, plus

one URMULE and one import MRL. Another 12 submissions were undergoing joint review or work share-based reviews.[1]

- *OECD Working Group on Pesticides (WGP)* works to help OECD countries to harmonize their pesticide examination procedures, share the work of evaluating pesticides, and reduce risks associated with pesticide use. The recently released OECD *Vision for a Global Approach to the Regulation of Agricultural Pesticides* calls for a regulatory system where, by 2014:
  - *The high level of protection afforded to human health, animals and the environment is further enhanced and the levels of risk arising for man, animals and the environment as a consequence of the marketing and use of agricultural pesticides are minimized to the extent possible.*
  - *The regulatory system for agricultural pesticides will have been harmonized to the extent that monographs for pesticides prepared in the OECD format on a national or regional basis (e.g., EU or NAFTA) can be used to support independent risk assessments and independent regulatory decisions made in other regions or countries.*
  - *The preparation of data submissions (dossiers) for active substances and for end-use products is co-ordinated globally by industry, to the extent possible, such that opportunities are maximised for work-sharing between the regulatory authorities of OECD member countries,*
  - *Work sharing arrangements between regulatory authorities in OECD countries take place as a matter of routine such that data submissions (dossiers) prepared by industry in the OECD format are accepted in all OECD countries and made available and used globally, …*
  - *The generation for each active substance of a single monograph, serving the needs of the regulatory authorities in all countries has become commonplace, notwithstanding the need for separate independent risk assessments and separate independent regulatory decisions in each jurisdiction.*[2]

The WGP has championed the development of a standardized format for submissions by applicants (dossiers) and evaluators' review reports (monographs). PMRA accepts submission dossiers that use the OECD format. PMRA also uses review monographs prepared by other pesticide regulatory agencies when available in reviewing registration submissions and for reregistration of existing pesticides.

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1 PMRA, *Status of NAFTA Joint Reviews (JR): US EPA, Canadian PMRA and Mexican CICOPLAFEST*, JR2004-01, January 1, 2004. (Accessed at: www.hc-sc.gc.ca/pmra-arla/english/pdf/nafta/naftajr/nafta-jr2004-01-e.pdf.)

2 OECD Working Group on Pesticides, *OECD Member Countries' Vision For The Future: A Global Approach To The Regulation Of Agricultural Pesticides*, April 28, 2004. (Accessed at: www.oecd.org/department/0,2688, en_2649_34383_1_1_1_1_1,00.html.)

b) *Factors offsetting actions taken to improve submission examination efficiency*

PMRA's ability to reap the full returns from steps taken to improve the management and processing of submissions have been at least partially offset by a number of factors that increase the amount of time required for submission examinations. These offsetting factors include:

- ***Increased scientific complexity and absolute size of submissions.*** Approaches to the preparation, and examination, of submissions are continuously evolving in response to such factors as:

  - Changes in approaches to the assessment and management of pesticide risks considered in the Agency's regulatory decision-making.
  - Advances in relevant scientific knowledge.
  - Legislative and regulatory changes.
  - Actions to harmonise requirements with those of other pesticide regulatory agencies, particularly the EPA.

  Data requirements for submissions are defined by use-site categories (USCs) and data code tables (DACOs). Protocols for generating this data and approaches to the assessment of such data (for example, the assessment of endpoints) have evolved in response to such factors as those listed above, leading to more complex submissions. Examples of changes in the parameters for the Agency's risk assessments include the Toxic Substances Management Policy, the Agency's new formulants program, and the introduction of the U.S. *Food Quality and Protection Act* (FQPA). The FQPA established a single standard for assessing the risks of pesticide residues in food and feed that considers the aggregate risk from dietary exposure and other non-occupational sources of exposure. The Act also requires an explicit focus on exposures and risks to infants and children (including an additional safety factor of up to ten-fold, if necessary, to account for uncertainty in data relative to children) when new tolerances are established and existing tolerances are re-assessed, with the tolerance level based on a "reasonable certainty" that no harm will result from aggregated exposure.

  The absolute size of many submissions has also increased, as applicants have increased the number of proposed end-use products within single submissions to register new active ingredients, rather than seek initial registration for key end uses and to then submit a subsequent application (or applications) for end-use products.

  Pesticide regulatory agencies in other jurisdictions contacted by KPMG also reported similar experiences as pesticide companies seek to maximize the number of product applications approved on the first round of regulatory evaluation, the period of time in which they have market exclusivity rights, and opportunities to accelerate recovery of their R&D costs.

  Internal research by PMRA shows that the average size of Category A and B submissions has increased from an average of 3,605 and 781 pages, respectively,

during the 1990 – 1996 period prior to MOSP to an average of 9093 and 1137 pages post-MOSP (1997 – Oct., 2000).[1] The increased size of submissions means that reviewers have to spend more time systematically reviewing the submitted information and preparing review reports for use in risk assessments and registration decisions.

Findings from research conducted for CropLife America and the European Crop Protection Association regarding the cost of developing new agricultural chemical products support claims of increased submission size and complexity. For example:

Total product development costs increased by 17.9% from 1995 to 2000 and this increase was led by the 38.9% rise in expenditure on field trials, followed by environmental chemistry whose costs rose by 23.1% and developmental chemistry with an increase of 11.1%. …

The substantial rise in the costs of field trials in product development could arise from a need to increase efficacy data both for regulatory bodies and for companies as they set increasingly stringent commercial hurdles in the development process. … In order to satisfy these targets products may well have to have an application in multiple crop and pests situations. If this is the case, it could potentially increase the number of field trails that have to be undertaken. The increase in the costs of environmental chemistry at the development stage will in part be attributable to the need to undertake more comprehensive studies to investigate the environmental fate and impact of new molecules.[2]

- ***Follow-on effects of temporary registrations.*** One of the options open to PMRA in assessing the risks of prospective new pesticide products and/or uses and arriving at a registration decision is to provide temporary registration. This occurs when the risks to health and the environment are found to be acceptable but the review process has identified needs for confirmatory data or information to support full registration. The Agency then approves a temporary registration on condition that the applicant agreeing to undertake further work and produce the required confirmatory or other information within a specified time period. Temporary registrations are good for a period of one year, and may be extended for another year or converted to a full registration upon satisfaction of the conditional requirements. In both cases, the applicant makes a Category B submission (B.4 – conversion or extension of a temporary registration) and PMRA reviews the required data and makes a regulatory decision regarding registration.

  This means that whenever a temporary registration decision is made there will likely be at least one follow-on Category B submission in subsequent years. Over the period from FY 1998/99 to FY 2003/04, between 38% and 55% of the Category B outcomes (registration, withdrawal or rejection) have been for conversion or extension of temporary registrations. In FY 2002/03, 86% of the B.4 outcomes

1 PMRA, *An Analysis of Workload and Resource Requirements for Business Line 1 During Fiscal Year 2002-2003*, April 16, 2002, p.5.

2 Phillips McDougall, *Final Report: The Cost of New Agrochemical Product Discovery, Development and Registration in 1995 and 2000*, Prepared for CropLife America and the European Crop Protection Association, Midlothian, UK, 2003, p.10. (Accessed at: www.ecpa.be/library/ reports/PhillipsMcDoug-4-03.pdf.)

related to extensions and only 14% for conversions; in FY 2003/04 the extensions share was 74% and conversions rose to 26%.

- ***Additional time demands generated by joint reviews.*** Joint reviews with the EPA are pursued by PMRA as a means of accelerating the availability of new products for Canadian users and as a basis for work sharing between the two agencies, and thereby achieving efficiencies in the submission examination process. However, PMRA directors and managers indicated to KPMG that joint reviews often require additional time for PMRA tasks than would otherwise be the case, due to such factors as increased demands for liaison between the two agencies, needs to be familiar with and provide input to two decision processes, and the challenges involved in becoming familiar with each other's processes, methods of work and personnel. While one would expect that these learning effects should moderate over time it may be that further review and refinement of the standard operating procedures will be necessary to maximize the efficiency gains expected from work sharing. Requirements for the EPA to achieve reductions in decision periods for new active ingredients and end-use product registrations established in FIFRA (2004) may lead to further alignment of the processes of the two organizations.

- ***Impacts of submission cycling.*** Submission deficiencies may be identified at three different points in the review process (for Category A submissions): at screening (Level B), during preliminary review (Level C) or during detailed review (Level D). When letters of deficiency are issued the "PMRA clock" stops until the requested data or justification for a waiver is submitted and reviewed. According to the MOSP, if deficiencies still exist following these loops in the examination process the submission should be withdrawn. We understand that, in practice, some submissions are granted additional loops to deal with deficiency issues, thus adding to the time required for submission examination. While a certain incidence level of deficiencies is inevitable, their occurrence means that reviewers have to stop work on a submission and then re-familiarize themselves with the file when requested data is received.

- ***Industry mergers and acquisitions.*** Rates of mergers and acquisitions in the pesticides industry have accelerated in recent years, resulting in an increased volume of ownership transfers of registered products (Category C.6.1). The number of such transfers went from 178 in FY 2000-01 (21% of Category C submissions) to 280 in FY 2001-02 (39%), and 329 in FY 2002-03 (33%).

3. Approximate contribution of performance improvement initiatives

The reasons presented in the previous section mean that it is not possible to *determine whether the CRI has contributed to the delivery of an efficient service (that is, at the least cost, while meeting the Agency's regulatory responsibilities and quality and time specifications)*, as requested in the study Statement of Work. It is possible, however, to comment on the general efficiency of PMRA's performance in examining submissions, noting that any improvements made are at least partially attributable to the CRI.

At the time, the Agency began operations and the CRI was in development, PMRA made a commitment to achieve a 40% improvement in the efficiency of the process of approving new

products by 2003. In its 1998-2003 Strategic Plan, PMRA defined this target as being a *40% efficiency improvement in the review of complex submissions by 2003, through international harmonization, process improvements, and an efficient, effective electronic environment*.[1]

Subsequent analysis by PMRA qualified this target by adding an "all others things being equal" rider, that is, a 40% efficiency improvement before considering the effects of changes in the size and complexity of submissions. This analysis focused on the numbers of full-time equivalent employees (FTEs) allocated to submission review (1.1), NAFTA and OECD Projects (1.3 and 1.4), and regulatory directives (1.5) in Business Line 1, New Product Evaluations relative to the number allocated to this activity prior to the Agency's creation. Exhibit III-13 presents this data and adds in data for more recent years and for resources that were committed to the examination of the backlog of pre-MOSP submissions (BL 1.2: Backlog)to provide a complete picture of the level of effort dedicated to examining MOSP and pre-MOSP submissions since the Agency was established.

Exhibit III-13
Changes in submission examination resources

Direct FTEs	Baseline[1]	97/98	98/99	99/00	00/01	01/02	02/03	03/04
BL 1.0 New Product Evaluations								
1.1 - Review Submissions	124	94	95	108	110	125	152	185
1.3/4 - International Harmonization (NAFTA/OECD)	6	8	7	7	5	6	5	5
1.5 – Regulatory Guidelines/Directives	7	6	3	1	1	2	2	3
Total	**137**	**108**	**105**	**116**	**116**	**133**	**159**	**193**
% Change Over Baseline		*-21%*	*-23%*	*-15%*	*-15%*	*-3%*	*+16%*	*+41%*
BL 1.2: Backlog	26	41	20	-	-	-	-	-
% Change Over Baseline		*+58%*	*-23%*	*-100%*				
BL 1.1 + 1.2	163	149	125	116	116	133	159	193
% Change Over Baseline		*-9%*	*-23%*	*-29%*	*-29%*	*-18%*	*-2%*	*+18%*
# of Submissions Received								
Category A		*55*	*82*	*73*	*55*	*49*	*53*	*51*
Category B		*364*	*375*	*334*	*384*	*455*	*413*	*509*
Category C			*910*	*797*	*1095*	*809*	*966*	*809*
Category D, E, Misc.			*651*	*835*	*2030*	*1676*	*1791*	*1673*
Total		*419*	*2018*	*2039*	*3564*	*2989*	*3223*	*3042*
Annual % Change:				*+1%*	*+75%*	*-16%*	*+8%*	*-6%*

1. From analysis for *Cost Recovery Discussion Paper*.

Source: PMRA: Financial Report: 2002/03 and internal documents.

PMRA concluded, based on the trend in BL 1.0 FTEs, that it had achieved efficiency gains in examining new product submissions between the Baseline period and FY 1998/99, with the trend thereafter reflecting the impact of increases in the size and complexity of submissions and thus, increases in the amount of examination time per submission. Further gains in efficiency were then

[1] PMRA, *Strategic Plan: 1998-2003*, Ottawa, 1998, p.11. (Accessed at: www.hc-sc.gc.ca/pmra-arla/english/pdf/pmra/pmra_stratplan-e.pdf.)

expected to be realized through the introduction of an electronic submission process and its adoption by industry, and opportunities for international harmonization and work sharing. The rate of development, and thus rate of adoption, of these mechanisms by regulatory agencies and/or industry has been slower than was anticipated at the time of the Agency's start-up. During the period to FY 1998/99, the Agency was also able to effectively eliminate its backlog of pre-MOSP (Type 1, 2 and 3) submissions and then re-allocate the resources engaged in that work to the re-evaluation of existing registrations (BL 2.0) without reducing the level of effort dedicated to new product submissions.

Does this mean that performance expectations built into the CRI have been achieved and that the CRI has contributed to the *delivery of an efficient service*? Reductions in the level of effort committed to examining submissions—as was achieved during the early years of PMRA's operations—provide only part of the picture.

Regarding workload management, the total volume of MOSP submissions received by PMRA increased sharply in FY 2000/01 and has subsequently remained at this new level. However, one cannot simply look at the total volume and calculate a workload per FTE because of the varying size and nature of different submission Categories, and it is not possible to measure actual workload without measures of the time spent reviewing submissions (versus the time they spend waiting to be reviewed). In order to provide a purely indicative estimate of the trend in overall volume of work required by submissions we developed approximate estimates of the number of "Category A Equivalent" MOSP submissions that the Agency has worked on in each year since FY 1998/99.

As the name suggests, we attempted to convert the number of submissions received and in-process each year to a number of equivalent Category A submissions that were in the Agency's examination stream, using a proxy indicator of the level of effort associated with each Category. The ratio of the median amount of time spent by PMRA examining Category B and C submissions (PMRA Time, Deficiency Time, and Consultation Time) to the time spent on Category A submissions was used as the basis for this conversion. This approach assumes that these figures provide an approximate indication of the relative times required to complete submission examinations. Submission data for Categories D and E was not analyzed in detail by KPMG so we used an average of the Ideal Times for each of the Category D and E sub-categories, weighted by the numbers of submissions received over the 98/99 – 03/04 period to estimate the Category D&E weighting factors. The results of this analysis are shown in Exhibit III-14.[1]

[1] If anything, these indicative estimates are likely to underestimate the overall level of effort invested in examining Category A submissions due to workload factors that cannot be captured by using trends in elapsed times per submission. For example, we understand that the review of Category A submissions often involves multiple reviewers working within each of PMRA's review divisions whereas submissions in other Categories do not involve the same level of workload intensity.

Exhibit III-14
Indicative estimates of PMRA's submission examination workload

Category	98/99	99/00	00/01	01/02	02/03	03/04
Median amount of all PMRA time (PMRA Time + Deficiency Time + Consultation Time)						
A	409	374	428	699	752	807
B	113	173	140	168	158	212
C	56	131	139	204	266	244
Weighting Factors (Cat. Median ÷ Cat. A median)						
A	1.000	1.000	1.000	1.000	1.000	1.000
B	0.276	0.463	0.327	0.240	0.210	0.263
C	0.137	0.350	0.325	0.292	0.354	0.302
D&E	0.265	0.289	0.253	0.155	0.144	0.134
Indicative estimates of the volume of "Category A Equivalents Worked On"						
A	127	175	165	151	153	133
B	156	301	243	200	180	240
C	125	469	547	479	668	518
D&E	172	287	607	334	318	282
Total	**580**	**1232**	**1563**	**1164**	**1319**	**1173**

Source: Derived from Category A, B and C data extracted from PMRA's submission management system.

The estimated "Category A Equivalents" in the above table suggests that PMRA experienced a combination of steady growth in the amount of submission examination work on hand over the period to FY 1999/00 while submission examination FTEs were initially constant. Increases in FTE levels tended to lag the growing backlog of work on-hand—especially given that it takes a substantial amount of time to bring new FTEs "up to speed"—and were further affected by the jump in the volume of Category B and D submissions that occurred in FY 2000/01. Increases in submission examination FTEs in FY 2001/02, FY 2002/03 and FY 2003/04, in combination with the impacts of actions to streamline the administration and conduct of submission examinations, appear to have contained the overall level of work on-hand and brought about some reduction during FY 2003/04.

In summary then, it appears that PMRA has made gains in the efficiency of its service delivery by streamlining its submission examination process but these improvements have been offset by increases in the size and complexity of major submissions, increases in the total volume of submissions and resulting increases in the Agency's workload, without commensurate increases (until FY 2002/03) in the level of resources available for submission examination work. As a consequence, the Agency's overall volume of work on-hand (that is, the volume of submissions undergoing examination at any one time) increased as well as the elapsed time required to complete submission examinations.

Results for FY 2003/04 show that PMRA may have achieved a slight reduction in the level of examination work on-hand and some recovery in the percentage of completed submissions meeting their applicable performance standards.

Further increases in the capacity of the Agency to complete submission examinations in accord with performance standards will depend on the rate of development and adoption by industry of

electronic submissions and international harmonization and work sharing between pesticide regulatory agencies in combination with careful matching of examination resources to demand for examination work. PMRA and EPA pilot projects with e-submissions found evidence of significant reductions in the time required to conduct examinations by reducing or eliminating data entry/re-entry tasks and facilitating the preparation of review monographs. Achievement of such gains will depend, however, on widespread use of full e-submissions by applicants, instead of the current dependence on a combination of paper and paper-electronic submissions, as well as their support for international work sharing.

Increases in the Agency's capacity to complete submission examinations in accord with performance standards will also depend on continuing efforts by applicants, with support from the Agency, to submit high quality, complete submissions and thereby minimize Applicant and Deficiency Time in the submission examination process.

4. Stakeholder observations on the efficiency of PMRA service delivery

Interviews were conducted with external stakeholder representatives familiar with the CRI to gain an understanding of these stakeholders' views on the extent to which the CRI has achieved its objectives and contributes to efficient service delivery. The participants in these interviews indicated that they were quite familiar with the history of the CRI initiative. Various participants in these interviews had been part of the original CRI consultation process in the mid-1990's and/or participated in the work of the Pest Management Advisory Committee (PMAC) or Economic Management Advisory Committee (EMAC)) and were familiar with the history of the CRI initiative.

The following sections summarize the most common themes and perceptions from the comments made by external stakeholders.

a) Relative success of the CRI

Our interviews also found a wide consensus that, in planning for cost recovery, PMRA over-estimated the expected revenues that would be generated from user fees, due to such factors as a faulty business impact test analysis together with inadequate internal data on projected submission volumes. They stated that PMRA CRI revenue volumes for the years subsequent to the introduction of CRI were considerably lower than expected and that the PMRA had to obtain resources from other sources in order to maintain an adequate level of program delivery. Nonetheless, several interviewees commented that they had supported the CRI initiative at the outset, believing that it should lead to efficiency gains and a more "predictable" registration process (that is, they would have more accurate guidance as to likely dates of approval and registration).

Many of the interviewees agreed that during the era of CRI development, much discussion took place about how CRI would lead to a reduction in the backlog of submissions and would lead to an improvement in efficiency. However, once CRI was a reality, the general feeling is that the Agency began to lose interest in the efficiency improvement goal. Some of the individuals who had been involved with the PMRA advisory committees stated that PMRA staff rarely addressed the subject of CRI and its impact on efficiency at these meetings. One registrant summed up their view on the history of CRI as follows:

> *Cost recovery raised hope on the part of industry that things would improve. Industry stakeholders devoted countless hours in meetings to move in that direction. It has been an exercise in frustration and has served to drive a broader wedge between stakeholders and the PMRA. … I do not believe that CRI was ever taken seriously. The PMRA really does not care where its money comes from, that is, whether it's from CRI or other areas of the public coffers. I have had senior management in the Agency tell me this. … Even once cost recovery was in place, when the PMRA was running several millions of dollars over budget and EMAC tried to table "balancing the budget" as an agenda item, we were told not to worry, since if PMRA ran a deficit it would be covered anyway. So, there was absolutely no motive to improve efficiency.*

Some interviewees believed that the revenue that the PMRA had received through CRI simply replaced the public funding that the Agency would have received anyway rather than providing an infusion of incremental funds that would enable the organization to make service delivery improvements.

One positive note mentioned by several interviewees is that the original cost recovery fee structure was to involve high annual maintenance fees. This would have had major negative impacts on growers of minor use crops, as the number of available minor use pest control products would have been severely reduced. Fortunately, the annual maintenance fees were reduced, which was viewed as a good decision for industry (notwithstanding the fact that it would have resulted in a lower level of revenue to PMRA and thus contributed to the resource management issue identified in the previous paragraph).

Not all stakeholders supported the general notion that CRI was a useful management tool for PMRA nor a means of improving service delivery. Some stakeholders interviewed emphasized that they disagreed with cost recovery being applied to a regulatory agency devoted to protecting the environment and human health. They felt that cost recovery inevitably leads to a perception that "those who pay shall have a say", and that cost recovery results in too much attention being paid to how to increase efficiency. Their concern is that this efficiency focus is at the expense of sufficient attention to other, more important public policy goals, such as reducing the use of traditional chemical pesticides and promoting the use of natural pest control products.

Some interviewees also indicated that they understood that the annual maintenance fees were to also cover the cost of re-evaluations, and were concerned that the agency may have collected insufficient revenues, leading to the conduct of fewer re-evaluations than planned.

b) Relationship between fees and actual costs of review work

Many of the stakeholders interviewed stated that the current fee structure does not seem to have any relation to the actual work required by the PMRA to complete the various submission examination activities. Some fees were actually felt to be too low in relation to the amount of work apparently required to complete the associated tasks. Some examinations require a huge amount of data to be reviewed but cost less than a thousand dollars, while other tasks are perceived to involve little work and cost tens of thousands of dollars.

Several also commented that the PMRA does have a good submission tracking system, and therefore should be able to measure the actual cost of each work activity, so that it could rationalize its fee structure in the future. (This comment assumes that PMRA is tracking actual time spent on submission examinations rather the elapsed time to complete activities at each review level, which is the basis for the current system.)

c) Extent to which efficiency gains have been achieved

The preamble to our questions on the impacts of CRI on efficiency made reference to the PMRA's commitment, in 1997, to "achieve a 40% efficiency gain in the examination of new submissions, through such actions as international harmonization, re-engineering of its evaluation processes, and the conduct of joint reviews." When asked about the extent to which this goal has been achieved, a commonly expressed opinion was that the 40% efficiency gain appeared to be an arbitrary and overly ambitious target, that is, they felt that it was not based on an in-depth analysis of forecast demand and resulting revenues. Interviewees also stated that they understood that the 40% efficiency gain was to be achieved strictly by the use of electronic submissions, and that the other factors mentioned in the preamble were identified later. This further bolstered their view that the original target was based on insufficient analysis. The perception is that the revenues obtained from CRI were put into a general revenue stream, and not used specifically for service delivery improvements.

d) Impacts of CRI on the timeliness of evaluations of submissions

The performance of PMRA received much discussion during our interviews, and is a particularly contentious issue, particularly amongst pesticide manufacturers and growers. Concerns highlighted related to:

- Operation of the submission examination process.
- Timeliness of submission outcomes.
- Performance reporting.
- PMRA versus EPA.

On the subject of the operation of the submission examination process, most stakeholders familiar with the process believe that the CRI initiative has lead to a limited, modest improvement in efficiency of PMRA submission evaluations, and certainly no where close to the original projection of a 40% improvement. Particular areas of concern focused on:

- ***An apparent increasing tendency by the PMRA to delay making decisions on submissions.*** They believed that this is due, in part, to growing public concern about, and recent media reports on, the potential impacts of pesticides on human health. In the words of one participant: *At the PMRA, no decision is felt to be a good decision, since it means they have achieved their goal of zero risk tolerance*.

- ***Onerous and slow process for minor use submissions***, which was not necessarily due to CRI, but to the overall submission examination philosophy and process. (This issue is discussed in more detail in the next chapter.)

- ***Some parts of the overall submission evaluation process are working better than others.*** The main criticisms focused on the "beginning and end" of the process. The screening process instituted by PMRA is particularly troublesome for some registrants, with concerns being expressed about the basis on which submissions are determined to be deficient. Examples were given where extremely minor deficiencies were identified by PMRA (e.g., minor formatting errors) that resulted in submissions being referred back to the applicants to be redressed, thereby "stopping the clock". Registrants firmly stated that they do not understand why very minor deficiencies in a submission are grounds for preventing the submission from going forward for review. They suggested that the working philosophy at the PMRA was to send the submission back to the registrant whenever possible, in order to help manage the workload and to ensure the performance standards are met. Their main suggestion was for the PMRA to work more cooperatively with registrants to quickly resolve minor screening deficiencies and to have the submission put forward for review while these deficiencies are still being resolved. Another bottleneck appears to happen at the decision stage, which some interviewees suspected is due to difficulties in convening decision-making committees, which can delay the process.

- ***Weaknesses in the PMRA's "single window" process.*** Stakeholders who commented felt that this process is not working as well as it could. They stated that a "single window" is fine for handling general questions or disseminating new policy information, but it is not appropriate for dealing with submission-specific issues. They would prefer that the PMRA take a "product management" approach, whereby one reviewer would be responsible for all submissions of a certain type, and would interact with the registrants directly, with the goal of achieving a completed submission examination in the least amount of time. Another concern for the industry representatives was the time required to set up pre-submission meetings and an associated reliance on pushing issues and decisions "up the chain of command" instead of seeking to provide a higher degree of authority for front-line staff.

A number of positive aspects of the submission examination process were also highlighted:

- Some of those interviewed who were familiar with the submission examination process noted that the ***evaluation of Category A submissions has improved over time***. This was particularly the case for submissions related to pesticide products targeted to major Canadian crops with significant domestic markets, such as wheat and canola. For these applications, it was stated that global manufacturers would want to register in Canada first. Interviewees were not sure of the reasons for the generally efficient processing of these types of submission examinations other than that the PMRA might be more concerned to ensure these high profile submissions are expeditiously processed.

- Others noted that ***once a submission finally reaches the detailed review level, the process goes much better*** although some commented that there appeared to be too many "hand-offs" at this stage in the process. They gave the example where one reviewer will do one piece of the review, and then another reviewer will do another piece, but often asking the same questions of the applicant as the first reviewer, suggesting that there seems to be some duplication of work going on

In summary, one respondent summed up the general view on the efficiency of the submission process as follows:

> *On the positive side, it is not the core business (scientific review) that causes the delays; it is the ancillary things, like the clerical screening stage and the review of label translation. It should be possible to fix these minor parts of the process, which would have a major impact on overall efficiency.*

Another major discussion topic for stakeholders focused on the issue of the PMRA's performance compared to its performance standards. Most stakeholders interviewed stated that they do not believe that the PMRA's performance statistics are true or valid measures of performance, and that the Agency manipulates its statistics to ensure it meets its standards for completing a submission within a particular period of time. They also said that PMRA focuses on the "middle" portion of the entire process (Review Time) and does not include the time taken at the beginning (time up to the point where PMRA has a reviewable submission) and end portions of the process.

Some stakeholders noted that the industry had decided to publish its own report on PMRA's submission examination performance, which was followed by a long rebuttal report by the PMRA a year later. The recent formation of a joint PMRA-industry working group to pilot a new measurement system, which industry participants believe will provide more detailed data breakdowns (e.g., by category type and sub-type, since submission examination tasks and thus, performance times, vary considerably between various sub-categories), was seen as a constructive move to address issues in this area. Several stakeholders concluded this discussion by saying that a lot of wasted energy had been spent by both sides on arguing about performance measurement, and that hopefully the pilot will lead to a more cooperative approach in the future and a performance report that *everyone can agree on*.

In the third area where interviewees expressed concerns—that of PMRA's general approach to submission examinations versus the U.S. EPA—a widespread perception is that the performance of the regulatory system is contributing to fewer new products being registered in Canada compared to the U.S. The Canadian regulatory system is viewed by most registrants as being much more difficult compared to the U.S. regulatory process. The following comment from one industry stakeholder summarized the core of this concern:

> *PMRA's published mandate is to protect human health and the environment, while providing growers with access to a full toolbox of pest control products. In my view, PMRA places the emphasis on the former rather than on the latter. Their approach is having major negative impacts on both manufacturers, in terms of fewer products being registered, and on growers, in terms of having access to fewer products compared to their U.S. competitors.*

Industry representatives and registrants stated that the EPA is more client-focused, responsive and user-friendly. One interviewee summed up the predominant view as:

> *If the EPA finds a minor problem during the screening stage, the reviewer will pick up the phone and we'll often resolve it on the spot, often by e-mail. However, when the PMRA finds a very minor problem, the tendency is to send the submission back to the registrant, which stops the clock and results in weeks or even months of delays.*

Also, the EPA believes in direct contact between the reviewer and registrant. The PMRA, however, seems afraid of direct contact; I never hear from a reviewer. This may be due to a reluctance for any one employee to take responsibility for the submission, that is, to hide behind a wall of anonymity.

While the PMRA has pursued the joint review process with the U.S. EPA, it appears that some of the multinational pesticides manufacturers are reluctant to make submissions that will be handled by this joint process. The reason cited is that the multinationals fear that the joint process may hurt their chances of a successful outcome, since the PMRA may identify an issue with the submission that will jeopardize their chances of success in both countries. As a result, manufacturers are more likely to register the product with the U.S. EPA first (where the U.S. represents 30% of their global market, compared to only 3% for Canada). Again, the exception is major Canadian products, where the manufacturer will likely decide to register in Canada first, due to the significant size of the Canadian market. Some industry stakeholders believe that multinational pesticide manufacturers have basically "given up" on the Canadian market, particularly for products where the Canadian market was projected to be a minor share of the global market.

Some of the interviewees who had in-depth experience with both PMRA and the EPA felt that there is insufficient interaction between the two agencies. As evidence of this, they cited examples where the applicant became the channel of information flow between the two agencies, e.g., information on the status of certain product re-evaluations and de-registrations by the EPA was passed on to the registrant, who in turn provided the information to the PMRA, which had no knowledge of these developments.

e) Impacts of CRI on the size of registration submissions

Only a few interviewees—predominantly registrants—were able to comment on this issue. They agreed that the CRI did encourage the bundling of submissions initially. However, with the advent of joint reviews, the tendency has been to break up new product submissions into separate examinations. Overall, registrants believed that bundling together of submissions results in a submission that is too long and complicated, and therefore takes too long to process. (Notwithstanding this, managers at PMRA—and at pesticide regulatory agencies in other jurisdictions—indicated to KPMG that the number of end-uses included in submissions for new active ingredients and major new uses were increasing so that applicants could secure more rapid market rollout of their new products.)

f) Impacts of CRI on other areas of its mandate

Participants in the stakeholder interviewing program were also asked if the CRI has had any impact on the quality and timeliness of PMRA's work in other areas of its mandate, such as the re-evaluation of older pesticides, compliance monitoring and enforcement, and promotion of sustainable pest management practices. Answers to this question tended to fall into three areas:

- Some stakeholders, particularly registrants, believe that CRI revenues were supposed to be used solely for the submission examination and annual maintenance fee processes, that is, they were not to be diverted to other business lines, such as re-evaluations or compliance enforcement. Other stakeholders believe that CRI

revenues are to be used to fund the entire PMRA mandate. To our mind, this divergence reflects some basic misunderstanding regarding the application of cost recovery, namely which activities confer private benefits and should be subject to cost recovery, and the actual extent to which these costs are recovered through the generation of fee revenues that then form a proportion of the overall Agency funding.

- The potential for future reductions in revenue without concomitant reductions in the volume of submission examination work if the number of traditional, chemical submissions declines in the future and the number of biopesticide submissions increases (in response to growing public concern regarding chemical pesticides and perceived benefits of biologicals). If this scenario comes to fruition then PMRA could face a decline in revenues, which could have serious consequences for PMRA's ability to fund all business line activities and carry out its entire mandate.

- Several stakeholders stated that PMRA has not made sufficient progress with its re-evaluation reviews. Some believed that the CRI has been partly responsible, in that the opportunity for PMRA to generate revenues via the evaluation of new products has diverted resources away from the important re-evaluation process. Several stakeholders called for the PMRA to publish comprehensive data on how its revenues from cost recovery are being spent on each of its main business lines.

* * *

These findings from our program of interviews with external stakeholders suggest that PMRA faces (as do its stakeholders) a number of significant issues related to the CRI and the Agency's service delivery and performance reporting. We see these issues as being:

- A common view—primarily among representatives of industry and user groups—that the CRI has not been accompanied by improvements in the efficiency of submission examinations, and concerns that PMRA is not strongly committed to achieving additional efficiency gains.

- Scepticism regarding PMRA's data regarding performance in examining submissions versus its published performance standards. This scepticism is influenced by such factors as: suspicions that PMRA puts submissions into deficiency status for trivial reasons, dissatisfaction with the functioning of the "single window" process, a perception that PMRA is not particularly "user friendly", and a lack of attention to time spent on screening (versus Review Time) and elapsed times to decisions in the Agency's performance reporting.

- Apparent confusion, or misunderstanding, regarding the intended application of fee revenues, with some stakeholders believing these revenues would, or should, be specifically "tagged" to fund submission examination and registration maintenance activities rather than to provide an overall share of the Agency's funding requirements. A related factor would appear to be a lack of awareness of the relatively low share of total Agency funding that comes from fee revenue.

- Concerns among some stakeholders that the CRI focuses attention on the examination and registration process for new products at the expense of activities that

have broader public benefits, such as product re-evaluation, sustainable pest management, and compliance and enforcement.

F. Effectiveness of consultation and communication mechanisms

1. Stakeholder consultation

PMRA has two principal mechanisms for consulting with, and communicating to, stakeholders on cost recovery matters and proposals:

- ***Economic Management Advisory Committee (EMAC).*** EMAC was established as one of the Agency's commitments in the development and implementation of the CRI, with a mandate to *advise the Executive Director, PMRA, on specific ways to improve efficiency and cost-effectiveness without compromising health or environmental protection and while maintaining industry competitiveness*. Members of EMAC are *users of pest control products and manufacturers who are impacted economically by decisions of the PMRA* (and presumably importers and/or distributors) plus PMRA representatives.[1] Since its inception, EMAC has contributed to the identification, qualification and development of changes in the performance of a variety of PMRA examination activities, such as, clarification of Category B submission requirements enabling certain types of submissions to be examined as Category C rather than Category B, changes to the label review process, updating of requirements for notifications/non-notifications.

- ***Posting of proposed and final PMRA documents and policies related to cost recovery and actions to improve the efficiency of examination processes.*** PMRA's web site provides unrestricted access to documents describing proposed and final changes to policies and processes, including e-mail alerts to interested stakeholders whenever new documents are added to the site.

The government-wide process for consultations on proposed changes to cost recovery structures provides a third mechanism for obtaining stakeholder input. However, because there have been no changes to PMRA's fee structures since 1997, it has not been required to seek broader, more formalized input on the Agency's cost recovery proposals and performance.

Based on a review of the documentation on the PMRA website regarding the work of the EMAC (meeting minutes and supporting presentations) it appears that the focus for EMAC's work (including EMAC working groups) is (or has been) shaped by:

- An EMAC Workplan that listed the following areas of concern and a set of possible actions for consideration:
  - Communication and interpretation of guidelines.
  - Submission evaluation

[1] PMRA, *Terms of Reference: Economic Management Advisory Committee.* (Accessed at: www.hc-sc.gc.ca/pmra-arla/english/pdf/emac/emac_tor-e.pdf.)

- Cost recovery
- Data ownership.

The majority of the items in this Workplan have been judged to be completed.

- Reviews of the Agency's performance in meeting its performance standards and resources levels (FTE's and operating expenditures) at each EMAC meeting.

- Items and issues identified by EMAC members for review and discussion on a more ad hoc, or as needed, basis.

Our review of this information suggests that EMAC's role is now more reactionary rather than proactively championing the agenda for improving the efficiency and cost-effectiveness at the Agency. As such, both EMAC and PMRA would likely benefit from a structured review of the focus of, and priorities for, its work, and a new strategy and work plan developed to provide a more integrated agenda for seeking further efficiency improvements in the Agency's submission examination process.

PMRA's approach to the communication of performance results and other outcomes from EMAC's work to registrants, users and other stakeholders has been quite passive, that is, information is posted to the EMAC section of the PMRA website several levels "below" the Home page and without any direct links from the Home Page or What's New section. This information may be more actively disseminated to registrants and user groups by their industry associations.

A more proactive effort by PMRA to communicate performance information could be used to ensure a better—or more consistent—basis for industry-PMRA interactions regarding Agency performance. PMRA's Regulatory Impact Analysis Statement on its proposed fee structure and fees in 1996 included a commitment to *publish an annual report, … to inform stakeholders of PMRA costs, activities and performance for the past fiscal year and projections for the coming fiscal year* (p. 9) but has not produced any such document to date. Some performance information is presented to EMAC on a regular basis, summarizing data on numbers of submissions received and examined, and average processing times, but does not go as far as that anticipated in the 1996 RIAS.

As we showed earlier in this chapter, performance times are a contentious issue for many industry stakeholders, and it is quite likely that a more transparent performance reporting effort may have obviated a perceived need by industry groups to produce a report summarizing data collected via Access to Information requests, and for the Agency to avoid having to produce a second report countering the conclusions drawn in the industry report. PMRA also commissioned an independent study of the extent to which PMRA is performing relative to it service standards and whether its reporting system is capturing data with integrity and accuracy, and we understand is currently considering how to respond to the recommendations of that report.

2. Fee dispute process

A requirement for departments and agencies with cost recovery activities to establish and maintain a fee dispute process has been a feature of the Government of Canada's cost recovery and user charges policies since their first inception. PMRA committed to the establishment of *an appeal*

process on fees (p. 10) in its cost recovery RIAS, and included details of this process in the Guidance Document on Pest Control Product Cost Recovery Fees, in April 1997 (p.16). Under this process:

- Initial decisions regarding requests for application fee reductions or exemptions are made by the PMRA's Reduced Application Fee Committee as part of the Agency's screening process for submissions accompanied by such requests. Decisions by the Committee are communicated to applicants via Clarifaxes or the issuance of a deficiency letter.

- If an applicant disagrees with the outcome to their request for an application fee reduction or exemption, they can appeal the decision to the Director, Submission Coordination Division (formerly the Submission Management and Information Division). The Director reviews the basis for the appeal, drawing on input from PMRA's submission review divisions, as required, and makes a final determination.

- Appeals or disputes concerning maintenance fees are also reviewed by the Director, Management Planning and Coordination Division.

Notice of an appeal or dispute must be made within 30 days of the issuance of an invoice and PMRA is required to provide a written decision and rationale within 30 days of receipt of the notice. PMRA's files show that it has received 15 appeals (including two cases where applicants filed two contiguous appeals) relating to application fees since the inception of the fee dispute resolution process in 1997, and no appeals regarding maintenance fee amounts. The nature of these appeals was as follows:

- Appeals and requests regarding fee exemptions, based on such factors as the interpretation of criteria for fee exemptions, e.g., whether a pest control product could be classified as a plant extract or food grade substance and thereby eligible for a fee exemption (refused).

- Submissions submitted after April 1, 1995 and prior to the introduction of the CRI on April 16, 1997, for which some or all of the submission examination work was performed after the fee regulations came into effect or where an initial pre-MOSP/CRI Type 1 submission resulted in a temporary registration and the subsequent conversion to a full registration was subject to a fee. In these cases the issue at dispute often related to the transition provisions for the CRI and their application, which were established to provide for equitable treatment of submissions in review and to prevent an influx of submissions eligible for reduced fees by virtue of submission just prior to the introduction of the CRI.

- Appeals based on the applicability of full fees versus reduced fees due to low Canadian sales potential, linked to the availability and/or interpretation of information regarding the projected sales of an active ingredient and its end-use products.

- Appeals based on the amount charged for a component of the review process relative to the amount of data or information submitted. In these situations, applicants argue that a lower fee should be applied because of the small amount of information to be

reviewed (for example, if they submit a request for waiver versus a more extensive package of primary data), but the current fee structure and regulations require that the full fee be charged. In situations such as this, the fee has been calculated as a function of the average time (and cost) to perform the applicable review tasks across a broad range of submissions within a particular Category, from larger more-detailed submissions to smaller less-detailed submissions. As such, the less-detailed submissions contain an element of cross-subsidization of the larger submissions.

- Appeals related to the interpretation and application of particular elements of the PMRA fee schedule. For example, an applicant described their application as being to transfer an existing registration from one company to another but, in fact, a review of the product chemistry was necessary before the transfer could proceed (that is, was a Category B submission rather than a Category C). In this case, the appeal was not upheld but it may have been that clearer communication of the basis for changing the submission category and related fee implications could have avoided the subsequent appeal.

In reviewing the PMRA's files on fee appeals and disputes we noted that, of the 15 appeals on file: two resulted in the appeals being upheld and the applicable fees being reduced; nine where the appeal was refused; one where the appeal was refused but a potential reduction due to low sales of the product in Canada was apparent; one where the appeal was refused but the fee was reduced to correct an error in the initial fee determination; one where the appeal concerned the reinstatement of an application rather than a fee assessment; and one where the outcome was not documented in the file. Twelve of the appeals were finalized within the 45-day period (from the date of receipt of the appeal) PMRA provides for reaching a decision, one exceeded the 45 days but related to the aforementioned request for reinstatement rather than a fee issue, and insufficient data exists for the remaining two to determine the timeliness of PMRA's decision.

We also noted that the quality of documentation maintained by PMRA on individual appeals was quite variable, as was the level of documentation on the analysis used to arrive at decisions. It could be beneficial for the Agency to establish some standard documentation requirements to support its review of fee appeals and disputes, in addition to the current documented procedure for reviewing fee appeals. For example, a number of appeal files contained concise summaries of the decisions at issue that clearly would have facilitated the work of the Director, Submission Coordination Division who reviews these appeals. Information in these summaries was presented under the following headings: issue, company's rationale, PMRA's rationale, decision, and rationale for decision. A standardized briefing note structure containing a 'proposed decision' could be used to facilitate decision-making by the Director, supported by pertinent documentation and analysis.

The current complaint mechanism and appeals procedure for fees is compliant with the requirements of the current (2003) and earlier versions of the Treasury Board policy on cost recovery, which requires departments to have a process available to stakeholders to raise disputes or issues related to external charging. However, the passing of the *User Fees Act* in April, 2004, establishes additional requirements for receiving and resolving fee complaints, notably the use of an independent advisory panel to review and decide on fee complaints that are not resolved to the complainant's satisfaction, which will need to be incorporated into PMRA's formal guidance on cost recovery fees.

3. Stakeholder observations on consultation and communications mechanisms

Interviews with external stakeholders were also used to explore perceptions regarding the effectiveness of PMRA's consultation and communication processes regarding the CRI and, to the extent possible, functioning of the fee dispute mechanism. The findings from these interviews are summarized in the following sections.

a) CRI and more general consultations and communications

Overall, most stakeholders believe that the PMRA has inadequate stakeholder communications and consultation mechanisms regarding both the CRI and more general interactions with external stakeholders. The feeling amongst most registrants is that although they now pay fees, and the total PMRA revenues from registrants are significant, they stated that *"we don't feel like we are being treated like a client."* On the other hand, some of the environmental advocacy groups that participated felt that the major problem with cost recovery is that fee payers now have too much influence over the Agency.

Some of the stakeholders interviewed stated that they had worked hard in the early years of the CRI to provide the PMRA with thoughtful, in-depth advice, only to feel that their views were largely ignored. They felt that PMRA senior managers were reluctant to attend the various advisory committee meetings at that time, even though the industry often sent company presidents and vice-presidents.

Some of the associations we interviewed that represent users of pesticide products stated that the PMRA is not proactive in seeking input from their groups.

Interviewees who have been involved with one of the PMRA committees commented that the discussion at these meetings seems to be "one way." One interviewee summed the situation as follows:

> *I joined the advisory committee to help the PMRA and provide my suggestions for improvement. Instead, the meetings consist of one PMRA presentation after another, with the PMRA staff projecting an atmosphere where 'everything is fine.' There is a major disconnect here—they seem to have no interest in reality. A more effective approach would be for the PMRA to say: 'here are the issues we are facing—can you help us find solutions?' I wonder why I bother to attend these meetings.*

Relationships seem to be much better with provincial government ministries, particularly those with mandates for pesticide compliance (for example, for inspection of product use practices). Representatives of these organizations stated that the reason for the good working relationship is that both government organizations (ministries and PMRA) have similar mandates to assess compliance, that is, it is natural for the two bodies to work closely together.

More broadly, many stakeholders made the comment that the PMRA is not sufficiently proactive in defending the quality of the submission examination and registration process. They commented that whenever a negative media report is presented, the PMRA does not stand up for its work and assure the public that pesticide products are carefully assessed by

the government and only registered if found to safe (that is, present acceptably low risks to human and environmental health).

b) Comments on the fee dispute resolution process

Few of the participants in our stakeholder interviews indicated that they were in a position to comment on the effectiveness of the PMRA process for resolving fee disputes. Some of the individual company representatives who participated indicated that their companies were reluctant to dispute the fees that they are assessed. Their biggest concern was that an appeal process should not have the regulator making the appeal decision. As one registrant stated, *it is like dealing with the judge, jury and executioner all in one body*. Another reason for avoiding the appeal process is the fear that any company that would participate in the process may be penalized by the Agency in some way during the examination of future submissions.

Some stakeholders stated that Health Canada's Therapeutic Products Directorate has a much better dispute resolution process, since it involves an external, independent panel that reviews the interpretation and application of fee regulations in fee dispute cases submitted to the Directorate on request from an applicant.[1]

* * *

In summary, PMRA has two principal mechanisms for consultation and communication with stakeholders regarding cost recovery and the efficiency of service delivery: the Economic Management Advisory Committee (EMAC) and the posting of information presented to EMAC on the PMRA web site. Both mechanisms work in a passive sense, that is, interested stakeholders have to find information on EMAC's work and PMRA's performance within the Advisory Bodies section of the PMRA web site or rely on the members of EMAC to distribute information if they are members of the stakeholder organizations represented on EMAC. A number of opportunities are apparent for improvements in the quality of consultation and communications:

- To update and revitalize the EMAC work plan, to provide renewed focus for joint Agency-industry work to advise on and contribute to proposals for continuous improvements in PMRA's submission examination process.

- To develop and introduce an annual (at least) performance report summarizing key aspects of the Agency's submission examination performance and actions taken or proposed to improve performance.

While industry representatives may have reservations about the transparency of the appeal process for fee disputes it is apparent that the mechanism works fairly and effectively within the current parameters set by the PMRA fee regulations. However, in order to comply with the new *User*

[1] The Therapeutic Products Directorate (TPD) process uses a two-step process. In Step 1, written appeals are reviewed by the Cost Recovery Office and the relevant review bureau, leading to a decision and supporting rationale. If the issue is not resolved at Step 1, the appellant may appeal to the Director General of the Drugs Directorate to have the matter examined by an independent Appeal Committee. This Committee is composed of three members—a branch or departmental financial officer who chairs the committee, a member nominated by the Drugs Directorate, and a member nominated by the appellant.

Fees Act it would appear that the Agency would have to establish an independent review committee for fee disputes, which should also address industry's transparency reservations.

G. Characteristics and performance of regulatory systems in other jurisdictions

Information on the approach to cost recovery by pesticide regulatory agencies in the U.S., Australia and the U.K. and European Union was collected using a combination of interviews with agency representatives and, in the case of Australia and the EU, industry associations plus a review of web sites and published reports. This research investigated:

- The extent to which cost recovery is applied.
- Key features of the way in which cost recovery has been applied, including linkages to timelines for the conduct of submission examinations.
- The impacts on the regulatory agencies and the regulated users in each jurisdiction.

1. Policy basis for cost recovery

The U.S., U.K. and Australian governments all have organizations dedicated to the examination, registration and re-registration of pesticide products. While these organizations—the Office of Pesticide Programs in the U.S. EPA, the Pesticides Safety Directorate in the U.K. and the Australian Pesticides and Veterinary Medicines Agency—share this common focus differing legislative and policy bases for their roles and activities result in a number of distinct differences in which cost recovery requirements are applied. These contextual factors are summarized below.

a) Office of Pesticide Programs (OPP), U.S. Environmental Protection Agency (EPA)

The EPA is responsible for the national regulation of pesticides manufactured or imported for use in the U.S. In addition, states also maintain registration requirements and undertake a significant amount of compliance monitoring and enforcement activity. Within the EPA, the OPP has primary responsibility for pesticide registration and reregistration. Authority for the OPP's regulatory activities is provided by several pieces of legislation:

- *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA), which authorizes EPA to examine and register pesticides for specified uses, and to suspend or cancel the registration of a pesticide if subsequent information shows that continued use would pose unreasonable risks.
- *Federal Food Drug and Cosmetic Act* (FFDCA), which authorizes EPA to set maximum residue limits, or tolerances, for pesticides used in or on foods or animal feed.
- *Food Quality Protection Act* (FQPA), which amended FIFRA and FFDCA in 1996 to set tougher safety standards for new and old pesticides, and uniform requirements regarding processed and unprocessed foods.

- *Pesticide Registration Improvement Act,* which established pesticide registration fees and registration performance standards for actions to register pesticide products.

Unlike PMRA, compliance and enforcement activities are not a direct responsibility of OPP but of the Office of Enforcement and Compliance Assurance (OECA) and EPA's regional regions as well as state regulatory authorities.

Prior to PRIA taking effect in March 2004, EPA collected annual registration maintenance and reregistration fees under FIFRA to support the funding of reregistration activities. Tolerance petition fees—to establish new tolerance (maximum residue) limits for pesticides—used to be collected, with the funds received going to the U.S. Treasury (equivalent to Consolidated Revenue), but have been prohibited for a number of years.

The introduction of PRIA was an outcome of a process lasting approximately 10 years during which a coalition of industry, agriculture and environmental groups came together to advocate increased resources for the examination of new product submissions and the reregistration of existing products. PRIA is intended to increase and stabilize the level of funding for OPP's work by establishing new pesticide registration service and maintenance fees that can be collected for at least five years on condition that the public appropriation for OPP is maintained at fiscal 2002 levels or increased. Funds generated are to be applied to the funding of additional resources directly engaged in submission examinations and reregistration work. Specific amounts are also earmarked to enhance current scientific and regulatory activities related to worker protection, and for the examination of new inert ingredients.

Explicit decision times to complete submission examinations have been set for each of the 90 fee categories introduced in March for each of the next five years. EPA is required to publish annual performance reports providing breakdowns of revenues, expenditures and resources; performance against the decision time periods; and actions taken to improve efficiency and cost-effectiveness. EPA expects that the new fee structures will fund approximately 40% of the cost of completing product registrations will be generated through its registration fees, and the remaining 60% will be funded by public appropriations

b) U.K. Pesticides Safety Directorate (PSD)

The Pesticides Safety Directorate (PSD) was established as an Executive Agency of the U.K. Ministry of Agriculture, Fisheries and Food in 1993, which was then replaced by the Department for Environment, Food and Rural Affairs in 2001. PSD administers the regulation of agricultural, horticultural, forestry, food storage and home garden pesticides in the U.K. Legislative authority for PSD's activities is provided by a combination of U.K and European Commission legislation:

- *Food and Environmental Protection Act 1985* (FEPA), which defines statutory powers to control pesticides in order to protect the health of human beings, creatures and plants; safeguard the environment; secure safe, efficient and humane methods of controlling pests; and make information about pesticides available to the public.

- *Control of Pesticides Regulations (COPR) 1986*, and as amended in 1997, define the detailed means by which the aims of FEPA are to be achieved. The regulations allow

for three types of product approvals—Full Approval, Provisional Approval (equivalent to a temporary registration in Canada), Off-Label Approval (akin to minor use approvals requested by users or user groups), and Experimental Approvals.

- *European Directive 91/414/EEC.* The Plant Protection Products Directive (91/414/EEC), which was adopted in 1991 and came into force in July 1993, established a harmonized approach for authorising plant protection products. The Directive is *based upon a two-tier registration system with active ingredients being assessed at Community level* (and shown to be without unacceptable risk to people or the environment) *for inclusion on a 'positive list'* (Annex I) *and products subsequently being registered by Member States. The Directive includes a provision for mutual recognition of regulatory decisions whereby a second Member State does not need to request any supporting data in order to register a product already registered in another Member State, provided that agronomic, climatic and environmental factors are similar and the active ingredient has been included on the positive list*[1]. PSD is the responsible authority in the UK for product authorisations under this Directive. The Plant Protection Products Regulations provide the detailed guidance for the application of Directive 91/414/EEC by PSD.

  The EC approvals system is gradually replacing the former U.K. system, with new active ingredients and products introduced since July 1993 being subject to the Directive existing products becoming subject once they have been re-evaluated under the EC's examination program. PSD summarizes the differences between requirements of the Directive and the prior U.K. requirements as:

  > *Directive 91/414/EEC is more specific than the UK's national legislation as to the role of science. The Directive makes it clear that both active substances and products are to be evaluated in the light of current scientific and technical knowledge based on the appraisal of a dossier of scientific data supplied by the applicant. The Directive includes detailed rules as to what data should be supplied (Annexes II and III) and guidance for member states on how to evaluate it and reach decisions according to agreed uniform principles (Annex VI). Authorisations can be amended if developments in scientific and technical knowledge establish that the manner of use and amounts used can be modified.*[2]

PSD is similar to PMRA in that it performs both a pesticides policy function and administers the application of the applicable legislation regulating the registration and use of pesticides. PSD has operated on the basis of full cost recovery since its establishment in 1993, whereby the full cost of operations (including capital charges) is recovered from the following sources:

- Application fees paid by applicants cover the costs to assess new and existing products.

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1 PSD, *Plant Protection Products Regulations* (PPPR). (Accessed at: www.pesticides.gov.uk/approvals.asp?id=871.)

2 PSD, *Introduction To The Application Handbook: A Summary of the Controls on Pesticides*. (Accessed at: www.pesticides.gov.uk/approvals.asp?id=634.)

- The Department of Environment, Food, and Rural Affairs (DEFRA) funds work on the analysis of pesticide issues and provision of policy advice to the government.

- A levy on the sale of pesticide products partially recovers the cost of compliance monitoring and enforcement, with the balance coming from public funding, via DEFRA. (For example, costs of enforcement and part of the cost of residue monitoring are funded by DEFRA.)

- A small amount of funding comes from other sources, such as payment for contract work performed on behalf of the EC, for example, assistance to new EU members to develop their regulatory systems.

Full cost recovery is a long-standing policy requirement for Executive Agencies of the U.K. government, and is incorporated into the formal strategic objectives of the Directorate. In 2002/03, 21% of PSD's funding came from application fees, 32% from levy payments, 45% from DEFRA, and 3% from the EC and other sources, that is, 53% from cost recovery fees and 47% from arms-length public funding sources

Another of the PSD's six strategic objectives requires PSD to deliver high quality scientific work (measured via independent scientific quality assessments), and complete at least 90% of approval applications (that is, submission examinations) within published processing time and in accord with published fees and charges. Information on the extent to which the target for approvals throughput is published in the annual report, as is summary information on the extent to which efficiency savings and cost recovery targets are met.

c) Australian Pesticides and Veterinary Medicines Authority (APVMA)

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is Australia's national regulatory authority for pesticides and veterinary medicines. It was established as the National Registration Authority in 1993 and become fully operational in 1995 as an independent statutory authority responsible for the regulation and control of agricultural and veterinary chemicals up to the point of retail sale. APVMA is a partnership between the commonwealth (federal) and state/territory governments, and any changes to its mandates and role, including fees, have to be approved by all of the partners. Prior to its establishment, pesticide products had to be individually registered in each of the six states and two territories. States continue to be responsible for control of use activities.

As such, APVMA is an independent statutory authority within the portfolio of the Minister for Agriculture, Fisheries and Forestry. The commonwealth's role is primarily defined by two pieces of legislation:

- *Agricultural and Veterinary Chemicals Administration Act 1992,* which defines the role and powers of the Authority.

- *Agricultural and Veterinary Chemicals Code Act 1994* (the Code Act), which details the operational requirements for assessing and registering pesticide and veterinary medicine products.

Strategic direction is provided by a Board of Directors accountable to the Parliamentary Secretary (equivalent to a Canadian Minister of State) comprising nine non-executive part-time members. Members possess experience in various fields relevant to pesticide regulation and use, but do not represent organizations or interest groups.

APVMA does not formulate policy regarding the regulation and control of pesticides, that is, its role is to administer policies and regulations. As part of its role, however, is does provide input to the formulation of policies, as one of a number of interested public and private stakeholders.

APVMA has operated on a 100% cost recovery basis since its establishment with the authority to set and collect fees was established by four acts linked to the Code Act. Formulation of fees and their application must also be compliant with the *Commonwealth Cost Recovery Guidelines for Regulatory Agencies*. These Guidelines require regulatory agencies to apply cost recovery approaches that are efficient, cost-effective and consistent with agencies' policy objectives. Unlike Canada, the Guidelines take the view that *partial cost recovery is generally inappropriate* and (w)*here cost recovery is justified, all the costs of the activity should generally be recovered.*[1]

The APVMA's current cost recovery framework was established at the time the Authority, and national registration scheme for pesticides and veterinary medicines, was itself established. A number of reviews of the framework and APVMA's cost structures were conducted in recent years, and lead to the development of a proposed new framework that was endorsed by the Primary Industries Standing Committee[2] and intended to take effect on July 1, 2004.

The proposed new fee structure calls for 23 fee categories—16 fixed-cost application fee categories, 5 categories linked to an expanded set of modular fees, and two for emergency permits and minor variations requested by APVMA (with a zero fee)—plus an annual levy on pesticide product sales. The expanded modular fee structure is expected to more closely match fees to the types of review work performed and the level of complexity of such work. The combination of application fees and annual levy is designed to recover 40% of submission examination costs, with the remaining 60% recovered on a deferred basis, via the annual levy.

However, in March the Parliamentary Secretary announced that the proposed changes would be deferred until 2005/06 (that is, July 1, 2005) to enable the Department of Agriculture, Fisheries and Forestry to more adequately analyse concerns raised by a number of stakeholders. In the interim, APVMA is continuing to apply the existing combination of application fees, annual registration renewal fees, and annual sales levy, with the registration renewal fee increased by 25% to maintain the Authority's financial viability through 2004/05.

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1 Commonwealth Department of Finance and Administration, *Commonwealth Cost Recovery Guidelines for Regulatory Agencies*, Canberra, 2002, p.5. (Accessed at: www.finance.gov.au/finframework/fc_2002_02.html.)

2 This committee advises the Primary Industries Ministerial Council, which was established to facilitate the implementation, nationally, of plans and proposals which would not otherwise be possible because of the limitations imposed by the division of constitutional powers between Australian, State and Territory governments.

APVMA has similar performance requirements to the PSD—performance standards are set in the Authority's regulations, with a target of completing 95% or more within the applicable examination period, and performance outcomes reported in the annual report.

2. Key features of fee structures at the EPA, PSD and APVMA

All three of the pesticide regulatory agencies reviewed by KPMG apply similar broad approaches to cost recovery, using combinations of fixed application fees and levies calculated as a percentage of the sales of registrants' products. Differences occur in the extent to which actual costs are recovered, the application of levy fees, and the scope of exemptions and reductions available to registrants. The similarities and differences between the agencies' fee structures are summarized in Exhibit III-12, and the highlights summarized below. Summary details of the PMRA cost recovery initiative are included for comparison purposes.

- ***Fee structures.*** All three jurisdictions use combinations of application fees to review and register products, and annual maintenance fees calculated as a percentage of sales of the registered products.

- ***Ability to accommodate cost variability within submission/fee categories.*** All three recognize that the amount of time (and thus, cost) involved in examining applications within key fee categories, such as the examination of proposed new uses, varies significantly, and have developed fee strategies to better accommodate this variability rather than applying fees that reflect average costs. The PSD and APVMA use modular fee structures that set fees for the conduct of different components of the examination process with the total fee reflecting the various elements and, within element, relative degree of work. The fee structure introduced by the EPA in March, 2004, uses a large number of different categories to accommodate different types of new active ingredients and new uses. This structure also recognizes that submissions with multiple end-uses involve greater costs than those with single or limited end-uses by including separate fee categories for single and multiple new food uses, with bundled submissions subject to a fee per use, with the fee capped for 6 or more end uses in a single, bundled submission.

- ***Level of agency funding from fees***. The level of cost recovery from applicants and registrants varies; PSD and APVMA are required to recover 100% of the full costs of activities that confer direct benefits to registrants, principally the examination of new product submissions, compliance monitoring, re-evaluation/reregistration and supporting administrative and management costs. Policy-related work—for example, related to the development of legislation, regulations and policies—and associated research and analysis as well as public outreach and information activities continues to be publicly funded (U.K.) or performed (Australia) by the parent department. In the case of the PSD, this translates into an approximate 50:50 split between fee revenues and public funding. EPA's new registration fees have been set to recover 40% of the cost of new product registration activities, and fee revenues from all sources under the new EPA fee structure appear likely to provide approximately 15% of funding for the Office of Pesticide Programs.

- ***Reliance on front-end versus deferred fees to recover examination costs.*** PSD's fee structure is designed to recover 100% of the cost of examination activities through

front-end application fees while the APVMA uses a combination of front-end and deferred fees, with approximately 30% of examination costs covered by application fees. The APVMA's rationale for this approach is that a 100% front-end recovery of costs would act as a disincentive for new product development and marketing.

Industry support for full or partial front-end cost recovery appears to depend on whether companies are typically developers of new active ingredients and products (and thus more likely to have a measure of market exclusivity) or are producers of generic, "me too" products. Industry associations in Europe and Australia interviewed by KPMG suggested that major companies do not see application fees as a major disincentive compared to the cost to develop new products, and that the examination time is a much greater concern given the impact it can have on a new product's time to market and potential break-even performance. Although, they also noted that minor use applications could problematic if they could not be bundled with applications for other end-uses or processed via publicly supported minor use programs. Interestingly, we understand, the generic products sector of the Australian market is relatively strong, and that producers of generic products there argue for greater reliance on deferred recovery of submission examination costs, because they can benefit from cross-subsidies created by differences in levy rates/levels between products with low annual sales revenues and higher-volume, higher-value products.

- ***Fee waivers and reductions.*** The EPA provides the most extensive provisions for fee waivers and reductions. This includes application and maintenance reductions or waivers for small businesses, where the definition of a small business appears to be quite generous by Canadian standards (but is generally consistent with U.S. government definitions), with a permitted maximum sales limit by these entities of $US 60 million (gross revenues from global pesticide sales). Compared to the EPA and PMRA, the PSD and APVMA provide very limited fee waivers and reductions, primarily related to minor use, emergency and (in the case of the U.K.) applications for new biological products.

Exhibit III-12
Key features—EPA, PSD and APVMA fee structures

OPP - U.S. EPA	U.K. PSD	APVMA	PMRA
Application Fees			
Pesticide Registration Service Fees: • 90 fee/registration categories set to reflect costs of different types of submissions: - 37 for conventional chemical products; - 20 for antimicrobials; and - 33 for biopesticides and plant-incorporated protectants. • Fees to register new active ingredients can go as high as US$525,000 (experimental use permit with application for registration). • Fees are based on cost information collected via EPA's time recording system and costs for contracted reviews of data submissions. • Fee regulations also prescribe decision times for each fee category; many of which incorporate reductions over the 2004 – 2008 period. • Set to recover ~40% of the cost of conducting product examinations.	*Application Fees:* • Fees for applications through the Approvals Committee Procedure for new active substances and submissions to the EU existing substance review program. If the UK acts as the Rapporteur for a new Annex I listing (Directive 91/414/EEC) the fee is £115,000. • Applications re-submitted following an unsuccessful Committee Stream application attract a sliding fee, linked to the time/cost to examine the additional data submitted (e.g., £35,000 if equivalent to 10-25% of full package fee, £71,000 if 50-75%). • A modular fee structure for applications through the Approvals Secretariat Procedure for products with previously approved active substances and experimental approvals, where the total fee depends on the type of application (e.g., parallel import, mutual recognition), and the number and type of specialist technical case or data examinations to be conducted. • Fees are based on cost information from PSD's time recording system. • Target processing times have been set by PSD for each fee category. • Designed to recover 100% of the cost of examining applications.	*Application Fees:* • Current fee schedule contains 50 fee categories for the examination and registration of new products and product variations, and permits for minor use, emergency use, and field trials and research. Fee for a submission to register a new active and associated products is $AUS 20,620. *APVMA Code Act* limits the fee for review elements to a maximum of $AUS 20,000. • Applications that do not fit the 'standard' fee categories may be assessed modular fees based on fees for different components of the overall examination process (e.g., 3 levels of toxicology assessment; 3 levels of efficacy review; etc). • Activity-Based Costing (ABC) study conducted in 2002/03 found that approximately 30% of the cost to examine and register products is recovered through application fees. The remaining cost is recovered through annual levies and registration renewal fees. • Target assessment periods are set for each fee category in the fee regulations, e.g., target period to examine a new active with new products is 15 months.	*Application Fees:* • Current fee schedules introduced in April, 1997. • Fee schedule provides fees for various data review elements in the submission examination process. • Fee payable depends on the type of application and level of effort for each applicable review element. • Applications for new active ingredient(s) and associated end – use product(s), can be up to $228,832. • Fee structure, including maintenance fees (see below), was designed to generate $12.3 million in fee revenue per year, equivalent to 45% of the Agency's proposed 1997/98 budget of $27.6 million. • Actual fee revenues received are significantly below this level, e.g., about 18% recovery in FY 2002/03. • Costing analysis used to develop fees drew upon costing data for FY 1995/96 and Agency assessments of workload levels and processes. • Interim performance standards for completing submission examinations were set in the Agency's *Management of Submissions Policy*, and subsequent modifications/ reductions for selected sub-categories.

OPP - U.S. EPA	U.K. PSD	APVMA	PMRA
Other Fees			
Maintenance Fees: • Total annual maximum amounts: '04 - $US26 million, '05 and '06 - $27m., '07 - $21m., '08 - $15m. • Principal purpose is to generate additional funding and resources for the conduct of reregistration reviews, with small amounts earmarked for reviews of inert substances and expedited reviews of products identical or substantially similar to currently registered products. • Maximum fee per registrant depends on: number of registered products owned by registrant, and whether registrant meets definition of a small business. • Maximum fee per registrant: (Fiscal) 50 or less Over 50 2004 $84,000 $145,000 2005 $87,000 $151,000 2006 $87,000 $151,000 2007 $68,000 $117,000 2008 $55,000 $95,000	*Annual Renewal Fee:* • Registrants pay an annual levy based on sales turnover to cover the costs of: review of older products, monitoring pesticide usage, monitoring wildlife incidents involving pesticides, part of the cost of monitoring pesticide residues in food. • The levy varies from year to year, and is set to fund the difference between forecast total costs to operate the PSD and forecast application fee and other revenues. • The rate differs between products registered under the Control of Pesticides Regulations (COPR) and Plant Protection Products Regulations (PPPR). • According to the Crop Protection Association web site the levy for COPR-registered products is 1.19%, and 0.8% for PPPR-registered products. • Registrants are required to provide sales data for the prior year, supported by an auditor's certificate. PSD then calculates the fee owed for each registered product.	*Annual Renewal Fee:* • Designed to recover the administrative and compliance costs of maintaining a product registration. • Minimum fee is $200 if disposals (prior year sales in Australia) are less than $AUS 10,000 per year, and all sales of pool/spa hypochlorite. • $600 for disposals between $10,000 and $25,000, and $1000 for disposals over $25,000. *Annual Levy on Disposals:* • Annual disposals of less than $AUS 100,000 incur no levy. • Disposals of over $100,000 incur a fee of 0.65% up to a maximum of $25,000 (i.e., capped at annual disposals over $3,846,154). • Levy rate can be varied to ensure all costs are funded. APVMA conducts audits of registrants' disposals to confirm the accuracy of sales declarations, and publishes the outcomes. 2003 audits of 20 companies found incorrect declarations at 10 companies and poor record keeping at 7.	*Maintenance Fees:* • Registrants pay an annual fee of up to $2,690 per registered product. • Products with annual sales below $89,667 pay a reduced fee, set at 3% of the annual sales revenues, subject to a minimum payment of $75. • Registrants must submit sales data for the prior year certified by a designated company official.

OPP - U.S. EPA	U.K. PSD	APVMA	PMRA
Fee Waivers and Reductions			
• *Minor uses*. Registration fees are waived for IR-4 applications and reduced or waived for minor use applications submitted directly by registrants. • *Small Businesses*. Registration fees: - 50% reduction if global gross revenues from pesticides are in the range of $US 10-60 million - 100% reduction if global gross revenues are below $US 10 m. Definition of small business: - 500 or less employees. - Average annual global gross revenues from pesticides over the previous 3 years of $US 60 million or less. Maintenance fees set at 70% of the regular fee. • F*ederal and state agencies* are exempt from fees. • *Antimicrobials and bio-pesticides* have reduced fees.	• *Biologicals*. Reduced application fee to approve new active ingredients and products containing biologicals or pheromones – a maximum of £40,000 instead of £110,000. Fee to examine re-submitted applications for new biological/ pheromone products (i.e., for a previously unsuccessful application) is set at £20,000 (versus a sliding scale of £26-90,000). Part of the rationale was that these submissions would involve less data than chemical submissions and thus have lower examination costs. To date, have had insufficient applications to test this assumption. • *Minor Use (Off Label)*. Minor use applications pay a small fee (£470) instead of being subject to the Modular Fee structure applied through the Approvals Secretariat Procedure.	• *Reduced renewal and levy fees for products with low sales*. As described above: - Products with sales below $AUS 10,000 pay a lower renewal fee. - Products with annual sales below $AUS 100,000 are exempt from the annual levy, and products with annual sales over $AUS 3.85 million have their levy capped at $AUS 25,000. • *Government agencies and primary producers* are exempt from fees for *minor use permits*. • *Emergency use permits* are exempt from fees.	• (See previous section for reductions to annual maintenance fees.) • Applications for new active ingredients and new products (Category A and B submissions) are eligible for reduced application fees if estimated sales for the first three years the new product(s) is(are) on the market are less than ten times the application fee. The reduced fee is set at 10% of the anticipated revenue during the 3-year verification period subject to a minimum fee of 10% of the total applicable fee. • Exemptions from application fees are available for: - URMULE submissions submitted via Provincial or Forestry Minor Use Coordinators. - Pesticide own-use import (OUI) permits. - Category A and B biopesticide submissions. - Research permits (other than a nominal $150 administration fee).

OPP - U.S. EPA	U.K. PSD	APVMA	PMRA
Fee Review Processes:			
• New fee structures were the outcome from an extensive, multi-stakeholder effort stretching back approximately 10 years to increase the resources at EPA for new product examinations and reregistration. • Legislation (FIFRA) provides for a once-only increase in Registration Service Fees of 5% on or after October 1, 2005, for the period 2004 – 2008.	• Fees are reviewed annually. • All registrants receive written notice of proposed changes and have 12 weeks in which to comment. • Major changes, e.g., introduction of modular fees, involve more extensive consultation and input to the fee design. • Proposed final fees go to Minister for sign off and then to Parliament for approval. Parliamentary process ("negative resolution") is such that MP's have 21 days to object otherwise proposed changes are approved.	• Current application fees were set when APVMA became fully operational in 1995. • Regulations concerning the levy rate were amended in 2000 to reduce the levy rate from 0.75% to 0.65%. • Government cost recovery policy for regulatory agencies (introduced in 2002) requires these agencies to review their cost recovery arrangements every five years.	• No formal review period established , other than a commitment made in the Regulatory Impact Analysis Statement to *review the modified fee structure at the end of the two year period from the date of implementation of cost recovery (in April, 1997).* • Health Canada subsequently, commissioned a Benchmarking Study that examined management issues, and made recommendations, related to costs, performance standards and cost recovery based on comparisons to the pesticide regulatory agencies in the U.S., U.K., and Australia.

- ***Fee adjustments.*** EPA's new fee structure is permitted (by the 2004 amendments to FIFRA) to increase its Pesticide Registration Service Fees once only during the 2004 – 2008 period, by 5% on or after October, 2005. In the U.K., PSD reviews its fees annually. If the proposed changes are relatively minor all registrants receive notice of the proposed changes and have the opportunity to comment prior to formal approval by Parliament. Major changes, such as the introduction of modular fees, involve more extensive stakeholder consultations. The approach in Australia is similar to that in Canada, in that cost recovery arrangements are reviewed every five years and any changes are subject to a consultation process similar to the Canadian RIAS process. APVMA's proposed new levy structure incorporates a provision to vary the levy rate between 0.65% and 0.85% of product sales using a notification in the Commonwealth Gazette.

3. Performance measurement and reporting

EPA, PSD and APVMA are all subject to similar performance reporting requirements. Key features of these requirements are as follows:

- ***EPA.*** Amendments to FIFRA in 2004 established maximum time periods for the conduct of product examinations in each of the EPA's 90 new fee categories for each of the next five years. It would appear from the FIFRA amendments that these performance standards apply to complete submissions, that is, on initial receipt of a submission, EPA *conducts an initial screen to determine if the submission contains all necessary forms, data, draft labeling, and documentation certifying payment of any registration service fee required*[1], before the decision time review period can commence. Annual reports on submission examination performance are required, covering:

  - Numbers of applications examined and their individual decision timeframes, and numbers of actions pending.

  - Progress in improving the efficiency and cost-effectiveness of the registration program, and thereby meeting the performance timelines, which feature progressive reductions in the timelines for many fee categories, for example, for a food use based on a new, conventional chemical active ingredient the target decision time will go from 38 months in fiscal 2004 to 24 months in 2008. (This compares with a current Ideal Time at PMRA for Category A submissions of 737 days or ~24 months.)

  - Staffing and resource allocations in support of registration activities.

  - Audited fee revenues, expenditures covered by fees, overall performance in making registration decisions, and "reasonableness" of overhead costs.

[1] *Federal Insecticide, Fungicide, and Rodenticide Act*, as amended on January 23, 2004, Section 33 (f) (4) (B) – Completeness of Application.

EPA is not subject to any explicit penalties if it is unable to meet its performance targets, however, poor performance will likely affect the willingness of Congress to extend the fee strategy beyond the current five-year period.

- ***PSD.*** One of PSD's six formal Key Objectives is to complete at least 90% of its examinations of applications within its published target time periods, which also incorporate targets for progressive reductions, for example, the target time for the equivalent of screening for new active substances was 6 weeks in 2001/02 and 5 weeks in 2002/03, and the target examination period went from 48-52 weeks (depending on sub-category) to 42 weeks. The Directorate's Annual Report includes tables reporting on actual target times achieved, the numbers of completed examinations, and the number of examination streams (fee categories) in which the 90% target was achieved as well as the overall performance rate.

  PSD also has a Key Objective to achieve annual efficiency savings, for example, to deliver 3% efficiency savings in 2002/03 and for percentage increases in support function costs to be no greater than the percentage increase in revenue in 2003/04. Outcomes achieved are reported in the Annual Report, in the form of an Achieved/Partially Achieved notation, supported by descriptions of actions taken to improve efficiency and effectiveness elsewhere in the text.

  Periodic feedback is collected on stakeholders' perceptions of the Directorate's performance via periodic independent surveys of members of committees (e.g., Advisory Committee on Pesticides and the Pesticides Residue Committee), industry (registrants) and interest groups. Examples of the key findings from the 2001/02 survey include:

  > Interest groups: *Generally PSD is performing well overall. Particular strengths are the quality and integrity of its output, and the move away from being an old-style Government department to a more open, customer-focussed organisation (the introduction of open meetings was one example of the latter).*
  >
  > Registrants: *PSD is praised for its expertise, the knowledge of its staff and the quality of its output. PSD continues to communicate well with industry and its information on legislation and Europe is particularly key. As with interest groups, there was recognition that the organisation is continuing to move away from its bureaucratic past, and becoming more customer focussed. The re-developed website was also held up as a valuable resource. …*
  >
  > *While a number of PSD initiatives were felt to have had some positive impact, these were to some degree overshadowed by the recent changes in fees and payment terms. Over half of the industry customers felt these have worsened in the last two years as they had seen an increase in the initial fee for approvals and also for rejections. Although some appreciate it is a fairer method, others felt it hit smaller companies harder. However, greater flexibility in payment methods was widely recognised and appreciated. It was also felt that PSD does well in keeping people informed of progress during the*

application process, though shorter time frames to process applications would be welcomed as it is still felt to be a lengthy process.[1]

- ***APVMA***. APVMA has worked with a set of prescribed performance standards established in its regulations and applied since its inception. The Authority is expected to satisfy the standard for at least 95% of the submissions it examines. APVMA publishes the following breakdowns of its performance against each of its groups of time standards (15, 8, 6, 5 or 3 months) in its Annual Reports:

  - Number of products registered or approved.
  - Number finalized within prescribed timeframe.
  - Number between 100% and 120% of the prescribed time frame.
  - Number in excess of the prescribed time frame.
  - Average clock time (agency time) to finalize.
  - Average elapsed time to finalize.

  The Authority consistently meets or exceeds its overall performance target, although performance on a category-by-category basis is more variable, with the more complex submission examinations often exceeding the target. For example, applications with 15 month timelines (for new active ingredients and/or major new uses) were at 50% in 2002/03, 80% in 2001/02, and 90% in 2000/01, and applications with 5 month timelines (for new products with approved active ingredients and similar to existing products) met the target in 76%, 91% and 82% of cases over the same three year period.

4. Lessons and insights from other pesticide regulatory agencies' approaches to cost recovery

A number of common themes are apparent in the information and comments provided by representatives of the pesticides regulatory agencies in the U.S., U.K. and Australia, and industry associations representing major pesticides companies in Europe and Australia regarding the approaches to various elements of their cost recovery programs.

The first lesson is that differing legislative and government policy approaches mean that there is no common "model" for structuring pesticides regulatory agencies and their approaches to cost recovery, other than a common core focus on examining new and existing products. In regard to cost recovery, we found that two agencies—PSD in the U.K. and APVMA in Australia—both operated under broader government requirement for full cost recovery as well as agency-specific legislation. However, if one translates their operating structures and funding arrangements into a structure approximately equivalent to PMRA's role in both developing and administering legislation and regulations related to pesticide approvals, the level of cost recovery from registrants is probably of the order of 50-60%. The EPA's approach differs, by functioning as a mechanism to enable additional resources to be employed and backlogs of submission

[1] PSD, *Stakeholder Satisfaction Study*, Research Report prepared for Pesticides Safety Directorate by IFF Research Ltd., January 2002, pp. 1-2. (Accessed at: www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/PSD_Customer_Satisfaction_2002.pdf.)

examination and reregistration work to be addressed. In other words, cost recovery at the EPA is intended to add significant incremental resources rather than to fund the existing resource base.

A second lesson is the extent to which agencies have sought to tailor their fee structures to widely varying types of reviews and, within these categories or sub-categories, the potential for substantial variation in the amount of review work required. This approach results in a large number of distinct fee categories with each category based on a narrowly defined type of submission and product, as at the EPA, or modular structure in which separate fees are set for a "menu" of review activities and complexity levels, and the total fee is the sum of the fees for each of the different review activities required for each separate submission. However, the increased flexibility to match costs and fees involved in such approaches depends upon agencies being able to generate more detailed breakdowns of the costs of their activities. Both the EPA and PSD use time tracking systems as the foundation for their costing approaches while APVMA has used a number of periodic activity costing studies.

Both agency and industry representatives indicated that the cost for product examinations and registrations represented a relatively small component of the overall cost to develop and market new active ingredients and products, and that the most important issue for applicants is the time required to reach a registration decision. Information published by the European Crop Protection Association and CropLife America in 2003 would appear to support this conclusion, which found that both the relative and absolute cost of registration for the major companies that participated in their study had declined, from 9% of the global cost of product development ($US13 million) in 1995 to 6% ($US11 million) in 2000.[1]

Finally, all three agencies examined have performance standards for the conduct of the different categories of submissions prescribed in their legislation and regulations or set in their business plans, and are required to publicly report on their performance outcomes on an annual basis. These agencies are also required to report on actions taken to improve the efficiency and cost-effectiveness of their review activities.

[1] Phillips McDougall, *op cit*, p.16.

IV. Task 3 — Impacts Of The CRI On PMRA Stakeholders

A. Overview

1. Business Impact Study

This section of our report provides the findings of a study carried out by TNS Canadian Facts (formerly ARC Applied Research Consultants) to provide an estimate of the impacts of the cost recovery initiative (CRI) of the Pest Management Regulatory Agency (PMRA). A representative sample of 31 firms paying cost recovery fees for pest control products is included in the analysis. In total, 58 questionnaires were sent to registrant firms with operations in Canada.

Business impacts of government regulations can take a variety of forms. In the case of the cost recovery initiative, the initiative may affect the prices of products, the number of new products introduced, the amount of research and development conducted by the firms affected, and the competitiveness of some sectors of the industry. This report evaluates the impacts on affected firms of the PMRA-related cost recovery initiative.

2. Impacts of the CRI on pesticide users and other stakeholders

In addition to business impacts of the cost recovery initiative related to covered firms, there are also potential impacts on a wide range of other stakeholders. These include consumers, including institutional users, growers, vegetation management specialists, provincial Agriculture and Environment Ministries and members of the public. We obtained information on these impacts through a series of semi-structured interviews with 29 key informants from these sectors.

A potential impact of the CRI is that it leads to reductions in the rate of introduction of new pest control products in Canada and/or increased prices for these products. To the extent to which significant effects of this kind are estimated, there will be broader effects of the CRI. This report provides evidence on the extent to which consumers, including institutional users, growers, vegetation management specialists, provincial Agriculture and Environment Ministries and members of the public, may feel these effects.

3. Structure of Task 3 reporting

This chapter of our report is structured as follows. Section B describes the project methodology while Section C contains a description of responding firms. In Section D, survey results are provided for responding firms. In Section E, we provide the findings on the impacts of the CRI on users and other stakeholders. In Chapter V of this report, the survey results are used to provide an assessment of the overall impact of the cost recovery initiative on responding firms. The appendices to this report contain the survey questionnaire (Appendix 6), the list of responding firms (7) and a list of the members of the Pest Management Sub-Committee (8).

B. Project methodology

1. The Pest Management Sub-Committee

At the beginning of this project, KPMG/TNS proposed the establishment of a Pest Management Sub-Committee (PMSC) to guide this component of the work. This proposal was accepted by PMRA and the PMSC was established with equal representation from the PMRA and the industry. The PMSC operated on a consensus basis. .

2. Survey questionnaire

The questions in the survey instrument for this study were developed to reflect the approach to gathering data that is described in the Business Impact Test (BIT). The key topics and general structure of the BIT were followed to meet the requirements of the federal regulatory and cost recovery policies and tailored to the specific circumstances of the PMRA.

In preparing the questionnaire, TNS reviewed the Business Impact Cost Analysis Protocol (BICAP). BICAP is a supplement to the BIT process and is designed to provide more quantitative cost data than is normally available with the BIT alone. The questionnaire developed by TNS and the PMSC reflects the objectives of the BICAP framework. References for the BIT and BICAP are the following Industry Canada publications: "*Designing Effective and Efficient Regulations: the Role of the BIT*" and "*Guide and Manual for Determining the Impacts of Regulation On Business Activities and Their Costs: A Functional-Based Approach To Regulatory Costing*".

3. Pre-testing the questionnaire

Four firms were selected for the administration of the pre-test. The survey instrument was sent to the respondents at these four firms. These respondents were asked to review the questionnaire and to develop a list of questions or areas of uncertainty. These respondents were then contacted and the questionnaire was revised based on their input.

Special attention was paid to the clarity of questions and the availability of data to answer them. Pre-test respondents were not asked to provide data at this stage but rather to indicate whether or not they would be able to do so.

4. Sample selection

The intent of the business impact assessment is to provide an overall assessment of the impacts of the CRI on affected firms. The intent of the sample selection process was to develop a set of respondents who would be broadly representative of the sectors that they were drawn from. This type of sample is common in business impact assessments. The sample is not, and was not intended to be, a random sample of the firms that pay cost recovery fees to the PMRA. Results from a broadly representative sample of firms cannot be extrapolated to all fee-paying firms but will provide useful overall results and will identify particular issues of concern.

The methodology for this study was based on the assumption that the final dataset will contain completed questionnaires from at least 30 firms. To deal with possible non-response, questionnaires were sent to 58 firms. All completed questionnaires returned by May 18, 2004 were analyzed. Note that the approach is intended to provide a sample of firms that is broadly

representative of firms affected by the CRI. In particular, emphasis has been placed on ensuring a reasonable representation of firms in different size categories. Since the beginning of the project, this issue of ensuring adequate representation of small and medium enterprises has been a key selection factor. With the agreement of the PMSC, in categorizing annual sales data, this study uses the following firm size definitions:

- Small—up to $20 million.
- Medium—$20 to $150 million.
- Large—over $150 million.

The sales categories of firms in the sample were initially assessed using sales data from Dun and Bradstreet along with information on the sizes of some firms from the industry associations. After receiving and reviewing the competed questionnaires, the PMSC decided that the analysis by firm size should be carried out both in terms of total sales and in terms of sales of pest control products.

The other factor used in selecting firms was their exposure to the CRI. To do this, PMRA data on fees and applications of registrants were reviewed. Firms were more likely to be selected to be in the sample if they showed more activity in this PMRA database but subject to the constraint of having adequate numbers in each of the size categories. The initial sample was reviewed using registrant data from the PMRA. Following this review, a number of additional firms were added to the sample to ensure a reasonable sectoral distribution of sample firms.

As the following section shows, the survey was successful in ensuring adequate representation of small and medium size enterprises. In addition, the sample of respondents provides reasonable coverage of registrants by sector within the pest control products industry.

5. Questionnaire administration

Following the approval by the Pest Management Sub-Committee of the content and design of the questionnaire, TNS formatted a final version that was then translated. Questionnaire packages were sent out to respondents in both French and English. The final questionnaire is provided in Appendix 6. Respondents were provided with alternate means of returning completed questionnaires including fax, courier, and regular mail.

6. Telephone follow-up with respondents

TNS followed-up with respondents in order to clarify responses, where answers to questions were inconsistent or when respondents provided “don’t know” as an answer. Our interviews focused on the following types of issues/questions:

- Information on how firms decide to introduce new pest control products in Canada.
- Why missing information cannot be provided.
- Inconsistency of information provided.
- Clarification of stated impacts.

7. Confidentiality

Survey respondents have been assured that TNS will treat all information provided in complete confidence. The results of this study of the impacts of the cost recovery initiative have been aggregated in order to ensure that the confidentiality of individual responses is preserved.

C. Summary and analysis of survey responses

The survey questionnaire was sent to a total of 58 firms that pay cost recovery fees to the PMRA. This section provides a profile of the survey respondents based on ownership, size (in terms of annual sales), and number of employees. Throughout this chapter, we summarize the survey responses from all the respondents. For some of the key survey questions, we have used cross tabulations to present results for different subgroups. Specifically, we present some data by size of firm by using four categories for annual sales.

Of the 31 respondents, the majority (16 of 31) are multinational firms and 15 of 31 are Canadian owned. Seventeen firms (55%) reported that they sell pest control products only in the Canadian market. On average, responding firms have operated in Canada for 31 years with a range of 1 year to 126 years. The response rate to the survey was relatively high with 31 of 58 firms responding for a rate of 53%.

Data on sales for the most recent year available were collected by asking respondents for total annual sales and the fraction of sales of PMRA-regulated products to which cost recovery fees apply. Based on the sales distributions of responding firms, we developed four firm size categories in terms of total and pesticide sales. The choice of four categories balances providing a more detailed breakdown and not putting so few firms in a cell that confidentiality issues might arise. Of the 31 responding firms:

- Twelve (39%) had total sales below $10 million.
- Seven (23%) responding firms had total sales of $10 to $99 million.
- Six (19%) respondents had total sales of $100 to $250 million.
- Six (19%) had total sales of over $250 million.

For all respondents, the mean percentage of total sales derived from pest control products regulated by the PMRA was 51%. Using the data above, the distribution of respondents in terms of sales of pest control products is as follows:

- Twelve (39%) had pesticide sales below $4 million.
- Seven (23%) responding firms had pesticide sales of $4 to $22 million.
- Six (19%) respondents had pesticide sales of $23 to $50 million.
- Six (19%) had pesticide sales of over $50 million.

In terms of the three size categories noted in section B4, the breakdown of respondent firms for total sales achieves the original intention of adequately representing small and medium size firms. The breakdown of respondents in terms of firm size (total firm sales) is:

- Small: 39%.
- Medium: 39%.

- Large: 23%.

Using the responses described above and the mid-points of the reported sales ranges, we estimate the total annual sales (including pesticide and non-pesticide sales) of responding firms to be $4.53 billion. Estimated pesticide sales of these 31 firms are $1.6 billion.

The 31 survey respondents also provided information on their employment levels in Canada and for activities related either directly or indirectly to PMRA-regulated pest control products. The 31 respondents employ a total of 7,871 full-time employees in Canada. Of these employees, 1,150 people, or 15%, work in lines of business related, either directly or indirectly, to PMRA-regulated products to which cost recovery fees apply.

Exhibit IV-1 presents cross-tabulations for the employment data broken down by job category, and annual sales category. Comparing the last two columns of Exhibit IV-1, the six largest firms (with sales over $250 million) have a total of 5,887 full-time employees and of these, 719 are in jobs that are related to PMRA regulated products to which cost recovery fees apply. This represents approximately 12% of the total workforce of these firms. Responding firms with smaller sales tend to have a higher proportion of employees whose jobs are related to PMRA regulated products or services.

Exhibit IV-1
Number of employees and PMRA-related employment, by total sales category

Job Category / Firm size: total sales	Scientific & Research	Management & Admin.	Manufact. & Operations	Sales, Marketing, Other	Total Employment	Total PMRA-Related Employment
Less than $10,000,000	25	70	84	50	230	163
$10,000,000–$99,999,999	23	85	202	197	529	203
$100,000,000–$249,999,999	34	213	527	452	1225	65
$250,000,000 and over	348	535	4055	950	5887	719
Total	**430**	**902**	**4867**	**1649**	**7871**	**1150**

Exhibit IV-2
Number of employees and PMRA-related employment, by pesticide sales category

Job Category / Firm size: total sales	Scientific & Research	Management & Admin.	Manufact. & Operations	Sales, Marketing, Other	Total Employment	Total PMRA-Related Employment
Less than $4,000,000	11	41	70	58	181	36
$4,000,000–$22,999,999	30	261	563	461	1338	210
$23,000,000–$49,999,999	241	350	3381	350	4322	236
$50,000,000 and over	148	250	853	780	2030	668
Total	**430**	**902**	**4867**	**1649**	**7871**	**1150**

With respect to employment, Exhibit IV-3 summarizes answers provided by respondents on the impact of the cost recovery initiative on domestic employment, by job category, within their companies. Overall, approximately two-thirds of respondents reported that the cost recovery initiative has had no impact on the number of domestic jobs. A number of firms (ranging from 19% to 26% depending on the job category) reported that the cost recovery initiative has resulted in a loss of jobs. Summing the estimated total of jobs lost as a result of the cost recovery initiative, the estimated total is 105 jobs. Firms reporting increased employment said that this would total 10 jobs. The net job loss is 95 full-time jobs. Twenty-eight of these net lost jobs are in the Scientific Research job category. Net job losses for the Management and Administration, Manufacturing/Operations, and Sales and Marketing categories are 14, 25, and 28 respectively. These employment data provide an estimate for the full six-year impact of the CRI but may, in some instances, provide an estimate for 2003.

Exhibit IV-3
Summary of responses for impact of the CRI on domestic jobs

Job Type	Zero impact on Jobs	Loss in Jobs	Increase in Jobs	Don't Know
Scientific and Research	65%	23%	7%	6%
Management and Administration	61%	19%	13%	6%
Manufacturing/Operations	68%	19%	0%	13%
Sales, Marketing and Other	65%	26%	3%	6%

These job losses represent 8% of total PMRA-related employment in responding firms. Total PMRA-related employment for responding firms was 1,150 and the distribution among the different job types is as follows:

- Scientific and Research: 149 employees.
- Management and Administration: 186 employees.
- Manufacturing and Operations: 258 employees.
- Sales, Marketing, and Other: 557 employees.

By pesticide sales, estimated net job losses as a fraction of PMRA-related employment by category are as follows:

- Less than $4 million: -27.8%
- $4-23 million: -7.6%
- $23-50 million: -9.3%
- Over $50 million: -7.0%

Firms were also asked whether the CRI had affected the extent of contract work carried out. Most respondents answered no to this question. Among those responding yes, some reported increases and some reported decreases. One respondent said that contract work is carried out for collection and generation of samples and compilation of data to support submissions. This respondent said that the CRI results in less money being available for contract work. Another firm also said that fewer submissions (due to CRI) means less supporting contract work. Other firms reported more

contract work related to increased detail required in submissions and more contract work to deal with the increased regulatory burden. Another firm noted that PMRA fees have diverted funds away from contract work.

The job impact questions discussed above refer to Canadian operations. When respondents were asked whether there were employment impacts outside Canada related to the CRI, most said no.

In the commentaries on the question about jobs outside Canada, one of the 14 firms with operations outside Canada noted that PMRA delays were responsible for delays in introductions in foreign markets, which reduces employment. Another firm noted that the CRI led to shifting one product line to US. One other firm said that the CRI had led to more accounting and regulatory work in the US.

D. Results of survey for pest control products

1. Effects of the CRI on registration activities

(a) Application Fees

Survey respondents were asked to provide data on the number of pest control product applications by type for the period from January 1, 2003 to December 31, 2003. We also asked respondents to estimate the number of applications that would have been made in the absence of PMRA cost recovery fees as well as the number of applications for which fee reductions and exemptions were granted. Exhibit IV-4 summarizes the information provided by respondents according to the type of application.

Exhibit IV-4
Total number of applications by respondents, by type (January 1, 2003–December 31, 2003)

Application Type	Actual # of applications for the period	Estimated # of applications if application fees had not been in place	# of applications for which fee reductions were granted	# of applications if no fee reductions	# of applications for which fee exemptions were granted	# of applications if no fee exemptions
Category A	17	39	2	17	2	17
Category B	242	282	2	242	0	242
Category C	424	471	1	423	2	423
Category D	635	654	5	635	2	635
Category E	40	44	0	40	0	40
Total	**1358**	**1490**	**10**	**1357**	**6**	**1357**

Note: Respondents reported submitting 17 Category A applications. In crosschecking with PMRA data, this total is larger than the applications received in 2003. Some respondents may have counted applications for which acknowledgment from PMRA was received in 2003 or for which they made payments in 2003. In addition, respondents reported five Category D applications for fee reductions that were not consistent with PMRA data.

In overall terms, the largest impact shown in Exhibit IV-4 relates to Category A applications. Category A includes submissions to register new technical grade of active ingredient (TGAI) or integrated system products (ISP) (not previously registered in Canada) and their related end-use product(s) (EPs), manufacturing-use products (MAs) or major new

use (defined as the addition of a new use–site category to the use pattern for a specific registered TGAI), or to establish an import maximum residue limit (MRL) for a new active ingredient. These submissions are usually accompanied by a significant amount of data supporting safety and value, and include URMURs (user requested minor use registrations) and joint reviews.

For Category A submissions, respondents stated that the application fees were associated with a very significant reduction in these applications, from 39 to 17. Respondents reporting reduced Category A applications noted that products not introduced in Canada tend to be minor use products. The minimum fee, according to respondents, means that the return on investment in such products is too low. Some respondents also noted that the lack of predictability in PMRA response time contributes to a reduced incentive to invest. One Category A applicant noted that PMRA fees on existing Category A applications would have been used to pay for the preparation of additional minor use product applications. A number of respondents with reduced Category A applications noted that the application cost barrier and delays in the application process are particularly important for these minor use products.

Exhibit IV-4 also shows reduced applications for the other four application categories. These other reductions are much smaller in percentage terms. These reductions are 14%, 10%, 3% and 9% for Categories B to E respectively.

Respondents were asked about the extent to which their responses on the number of applications submitted resulted from combining applications. One respondent noted that the *Management of Submissions Policy* Timelines were a greater factor in combining submissions. Respondents generally seemed to feel that for 2003, combining applications was only a small factor. Most respondents specifically answered that their responses did not reflect combined applications.

Fee reductions were applied to a total of 10 applications with an additional six applications being granted a fee exemption. Given the scale of the application data in Exhibit IV-4, neither the fee reductions nor the fee exemptions appear to have a significant impact on the overall extent of application activity for the firms in this sample.

Exhibit IV-5 summarizes respondents' answers on the number of applications, the number of applications that would have been made in the absence of cost recovery fees and the number of fee reductions and fee exemptions granted by size of firm (in terms of annual sales). Exhibit IV-6 provides the same information tabulated in terms of pesticide sales.

Based on information provided by respondents, the smallest firms, those with annual sales of less than $10 million and $10 million to $99.9 million, filed relatively fewer Category A and Category B applications as a result of the cost recovery initiative. For Category C and Category E applications, firms with sales between $10 million and $99.9 million reported relatively fewer applications as a result of the CRI.

Exhibit IV-5
Total number of applications by responding firms, by total sales category
(January 1, 2003–December 31, 2003)

Company Sales	Actual # of applications for the period	Estimated # of applications if application fees had not been in place	# of applications for which fee reductions were granted	# of applications if no fee reductions	# of applications for which fee exemptions were granted	# of applications if no fee exemptions
Category A						
Less than $10,000,000	2	8	2	2	0	2
$10,000,000–$99,999,999	4	12	0	4	0	4
$100,000,000–$249,999,999	3	9	0	3	0	3
$250,000,000 and over	8	10	0	8	2	8
Total	**17**	**39**	**2**	**17**	**2**	**17**
Category B						
Less than $10,000,000	11	15	2	11	0	11
$10,000,000–$99,999,999	16	23	0	16	0	16
$100,000,000–$249,999,999	77	81	0	77	0	77
$250,000,000 and over	138	163	0	138	0	138
Total	**242**	**282**	**2**	**242**	**0**	**242**
Category C						
Less than $10,000,000	42	44	1	42	0	42
$10,000,000–$99,999,999	36	53	0	35	0	35
$100,000,000–$249,999,999	74	74	0	74	0	74
$250,000,000 and over	272	300	0	272	2	272
Total	**424**	**471**	**1**	**423**	**2**	**423**
Category D						
Less than $10,000,000	41	43	5	41	2	41
$10,000,000–$99,999,999	57	65	0	57	0	57
$100,000,000–$249,999,999	231	231	0	231	0	231
$250,000,000 and over	306	315	0	306	0	306
Total	**635**	**654**	**5**	**635**	**2**	**635**

Company Sales	Actual # of applications for the period	Estimated # of applications if application fees had not been in place	# of applications for which fee reductions were granted	# of applications if no fee reductions	# of applications for which fee exemptions were granted	# of applications if no fee exemptions
Category E						
Less than $10,000,000	0	0	0	0	0	0
$10,000,000–$99,999,999	3	5	0	3	0	3
$100,000,000–$249,999,999	10	10	0	10	0	10
$250,000,000 and over	27	29	0	27	0	27
Total	**40**	**44**	**0**	**40**	**0**	**40**

Exhibit IV-6
Total number of applications by responding firms, by pesticide sales category
(January 1, 2003–December 31, 2003)

Pesticide Products Sales	Actual # of applications for the period	Estimated # of applications if application fees had not been in place	# of applications for which fee reductions were granted	# of applications if no fee reductions	# of applications for which fee exemptions were granted	# of applications if no fee exemptions
Category A						
Less than $4,000,000	5	12	2	5	0	5
$4,000,000–$22,999,999	0	8	0	0	0	0
$23,000,000–$49,999,999	1	4	0	3	0	3
$50,000,000 and over	11	15	0	9	0	9
Total	**17**	**39**	**2**	**17**	**0**	**17**
Category B						
Less than $4,000,000	10	12	2	10	0	10
$4,000,000–$22,999,999	5	8	0	5	0	5
$23,000,000–$49,999,999	34	41	0	34	0	34
$50,000,000 and over	193	221	0	193	0	193
Total	**242**	**282**	**2**	**242**	**0**	**242**

Pesticide Products Sales	Actual # of applications for the period	Estimated # of applications if application fees had not been in place	# of applications for which fee reductions were granted	# of applications if no fee reductions	# of applications for which fee exemptions were granted	# of applications if no fee exemptions
Category C						
Less than $4,000,000	18	20	1	17	0	17
$4,000,000–$22,999,999	67	67	0	67	0	67
$23,000,000–$49,999,999	76	93	0	76	0	76
$50,000,000 and over	263	291	0	263	2	263
Total	**424**	**471**	**1**	**423**	**2**	**423**
Category D						
Less than $4,000,000	19	21	5	19	2	19
$4,000,000–$22,999,999	152	152	0	152	0	152
$23,000,000–$49,999,999	173	181	0	173	0	173
$50,000,000 and over	291	300	0	291	0	291
Total	**635**	**654**	**5**	**635**	**2**	**635**
Category E						
Less than $4,000,000	1	1	0	1	0	1
$4,000,000–$22,999,999	0	0	0	0	0	0
$23,000,000–$49,999,999	2	4	0	2	0	2
$50,000,000 and over	37	39	0	37	0	37
Total	**40**	**44**	**0**	**40**	**0**	**40**

(b) Fees for maintenance of product licenses

Exhibit IV-7 and Exhibit IV-8 summarize information provided by responding firms on the number of registered products and the estimated number of registered products responding firms would have had if the cost recovery initiative had not been in place since 1997. Respondents reported holding 1,647 product registrations in total as of April 1, 2003. Responding firms reported that without the cost recovery fees, they would have held 1,997 registrations. In other words, the number of registered products was 18% lower than would have been the case without maintenance fees.

Many respondents did not feel that the fees presented a large obstacle for holding registrations although some did say that products with low sales tended to be removed from

the market sooner due to the cost recovery fees. Firms in the smallest size class reported the largest percentage reduction in registrations.

In addition to providing their current number of registrations and the estimated number in the absence of the CRI, respondents were also asked to estimate what fraction of this difference was due to dropped registrations of previously registered products and what fraction was due to a decision not to register products in this time period (since 1997). The overwhelming majority of the difference (nearly 90%) was due to dropped registrations.

Exhibit IV-7
Registrations held by responding firms (April 1, 2003), by firm size (based on annual sales)

Firm Size	Actual # of registered products	Estimated # of listings if cost recovery fees not in place
Less than $10,000,000	168	224
$10,000,000–$99,999,999	217	265
$100,000,000–$249,999,999	525	525
$250,000,000 and over	737	983
Total	**1647**	**1997**

Exhibit IV-8
Registrations held by responding firms (April 1, 2003), by firm size (based on pesticide sales)

Pesticide Sales	Actual # of registered products	Estimated # of listings if cost recovery fees not in place
Less than $4,000,000	140	175
$4,000,000–$22,999,999	407	453
$23,000,000–$49,999,999	320	353
$50,000,000 and over	780	1016
Total	**1647**	**1997**

The maximum annual product maintenance fee charged by the PMRA is $2,690. The fee reduction formula means that some firms pay 3% of sales (minimum $75) instead of $2,690. Survey respondents reported that they pay, on average, 1.57% of sales in maintenance fees (simple average of responses). In response to the question about the maintenance fee formula to pay 3% instead of $2,690, firms responded as follows:

- 50% reported that this results in substantial savings in fees.
- 20% reported that this results in a moderate saving in fees.
- 30% reported that there is little impact.

Firms were also asked about the desirability of the existing fee system relative to an alternative system in which all firms would pay the same percentage of registered product

sales in maintenance fees. Approximately two thirds of respondents said that they did not favour an alternative system in which all firms would pay the same percentage of sales in maintenance fees. Firms reporting that they would favour such a system were generally in the smaller sales categories (less than $10 million in total sales and less than $4 million in pesticide sales).

2. Estimated impacts of the CRI: prices and exports

The majority of respondents (59%) indicated that the cost recovery initiative has resulted in an increase in prices for PMRA-regulated pest control products over the six years of the CRI. The other 41% said that the cost recovery fees had no impact on product prices. Nearly half of those who felt that the cost recovery initiative had resulted in an increase in prices were unable to provide an estimate of the percentage increase in prices resulting from the CRI. Some of these respondents felt that it is difficult to attribute an exact percentage of price increases to cost recovery since so many other factors come into play when setting product prices. Among respondents who were able to estimate the increase in product prices resulting from cost recovery, the increase that they reported varied from 0.5% to 5%.

TNS asked respondents to estimate the proportion of the costs associated with the CRI that are passed on to customers. The majority of firms (52%) reported that 100% of the CRI costs are passed on to their customers. Another 28% reported that none of these costs were passed on to customers. A number of respondents reporting that the costs were not passed on said that the competitiveness of their market segment makes it impossible to raise prices. The remaining 20% of firms reported varying proportions of costs that are passed on to customers.

We also asked firms to estimate the impact of the cost recovery initiative on export sales of PMRA-regulated product from Canadian operations. A total of seven respondents (23%) export products produced in Canada. Of these seven firms, two firms (29%) reported a decrease in exports while five firms reported no impact on exports. Neither of the two firms reporting a decrease in exports was able to provide a quantitative estimate of the impact of cost recovery on exports.

3. Effects of the CRI on the availability of specialty[1] PMRA-regulated products in Canada

Respondents were asked to describe the impacts of the cost recovery initiative on changes made to PMRA-regulated products brought to the Canadian market and about the availability of specialty pest control products. To provide information on product changes, respondents replied using a scale from one to five, where 1 means many fewer changes to products, 3 means no impact, and 5 means many more changes to products, Exhibit IV-9 and Exhibit IV-10 summarize the average scores for this question on the changes to PMRA-regulated products using a cross tabulation for size (annual sales) of responding firms. The last columns of Exhibit IV-9 and Exhibit IV-10 summarize the average scores across all responding firms.

Average scores in Exhibit IV-9 and Exhibit IV-10 indicate that responding firms in the smallest size category experienced very little impact in terms of making changes to PMRA-regulated

[1] In this section, specialty products refer to novel or niche products, minor use products, and products based on unique technologies. These factors tend to be associated with low sales volumes.

products. The largest firms indicated the largest impact (fewer changes to PMRA-regulated products).

Exhibit IV-9
Effects of the CRI, average score by firm sales

Effect of Cost Recovery	Less than $10 million	$10 – $99M	$100 - $249M	$250M and over	Av. Score, all Firms
Changes to PMRA-regulated products brought to the Canadian market.	3.1	2.6	2.5	2.5	2.7

Note: In Exhibit IV-9, a score of 3.0 means no impact. Lower scores imply fewer changes.

Exhibit IV-10
Effects of the CRI, average score by pesticide sales

Effect of Cost Recovery	Less than $10 million	$10 – $99M	$100 - $249M	$250M and over	Av. Score, all Firms
Changes to PMRA-regulated products brought to the Canadian market.	3.0	2.3	2.5	3.0	2.7

Note: In Exhibit IV-10, a score of 3.0 means no impact. Lower scores imply fewer changes.

TNS also asked respondents whether the cost recovery initiative has affected the overall number of small volume or "specialty" pest control products available in Canada. Specialty products refer to novel or niche products based on unique technologies. These factors tend to be associated with low sales volumes. Respondents reported that, on average, they used an annual sales volume of C$1.2 million to classify products as a specialty product.

Fourteen (45%) of 31 respondents said that the cost recovery initiative has reduced the number of small volume or "specialty" pest control products that their firm has made available in Canada. Ten firms (32%) said there was no impact and seven firms (23%) were not able to provide a specific answer. (Don't know). We asked respondents who answered in the affirmative to estimate the number of such products. Taken together, respondents estimated that the total number of small volume or "specialty" products not introduced was 162. This estimate covers the six year time period of the CRI. The following list provides a summary of the types of products that respondents said that they have not made available due to the CRI.

- *Minor crop, special use products.*
- *Rodenticides.*
- *Broad spectrum crop insecticides.*
- *Aquatic weed control products.*
- *Human health insecticides.*
- *Many minor use crop products that are registered in the US.*
- *Insecticides, new safer technologies.*
- *Fungicides.*

- *Disease control products.*
- *Nursery herbicides, botanicals.*
- *Fly, roach, ant control products.*
- *Algae control.*
- *Smaller volume products.*
- *Turf grass fungicides.*
- *Lindane replacements.*

Respondents were also asked whether the CRI had changed the uses of specialty pest control products made available by their firm in Canada. Eight firms (26%) reported that the CRI had led to a reduction in uses with a total of 164 fewer uses. This estimate covers the six year time period of the CRI. Reduced uses of specialty pest control products were reported for the following uses:

- *Structural pest control.*
- *Specific crop insecticides and fungicides for each compound.*
- *Different rodent species.*
- *Tank mixture combinations.*
- *Label expansion to new crops.*
- *Insect control on mustard and beans.*

Sixteen per cent of respondents whose firms introduced small volume or "specialty products" said that the fee reduction and exemption provisions affected their estimates of the number of specialty products introduced. The possibility of fee reductions was described as one factor that was considered.

4. Effects of the CRI on R&D, manufacturing and corporate strategy

Eighteen of 31 responding firms perform research and development related to the introduction of new pest control products in Canada. Eight of the 18 firms that conduct R&D in Canada indicated that R&D has decreased in Canada as a result of the cost recovery initiative.

We asked respondents who had indicated a decrease in R&D to estimate the percentage impact of the cost recovery initiative. Five respondents provided an estimate. The average estimate across these five respondents was a decrease of 17%. We also asked these respondents to estimate the dollar amount of R&D conducted in Canada by their firm. The total amount of R&D conducted by the five firms responding to this question is $20.1 million. Some of these respondents explained that due to lengthy submission examination times and lost revenues from sales, their firms have conducted significantly less research and development. One respondent did indicate specifically that money that would have been spent on research and development is now spent on paying the cost recovery fees. These five firms reported that their average ratio of R&D to sales was 2.6%.

Three of 31 (10%) responding firms reported that the cost recovery initiative has affected their firm's decision to manufacture technical active ingredients in Canada. The comments of these

firms indicate that the impact was negative. Six firms (19%) said that the CRI has affected the extent to which they formulate pest control products in Canada (includes repackaging of end use products). Delays in PMRA registrations were reported as a factor in formulating outside of Canada.

Twenty-two (71%) of respondents indicated that the CRI has negatively affected product development plans of their firm. According to several respondents, cost limitations slow down development plans. Some of the specific responses on product development by firms that said the CRI had been a negative factor include the following:

- *Development plans for Pneumocystis carinii pneumonia antimicrobials were not pursued due to CRI costs.*
- *CRI costs delay product development plans.*
- *CRI fees act as a barrier to bringing products to Canada.*
- *A number of recent US registrations are not available in Canada.*
- *We no longer develop basic new formulations partly because of the CRI cost component.*
- *CRI costs are included together with other new product costs.*
- *CRI delays the introduction of updated product formulae.*
- *CRI costs are linked to research reductions and fewer new products.*
- *CRI and associated performance standards reduce new product development because of uncertainty about bringing it to market for a specific crop year.*
- *CRI keeps some ingredient suppliers out of the Canadian market.*

We asked respondents whether the CRI has affected any strategic plans of their firm in Canada. Of 31 responding firms, 18 (58%) indicated that the CRI has negatively influenced their firm's strategic plans. Firms that produce or market products with low sales volumes (niche products) have decreased the number of products they carry since the added cost of the PMRA cost recovery fees has made some of these products unprofitable. Some firms indicated that any additional costs, such as cost recovery fees, affect the strategic plans of the firm since all costs must be considered in the decision to launch a product. In this sense, the PMRA cost recovery fees are seen as an additional cost of doing business. One respondent said that many more options could be provided to the horticultural sector if the CRI and regulatory requirements were streamlined.

Other responses include the following:

- *CRI increases the difficulty of predicting the date of first sales.*
- *Reduced our ability to enter specialty markets.*
- *CRI makes it too expensive to plan new products.*
- *Many active ingredients not available in Canada to develop new business lines.*
- *Can't bring best products to Canada for specialty crops.*
- *CRI and associated uncertainty about performance standards reduce the ability to do forward planning.*

- *Very little opportunity for niche product development.*

Thirteen of 31 respondents (42%) said that they were aware of the existence elsewhere of technical active ingredients or manufacturing concentrates that they are not able to buy in Canada because of the CRI. Business development costs are too high for a small market. CRI and excessive data requirements (beyond EPA) are identified as the main problem. The technical active ingredients or manufacturing concentrates that respondents indicated that they could not buy in Canada because of the CRI are identified in the following list:

- Esbiothrin
- Mesosulfuron
- Propoxycarbazone
- Fluquinconazole
- Fipronil
- Prochloraz
- Ipconazole
- Fluoxastrobin
- Spiromefesin
- Bromuconazole
- Thiacloprid
- Dichlorpop-P.
- Flonicamid
- Pyradalyl
- Azadiractin
- Novaluron
- Cyazofamid
- Milsana
- Milbemectin
- Etoxazole
- Chlorfenapyr
- Chol-calciferal
- Sulfluramid
- Azoxystrobin
- Pyriproxyfen
- Permethrin
- Cypermethrin

Note: PMRA data indicate that from this list, Azoxystrobin, Pyriproxyfen, Permethrin and Cypermethrin are registered for manufacture, sale and use in Canada. We also understand that data submissions are being generated for Thiacloprid and Novaluron under the AAFC Minor Use initiative.

5. Program services

(a) PMRA responsiveness and efficiency

We asked respondents whether their firm had observed any change in the availability or responsiveness of PMRA staff or changes in PMRA efficiency that they would attribute to the CRI. Exhibit IV-11 summarizes these responses.

Exhibit IV-11
CRI impacts on PMRA

	PMRA Staff	PMRA Efficiency
Much less responsive/efficient	23%	25%
Less responsive/efficient	31%	36%
No impact	42%	36%
More responsive/efficient	4%	4%
Much more responsive/efficient	0%	0%

The responses shown in Exhibit IV-11 indicate that 54% of respondents to this question find PMRA staff either much less responsive or less responsive as a result of the introduction of the CRI. PMRA efficiency or effectiveness is judged to be lower by 61% of respondents. Approximately 42% of respondents note no change in PMRA staff responsiveness and 36% note no change in PMRA efficiency. The PMRA was reported to be more responsive and more efficient by 4% of respondents. However, the average view is that the PMRA is less responsive and less efficient or effective.

In answering these questions, many respondents pointed out that as part of the CRI, the PMRA made a commitment to meeting performance standards. According to respondents, this commitment has not been fulfilled. Respondents also feel that there is no recourse available to them in order to ensure that value is received for the fees paid. Some respondents said that the PMRA is not held accountable for its performance.

(b) Unintended impacts

Respondents were asked about any possible unintended impacts of the CRI on the performance of the PMRA. Thirteen respondents (42%) said that there were such impacts while the remainder either said that there were none (10%) or that they did not know (48%). The following points are representative of the wide variety of unintended impacts identified by these 13 firms.

- *Less opportunity for status updates.*
- *PMRA has less understanding of product development process.*
- *Implemented polices without consultation (tailgating and split submissions).*
- *Requests for additional data driven by need to collect more fees.*
- *CRI is a built-in source of income for new PMRA initiatives.*
- *Unimportant "deficiencies" used to stop clock.*
- *Not enough digital filing.*
- *Increased administrative complexity.*
- *Flawed MOSP timelines.*
- *Even if submitted early, there is a crunch by PMRA to get renewals reviewed so that the annual maintenance fee can be charged.*
- *Applicants not treated as clients.*
- *PMRA treats timelines as minimums.*

(c) Appeals or complaints

Respondents were asked whether they had disputed any of the fees applied by the PMRA since 1997 and submitted an appeal or complaint. The appeal or complaint could have been with regard to an application to register or amend a product registration or to an annual maintenance fee. Four firms reported a dispute related to product registration and two firms said they had disputed a maintenance fee. One firm noted satisfactory resolution following the provision of more information. Another firm reported a successful review but noted

that it took a long time. Overall, the number of respondents with experience with appeals is so small that no definitive conclusions can be reached.

6. Other federal government fees (cumulative impact)

We asked responding firms whether they were subject to other federal government fees (not taxes) for PMRA-regulated products and services. Five of 31 (16%) responded that they were subject to other fees.

We also asked respondents whether their firms were subject to other federal fees other than for PMRA-regulated products and services. Seventeen respondents (55%) answered that their firms were subject to other federal fees.

- New Substance Notification fees (several mentions).
- Hazardous Materials Information Review Commission trade secret fees (several mentions).
- CFIA biotechnology submission fees.
- Health Canada drug DINs and Establishment License fees (several mentions).

7. Other impacts of cost recovery

We asked respondents whether the introduction of the cost recovery initiative has led to any impacts not identified in the questionnaire and whether they had other comments about the CRI. There were many responses to these questions. These opinions and viewpoints of respondents are presented in Exhibit IV-12.

Exhibit IV-12
Survey respondents' comments regarding other impacts of the CRI

1. PMRA have a mindset that cost recovery fees are a minor cost as every company has large margins to work with.
2. The use of CRI for PMRA initiatives such as re-evaluation is not fair. Fees have been paid to register a product. If PMRA wants the rules changed, the re-evaluation should be at their expense.
3. It is not so much the CRI, which is of concern to us but rather the time it takes to get a registration approved. The longer the review period, the higher the lost opportunities.
4. Make the system fair. Pay fees (%) on total sales.
5. Small business in Canada pays 500% higher fees than Australia and Great Britain. Maintenance fees were estimated at 0.005% for large firms and 3% for small.
6. More PMRA staff but less productivity in submission process.
7. URMUR fees should be reduced in relation to new minor use products.
8. Cost recovery tied to timelines served to improve predictability of review timelines. Timelines are an important part of cost recovery.
9. The Management of Submissions Policy (MOSP) is flawed. It is impossible to separate CRI and MOSP.
10. Bill C212 must be considered.
11. There must be more accountability to meet service standards and to communicate with applicants. "Fee for service" is an excellent concept. Service standards must be maintained and audited.

Exhibit IV-12 (Cont'd.)

12. As a formulator, distributor and registrant of generic products, we are not greatly affected by the CRI.
13. CRI review fees are linked to regulatory data requirements. CRI is purportedly linked to performance standards. This questionnaire isolates the CRI from performance standards so is applicable to maintenance fees alone.
14. The PMRA administrative processes enacted to facilitate CRI such as segmenting required data into disciplines for review, although appropriate for Category A submissions have caused simple, inexpensive submissions (Category C) to be forced into an inefficient and lengthy review system. The cost to business for Category C submissions is the lost opportunity to realize an increase in value, brought on by the time consumed by the agency in forcing these simpler amendments into the same CRI-driven processes used to administer more involved reviews.
15. Review fees for some disciplines should be split in a similar fashion to how review fees are split for acute tox reviews vs. a full tox review. The resources required to assess an application based on existing reviewed data, or a minimal supporting data submission are much less than those required for a new active ingredient where a complete risk assessment would be conducted.
16. CRI hits small and medium firms hard and especially affects minor use products. There is an unfairness about double charging for TGAI and EUP when the data need reviewing only once. This applies to a $26,000 fee charged for each of the technical AND the end-use products to evaluate the Environmental Fate package. The technical doesn't go into the environment-why should we be charged twice to look at the same package for both the TGAI and the EUP?
17. Maintenance fees discriminate against small firms. If we sell $90,000 of a registered product, we pay $2690 or 3%. If our competition sells $1,000,000 of registered product, they pay $2690 or 0.27% of gross sales. This makes us uncompetitive.
18. These questions target our submissions. However, delays in submissions of our suppliers have also negatively impacted our business.
19. Fees alone are not the issue. The fees as they relate to service are the issue. The fees should guarantee a service standard for review activities.
20. Added costs reduce company interest in certain product lines. Cost coupled with length of time required to register products makes companies hesitate before pursuing plans for registrations.
21. The current fee structure in combination with costs for crop residue, soil dissipation and efficacy requirements of the PMRA are the key disincentive that leads to companies bypassing the Canadian market. This will not change until PMRA reviews possible ways to streamline either data requirements or the internal review process and reduce the fees (particularly for minor use). The opportunity to use US regulatory decisions for minor crops, mutually accepting US tolerances in Canada would go a long way to help address the equal access problem.
22. Fees are paid and there has only been a slight performance improvement in some areas and no improvement in other areas.
23. There should be a fee reduction based on the number of studies submitted.
24. The CRI is directly linked to performance standards and efficiencies at the PMRA. When the CRI was initiated, the PMRA promised to improve productivity by 40%. There is no evidence that this has been accomplished. In fact, the PMRA processes implemented in the context of the CRI have resulted in additional costs to industry:
25. Additional resources required to address PMRA administrative processes.
26. Decreased resources available for R&D as a result of additional resources focussed on Regulatory Affairs
27. Estimated decrease in value of business as a result of missed service standards (see response to question F1 where we identify a 11.4 % decrease in business).

Exhibit IV-12 (Cont'd.)

28. The first comment is related to the definition of the scope of the CRI. It has been stated that this definition needs to separate the Regulatory requirements/scope of PMRA requirements. The PMRA have indicated that the regulatory requirements would have been implemented even if the CRI were not in place. Although you have a good point, the scope of the CRI really needs to be examined. Just the fact that we are unsure of the definition indicates that it has not been definitively defined before. I can however indicate some of the things that the definition needs to incorporate. Please reference the Regulatory Impact Assessment Statement which indicates that the

    "...The proposed cost recovery initiatives are designed to recover $12 million..."

    The document goes on to state:

    "...An integral part of this initiative was the publication, in June 1996, of the Management of Submissions Policy which presents interim performance standards and the re-engineered submission review process, which will enable the PMRA to improve service to its clients..."

    "Improved performance by the PMRA will provide quicker access to new technology for user groups, longer marketing time under patent protection for manufacturers, as well as quicker access to market for generic manufacturers and formulators..."

    "...While the fees will have an impact on the industry in terms of increased business costs, the reward will be a more efficient, streamlined, and effective pest control product review process..."

    "...The PMRA announced the formation of an Economic Management Advisory Committee (EMAC) on November 7. The committee will provide strategic advice to the Agency on streamlining operations and reducing costs associated with delivering the program. The EMAC will, within two years, also look at performance targets, 3rd party reviews and the fee structure...."

    "...The PMRA will work with Agriculture and Agri-Food Canada (AAFC) to conduct a post implementation impact analysis that would monitor prices, develop meaningful approaches to assess the impact of product withdrawals taking into account the normal flux of registered products; and assess the impact of these two factors on competitiveness. The Agency will also cooperate with AAFC in a cumulative impact analysis..."

29. All of these issues, i.e., Service standards, performance, efficiencies, effectiveness, performance of the EMAC, consultations and joint review of impacts of the CRI with AAFC, etc. have been identified as being part of the CRI and therefore need to be included in the definition.

    With respect to the PMRA's contention that regulatory changes are separate from CRI, we must take into consideration that when there are regulatory changes in standards or processes, and/or new directives/guidelines are implemented that cause new or additional fees, then according to government policy, we must reassess the CRI on an ongoing basis.

    This is covered in the TB External Charging Policy (Aug 12, 2003 replacing the Cost Recovery and Charging Policy [1997]. This document states:

    "...After the implementation of new or amended charges, departments should periodically monitor the key factors identified in the environmental scan to the extent practical and reasonable and update their analysis as required. This is particularly important for sensitive or controversial factors and when the original analysis was inconclusive..."

30. Where changes in PMRA policy result in additional burden on industry and other stakeholders, then it is incumbent on PMRA in consultation with TB to ensure that the CRI is still valid after these changes. This has not been done despite major changes in PMRA policy which has resulted in additional revenue charges.

31. Please find below some examples of policies implemented without consultation by PMRA to deal with the CRI that should have required endorsement by TB and implemented in consultation with industry.
    - Tailgating policy - limitations on industry's ability to register new products and for other stakeholders to access new products
    - Formulants policy - results in the requirement for the submission of additional chargeable data requirements
    - PMRA decision (without consultation) to change policy and require the separation of submission for import tolerances from the submission of domestic registrations applications added additional costs and potential(ly) impacted imported commodities

Exhibit IV-12 (Cont'd.)

- PMRA decision (without consultation) to change policy and require response to deficiencies on 2003 renewals within 10 days (previously done through deficiency letters providing industry 45 days to respond)

32. Please also note that positive changes on PMRA workload, e.g., joint reviews and work sharing, have not resulted in reduced costs to industry.

33. With respect to the Management of Submission Policy which was identified above as an "integral part of the [cost recover] initiative....", this policy has been a Regulatory Proposal since its inception. Industry has provided detailed comments on the policy but it remains a proposal and has never been changed. This despite PMRA issuing in 2003 a new regulatory directive DIR2003-01 Organizing and Formatting a Complete Submission which builds on a Regulatory Proposal....

    "...The PMRA Regulatory Proposal PRO96-01, Management of Submissions Policy, dated June 7, 1996, outlines submission categories and the submission management process, including submission screening. This regulatory directive describes the procedures and criteria for submission screening ***in more detail****, and gives more complete direction on the organization of a submission and its supporting information package to companies that intend to apply to register new products, to amend existing registered products or to carry out research with new or currently registered pest control products..."*

34. The PMRA has implemented many changes to their processes which have had and will continue to have major impacts on the registration and availability of Pest Control Products. According to the TB guidelines, these changes should have been identified and the CRI reassessed prior to implementation. In many cases, industry and stakeholders were never consulted, and if consulted, their comments and suggestions were never considered. Industry has made many suggestions for improvements in the PMRA CRI process, which under TB guidelines should have been given careful consideration and were not.

    TB External charging Policy:

    "d) Service Delivery

    Whether engaged in external charging or not, departments are expected to manage programs and deliver services in an efficient and responsive manner and to be open to innovative ways of delivering services. This includes periodically reviewing the service delivery performance of their programs.

    Departments must also be receptive and respond to stakeholders' suggestions on how to improve the efficiency or responsiveness of their services. Suggestions received must be carefully assessed to determine whether they are reasonable, feasible and consistent with public policy objectives.

    When consulting with stakeholders on proposed or amended charges, departments must clearly describe the service to be delivered and explain why the service is being delivered in the manner in which it is. They must consult on the service standards to be achieved, respective responsibilities and accountabilities for their achievement and an exploration of feasible departmental options that could be adopted in the event they are not met. Feasible options could range from the consideration of alternative service delivery mechanisms to business re-engineering, fee reductions and rebates, etc.

    Departments must establish and communicate appropriate service standards (qualitative or quantitative) in the context of the inherent nature of the activity and the interests of their stakeholders. Appropriate standards could include those performance commitments related to client-focused aspects of service delivery (such as a commitment to promptly notify clients of receipt of material, to inform clients on the progress made as an application moves through processing stages, or to expected processing times)."

E. Estimated impacts of the CRI on other stakeholders

1. Overview

As outlined in the introduction, this component of the evaluation study involved interviews with a variety of stakeholder groups, including associations representing pesticide users (several of which were growers' associations), provincial government minor use coordinators, environmental non-governmental organizations and a number of foreign pesticide manufacturers.

Interviewees were asked several questions regarding the potential impacts of the PMRA CRI initiative on users of pest control products and on other stakeholders. The interview guide is included in Appendix 5. Specifically, interviewees were asked to comment on whether the CRI initiative has had any impacts in the following areas:

- The introduction and availability of new pest control products in Canada.
- The replacement of older, less-safe products with safer equivalents.
- The prices of pest control products in Canada.
- The rate of R&D of new pest control products undertaken in Canada.

The summary of the interview findings is provided below.

2. Rate of introduction of new pest control products in Canada

Many stakeholders stated that it was difficult to quantitatively assess the trends in the introduction of new pest control products in Canada, since the PMRA has published little data on this and other related issues. The overall perception is that fewer new products are being introduced in Canada, particularly compared to the U.S. However, cost recovery is not believed to have been the main factor behind the lower rate of new product introduction.

Many of the registrants interviewed stated that the main problem with the PMRA regulatory process is the absence of predictability, that is, they are not given a firm estimate of when the evaluation of their submission will be completed. A related factor is the greater perceived complexity of the PMRA regulatory process compared to the process followed by the U.S. EPA (particularly the additional requirements in Canada related to efficacy testing). The following two comments summed up many of the industry stakeholders' views on predictability:

> *The EPA is easier to work with. They have set timeframes, when they have to make a decision. They do their job. We are all frustrated with the PMRA; when asked when a decision will be made, the typical response is "maybe next fall."*
>
> *"(T)he problem with the PMRA is not the fees, it is the absence of predictability. This is causing pest control product manufacturers to shy away from entering Canada."*

Of all the topics covered by the interviews with stakeholders, the subject of minor use registrations by the PMRA received the most negative commentary. Minor user products are defined as pest control products intended for a use where there is a limited market in Canada.

Stakeholders commented extensively on PMRA's User Requested Minor Use Registration (URMUR) program and the User Requested Minor Use Label Expansion (URMULE) program. Many stakeholders suggested that fewer minor use products are being submitted for approval in Canada compared to the U.S., since the costs incurred by applicants to obtain product registration are a significant percentage of total expected sales, and the Canadian registration process is more onerous compared to the process followed by the U.S. EPA. Many of the examples concerned products intended for horticultural crops, where the potential Canadian revenue from product sales is relatively small. Animal pesticides were also provided as an example of a limited market product category. Some interviewees suggested that fees should either be waived for minor use submissions or they should be reduced when the submissions are made by small companies.[1]

Overall, most interviewees believe that the PMRA is not efficiently processing minor use registrations. Concerns exist that the agency imposes excessive requirements compared to the EPA, particularly in the area of requirements for efficacy data. However, stakeholders were divided on whether the PMRA puts too much emphasis on the submission and review of efficacy data. Some stated that the PMRA is actually going beyond its mandate by doing any efficacy reviews, since its mandate pertains to protection of human health and the environment, and does not include "consumer protection." However, this group also noted that the PMRA is too slow in carrying out this review work. They suggested that the PMRA could drastically reduce the amount of efficacy review it carries out, since the manufacturer can be held liable by farmers if the product does not work. The other side of the argument was that government should be involved in reviewing the efficacy of pesticides in order to protect the consumer—as several stakeholders stated, *if the government doesn't protect the consumer, who will?*

A few interviewees who were involved with the design of the original URMUR program stated that it was intended to piggyback on the U.S. EPA registration process. In other words, if the U.S. had registered a reduced-risk product, the PMRA was supposed to use the U.S. data package as the basis for the registration in Canada. However, interviewees noted that at some point in its development, the Canadian regulatory process decided to add special Canadian data requirements for efficacy, which has resulted in considerable delays in registration. Many interviewees in our study wondered why the PMRA has such comprehensive efficacy requirements for what are perceived to be generally benign products.

For many minor use products, the potential revenue stream is fairly low (the range was quoted from as low as $50,000 to a high of $300,000). Once the PMRA application fees are combined with the cost of field trials and the cost of hiring a consultant to coordinate the registration process, the resulting costs may be prohibitive and result in a no-go decision on the part of the manufacturer.

A particular frustration concerns the formula used to calculate the application fees under the URMUR program. Revenues must be estimated in advance for a three-year period, and the reduced application fee is based on this estimate. There is no refund if actual sales are less than planned (apparently only a credit against future submission costs). Several registrants commented that it is very difficult to forecast sales in advance.

[1] Notwithstanding this comment, it should be noted that URMULE applications are exempt from fees, and any Category A TGAI/EP or Category B new product application, including URMUR applications, is eligible for a fee reduction if product revenues are less than 10 times the applicable application fee.

We were told that PMRA had been asked to re-examine the fee structure for the URMUR program by the FPT minor use working group but PMRA's response was that no changes could be made without changing the fee regulations. (This was stated to be an example of PMRA's generally "rigid" response to most stakeholder suggestions.) The vast majority of interviewees who commented on the subject of minor use registrations stated that current PMRA policies were reducing the number of minor use registrations in Canada. The result is that Canadian growers are at a competitive disadvantage compared to their U.S. counterparts, where more pest control products are available. Several interviewees stated emphatically that U.S. horticultural products using these pesticides are being exported to Canada. They stated that if the Canadian government permits the U.S. products to cross the border, then why are Canadian growers not allowed to grow the same products on even terms with the Americans? Examples were also given where the U.S. had approved a reduced risk product on a particular crop that was then exported into Canada, while the Canadian grower was still using the older chemical pesticide. Another issue concerns the reluctance of the PMRA to take a "grouping of crops" approach. They said that the approach in Canada is that each use must be evaluated separately, whereas the U.S. EPA will conduct reviews of crop groupings (e.g., all tender fruits, instead of separate reviews for peaches, pears, etc.). This results in a slower and much more expensive regulatory process in Canada, with the result being that manufacturers will shy away from registering the product in Canada. Growers strongly believe that the agency is insufficiently concerned with the impacts on growers from being unable to access newer minor use pesticide products that are available to their U.S. competitors. The overall comment was that the PMRA is not taking a cost-benefit philosophy towards the examination of minor use submissions.

One positive development is the minor use program established by AAFC in the past couple of years, since that department is covering the cost of the required product field trials each year. Interviewees who were involved with the program were pleased with the workshops held annually that conduct a priority ranking process, since the workshops enable growers to present their major issues and results in the selection of some 30 priority projects each year. Growers also welcomed the involvement of a department that has a mandate to address their needs. However, growers are concerned that this program covers only a small number of projects each year (that is, 30 projects selected in the past year out of over 1,800 potential projects). Some also suggested that once AAFC starts to interact with PMRA following submission of the minor use registrations, they will encounter the frustrations long experienced by growers. They stated that it is too early to tell if this program will result in faster product approvals. Some interviewees suggested that the program should be expanded, to permit other organizations to get involved in the field trial process, which would help deal with the volume issue.

Several suggestions were made by growers on how to improve the current situation. One suggestion was that the PMRA should grant a registration within 30 days following registration of the product in the U.S. by the EPA, unless there was a significant reason for not doing so.

In summary, the issue of minor use pesticide registrations was one of the biggest areas of concern of interviewees.

3. Replacement of older, higher-risk pest control products

The overall view from stakeholders is that Canada lags behind the U.S. in the replacement of older, less-safe products with newer reduced risk products, such as biopesticides. Virtually all interviewees in all sectors shared this view.

Several interviewees commented that the PMRA has been slow in conducting re-evaluations of older, widely used pesticides. This was particularly a concern of several grower groups and environmental organizations. Again, they called on the PMRA to publish trend line data on this important issue, and to indicate which products have been deregistered in Canada as well as the U.S. A couple of interviewees made an important point that it is equally important for the PMRA to examine the actual use of older pesticide products by growers in Canada. Just because a product has not yet been de-registered in Canada does not mean that it is still being widely used in this country.

This perception of delays in product re-evaluations was reinforced by the 2003 report by the federal Commissioner of the Environment and Sustainable Development.[1] One theory put forward by several interviewees is that cost recovery has diverted attention away from the re-evaluation process and prompted the PMRA to focus on the evaluation of new products, since no fees are charged for re-evaluations.

A specific related issue raised by some of the environmental groups interviewed is that the PMRA is not devoting sufficient resources to the evaluation of formulants, some of which (e.g., volatile organics) were considered to pose major health risks. Again, their concern with CRI is that it diverts resources away from these important but non-revenue generating activities.

While several interviewees commented that the policy of no fees for biopesticide registrations (except for label review) was a good policy (since it supports economic development of this emerging industry), we were provided with several examples where a very benign product (e.g., garlic juice for mosquitoes, corn gluten) had not yet been approved by the PMRA, while widely available in the U.S. Another example provided by several interviewees was kaolin clay used on apples, a natural product that was registered in the U.S. well before it received approval in Canada. Several of the environmentalists interviewed were very concerned that Canada is lagging behind in the introduction of these reduced risk products. They noted that the PMRA says it has a policy to promote the registration of reduced risk products, but stakeholders don't see this policy being put into practice. On the other hand, some interviewees noted that the PMRA is still in the early stages of developing its framework, policies and guidelines for the evaluation of reduced risk products, and that they were starting to see some positive improvements.

Related to this, several stakeholders called on the PMRA to publish statistics on the issue of which reduced risk products are available in each country, and length of time taken to approve each product in each country. Some interviewees, in an attempt to be fair regarding their evaluation of PMRA performance, stated that some of the high profile examples where a reduced risk product has taken a long time to be examined by the PMRA may not be indicative of the overall situation. However, they noted that, whether real or imagined, this issue is widely discussed amongst stakeholder groups.

Several growers stated that the PMRA needs to take a more strategic approach to re-evaluations, particularly by aggressively evaluating replacement products to treat major issues of concern to stakeholders (e.g., West Nile virus). The comment was made that when the PMRA does decide to de-register an old product, no alternative product has been registered in parallel so that growers have at least something in their toolbox. They stated that the EPA does a better job of identifying

[1] ***2003 Report of the Commissioner of the Environment and Sustainable Development***, Chapter 1, p.9.

alternative products so that the growers are not adversely affected. For example, the EPA will apparently fast-track a replacement if an old product is being phased out.

Another suggestion made was that if a reduced risk product is registered in the U.S., then the PMRA should be forced to register it in Canada within 30 days, unless there is a specific reason for not doing so.

An important issue raised by some of the associations representing users of pesticides is that the lack of product availability in Canada is starting to have an impact on product resistance. Examples were given where the traditional pesticide used in Canada is not as effective as it used to be.

4. Prices of pest control products

Given that the stakeholder interviews involved only a few interviews with manufacturers and associations representing manufacturers, limited information was obtained on the impacts of CRI on prices of pest control products. The overall view is that PMRA registration costs incurred by manufacturers may or may not be passed on to customers, depending on the market situation. Where the company has a monopoly situation (that is, it has the only product to deal with a particular crop disease), then the cost will likely be passed on in the form of higher prices for the product. This parallels the practice taken by manufacturers to charge widely varying prices for the same product, depending on the particular use and the economics of each sub-sector (e.g., greenhouses versus small growers). Where there is a more competitive situation (that is, several products on the market that target the particular pest or disease), then the company may decide to absorb the cost.

Overall, the CRI fees were perceived to be a minor part of the overall cost of a product. However, they can be a significant part of R&D costs. One estimate, conducted by an association based on an informal survey of manufacturers, was that fees could be 25% of R&D costs for a company, with R&D costs accounting for 10% - 15% of total sales. As a result, CRI fees would account for only a few percentage points of the total product price. (We were not able to verify the basis for this estimate.)

5. Rate of R&D on new pest control products

The general view is that limited R&D takes place in Canada on developing new pest control products, and that the level of R&D has been declining over the past several years. This situation is not the result of CRI fees *per se*, but rather the overall regulatory environment, which is perceived to be slower, more difficult and onerous compared to Canada's competitors. Global companies will only do R&D in Canada for the local market. The overall view is that Canada has a "problematic regulatory system." Several interviewees stated that PMRA asks "unique questions" that are not asked anywhere else in the world. They said this does not make sense, given the very limited size of the Canadian market.

Interviewees also commented that the difficult Canadian regulatory environment is inhibiting R&D by small Canadian companies. We were told that venture capitalists may be reluctant to invest in Canadian pesticide R&D companies, as it may take too long for the product to obtain approval for market entry (and the U.S. competitor may reach the market first). Some interviewees noted that the current regulatory system is at odds with the federal government's

overall Science and Technology policy, which is intended to promote an innovation economy. They said that Canada has excellent science, but that the country is unable to fully exploit this capability due to the poor regulatory environment.

6. Competitiveness of sectors reliant on pest control products

Many of the industry stakeholders stated that the Canadian agri-food sector is being negatively affected by the PMRA's regulatory process, but this is not due to the CRI initiative alone. Canadian growers, particularly those engaged in minor use crops, believe that they have access to fewer registered pest control products compared to their U.S. counterparts. This creates a competitive disadvantage, particularly where the U.S. grower is able to use the particular product, thereby lowering its costs, making it very competitive when exporting the particular crop to Canada. Several interviewees made the following comment, *"if the U.S. government believes the product is safe, and the Canadian government believes the product is safe (otherwise the crop would be stopped at the border), then why doesn't the PMRA register the product?"*

A few examples were also provided where the Canadian export market required that certain Canadian crops be treated with a certain pest control product that was not yet registered in Canada. This created a competitive disadvantage for the Canadian exporter compared to the U.S. competitor.

V. Conclusions And Recommendations

A. Introduction

This chapter presents a summary of our key findings and a set of recommendations for consideration by the Evaluation Steering Committee and, subsequently, management of PMRA. The findings and recommendations presented have been developed in relation to the objectives set for the CRI evaluation, the scope and definition of the PMRA CRI, and requirements of the underlying government policies relating to cost recovery by regulatory agencies.

1. Evaluation objectives

The Statement of Work for this evaluation required us to:

> *… provide a value-added analysis for the PMRA, including substantiated recommendations, in order for the PMRA to make informed decisions regarding any alternatives and/or modifications which may be required to the application and maintenance fees charged and activities, including (but not limited to) fee levels, structure and/or other related cost recovery parameters. (p.2)*

In meeting this overall objective we were asked to consider specific aspects of:

- The effectiveness of the costing model used by PMRA (Task 1).
- The impact of the CRI on PMRA's performance (Task 2).
- The impact of the CRI on registrants, users of pest control products and other stakeholders (Task 3).

2. Scope of the PMRA CRI

As we noted in the introduction to this report, it appears that there is no clear, commonly understood definition of what is meant by the PMRA CRI. Our review of relevant background documents stretching back to the period in which PMRA developed its fee proposal and consulted with stakeholders suggests that "the CRI" consists of:

- A set of fees based on PMRA's best estimates of the cost of operating the Agency in FY 1997/98 (remembering that the PMRA was a start-up operation formed from the separate pesticide regulation activities undertaken by Agriculture and Agri-Food Canada, Health Canada, Natural Resources Canada and Environment Canada) and a negotiated agreement between the government, industry and other stakeholders regarding the amount of funding expected to be generated through cost recovery. The agreed amount of revenue to be collected via cost recovery fees was $12.3 million, which represented 45% of the estimated FY 1997/98 PMRA budget, of $27.6 million.

- A set of interim performance standards that PMRA has aimed to hold itself to, and measured its performance against.

- A mechanism for consultation and communication with economic stakeholders—the Economic Management Advisory Committee—with a mandate to *provide strategic advice to the PMRA on ways to improve efficiency and cost effectiveness without compromising the mandate of the agency*.

- A commitment to publish an annual report on performance, which currently takes the form of briefings on performance results to EMAC, and are published on the EMAC section of the PMRA web site.

- A fee dispute resolution process.

Readers should also note that the existence of a CRI does not, by and of itself, guarantee that regulatory processes will operate efficiently and effectively, or that all applications to register pest control products will be completed within target performance standards. As we noted in our evaluation of the cost recovery for the then Therapeutic Products Programme in 2000:

> *CRI as an implicit bargain.* The introduction of a CRI is intended to create some incentives and pressures that will result in more efficient program delivery. The introduction of a CRI also implies an implicit bargain. The bargain being that there will be improved service levels and improved business practices on the part of the implementing program in exchange for the cost recovery fees. While a CRI is the medium that encourages these changes, more than the existence of a CRI is required to bring fruition to this bargain.
>
> *Meeting performance targets*. The existence of the (PMRA) CRI does not, in itself, enable (PMRA) to meet its performance targets. Meeting performance targets is the result of a combination of factors, which are independent of the CRI fees. They include:
>
> - Adequate staffing levels
> - Access to qualified staff
> - Efficient processes
> - Receipt of complete submissions
> - Performance targets that are in line with both workload demand and existing staffing levels.
>
> *Improved business practices.* The existence of the (PMRA) CRI fees does not, in itself, change the manner in which (PMRA) conducts its business. Improved business practices are the result of a process of improvement that requires the adoption of a new "mind-set" together with an investment in the continual renewal of the (PMRA's) internal processes. The CRI fees alone will not directly result in improved business practices.

3. Policy framework for cost recovery

Guidance to departments regarding cost recovery is provided in Treasury Board cost recovery policies. At the time of PMRA's consultations on the introduction of a CRI and subsequent formulation of PMRA fees the policy context and guidance was provided by the 1989 Treasury Board policy. In April, 1997, an updated version of the policy, the *Cost Recovery and Charging Policy* was introduced. In turn, the 1997 policy requirement for the conduct of periodic reviews to ensure user-charge policy provided the context for this evaluation of the CRI. Accordingly, we

have used the 1997 policy as the principal frame of reference for assessing elements of the CRI and their impacts.

Key requirements of the policy include requirements for departments to determine an appropriate allocation of private and public benefits; follow appropriate costing and pricing practices; set fees on the basis of clear, and preferably agreed, service standards and performance measures unless it can be demonstrated that it is not practical or reasonable; to establish a fee dispute resolution process, and to conduct periodic reviews to ensure user-charge requirements are being met. The structure of the PMRA CRI is broadly consistent with the expectations of the 1997 Treasury Board *Cost Recovery and Charging Policy*.

In developing our recommendations—that is, looking forward to the future application of cost recovery by the Agency—it was necessary to take into account two more recent requirements regarding cost recovery: the 2003 Treasury Board *External Charging Policy* (which replaced the 1997 cost recovery policy), and the *User Fees Act*, which provides for parliamentary scrutiny and approval of user fees set by regulating authorities. The 2003 *External Charging Policy*, does not require a specific determination of public and private benefits, but does require departments to *fairly charg(e) those whose activities generate the need for regulation*. We understand that Treasury Board is currently considering whether to modify or revoke the 2003 cost recovery policy and how to implement the requirements of the *User Fees Act*.

PMRA did not determine the extent to which private or public benefits could be attributable to each of its business lines and their component activities at the time it developed its cost model and formulated its fee structures between FY 1995/96 and FY 1997/98, and nor was such a determination required by the 1989 Treasury Board policy on external user charges. Our broad interpretation of PMRA information suggests that the following allocations of benefits and related types of fees apply:

BL-1 – New Product Evaluations:	Primarily private benefits (Application Fees)
BL-2 – Registered Product Evaluation:	Combination of private and public benefits (Maintenance Fees)
BL-3 – Compliance:	Primarily private benefits (Maintenance Fees)
BL-4 – Sustainable Pest Management	Combination of private and public benefits (Maintenance Fees)
BL-5 – Business Line Improvements	Combination of private and public benefits (Maintenance Fees)

Note that this is a very high-level allocation, based on descriptions of business line activities and the breakdown of Division resources across business lines. Much more detailed analysis of business line activities and their beneficiaries would be necessary to arrive at a more definitive determination of the extent to which PMRA activities support the provision of public and private benefits.

B. Key findings—PMRA costing model

1. Effectiveness of the CRI costing model

In this section, we present our conclusions with respect to the effectiveness of the CRI costing model used for pesticides.

In FY 2002/03, PMRA recovered only a small proportion of its costs. It cost PMRA about $20 million to support new product evaluations. For this same period, PMRA received revenues of about $2.9 million from applicants. Similarly, PMRA spent about $23.4 million to enforce post-registration regulation, and registrants paid about $4.7 million in maintenance fees.

Through the evaluation we identified the following issues:

- The current fee schedule for new product evaluation and maintenance fees recovers only a small percentage (about 18%) of the cost of regulating pesticides.

- The current fee schedule was expected to recover approximately $12.3 million in FY 1997/98, ($3.3 million from applications and $9.0 million from maintenance fees). Revenues from application fees have come close to this forecast level (for example, $3.0 million in FY 97/98 and $2.9 million in FY 2002/03) but revenues from maintenance fees have consistently fallen short of the projected annual level of $9.0 million (for example, $4.3 million in FY 1997/98 and $4.7 million in FY 2002/03).

- A lack of flexibility in the fee structure that would allow PMRA to reflect changing costs or activity levels. PMRA's fee structure (in common with the approaches to cost recovery in many other federal regulatory agencies) and regulatory framework does not provide a practical mechanism for on-going adjustment to reflect changes in, for example, cost changes due to inflation, the basic structure of PMRA, or the organization and efficiency of the work performed.

- A lack of flexibility in the fee structure to recognize the level of effort associated with individual submissions. The PMRA's fee structure and regulatory framework do not provide a practical mechanism for matching the fee to the level of resources required to examine an individual application. The complexity of the examination depends on, for example, the nature of the product, the range of potential uses, the nature and previous uses of the active ingredients and the format of the submission.

- PMRA does not track the actual time required to evaluate applications to register new products or amend existing registrations. This means that the Agency does not have detailed breakdowns of actual time, and thus direct labour costs. Although we are comfortable that the periodic assessment by staff and management of time use is reasonable for understanding and tracking trends, detailed information on where costs are being incurred within the examination process or against submission sub-categories may be more problematic.

2. Potential options—fee structure

The Terms of Reference for the evaluation required presentation of options concerning the fee schedules in light of PMRA's regulatory activities and the objectives of the CRI and identification of any constraints to their implementation. (Examples of potential constraints are a requirement for capital investment, the time required to modify the process or changes in technological support requirements.)

In this section, we identify and provide a preliminary assessment of potential alternatives to the current fee structure.

Option 1: Use a set administrative fee plus the actual time and cost to assess each New Product registration submission

A two-part fee could be used that incorporates a fixed administrative component and a variable component. The fixed administrative component would include the cost of such things as documenting the specifics of the application, establishing the control file and processing the application fees. The variable component of the fee would be based upon the amount of time and resources PMRA anticipates will be required to assess a specific submission. The amount of time spent on a Category B submission, for example, would be tracked using the file tracking system. The hourly charge rate would be based upon the fully loaded cost of an hour of professional services. The hourly charge rate would include direct and indirect costs, such as staff salaries, benefits, facilities and departmental overheads.

Option 2: Use a complexity rating system to calculate application fees

The amount of time, and thus cost, to examine Category A and B submissions varies considerably, depending on such factors as product complexity, number of proposed end-uses and supporting studies, number of MRLs to be established, and extent to which data waivers can be applied. PMRA could establish a series of alternative fee levels for each review component (efficacy, toxicology, chemistry, exposure, environmental fate, etc.) that reflect varying levels of assessment complexity, with the total fee being the sum of the various modular elements. Applications would continue to be checked early in the evaluation process (during screening (level B)), the anticipated level of examination effort for each component determined, and the applicable fee level from each of the review modules aggregated to set the total fee.

This complexity-based modular system would allow PMRA to adjust fees applied within a pre-established range to better match the anticipated level of effort involved in examining individual applications.

Option 3. Develop a specific fee for re-evaluation of older pesticide products that are currently on the market.

When an active ingredient is scheduled for re-evaluation, all registrants would pay a share of the cost.

Option 4. Refine maintenance fees so that the registration fee reflects the level of effort required to regulate that type of product in the market.

For example, the level of effort may vary with the risks inherent in use of the product (e.g., prevalence of use, risk of entry into food chain, exposure by children). Clearly, further analysis, which is beyond the scope of this evaluation, would be required to determine whether differential risk factors have a material impact on post-registration regulatory resource use.

A preliminary assessment of the pros and cons of each option is provided below:

Fee Option	Pros	Cons
Current PMRA approach	Staff, applicants and registrants are familiar with the fee schedule.	The PMRA is not tracking cost and revenue information in sufficient detail to verify that fees set within a fee category are in line with the actual cost, or in certain instances, with the fees invoiced. (The cost and level of effort to support such an initiative, over and above current tracking of elapsed times, may be significant.)
Option one – administrative fee plus time reporting	Provides more accurate base for assigning costs to a specific fee-payer. Has the potential to become a useful tool for reviewing resource utilization and managing resources. Rewards users who provide quality submissions and/or take other steps to facilitate the conduct of the submission examination process.	Administration and management of system would likely be onerous. Implementation of a time based fee structure would require: ♦ Refinements to the submission tracking system. ♦ Inputting of time and increased administrative costs.
Option two – complexity rating	Provides flexibility to deal with the complexities of the new product evaluation process, which are difficult to anticipate in a fixed fee structure. Arguably would more fairly apportion the cost of new product evaluations among applicants.	Administration and management of system might be onerous. May be viewed by users as arbitrary, despite pre-set criteria.
Option three – specific fees for re-evaluation	Might encourage industry to consider the relative merits of introducing new products into Canada, rather than continuing to market older pesticide products, which arguably are potentially more harmful and/or less effective. More consistent with emerging international practices (e.g., United Kingdom).	Would be difficult to establish and administer a fee structure that would apportion the cost of the re-evaluations among the companies with registered products that contain the active ingredients being re-evaluated.

Fee Option	Pros	Cons
Option four – maintenance fees adjusted to reflect prevalence of a pesticide product in the market	Depending upon the criteria used to determine maintenance fee, might more fairly distribute the cost of post-market regulation among registrants.	Difficult to develop defensible criteria that link registered products to post-registration regulatory activities.

C. Key findings—impacts of the CRI on PMRA

The evaluation of the impacts of the CRI on PMRA primarily focused on the extent to which the Agency's performance in examining applications met targeted performance standards, the extent to which the CRI has contributed to more efficient service delivery, and the effectiveness of consultation and fee dispute resolution processes. We also investigated external stakeholders' views on the Agency's performance in these areas, and examined approaches to cost recovery at pesticide regulatory agencies the U.S., U.K. and Australia.

1. Establishment of performance standards and performance against these standards

PMRA established an initial set of performance standards relating to each of the major steps involved in examining and registering pest control products at the time it developed the MOSP in 1996. Since then, additional standards have been established to for various special sub-groups of products and categories, and for elements of the submission examination process, such as new requirements for the electronic submission of proposed label text. For example, standards have been set for the review of priority submissions; for the review of reduced risk products, pheromones and microbial products; and provisions made for negotiated timelines for joint reviews conducted with the U.S. EPA.

PMRA set a performance target in the MOSP to process 90% of submissions in all categories within published times. The set of current performance standards are contained in Exhibits III-1 and III-2, earlier in this report. These standards were introduced in a staged process, as part of the phased introduction of Category A – E requirements, between 1996 and 2000. In parallel, the Agency invested considerable time and effort in updating and standardizing requirements for submissions, for example, the establishment of use site categories and associated data code tables.

a) Factors shaping PMRA's ability to complete submission examinations within target times

Achievement of the Agency's target performance standards is not a straightforward process, but is determined by such factors as:

- ***The extent to which applicants submit complete, quality submissions that are consistent with the guidelines and templates developed by PMRA.*** The nature and complexity of the submission requirements for new pesticide products is such that a minority of Category A submissions, approximately half of Category B submissions,

and approximately 20-30% of Category C submissions go through the examination process without requiring submission of additional information by applicants.

- ***The MOSP sets performance standards for both PMRA and applicants.*** This approach means that rather than having to withdraw submissions, or PMRA rejecting less-than-complete submissions, applicants have a number of opportunities to provide data to fill identified gaps in the information reviewed by PMRA. This flexibility is not open-ended, however, and target times are incorporated in MOSP for applicants to redress deficiencies and PMRA to screen and review the additional data.

- As a consequence of the two previous points, the ***responsibility for achieving performance standards for submission examinations is shared between PMRA and applicants.*** For example, under current standards, the "permissible" time to examine and register a standard Category A submission for a new chemical product may range from 737 calendar days (~24 months) if the submission has no deficiencies up to 1592 days (52 months) if the maximum number of permissible deficiency loops is required (each of which has defined time standards for applicants and PMRA). Longer time periods for submission examination may be set on an exception basis by PMRA in consultation with individual applicants. The number of these prior agreed deviations has been increasing in recent years.

- ***Lags in matching submission examination resources to workloads.*** The ability of PMRA to conduct submission examinations in accord with the Agency's risk assessment requirements and meet its target performance standards is a function of the interplay between the numbers of submissions received, the number of available reviewers, and the relative size and complexity of the submissions received. In this regard:

  - The number of Category A submissions received jumped from a level of around 50 per year to 82 in FY 1998/99 and 73 in FY 1999-00. These highly resource-intensive submissions generated significantly higher demands on the Agency's review resources for approximately 4-5 years as they moved through the submission examination process.
  - In parallel, the size and complexity of Category A submissions has increased, as many applicants have increased the number of end-uses included in their applications and data requirements for submissions have expanded. This increase in "bundling" appears to be a function of applicants' efforts to ensure they can target as many market opportunities as possible and thereby maximize their return-on-investment in new product development and marketing. "Bundling" also benefits from the fact that PMRA's submission examination fees are fixed, regardless of the number of proposed end uses.
  - The number of Category C submissions received has exhibited an oscillating pattern, working on a 2-year cycle with the low years being approximately 10% below the annual average for the FY 1998/99 to FY 2003/04 period.
  - Category B and D submissions have exhibited an increasing trend, to the point where the number of Category B submissions received during FY

2003/04 was 52% higher than the FY 1998/99 level, and 149% for Category D submissions.

- The annual volumes of submissions received has been substantially above the levels forecast by the Agency's managers in their cost analysis prior to the introduction of the CRI and by participants in the Business Impact Test analysis in 1996. For example, the BIT findings suggested that between 15% and 17% of the new applications in 1994 and 1995 would not have happened if they had been subject to the proposed CRI application fees.

Taken together, these factors have generated a significant growth in the PMRA's submission examination workload, particularly in the period from FY 1997/98 to FY 2000-01. During this same period, the number of FTEs in Business Line 1.1—Review Submissions grew at a much slower rate. The number of FTEs has increased in each year since FY 2000-01, and reached 185 in FY 2003/04 (versus 110 in FY 2000-01 and 94 in FY 1997/98). However, it takes some time for these new resources to become fully effective due to requirements for orientation and training, which in turn, place additional demands on existing staff to provide supervision, guidance and mentoring for new staff.

b) Extent to which performance standards have been satisfied

The timeliness of the Agency's performance in reviewing submissions and making registration decisions may be best assessed on three levels:

- Are submissions received complete and of acceptable quality (that is, are they "ideal" submissions?), and thereby able to be reviewed within minimum performance time standards?
- To what extent is PMRA able to meet the components of the time standards that it has direct control over?
- How timely is the overall performance of the submission examination process? At this level, the responsibility for completing submission examinations and making registration decisions within the time standards set in the MOSP (and amendments/modifications made to the MOSP standards since 1996) is shared between PMRA and applicants.

The following sections highlight the key characteristics of PMRA's performance in these areas. In doing so, one must be careful in making comparisons between outcomes in the early years of the Agency's operations and those achieved in the latter years for Category A and B submissions. Outcomes in the early years of Agency operation reflect performance in reaching decisions for the better (that is, quicker to be completed) submissions rather than performance across the full spectrum of submission quality and complexity. Category A submissions, can take up to about five years to reach an outcome and still be within standard. We have focused our examination of trends in performance on the period from FY 2000-01 to FY 2003-04.

1. Quality and completeness of submissions

The quality and completeness of submissions may be considered using two proxy indicators. The first is the proportion of submissions that pass screening (Level B in the PMRA submission examination process) on the first try, which provides an indicator of the extent to which submissions are properly organized and formatted, contain all the required elements, and meet fee requirements. Data compiled and reported by PMRA on this measure for the period FY 2000-01 to FY 2003-04 shows that major gains in the percentage passing screening on the first try were achieved from FY 2000/01 to FY 2001/02 for Category A, B and C submissions, with 84%, 81% and 77%, respectively passing on the first try. Since then, the percentage passing has remained stable or declined slightly. Pass rates for Category D submissions have been consistently high, ranging between 89% and 95%, and over 90% for Cat. E, except in FY 2003/04 when the pass rate fell to 89%. Factors contributing to past improvements in pass rates suggested by PMRA include the introduction of pre-submission consultations with intending applicants, ongoing clarification of Category requirements and submission guidelines, improvements to the staffing and management of submission verification and review processes, and provision of training and guidance for both PMRA and applicants' staff members.

The second is the incidence of ideal submissions, that is, high quality, complete submissions that only involve PMRA Time and do not require any Applicant Time to address deficiencies nor Deficiency Time by PMRA. On this indicator:

- Only two Category A submissions since FY 2000/01 had no Applicant or Deficiency Times. These submissions recorded PMRA times of 46 and 237 days, respectively, whereas the median PMRA Time for the non-ideal Category A registrations varied from 549 days in FY 2000/01 up to 664 days in FY 2003/04. Median Applicant Time amounted to another 107 – 159 days, and median Deficiency Time another 90 – 222 days for these non-ideal submissions.

- The incidence of ideal Category B submissions ranged between 66% in FY 2001/02 and 48% in FY 2003/04. Median PMRA times for the ideal submissions were between 64 and 129 days between FY 2000/01 and FY2003/04, while median PMRA Times for the non-ideal submissions, ranged from 396 to 497 days. Median Applicant Times for non-ideal submissions were between 57 and 108 days, and median Deficiency Times between 5 and 90 days.

- Ideal Category C submissions had incidence rates between 30% (FY 2001/02) and 22% (FY 2003/04). The ideal submissions had median PMRA Times of between 67 and 168 days whereas the non-ideal submissions had PMRA Times of between 128 and 265 days, plus median Applicant Times of between 35 and 82 days. The majority of the non-ideal submissions had no Deficiency Time.

Taken together, these two indicators suggest that the initial completeness of submissions has improved compared to the initial years of the Agency's operations but the quality of submissions that undergo detailed evaluation has remained relatively constant in recent years. Ideal submissions have significantly shorter times for verification, screening, review, decision-making and label review compared to non-ideal submissions. As such, increasing

the incidence of ideal submissions should provide one avenue for achieving further efficiency gains in the submission examination process.

2. PMRA's review performance

For PMRA, the critical periods for evaluating submission examination performance are the Review Time for submissions versus the applicable review standard, and PMRA Time versus applicable Ideal Times. In both cases, the Agency's target is to complete at least 90% of submissions within standard. This indicator indirectly considers the overall timeliness of decision outcomes, which is of greater interest to applicants. Our key findings regarding these performance dimensions were as follows:

- Comparisons of Review Time to standards for the Review element in the submission examination process indicate that PMRA has encountered increased difficulty in meeting its 90% target:

Submission Types	% of Submissions Meeting Review Time Standards			
	00/01	01/02	02/03	03/04
Category A				
Priority	67%	57%	75%	50%
Standard	88%	81%	70%	86%
Category B	89%	91%	84%	82%
Category C				
Priority	18%	32%	44%	65%
Standard	97%	81%	64%	72%

Source: PMRA submission tracking system data.

- On comparisons of actual PMRA Time, including Consultation Time, to the applicable Ideal Time:

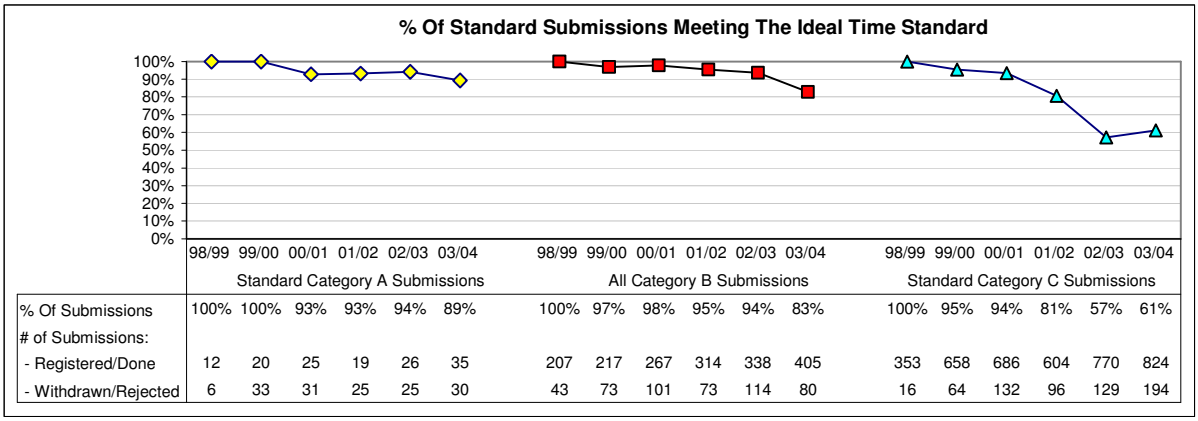
  - For Category A and all Category B submissions, the Agency has a better record in completing the submission examination elements included in Ideal Time than it does on completing the Review Time elements.

  - On Category C submissions, the Agency's performance on the review stage of the examination process has been consistently better than its performance in meeting standards for the overall submission examination process.

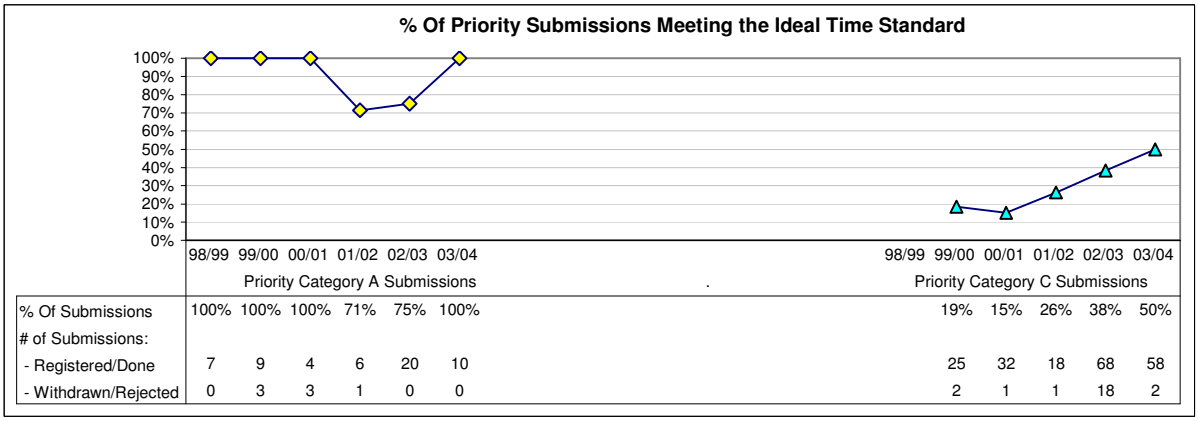
  - Overall performance against Ideal Time standards has mirrored the downwards-sloping trends in Review Time performance, except for priority Category C submissions where performance has consistently improved (albeit from a low base).

Exhibit V-1 summarizes the trends in the extent to which PMRA has been able to complete its primary submission examination elements (that is, PMRA Time plus Consultation Time, and excluding Deficiency Time) for Category A, B and C submissions within applicable Ideal Time standards.

Exhibit V-1
Extent to which PMRA Times plus Consultation Times have met Ideal Time standards



	98/99	99/00	00/01	01/02	02/03	03/04	98/99	99/00	00/01	01/02	02/03	03/04	98/99	99/00	00/01	01/02	02/03	03/04
	Standard Category A Submissions						All Category B Submissions						Standard Category C Submissions					
% Of Submissions	100%	100%	93%	93%	94%	89%	100%	97%	98%	95%	94%	83%	100%	95%	94%	81%	57%	61%
# of Submissions:																		
- Registered/Done	12	20	25	19	26	35	207	217	267	314	338	405	353	658	686	604	770	824
- Withdrawn/Rejected	6	33	31	25	25	30	43	73	101	73	114	80	16	64	132	96	129	194



	98/99	99/00	00/01	01/02	02/03	03/04	98/99	99/00	00/01	01/02	02/03	03/04
	Priority Category A Submissions						Priority Category C Submissions					
% Of Submissions	100%	100%	100%	71%	75%	100%	19%	15%	26%	38%	50%	
# of Submissions:												
- Registered/Done	7	9	4	6	20	10	25	32	18	68	58	
- Withdrawn/Rejected	0	3	3	1	0	0	2	1	1	18	2	

Source: PMRA submission tracking system data.

3. Timeliness of registration decisions

The critical consideration for most applicants is not PMRA's Review Time alone but the overall cycle time (sum of PMRA, Applicant, Deficiency and Consultation Time) from submission receipt to product registration, or to a decision by the applicant to withdraw or by PMRA to reject their submission. On this dimension, which is an outcome of the shared responsibilities and performance of both applicants and PMRA, cycle times for submissions to reach registration exhibited generally increasing trends for Category A and C registrations over the FY 2000/01 – 2003/04 period, and a more stable pattern for Category B registrations except in FY 2003/04, when the median time to registration rose sharply:

Submission Types (Subject to MOSP)	Median Cycle Times 00/01	01/02	02/03	03/04	Average Annual Rate of Increase
	(days)	(days)	(days)	(days)	(00/01 to 03/04)
Category A:					
Registrations	893	863	933	1021	4.7%
Withdrawals/Rejections	462	626	361	947	51.8%
Category B:					
Registrations	176	168	148	231	13.2%
Withdrawals/Rejections	190	300	359	304	20.7%
Category C:					
Registrations	231	281	371	287	10.4%
Withdrawals/Rejections	186	271	304	217	9.7%

Source: KPMG analysis of data from the PMRA submission tracking system.

2. Extent to which the CRI has contributed to more efficient service delivery

Consistent, comprehensive data (both quantitative and qualitative) regarding the impact of cost recovery on the delivery of an efficient service was difficult to develop and interpret, and was insufficient to permit any structured statistical analysis. While we were able to obtain qualitative information and opinions regarding steps taken to improve the efficiency of service delivery, we were not able to determine if (and the extent to which) process improvement and management actions were attributable to the CRI. The ability to isolate CRI effects from overall management practices is further affected by such factors as:

- Efficient service delivery, and continuous performance improvement, is generally accepted as being a required outcome of good management practice in both the public and private sectors. Efficient allocation of resources and process management has been a necessity for PMRA as Agency managers have sought to achieve targeted performance outcomes as the submission examination workload has grown at a faster rate than the resources available to review submissions.

- PMRA has implemented an effective system to manage the progress of submissions through the submission examination process but does not have a means of collecting and tracking information on the actual time (and thus, cost) to review submissions. PMRA relies upon consensus estimates by managers of time required for various activities for budgeting and planning purposes.

PMRA has taken steps to improve the efficiency, effectiveness and/or consistency of its service delivery process. However, other changes that lead to increases in the amount of time to examine individual submissions have, at least, partially offset these efficiency gains. Steps taken to improve performance include:

- Establishment and ongoing development of the submission tracking and management system.

- Introduction of pre-submission consultations to confirm the scope of data requirements and improve the quality and completeness of submissions.

- Submission verification and screening as the initial steps in the submission examination process, to ensure deficiencies are identified as early as possible and to minimize delays in the detailed evaluation of submissions.

- Introduction of joint reviews with the U.S. EPA, to accelerate the introduction of new products to the Canadian market and provide a basis for developing work sharing and harmonization between the two agencies.

- Development and implementation of standardized templates and workbooks for use by reviewers, to clarify and confirm data requirements for submissions, facilitate the conduct of review tasks and preparation of review monographs and public documents, and enable more consistent reviews and risk assessments, and improve transparency in the process of regulatory decision making.

- Development of standards and processes for electronic submissions, and establishment of processes for electronic filing and examination of submissions.

- Redesign of the Minor Use program with AAFC to establish a program similar to the U.S. IR-4 program that supports planning and conduct of field trials by AAFC, preparation of submission data packages, and examination of minor use submissions by dedicated review resources within PMRA.

- Transfer of the regulatory jurisdiction for hard surface disinfectants and disinfectant/sanitizers to the Therapeutic Products Directorate, Health Canada to simplify the application and evaluation process for companies and eliminate duplication of effort.

- Changes to the final label review process, to require electronic submission of proposed label text (in English and French) for review within 45 days of a registration decision, rather than a final version (or printer's proof) within 365 days.

- Revisions to PMRA's Notification/Non-Notification requirements to expand the list of product status changes that do not require examination and approval by PMRA.

Gains in efficiency and effectiveness flowing from the above changes have been offset by increases in submission examination workloads due to such factors as:

- Higher than forecast, and thus budgeted for, volumes of submissions received.

- Increased size and complexity of submissions, in response to changes in data requirements and associated breadth and depth of risk assessments, and increases in the numbers of end uses included in new product submissions.

- Additional administrative requirements of joint reviews. Joint reviews with the EPA have the benefit of improving access to new pest control products for Canadian users and providing work sharing arrangements between PMRA and the EPA. However, these submissions also generate increased demands for liaison and coordination between the two agencies, and provision of input to two risk assessment and decision-making processes.

- Follow-on effects of temporary registrations, to the point where between 8% and 13% of all Category B outcomes in each year since FY 2000-01 have been conversions of temporary registrations to full registrations (B.4.1), and another 32 – 47% were extensions of temporary registrations (B.4.2).

- Pauses in submission examination due to deficiency loops, which require reviewers to stop and start, and to have to re-familiarize themselves with the existing submission data and incorporate data provided in responses to letters of deficiency. In some cases, submissions are granted additional deficiency loops, thus adding to the time required for submission review.

- Rates of mergers and acquisitions in the pesticides industry have accelerated in recent years, resulting in an increased volume of ownership transfers of registered products (Category C.6.1).

Potential for further gains in the efficiency of submission examination activities and coordination are possible but are expected to take at least five years to realize the full benefits. Principal opportunities for further improvement in submission examination efficiency are:

- Adoption of a standardized formats and structure for applicants' submissions using the OECD format and PMRA's use-site categories and data code tables.

- Adoption of electronic submission protocols by applicants, leading to opportunities to streamline the receipt and administration of submissions, and preparation of review monographs.

- Further refinement and harmonization of requirements between the EPA and PMRA, and processes for conducting joint reviews.

- Sharing of review monographs between regulatory agencies. Achievement of an increased rate of work sharing among OECD regulatory agencies will also depend on global coordination of the preparation of submissions by industry.

- Ongoing efforts by PMRA and industry applicants to improve the completeness and quality of their submissions, and facilitation of such efforts by PMRA through such activities as pre-submission consultations and training for applicants.

In summary, our research into the extent to which PMRA has taken steps to improve its service delivery efficiency while meeting regulatory responsibilities and quality and time specifications suggests that the Agency has made efficiency gains by streamlining its submission examination processes. However, these gains have been overshadowed, or offset, by parallel increases in the size and complexity of major submissions, increases in the total volume of submissions compared to the Agency's initial forecasts, and resulting increases in the Agency's submission examination workload.

Further increases in the capacity of the Agency to complete submission examinations in accord with performance standards will depend on the rate of development and adoption of electronic submissions and international harmonization and work sharing between pesticide regulatory agencies in combination with careful matching of submission examination resources to demand

for submission examination work. Achievement of such gains will depend, however, on widespread use of full e-submissions by applicants instead of the current dependence on a combination of paper and paper-electronic submissions.

3. Effectiveness of consultation and fee dispute resolution processes

PMRA has two principal mechanisms for consultation and communication with stakeholders regarding cost recovery and the efficiency of service delivery: the Economic Management Advisory Committee (EMAC) and the posting of submission examination-related proposals and decisions on the PMRA web site. In order to keep abreast of changes, interested stakeholders (other than EMAC members and observers) have to find information on EMAC's work and PMRA's performance within the Advisory Bodies section of the PMRA web site or rely on distribution of information by the stakeholder organizations represented on EMAC.

A number of opportunities are apparent for improvements in the quality of consultation and communications:

- To update EMAC's strategy and work plan, and thereby move away from the current reactive approach to one that revitalizes the agenda for continuing improvements in the efficiency and cost-effectiveness of PMRA operations.

- To introduce regular performance reporting, summarizing key aspects of the Agency's submission examination performance and actions taken or proposed to improve performance. These reports should be published on either an annual or bi-annual basis, and be widely distributed and/or readily accessible on the Agency's web site.

While industry representatives may have expressed reservations about the transparency of the appeal process for fee disputes, based on their perceptions of the process rather than participation in any fee dispute claims, it is apparent that the mechanism works fairly and effectively within the current parameters set by the PMRA fee regulations. However, in order for justice to be seen to be done—and to comply with the new *User Fees Act*—it would appear to be in the Agency's interest to establish a second, independent level of review for fee disputes.

4. External stakeholders' views on the Agency's service delivery

Findings from our program of interviews with external stakeholders suggest that PMRA (and its stakeholders) faces a number of significant issues related to the CRI and the Agency's service delivery and performance reporting. We see the key issues as being:

- Concerns that the current fee structure appears to be out of balance with actual level of work undertaken by PMRA to examine submissions. Stakeholders noted that some submissions require a huge amount of data to be reviewed but cost less than a thousand dollars, while others are perceived to involve much less review work yet cost tens-of-thousands of dollars.

- A common view—primarily among representatives of industry and user groups—that the CRI has not been accompanied by improvements in actual timelines for submission examinations, that is, has not resulted in improved efficiency. These

stakeholders were also concerned that PMRA does not appear to be strongly committed to achieving additional efficiency gains.

- Scepticism regarding PMRA's data regarding performance in examining submissions versus its published performance standards. This scepticism is influenced by such factors as: suspicions that PMRA puts submissions into deficiency status for trivial reasons, dissatisfaction with the functioning of the "single window" process, a perception that PMRA is not particularly "user friendly", and a lack of attention to time spent on screening (versus Review Time) and elapsed times to decisions in the Agency's performance reporting.

- Apparent confusion, or misunderstanding, as to which Agency costs are intended to be recovered through application and maintenance fees, and the extent to which these costs are actually recovered through fees.

- Concerns among some stakeholders that the CRI focuses attention on the examination and registration process for new products at the expense of activities that have broader public benefits, such as product re-evaluation, sustainable pest management, and compliance and enforcement.

- A widespread perception among stakeholders that PMRA needs to improve the performance of its CRI-related consultation and communications activities, as part of a more widely based effort to improve the Agency's client-orientation. This is not to say that applicants and registrants should receive special treatment over and above what may be available to other stakeholders. Rather, it is the recognition that achievement of shared performance goals and accountabilities depends upon open and transparent communications as a foundation for building trust and mutual respect.

5. Insights from the approaches to cost recovery in other jurisdictions

Our investigation of the approaches to cost recovery at the EPA in the U.S., PSD in the U.K., and APVMA in Australia was useful in putting the PMRA's situation and performance into a wider context. This research found that:

- There is no common "model" for structuring pesticides regulatory agencies and their approaches to cost recovery, other than a common core focus on examining new and existing products. Beyond this, two of the three (PSD and APVMA) are also directly accountable for compliance and enforcement activities, and two of the three (PSD and EPA) perform policy and public benefit roles in addition to their product regulation roles.

- All three agencies investigated have a higher degree of cost recovery than the PMRA. Both PSD and APVMA are required to recover 100% of the costs of their regulatory activities (primarily submission examination and product registration, and compliance monitoring and investigations). In the case of PSD, which is also the lead agency for pesticide policy, about 50-55% of the agency's total costs are funded through application fees (including fees to review existing products) and a levy on product sales. The EPA recently established (March 2004) a comprehensive series of

registration and maintenance fees to fund additional resources for the examination of new product submissions and reregistration reviews of existing products. EPA estimates that approximately 40% of the costs of conducting new submission examinations will be generated through the new fees.

- Fee structures in place, or proposed for introduction (APVMA), provide for an increased level of tailoring to accommodate widely varying types of reviews and, within these review elements, the potential for substantial variation in the amount of review work required. This approach results in a large number of distinct fee categories with each category based on a narrowly defined type of submission and product, as at the EPA, or a modular structure in which separate fees are set for a "menu" of review activities and complexity levels.

- The ability to establish tailored or modular fee structures requires detailed information on the costs of submission examination activities. EPA and PSD both use time tracking systems, and APVMA uses periodic activity-based costing surveys, to generate this information.

- Regulatory fees account for a relatively low proportion of the costs of new product development and registration in the three jurisdictions investigated. Having said this, minor use (off label) applications are problematic and each location has evolved processes to reduce the barriers posed by high registration application fees relative to expected annual sales of such product uses. In the U.S., registration fees for minor use applications submitted through the IR-4 Project are waived, in the U.K., off label applications pay a fixed reduced fee; and in Australia, minor use submissions from growers and government agencies are currently exempt from fees for minor use permits (although this provision will be removed in APVMA's proposed new fee structure).

- All three agencies have performance standards and targets for the conduct of submission examinations, and requirements to report annually on their outcomes. Differences in the definition of submission categories, fee structures and the type of information reported make it difficult to compare PMRA's performance. Information published by PSD and APVMA suggests:

  - PSD had a target time to process submissions for new active ingredients and associated end uses under EC or UK rules of:

    - 5 weeks to check the completeness of submissions ("sift").
    - 42 weeks to conduct detailed evaluations and prepare a Draft Assessment Report (for EC review and listing).

    In 2002-03, PSD reported actual times achieved of 5 weeks for the Sift and 30-51 weeks for the evaluation of successful submissions. Note that this does not mean that the elapsed time for reviews and preparation of the DAR (which can then form the basis for a provisional authorization (temporary registration) following a completeness check by the European Food Safety Authority) is 35-56 weeks, because the applicant may have to spend time addressing any deficiencies identified during the completeness check.

- APVMA publishes information on the average APVMA clock time and average elapsed time to complete assessments of different types of applications, and the overall percentage of submissions for which the assessment was completed within the applicable performance standard (APVMA clock time). In 2002-03, APVMA completed over 97% of submissions finalized within the applicable statutory timeframes. Actual 2002-03 outcomes for submissions with 15 month assessment periods (new active ingredients) and 8 month assessment periods (typically, major new uses or major formulation changes) were:
  - Average APVMA clock times for registrations: 15.1 months and 7.4 months, respectively.
  - Average elapsed times to finalize registrations: 23.5 months and 15.1 months, respectively.

D. Key findings—impacts of the CRI on PMRA Stakeholders

This section provides an overall assessment of the business impacts of the PMRA cost recovery initiative on those firms that responded to the survey and the impacts on other stakeholders. The organization of this section is to summarize first the key findings in terms of the impacts of the CRI on affected firms followed by a section dealing with impacts on other stakeholders. The final section provides the core conclusions flowing from these results.

1. Business impacts

a) Jobs

Respondents provided estimates of the impact of the cost recovery initiative on domestic employment, by job category, within their companies. Overall, approximately two-thirds of respondents reported that the CRI had no impact on the number of domestic jobs. A number of firms (ranging from 19% to 26% depending on the job category) reported that the CRI has resulted in a loss of jobs. Summing the estimated total of jobs lost as a result of the CRI, the estimated total is 105 jobs. Firms reporting increased employment said that this would total 10 jobs. The net job loss is 95 full-time jobs. These employment data provide an estimate for the full six-year impact of the CRI but may, in some instances, provide an estimate for 2003.

The net job reduction of 95 jobs is 8% of the total number of jobs provided by these respondents in business operations regulated by the PMRA. By pesticide sales size, estimated net job losses as a fraction of PMRA-related employment are largest in percentage terms in the smallest firm size category.

b) Applications

Survey respondents indicated that the largest impact of the CRI was on the number of applications in Category A. Respondents stated that the application fees were associated with a very significant reduction in these applications, from 39 to 17. Respondents reporting reduced Category A applications noted that products not introduced in Canada

tend to be minor use products. The CRI fee, according to respondents, means that the return on investment in such products is too low. Some respondents also noted that the lack of predictability in PMRA response time contributes to a reduced incentive to invest. One Category A applicant noted that PMRA fees on existing Category A applications would have been used to pay for the preparation of additional minor use product applications. A number of respondents with reduced Category A applications noted that the application cost barrier and delays in the application process are particularly important for these minor use products.

Respondents also reported a reduced number of applications for the other four application categories. These other reductions are much smaller in percentage terms. These reductions are 14%, 10%, 3% and 9% for Categories B to E respectively.

The key finding of this section of the report is that there were many fewer applications in Category A. Of the reported reductions in applications (a total of 22 fewer), firms with sales less than $10 million accounted for six fewer applications. Firms with sales between $10 million and $100 million accounted for an additional 14 fewer applications. In terms of pesticide sales size, firms with pesticide sales less than $50 million reported 18 of the 22 cases of fewer applications.

c) Numbers of registered products

Responding firms provided information on the number of registered products and the estimated number of registered products responding firms would have had if the cost recovery initiative had not been in place since 1997. Respondents reported holding 1,647 product registrations in total as of April 1, 2003. Responding firms reported that without the cost recovery initiative, they would have held 1,997 registrations. In other words, the number of registered products was 18% lower than would have been the case without maintenance fees.

Many respondents did not feel that the CRI presents a large obstacle to holding registrations although some did say that products with low sales tended to be removed from the market sooner due to the cost recovery initiative. Firms in the smallest size class reported the largest percentage reduction in registrations.

The maximum annual product maintenance fee charged by the PMRA is $2,690. The fee reduction formula means that some firms pay 3% of sales (minimum $75) instead of $2,690. Firms were asked about the desirability of this fee system relative to an alternative system in which all firms would pay the same percentage of registered product sales in maintenance fees. Approximately two thirds of respondents said that they did not favour an alternative system in which all firms would pay the same percentage of sales in maintenance fees. Firms reporting that they would favour such a system were generally in the smaller sales categories (less than $10 million in total sales and less than $4 million in pesticide sales).

d) Prices and exports

The majority of respondents (59%) indicated that the cost recovery initiative has resulted in an increase in prices for PMRA-regulated pest control products over the six years of the

CRI. Half of these respondents were unable to provide an estimate of the percentage increase in prices resulting from the CRI. Among respondents who were able to estimate the increase in product price resulting from cost recovery, the increase that they reported varied from 0.5% to 5%. The majority of firms (52%) reported that 100% of the CRI costs are passed on to their customers. Another 28% reported that none of these costs were passed on to customers. The remaining 20% of firms reported varying proportions of costs that are passed on to customers.

We also asked firms to estimate the impact of the cost recovery initiative on export sales of PMRA-regulated product from Canadian operations. A total of seven respondents (23%) export products produced in Canada. Of these seven firms, two firms (29%) reported a decrease in exports while five firms reported no impact on exports.

e) Availability of specialty PMRA-regulated products in Canada

TNS asked respondents whether the cost recovery initiative has affected the overall number of small volume or "specialty" pest control products available in Canada. Specialty products refer to novel or niche products based on unique technologies. These factors tend to be associated with low sales volumes. Fourteen (45%) of 31 respondents said that the cost recovery initiative has reduced the number of small volume or "specialty" pest control products that their firm has made available in Canada. Ten firms (32%) said there was no impact and seven firms (23%) were not able to provide a specific answer. Taken together, respondents estimated that the total number of small volume or "specialty" products not introduced was 162. This estimate covers the six-year time period of the CRI.

Respondents were also asked whether the CRI had changed the uses of specialty pest control products made available by their firm in Canada. Eight firms (26%) reported that the CRI had led to a reduction in uses with a total of 164 fewer uses.

The potential impacts of the cost recovery initiative on changes made to PMRA-regulated products brought to the Canadian market were also assessed by respondents. Responding firms in the smallest size category experienced very little impact in terms of making changes to PMRA-regulated products. For total sales, the smallest firm size category is annual sales of $10 million or less. For pesticide sales, the smallest category is sales of less than $4 million. The largest firms reported the largest negative impacts (fewer changes to PMRA-regulated products).

f) Impacts of the CRI on R&D, manufacturing and corporate strategies

Eighteen of 31 responding firms perform research and development related to the introduction of new pest control products in Canada. Eight of the 18 firms that conduct R&D in Canada indicated that R&D has decreased in Canada as a result of the cost recovery initiative. The average estimate across the five respondents who could provide a quantitative estimate was that there had been a decrease in R&D spending of 17%.

Twenty-two (71%) of respondents indicated that the CRI has negatively affected product development plans of their firm. According to several respondents, cost limitations slow down development plans. Related to this, three of 31 (10%) responding firms reported that the cost recovery initiative has negatively affected their firm's decision to manufacture

technical active ingredients in Canada. Six firms (19%) said that the CRI has reduced the extent to which they formulate pest control products in Canada (including repackaging of end use products).

A majority of respondents (18 of 31 or 58%) indicated that the CRI has negatively affected strategic plans of their firm in Canada. Firms that produce or market products with low sales volumes (niche products) have decreased the number of products they carry since the added cost of the PMRA cost recovery initiative has made some of these products unprofitable. Some firms indicated that any additional costs, such as cost recovery fees, affect the strategic plans of the firm since all costs must be considered in the decision to launch a product.

Thirteen of 31 respondents (42%) said that they were aware of the existence elsewhere of technical active ingredients or manufacturing concentrates that they are not able to buy in Canada because of the CRI. Respondents noted that business development costs are too high for a small market. Respondents identified the CRI and excessive data requirements (beyond EPA) as the main problem.

g) PMRA program services

In the questions related to programme services, TNS asked respondents whether their firm had observed any change in the availability or responsiveness of PMRA staff or changes in PMRA efficiency that they would attribute to the CRI. The responses indicate that 54% of respondents to this question find PMRA staff either much less responsive or less responsive as a result of the introduction of the CRI. PMRA efficiency or effectiveness is judged to be lower by 61% of respondents. Approximately 42% of respondents noted no change in PMRA staff responsiveness and 36% noted no change in PMRA efficiency. The PMRA was reported to be more responsive and more efficient by 4% of respondents. However, the average view is that the PMRA is less responsive and less efficient or effective.

In answering these questions, many respondents pointed out that, the PMRA made a commitment to meeting performance standards and that this commitment has not been fulfilled. Some respondents said that the PMRA is not held accountable for its performance. Respondents did not have enough experience with the complaint procedure to draw any definitive conclusions from their responses.

Respondents were also asked about any possible unintended impacts of the CRI on the performance of the PMRA. Thirteen respondents (42%) said that there were such unintended impacts. These impacts reinforce the view that among many respondents, there are negative perceptions about their relationship with the PMRA.

2. External views on the impacts of the CRI on PMRA stakeholders

The main findings from the interviews with stakeholders included the following:

a) The PMRA's process for evaluation of minor use submissions is a particularly problematic area

Stakeholders made many negative comments regarding registration of minor use products, although it should be noted that the term "minor use" appears to have a different meaning for many stakeholders compared to PMRA. For PMRA, minor use refers to specific types of applications—URMULEs, in particular, and URMURs—whereas many stakeholders appear to refer to minor use as demand for pest control for products with limited production areas/volumes without necessarily considering the route by which registration of the applicable products may occur. This different context for minor use could then explain comments that fees were viewed to be a deterrent for minor use submissions, even though URMULE submissions are exempt from application fees and URMURS should, in theory, be eligible for reduced application fees.

The more critical factor is the perception that Canada has a more onerous regulatory process, particularly in regards to requirements for the submission and review of efficacy data. Overall, stakeholders believe that the PMRA does not take a "cost-benefit" philosophy, in that the examinations are too costly given the limited potential for revenue generation on the part of the industry.[1] Growers believe that their U.S. counterparts have access to a greater range of products, giving them a competitive advantage in the Canadian market. The establishment of the AAFC-PMRA Minor Use program was positively endorsed.

b) Growers do not believe that the PMRA considers the full implications when deciding to de-register a product

The main issue raised was the perception that when the PMRA decides to de-register a pest control product as an outcome from its re-evaluation program it does not identify a potential replacement product at the same time, so that growers continue to have products "in their toolbox."

c) The PMRA needs to continue to improve its processes for evaluating reduced-risk pest control products

The overall view from stakeholders is that the PMRA is starting to get better at handling submissions for reduced-risk pest control products, but more work needs to be done. Stakeholders had a variety of suggestions, including establishing a separate category of "generally regarded as safe products" that are provided with fast-track approval (a process that exists in the EPA).

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[1] The primary objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. As such, PMRA's mandate does not require, or permit, the Agency to take a cost-benefit regulatory approach.

d) CRI appears to have had little effect on prices and on R&D

The CRI fees are just one component of the overall costs faced by registrants in bringing a product to market. The more important component relates to the costs incurred in generating data for submissions.

There appears to be little R&D conducted on pest control products in Canada, but, again, this is not due to the existence of CRI. The other more important factors are the limited size and attractiveness of the Canadian market, together with what is perceived to be amore onerous Canadian regulatory environment. Several stakeholders commented that Canada is losing out on the global R&D battle, and they would like the PMRA to work more closely with other government agencies to develop policies that would promote agri-food research in Canada.

E. Key issues

The key issues flowing from our evaluation of the effectiveness of PMRA's cost recovery model and the impact of the CRI on PMRA's performance or external stakeholders are as follows. These issues provide the foundation for our recommendations, presented in the following section.

- In FY 2002-03, PMRA recovered about 18% of its expenditures through the application of registration and maintenance fees.
- Cost recovery fees have remained constant since FY 1997/98 while Agency costs have continued to increase, in response to such factors as inflation, and changes in the nature, size and complexity of submission examination requirements.
- PMRA's cost recovery revenues have never achieved the revenue target—of $12.3 million (45%) out of a total proposed budget of $27.6 million for FY 1997/98—agreed with stakeholders at the time of the Agency's creation and introduction of its cost recovery fees.
- The level of effort, and thus time and cost, to examine submissions varies significantly, both between and within application categories. The current fee structure, which is based on average costs for these widely varying levels of effort, lacks sufficient flexibility to more closely match costs and fees.
- PMRA lacks detailed tracking of actual breakdowns of times spent on submission examination (and other) activities. It does, however, have a well-developed and effective submission tracking system able to track submissions through different review levels and record elapsed times for submission examinations.
- Performance standards for the examination of submissions have been established, including modifications to recognize needs for accelerated reviews of reduced risk and other priority products. PMRA has encountered increased difficulty in meeting its target of completing 90% of submissions within applicable performance standards.

- PMRA has taken steps to improve the efficiency of service delivery, and is continuing to pursue further incremental improvements in its own processes and through international harmonization and use of review monographs by pesticides agencies in other jurisdictions. Increases in the volume of submissions received and level of effort involved in examining submissions have tended to offset efficiency gains.

- A significant level of mistrust exists between external stakeholders, particularly registrants and users, and PMRA. This mistrust would appear to be a function of a perceived lack of empathy by PMRA for the needs and challenges facing pesticides registrants and users, a related lack of responsiveness and service orientation in Agency dealings with applicants and registrants, scepticism regarding performance levels versus standards and the extent to which PMRA has acted to improve the efficiency of service delivery, and a passive approach to communications relating to the overall performance of the CRI.

- The results from the survey of 31 registrants representing a cross-section of large, medium and small pesticides firms in Canada suggests that the overall impact of the CRI on the number of applications is negative, particularly for Category A applications where the number of applications was reported to be less than half of the number that would have been made in the absence of the CRI (from 39 applications to 17). Registrants indicated that potential minor use applications were most likely to have been reduced.

- The majority of registrants (59%) surveyed indicated that the CRI had resulted in price increases for registered products, with increases being in the range 0.5% to 5% over the six year period in which the CRI has been in effect. A minority of respondents export pest control products and most said that the CRI had no impact on exports. Although this issue is more difficult to quantify, approximately 10% of respondents felt that the cost recovery initiative had negatively affected decisions of their firm to manufacture in Canada. Approximately 71% of respondents felt that product development plans had been negatively affected and 58% reported a negative impact on strategic plans in Canada.

- There is evidence indicating that the CRI had a greater negative impact on small and medium-sized firms more than larger firms. Category A application reductions were concentrated in the smaller firm size categories and reductions in the number of registered products due to maintenance fees were greater for the smallest firms.

F. Recommendations

This final section of our report presents recommendations regarding any alternatives and/or modifications that may be required to the application and maintenance fees charged and activities, including fee levels, structure and/or other related cost recovery program parameters, as required by the Statement of Work for the CRI evaluation.

1. Appropriate level of cost recovery

The government's *External Charging Policy* requires departments *to promote an equitable approach to the funding of government programs by fairly charging those who derive benefits beyond those enjoyed by the general taxpayer or by fairly charging those whose activities generate the need for regulation*. At the same time, the policy also states that departments are also expected to evaluate whether such *external charging significantly compromises the achievement of broader federal policy objectives*.[1]

The process that lead to the creation of the PMRA included the establishment of a 45% cost recovery target, based on estimated FY 1997/98 expenditures and revenues, yet PMRA's current fee structure recoveries are well below this level, and PMRA's level of cost recovery is below that of similar regulatory agencies in the U.S., U.K. and Australia. It is appropriate to re-visit the question of what is an appropriate level of cost recovery and therefore what is an appropriate A-base for the Agency, which is a policy issue for the Minister. Discussion regarding this question should take into account the fact that that PMRA has never achieved its targeted level of cost recovery yet the Cost Recovery Initiative has apparently contributed to a lower rate of introduction of new pesticides in Canada than would have otherwise been the case, according to the findings from our business impact survey.

We recommend that PMRA:

1. **Seek clear guidance from the Minister of Health, in consultation with the Minister's colleagues on the Treasury Board, regarding an appropriate level of cost recovery for the regulation of pest control products, and to set the Agency's A-base to reflect the difference between the level of cost recovery so realized and total costs incurred to satisfy PMRA's mandate. Input from external stakeholders and such information as the findings from the business impact survey conducted for the CRI evaluation will need to be considered in reaching such a decision, as would potential implications for submission examination timelines.**

2. Update PMRA's current fee structure and levels

PMRA's costs to examine and register new pesticide products are no longer in line with the fees charged to examine applications due to such factors as changes in submission requirements, conduct of additional activities, and inflation.

We recommend that PMRA:

2. **Update PMRA's fees to reflect changes in its costs and activities since the introduction of the current fees in FY 1997/98, taking into account the outcome from Recommendation #1.**

3. **In doing so PMRA should:**

[1] Treasury Board of Canada, *External Charging Policy*, Treasury Board of Canada Secretariat, Ottawa, August 2003, p.3 and p.5.

(a) **Investigate the feasibility of applying alternative approaches to structuring its application fees to provide greater flexibility to more closely match submission examination costs to fees charged, for example, by using the suggested modular fee structure option.**

(b) **Investigate the feasibility of adopting a system to measure the actual time spent by staff on the conduct of submission examination and other PMRA activities—for example, through the use of a time tracking system or periodic activity surveys—to provide the detailed time and cost information required to more closely match costs and fees.**

4. **Periodically review the alignment of fee levels and structures with underlying costs and changes in cost structures, and make changes where necessary. We recommend that such reviews be conducted at least every five years, and more frequently, if time and cost information demonstrates that costs and fees are diverging. Consideration should be given to establishing a formula basis for adjusting fee elements, for example, to accommodate changes in labour costs that account for close to 80% of PMRA's total costs, subject to satisfactory performance by the Agency against performance standards.**

Both PMRA and the EPA impose application fees for the examination of new product submissions but neither has established a basis for fees applicable to joint reviews that provide a basis for applying a single fee for situations where review work is shared between the two agencies. As a result:

5. **PMRA should consult with EPA, and potential participants in future joint reviews, to determine how fees could be assessed for joint review submissions without creating disincentives for simultaneous application and registration of new products, and how such a mechanism could be incorporated into PMRA's, and EPA's, future fee schedules.**

3. Efficiency and cost-effectiveness of service delivery

This evaluation focused on the impacts of the PMRA CRI, and as such, did not examine nor question the appropriateness of the Agency's specific regulatory responsibilities for examining and registering pesticide products. In reviewing the extent to which CRI has contributed to the delivery of an efficient service, we were primarily concerned with the way the submission examination process is managed and functions, so that opportunities to streamline elements of the examination process are acted upon and delays in examining submissions are minimized. In this regard, the Agency needs to continue with ongoing performance improvement initiatives and investigate performance issues affecting particular product categories to which the CRI may be contributing.

In this regard, we recommend that PMRA should:

6. **Issue an updated *Management of Submissions Policy* incorporating revisions and additions made to the performance standards for examining submissions and other elements of the submission management processes since the Policy was first issued in June, 1996.**

7. **Continue to aggressively pursue current initiatives to improve the efficiency of service delivery by such means as:**

   (a) International harmonization of review elements and standardization of templates and work sharing, especially with the U.S. EPA.

   (b) Working with applicants to encourage their participation in joint reviews and work sharing.

   (c) Use of review monographs prepared by equivalent pesticide regulatory agencies in other jurisdictions.

   (d) The introduction of electronic submissions and their adoption by industry.

8. **Conduct detailed reviews of performance and possible fee-related issues that may be limiting:**

   (a) The rate of introduction of new products (Category A submissions), as identified in the business impact survey conducted as part of this evaluation.

   (b) The performance of the AAFC-PMRA Minor Use program to facilitate the introduction of new products for minor use applications, and the extent to which current cost recovery fees and their application may be limiting the broader introduction of pest control products for minor use applications

   Based on the findings from these investigations, determine how any limiting factors attributable to the CRI or other aspects of PMRA's performance may be modified to minimize future barriers to the provision of suitable pest control products to Canadian users. (It is likely that these two aspects of the supply and demand for pest control products will overlap and a joint, or parallel, study would likely afford opportunities for common lines of enquiry and data gathering.)

4. Accountability for performance

Accountability for performance against the standards for the examination and registration of pest control products needs to be strengthened while continuing to ensure that PMRA meets its primary mandate to prevent unacceptable risks to people and the environment from the use of pest control products. It is often suggested that the best means of imposing such accountability is to impose penalties for non-compliance with performance standards, for example, by requiring partial refund of fees paid. However, this approach may punish regulatory agencies by reducing the amount of funding available to them for the conduct of future submission examinations, potentially leading to further shortfalls in performance and increased potential for "game playing" to stop the PMRA review clock and avoid penalties for not meeting performance standards.

We understand that the performance agreements of the Agency's senior managers include expectations regarding performance in completing applicable submission examinations against the applicable performance standards established in (or subsequent to) the *Management of Submissions Policy*, and that pay-at-risk is linked to the achievement of these expectations. This aligns the senior managers' performance objectives with PMRA's 2003-2008 Strategic Objective

to provide timely access to new, safer and effective pest control products. We further understand that these performance expectations apply to the completion of submission examination activities under the direct control of each manager that lead, or contribute to, decisions to register new pest control products, amend registrations, withdraw or reject submissions.

9. **We strongly endorse the inclusion of performance expectations linked to the Agency's 2003-2008 Strategic Objective—to provide timely access to new, safer and effective pest control products—in the performance agreements of the Agency's senior management. We recommend that PMRA review the alignment of the performance expectations in senior managers' performance agreements relating to this Strategic Objective to ensure due attention is paid to the timely and efficient conduct of product evaluations and re-evaluations. This element of the performance agreements should have equal weight with performance expectations relating to applicable elements of the Agency's other two 2003-2008 Strategic Objectives regarding protection of human health and the environment from unacceptable risks associated with pest control products, and to provide a workplace of choice.**

In order for this type of accountability mechanism to be "real", and accepted by the affected managers, it is necessary to ensure that there is an adequate level of suitably qualified staff available to review the anticipated volume of submissions, and submissions received are of consistently good quality.

External communication of information on PMRA's performance has failed to meet the commitment made in the cost recovery RIAS, to publish an annual report to *inform stakeholders of PMRA costs, activities and performance for the past fiscal year and projections for the coming fiscal year.* We do note, however, that PMRA commissioned a study on its performance standards that included recommendations on performance reporting and published a Progress Report on its program results for the period 1998-2003 in September, 2004.[1] Introduction of a regular report on performance for external dissemination would bring PMRA into line with the performance reporting practices of equivalent pesticide regulatory agencies in such countries as the U.K., Australia and, starting in 2005, the EPA. Given these factors, we recommend that:

10. **PMRA introduce a system of regular performance reports to registrants, users and other stakeholders that build upon the recommendations of the recent report on performance standards and results presented in the Agency's *Progress Report, 2003*. Aspects of performance that should be considered in the design of the system include, as a minimum:**

    (a) **Numbers of products registered, withdrawn or rejected, by category; average and median times to decision; distributions of times to decision around the applicable performance standards; the relative incidence of ideal and non-ideal submissions; and, significance of different contributions to these outcomes (for example, patterns of screening, review, applicant, deficiency, and consultation times for non-ideal submissions).**

[1] PMRA, *Review of Performance Standards*, prepared by Top Box Consulting Group Inc., Ottawa, June, 2004, and, PMRA, *Progress Report: 2003*, Ottawa, September, 2004. The Progress Report is accessible at: www.pmra-arla.gc.ca/english/aboutpmra/plansandreports-e.html

(b) Periodic surveys of satisfaction among registrants and other key stakeholder groups regarding PMRA's performance, similar to the surveys conducted by the U.K. Pesticides Safety Directorate.

(c) Performance in examining and registering products of particular interest to stakeholders, such as joint reviews with the EPA, reduced risk products, minor use products.

(d) Progress in achieving process efficiency improvements, and their impacts.

(e) Progress in the conduct of re-evaluation of existing pesticide products.

(f) Compliance performance, and compliance issues encountered.

5. Effectiveness of communications and consultation processes

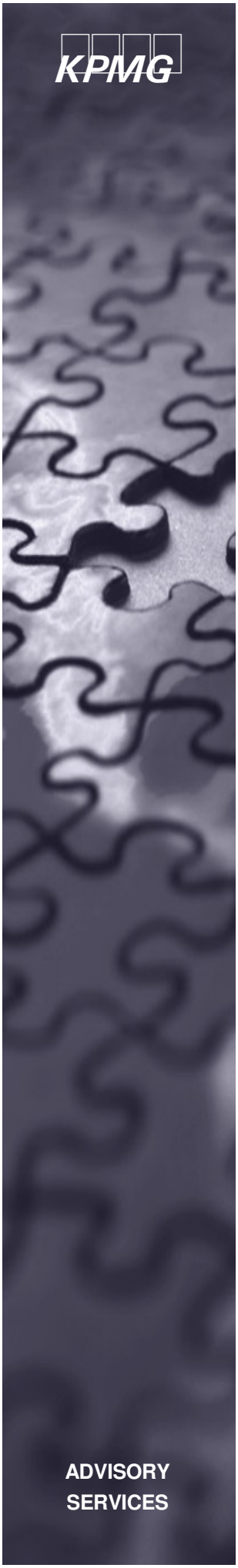
As we noted elsewhere in this report, the introduction of a cost recovery program involves an implicit bargain—that there will be improved service levels and business practices in exchange for cost recovery fees. This does not mean, and nor should it mean, that applicants have an enhanced influence over submission decisions, but it should reinforce the notion that the regulatory agency should have an open and empathetic approach to interacting with applicants and registrants, and providing a high degree of service quality.

Feedback from external stakeholders indicates that a significant "disconnect" exists between the Agency and its external clientele, and that this issue appears to permeate many of the Agency's areas of external interaction, going well beyond the CRI. PMRA needs to re-invigorate its stakeholder communication and consultation processes as part of a broader effort to engage with stakeholders and overcome a legacy of mistrust.

In this regard, we recommend that:

11. The Economic Management Advisory Committee (EMAC) to develop a new strategy and work plan to proactively guide its work on advising the Executive Director on specific ways to improve the efficiency of the submission examination process and timeliness of submission decisions.

12. Notwithstanding the fact that PMRA's fee dispute process has functioned as intended, PMRA should establish a second level of independent appeal for fee disputes. In this regard, PMRA should consider a similar approach to the approach used for fee disputes regarding cost recovery for therapeutic products elsewhere in Health Canada. As with the current mechanism, the mandate of this appeal level should be to review the interpretation and application of the fee regulations, not the philosophical basis and structure of the fee regulations.



FINAL REPORT
March 23, 2005

Evaluation Of The Pest Management Regulatory Agency's Cost Recovery Initiative:

Appendices

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March 23, 2005

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Appendix 1

ESC And TSC Mandates And Membership

Appendix 1

ESC and TSC Mandates And Membership

A. Evaluation Steering Committee

1. Mandate

The Evaluation Steering Committee (ESC) encompasses the following two functional areas:

a) **Communications Functions** - the responsibilities of the ESC will be to:

i) for those ESC members who are representing an organization, act as a two-way communication conduit and liaison between their organization and the ESC to ensure that information and opportunities for comment related to the process are available; and

ii) serve in an oversight capacity on issues of concern for stakeholders throughout the evaluation process.

b) **Review Functions** - the responsibilities of the ESC will be to:

i) monitor the evaluation process, keeping in mind the needs of all stakeholders impacted by the cost recovery initiative;

ii) provide input into the broad principles that underlie the review; and

iii) review and comment on any policy and/or regulatory changes that might be proposed as a result of the evaluation process.

2. Membership

Member	Title	Organization
Federal Government		
Janice Hopkins, Chair	Director, Alternative Strategies and Regulatory Affairs Division	PMRA, Health Canada
Robert Woods Secretary	Director, Management Planning and Coordination Division	PMRA, Health Canada
Brian Glabb	Director, Revenue and Costing Corporate Services Branch	Health Canada
Ken Lee	Director, Departmental Program Evaluation Division	Health Canada
Jack Cornett	Director, Radiation Protection Bureau (Dosimetry) Healthy Environments and Consumer Safety	Health Canada

Member	Title	Organization
Randy Legault	Senior Analyst	Treasury Board Secretariat
Cameron Short	Chief, Agri-Food Support Measurement and Analysis	Agriculture and Agri-Food Canada
Jean Hollebone	Assistant Vice President of Program, Office of the Vice President of Programs	Canadian Food Inspection Agency
Arthur Sheffield	A/Director, Strategic Policy and Management Services	Environment Canada
Provincial/Territorial		
Cameron Wilk	Provincial Pesticide Regulatory Management Specialist, Inspection and Regulatory Management Branch	Federal/Provincial/Territorial Committee on Pest Management and Pesticides (Saskatchewan), F/P/T Co-chair
Industry		
Jay Bradshaw	President	Syngenta Crop Protection Canada Inc.
Michael Grant	President	Can-Vet Animal Health Supplies Ltd.
Veldon Sorensen	Product Development Director, Crop Protection, Crop Science	Bayer Inc.
Brian Tuffin	President and General Manager	S.C. Johnson & Son Ltd.
Bob Friesen	President	Canadian Federation of Agriculture
Dean Thomson	Chair, CHC Crop, Plant Protection and Environment Committee	Canadian Horticultural Council
JoAnne Buth	Vice-President	Canola Council of Canada
Public Interest		
Julia Langer	Director, International Conservation Program	World Wildlife Fund
Academia		
Len Ritter	Executive Director, Canadian Network of Toxicology Centres	University of Guelph
Observers		
Shannon Coombs	Director, Government Relations	Canadian Consumer Specialty Products Association
Nicole Howe	Policy Analyst	Canadian Federation of Agriculture
Peter MacLeod	Executive Director, Crop Protection Chemistry	CropLife Canada

B. Technical Sub-Committee

1. Mandate

a) Technical Functions - the responsibilities of the Technical Sub-Committee will be to:

i) assist in finalizing the Request for Proposal (RFP) on the basis of the direction provided by the Evaluation Steering Committee (ESC);

ii) further revise the draft evaluation criteria prepared by the Pest Management Regulatory Agency;

iii) evaluate RFP submissions and select the winning proposal; and

iv) participate, when and if required, in meetings with contractor(s) on technical issues related to carrying out the project.

b) Individual Members' Functions - Technical Sub-Committee members may be asked on an individual basis to:

i) attend and/or participate in any consultations that might be required as the RFP and evaluation processes proceed;

ii) review and assess the results of such consultations as they relate to the RFP development and evaluation processes; and

iii) identify and facilitate access to information and expertise to the project.

2. Membership

Member	Title	Organization
Robert Woods, Chairperson	Director, Management Planning and Coordination Division	PMRA, Health Canada
Brad Buxton	A/Director, Revenue and Costing Corporate Services Branch	Health Canada
Walter Zubrycky	Manager, Information Analysis and Connectivity, Departmental Program Evaluation Division,	Health Canada
Randy Legault	Senior Analyst	Treasury Board Secretariat
Chuck A. Beach	Vice President, Technical Support	S.C. Johnson & Son Ltd.
Len Ritter	Executive Director, Canadian Network of Toxicology Centres	University of Guelph
Peter MacLeod	Executive Director, Crop Protection Chemistry	CropLife Canada
Nicole Howe	Policy Analyst	Canadian Federation of Agriculture

Appendix 2

Glossary of Terms and Acronyms

Appendix 2

Glossary of Terms and Acronyms

Term	Description
AAFC	Agriculture and Agri-Food Canada
Activity	A recognized and related group of tasks undertaken by PMRA that directly or indirectly support the products and services regulation of pesticides of PMRA.
APVMA	Australian Pesticides and Veterinary Medicines Authority.
Business Line Improvement	Development of Agency strategic initiatives for information technology, costs recovery, legislative change and all development projects that cross divisional lines to improve performance and reduce costs while maintaining a high level protection of health and the environment.
CFIA	Canadian Food Inspection Agency. Provides administrative and support services as per the Memorandum of Understanding with PMRA.
Category A	Submissions to register a new technical grade of active ingredient or integrated system product (not previously registered in Canada) and their related end-use product(s), manufacturing-use products or major new use, or to establish an import maximum residue limit(s) for a new active ingredient.
Category B	Submissions to register new pest control products (must contain an active ingredient that is currently registered for use in Canada) or to amend existing products.
Category C	Submissions with no or reduced data requirements for new or amended registrations requiring minor label or formulation reviews, such as product registrations based on precedent.
Category C "Fast Track"	Category B submissions that require only efficacy or value data are eligible to be classified as Category C "fast track" submissions concerning: • a decreased use rate • change in level of control (e.g., from suppression to control) • tank mixes: non-food uses, or food uses where the application is not intended for application to a transgenic crop • addition of pest(s) to a maximum of two. The following types of submissions are eligible for this "fast track", which features shorter time standards for submission evaluation:
Category D	Submissions to register or to amend products within particular programs, such as the Import for Manufacture and Export Program, Own Use Import, Master Copy, Private Label, User Requested Minor Use Label Expansion and renewals.
Category E	Submissions for research permits for new TGAIs, new use(s) of registered TGAIs, and research notifications carried out in Canada.
Chemistry specification and analytical methodology	A review of the product identity, product composition and chemical and physical properties.
Compliance	The promotion, maintenance and enforcement of compliance with the *Pest Control Products Act (PCPA)* through investigations, inspections and consultations that are coordinated with provincial and territorial governments and other federal departments.

Consultation Time	A period of time for public review of Proposed Regulatory Decision Documents relating to all new active ingredients and some major new uses of currently registered pesticides. The consultation period for all PRDDs is normally 45 days from the date of publication. The comments received during the consultation period are assessed, and the final decision is made within 45 days from the end of the comment period.
CRI	Cost Recovery Initiative.
DACO	Data Code tables. Data required to support an application depends on the nature of the product, e.g., chemicals, microbials or IMEP, and the purpose of the submission. As a guide for determining data requirements, PMRA grouped possible use-sites into a series of use-site categories (USCs) and established lists of required and conditionally required data for each USC, called data-code or DACO tables.
Direct activities	Activities that contribute directly to the delivery of a PMRA product or service.
EAD	Environmental Assessment Division. Evaluates data on the environmental chemistry and toxicology of products as well as their environmental fate.
Environmental fate and toxicology data	Activities to assess data related to the effect of a new active ingredient or end use products on the environment.
EPA	Environmental Protection Agency (United States)
ESAD	Efficacy and Sustainability Assessment Division. Establishes the value and efficacy of the products/uses at various doses to establish the lowest effective rate at which the pesticide can be applied.
Exposure data	Activities in support of the assessment of data to support a new active ingredient and associated end use product. This includes assessment of the types of exposure (e.g., occupational and residential; and routes of exposure (e.g., dermal and inhalation).
FIFRA	(U.S.) *Federal Insecticide, Fungicide and Rodenticide Act.*
FTE	Full Time Equivalent
FY	Fiscal year.
HED	Health Evaluation Division. Reviews three areas of human health effects: • Toxicological assessment to set acceptable daily intakes, the amount of compound that can be consumed daily for a lifetime with no adverse effects; • Occupational exposure assessment to determine how much exposure could occur in a typical day from direct exposure and residues; and • Food residue exposure assessment for all products that could cone into contact with food, including field crops, meat and dairy products, and processed foods to set maximum residue limits. Dietary risk assessment is also conducted, to assess the potential daily potential daily intake of pesticide residues from all possible food sources.
HPFB	Health Products and Food Branch Inspectorate. Manages the inspection, investigation, monitoring activities and enforcement strategies related to the fabrication, packaging/labeling, testing, importation, distribution and wholesaling of regulated health products.
Ideal Submission	A complete and high quality submission with no data deficiencies and, as such, does not involve any Applicant Time nor Deficiency Time.
Ideal Time	The sum of standard time frames for verification, first screen, review (last preliminary review for deficiencies, detailed evaluation, first decision and PRDD preparation), decision time after public consultation, and the first final label review.
Indirect activities	Overhead activities that are necessary to the overall operation and

	management of PMRA but do not contribute directly to the delivery of a PMRA product or service.
KPMG Model	The costing model developed in the course of the Review by KPMG to assess the cost of pesticide related activities.
Labelling	This activity involves the review, verification and approval of information to support a new or change to label.
Metabolism Residue data	Activities to assess data related to the metabolism rates and residue levels in support of a new active ingredient and associated end use product.
MOSP	Management of Submissions Policy, which established the basic process for managing submissions and set associated performance standards.
MRL	Maximum Residue Limit.
New product evaluation	The process of making regulatory decisions within specified performance standards on applications for the registration of new pest control products through the conduct of human, health, safety and environmental risk assessments, efficacy assessments, value assessments and the establishment of Maximum Residue Limits for pest control products.
Overhead costs	The cost of program support, management services and other central expenses (e.g., communications, payroll processing)
PCPA	*Pest Control Products Act*
PMRA Model	The costing model developed by PMRA to estimate the cost of pesticide related activities. This model was developed in 1995-96 and was used to support consultation on the development of the fee structure used for pesticide regulation.
PMRA Time	Time taken by the PMRA on a submission that has no deficiencies or applicant time. It includes the time at verification, the first screen, review time, final decision time after public consultation and final label review time
PRDD	Proposed Regulatory Decision Document. A summary of the information on which PMRA bases it registration decisions for all new active ingredients and some major new uses of currently registered pesticides.
PSD	Pesticides Safety Directorate (United Kingdom)
Registered Product Re-evaluation	The process of ensuring registered products meet current standards by periodically re-evaluating the data supporting the registered technical active ingredients and end-use products and reflecting the necessary changes in the regulatory status and labelling of the products.
RIAS	Regulatory Impact Analysis Statement.
Risk assessment and risk management	Risk assessments are based on a prescribed set of scientific data provided by registrants. These assessments provide best estimates of risk to defined populations exposed under defined exposure conditions. They are conducted in the context of well defined use scenarios, such as the use of a new pesticide on a particular field crop using specified application rates, methods and equipment. Potentially exposed populations and environments are also defined and considered in the risk assessment. The data required from registrants in support of a pesticide are tailored to provide the necessary information for the different proposed uses. Value is the third component assessed for determination of the acceptability of a pesticide. The primary consideration is whether the product is efficacious, i.e., 'does it do what it is claimed to do'. The assessment is based on results from field studies. These are conducted under typical use conditions and they must demonstrate that the pesticide provides effective control or suppression of a pest that is threatening animal and human life or health, or an agricultural and industrial commodity, process or product.

SCD	Submission Coordination Division. Manage the flow of application requests to track performance against the established standards and to ensure all required forms and fees have been submitted. Additionally, the division completes the administrative aspects of the review process.
Sub-activity	One or more sub-activity for which a user fee is charged. As of April 1997, PMRA charges fees using the following categories: Schedule I: ▪ Label ▪ Product chemistry specification and analytical methodology ▪ Toxicology data ▪ Exposure data ▪ Metabolism data ▪ Residue data ▪ Environmental fate data ▪ Environmental toxicology data ▪ Value and effectiveness data. Schedule II: ▪ Renewal of certificate of registration ▪ Research permit (administration fee) ▪ (a) Import for manufacture and export program ▪ (b) Amendment to import for manufacture and export registration ▪ Establishment of maximum residue limit for an unregistered pest control product or for an unregistered use of a pest control product.
Submission examination process	The process used to reach decisions for applications to register new products, amend details of existing registrations, establish import MRLs and approve research permits. In the Category A applications the key steps are: verification, screening for completeness, review of required data, formulation of a proposed regulatory decision for public consultation, final regulatory decision and verification of the final label.
Sustainable Pest Management	Creation of opportunities for pesticide risk reduction in major pesticide use sectors. This is done by: developing risk reduction strategies; measurement and reporting on risk reduction trends through risk indicators; facilitation of the registration of reduced risk products; and provision of information and advice on Sustainable Pest Management.
TGAI	Technical Grade of Active Ingredient.
Toxicological data	Evaluation activities related to identification of possible human effects and determination of acceptable levels for human exposure.
Value and effectiveness	Evaluation of the efficacy of a product at its minimum dosage or application.

Appendix 3

Estimate of Costs for FY 2002/03

Appendix 3

Estimate of Costs for FY 2002/03

This appendix provides an overview of how we developed cost estimates for FY 2002/03. We developed an estimate of costs using the cost categories outlined in Exhibit D-1, which were developed from Treasury Board's *Guide to Costing of Service Delivery for Service Standards*, October 1995.

Exhibit 1
Cost Identification Framework

1. Direct PMRA program costs Employee salary and wages Employee benefits (including costs borne by TBS, Human Resources and PMRA) Operating and maintenance
2. PMRA Program support overhead Regulations Policy issues Communications Continuous learning Regional pesticide workshops Regional travel (includes fleet vehicles, car rentals, use of personal vehicles, taxi) Mail/courier Enforcement Officer advice/briefings Inspector cars for CFIA staff PMRA systems development and maintenance Continuous learning program Human resource operational support, including pay, benefits, advice and guidance
3. Corporate Services Branch overhead (Health Canada) Training in Health Canada wide initiatives Connection to corporate databases and central internet services Maintenance of corporate databases and central internet services Accommodations Health, safety and security Records Central human resource policy development
4. Non-cash items Depreciation of capital assets Accommodation Worker's compensation coverage (HRDC) Contribution covering employees' share of employees' insurance premiums and expenditures paid by Treasury Board Secretariat Legal services from Justice Canada
5. Cost of capital

1. Direct Program Costs

Direct program costs include labour costs, benefits and operating and maintenance costs charged to the PRMA and to activities within the HPFB Inspectorate. The basis for these costs is as follows:

- Direct labour costs are based on the salaries and wages paid to staff in FY 2002/03.
- Benefit costs are estimated as 20% of salaries and wages. It includes an allowance for such things as the employer's share of Canada Pension Plan, Unemployment Insurance, long-term disability, superannuation and medical and dental coverage.
- Other direct program costs identified as operating and maintenance costs and minor capital.
- The cost of the CFIA memorandum of understanding for the time and associated costs of inspections.

2. Program Support Overhead

Program support overhead includes an allotment of PMRA support services. This includes payments related to communications, continuous learning, regulations and policy issues, translation services and the support of the Management Planning and Coordination Division (e.g., human resource management, employee services, financial analysis, technical services, travel coordination, mail and records and printing).

3. Corporate Services Branch Overhead

An allowance for Corporate Service Branch overhead cost has been made, based on the original cost estimate used in the PMRA costing model and inflation as measured by the Consumer Price Index (from January 1995 to January 2003).

4. Non-Cash items

We estimated depreciation costs for capital assets used in support of PMRA. Depreciation costs were calculated for personal computers, laboratory equipment, and office equipment.

We estimated the annual cost of depreciation as follows:

- Personal computers and peripherals equipment were estimated at $339,955 and depreciated over a three to five-year period;
- Laboratory equipment costs were estimated at $405,611 and depreciated over a 15-year period; and
- Office equipment costs were estimated at $177,885 and depreciated over a five to ten-year period.

We estimated other non-cash items using the estimates included in Health Canada *2001-2002 Estimates, Part III – Report on Plans and Priorities.* The relative shares of these costs that relate

to PMRA were estimated based on the number of FTEs in Health Canada and in the PMRA, as follows:

	$ per FTE
Accommodation	3,433
Contribution covering employees' share of employees' insurance premiums and expenditures paid by TSB	4,254
Worker's compensation coverage (HRDC)	97
Legal services from Justice Canada	361

5. Cost of capital

To develop an estimated cost of capital we first developed an estimated cost of capital for PMRA. This estimate was based on the estimated book value of assets only. We did not adjust the capital cost estimate to reflect:

- The replacement cost of capital assets;
- Capitalized interest;
- Loss carry forward; and
- Goodwill.

We estimated the capitalized assets to be approximately $922 thousand, which includes $177 thousand for office equipment, $405 thousand for laboratory equipment, and $340 thousand for personal computer equipment.

To determine the average cost of capital we used the average long-term bond rate for FY 2002/03 plus an industry risk adjustment factor. We estimated the industry risk adjustment factor by considering other Federal Government projects that required the calculation of a cost of capital. We estimated the long-term bond rate to be 4.90% and added an industry risk factor of 0.5%, for a total cost of capital of 5.40%.

We multiplied the estimated capitalization of the PRMA by the risk adjusted interest rate to develop an estimate of the annual cost of capital, which was $35,368.

6. Estimating Direct Staff Costs

We assigned direct staff, benefits, operating and maintenance costs to activities based on the best possible estimate of how staff time was spent in FY 2002/03. We developed estimates using the FY 2002/03 work plans for each business line. These work plans are reviewed and amended by management on a regular basis based on their professional judgement and any additional information sources available to them.

Appendix 4

Participants: External Interviews

Appendix 4

Participants: External Interviews

A. Interviews regarding the impacts of the CRI on PMRA and external stakeholders

Participants in our interviews regarding the impacts of the Cost Recovery Initiative on PMRA are listed below. A significant number of the stakeholder representatives also responded to our (separate) questions regarding the impacts of the CRI on users and other external stakeholders. The list shows those participants who commented on both areas of impact and those who commented on either impacts on PMRA or impacts on users only. The interview guide for these interviews is shown in the following appendix.

Participating Organization	Commented on CRI Impacts on PMRA	Commented on Impacts of CRI on Users
A. Associations Representing Growers, Pest Control Products Manufacturers and Users		
Canadian Consumer Specialty Products Association Ottawa, Ontario	X	X
CropLife Science and Regulatory Committee Toronto, Ontario	X	X
Canadian Animal Health Institute Guelph, Ontario	X	X
AGCare Guelph, Ontario	X	
Canadian Federation of Agriculture Ottawa, Ontario	X	X
Ontario Agri-Food Technologies Guelph, Ontario		X
Canola Council of Canada Winnipeg, Manitoba		X
Canadian Seed Trade Association Ottawa, Ontario		X
Canadian Institute of Treated Wood Ottawa, Ontario	X	X
Ontario Tender Fruit Producers' Marketing Board Mississauga, Ontario		X
Canadian Golf Superintendents' Association Toronto, Ontario		X
Ontario Processing Vegetable Growers St. Marys, Ontario		X
Ontario Fruit and Vegetables Growers Association Guelph, Ontario	X	X
Canadian Horticultural Council Ottawa, Ontario	X	X

B. Environmental Non-Governmental Organizations and Consumers Groups		
Sierra Club of Canada Ottawa, Ontario	X	X
Consumers Association of Canada St. Albert, Saskatchewan	X	X
Canadian Association of Physicians for the Environment Toronto, Ontario	X	X
World Wildlife Fund Canada Toronto, Ontario	X	X
Canadian Environmental Law Association Toronto, Ontario	X	X
C. Research Networks		
Biocontrol Network Montreal, Quebec	X	X
D. Government Departments and Agencies		
Agri-Food Support Measurement and Analysis Agriculture and Agri-Food Canada Ottawa, Ontario	X	X
Ontario Ministry of Agriculture and Food Guelph, Ontario	X	X
B.C. Ministry of Agriculture, Food and Fisheries Abbotsford, B.C.	X	X
P.E.I. Department of Environment and Energy Kensington, P.E.I.	X	X
Alberta Agriculture, Food and Rural Development Edmonton, Alberta	X	X
E. International Pest Control Product Manufacturers		
Evergreen Bio-ceuticals, Guelph, ON	X	X
Valent Biosciences, USA	X	X
Bedoukian Research Inc., USA	X	X
Clariant Corporation, USA	X	X
Pacific Biocontrol Corp., USA	X	X

B. International interviews

Organization	Location
Office of Pesticides Programs Environmental Protection Agency	Washington D.C., U.S.
Pesticides Safety Directorate	York, U,K.
Australian Pesticides and Veterinary Medicines Authority	Canberra, Australia
DG Health and Consumer Protection European Commission	Brussels, Belgium
Avcare	Canberra, Australia
European Crop Protection Association	Brussels, Belgium

Appendix 5

Interview Guides — External Interviews

Appendix 5

Interview Guides — External Interviews

A. Interviews regarding the impacts of the CRI on PMRA and external stakeholders

Note: This interview guide provided the basis for interviews with external stakeholders regarding both Task 2 – Impact of the CRI on PMRA and Task 3 – Impacts of the CRI on Other Stakeholders. This design reflects the fact that a significant proportion of the external stakeholders interviewed indicated that they felt able to comment on both areas of impact. Section A of the Guide focuses on the impacts of the CRI on PMRA, Section B focuses on the impacts on users of pest control products and other stakeholders, and Section C was asked of all participants in these interviews.

KPMG LLP and ARC Applied Research Consultants (KPMG/ARC) have been commissioned by the Pest Management Regulatory Agency (PMRA) to evaluate the impacts of the PMRA's Cost Recovery Initiative (CRI). As part of this we are conducting a program of interviews with representatives of industry, government and other stakeholder organizations investigating their views on:

- The impact that cost recovery has had on the efficiency and effectiveness of PMRA's processes and performance.
- The downstream impacts of cost recovery on such groups as users of pest control products, members of the public, and other levels of government.

Individual comments will be kept confidential to KPMG/ARC with only aggregated responses and key themes addressed in our reporting. The findings from these interviews represent one line of enquiry and will be considered in conjunction with findings from an extensive internal analysis and a survey of registrants.

In some cases, the organizations we are contacting may not be able to speak to the questions in either Section A or Section B, below. Please let us know if this is the case for your organization and we will focus on the sections that you are best able to speak to.

* * *

In Canada, the federal government's cost recovery policy requires government departments to consider charging fees for services. The objectives of the policy are to:

a) Promote more efficient use of government services;

b) Introduce more business-like and client-oriented practices in the supply of government services;

c) Ensure that the costs of services that primarily benefit the general public are financed through taxes; and

d) Ensure that the costs of services that primarily benefit specific subsets of the population are recovered from those who benefit from or cause such services.

Cost recovery for the regulation of pesticides was introduced in April 1997 after extensive consultation with stakeholders. The Pest Management Regulatory Agency charges one-time application fees in accordance with a prescribed fee schedule for the review of applications for the registration of pesticides and an annual maintenance fee per registered product for the right to manufacture or sell a product in Canada. Fee reductions apply to both types of fees. Biopesticides and proposals for user requested minor use label expansion (URMULE) are exempt from fees.

1. Impacts of the PMRA CRI on PMRA's performance

1. Please describe the nature of your organization's interactions with the PMRA.

2. What do you understand to be the key features of the approach to cost recovery at PMRA?

3. To what extent are cost recovery questions and issues a factor in your organization's interactions with the PMRA?

4. To what extent do you believe the PMRA's Cost Recovery Initiative has had an impact on any of the following aspects of its performance? Please provide examples of these impacts to support your observations, if possible.

   a) The quality and timeliness of PMRA evaluations of submissions to register new active ingredients and end-use products, or to amend existing registrations;

   b) The size of registration submissions, in terms of requesting registration of products for a broader range of uses than would have otherwise been the case;

   c) The quality and timeliness of PMRA work in support of other areas of its mandate, such as the re-evaluation of previously registered products, conduct of compliance monitoring and enforcement activities, promotion of sustainable pest management practices, etc.;

   d) Priority setting and allocation of resources between different principal areas of activity (business lines)?

5. At the time the current fee schedule was implemented, in April 1997, PMRA made a commitment to achieve a 40% efficiency gain in the review of new submissions, through such actions as international harmonization, re-engineering of its evaluation processes, and the conduct of joint reviews.

a) To what extent do you believe this goal has been achieved?

b) Have these efficiency gains been offset by increases in the complexity and size of submissions and assessment requirements (i.e., involve increased scientific complexity and more supporting scientific studies) or other changes in submissions?

c) What other factors have affected the efficiency and productivity of the PMRA's assessments of new submissions?

6. Has the ability of PMRA to implement its CRI or achieve its efficiency improvement targets been limited, or enhanced, by other government policies, programs or actions? If yes, what is the nature of these other parameters that fall outside of PMRA's direct control, and how have they limited the Agency's performance improvement efforts?

7. How effective are the PMRA's processes for consulting and communicating with registrants and other stakeholders regarding cost recovery? Which aspects of its cost recovery consultation and communication activities are most effective and which could be improved?

8. Are you aware of the process established to enable clients to submit formal appeals or complaints relating to fee decisions? If yes, is this fee dispute resolution mechanism working effectively or are there aspects that require clarification or improvement?

2. Impacts of the CRI on users of pest control products and other external stakeholders

9. What is the nature of your organization's interactions with:

a) PMRA. [Skip if already covered in Section A, Q.1]

b) Companies that market pest control products in Canada.

c) Organizations and individuals that use pest control products.

10. Please describe your understanding of the structure and significance of the fees charged by PMRA for the assessment and maintenance of pest control product registrations?

11. In your opinion, what is the level of awareness of the fees charged by PMRA under its cost recovery initiative beyond the firms paying fees?

12. To what extent, if any, would you say the PMRA cost recovery initiative has had an impact in such areas as:

a) The introduction and availability of new pest control products in Canada.

b) The replacement of older, less-safe products with safer equivalents.

c) The price of pest control products in Canada.

d) The rate of research and development of new pest control products undertaken within Canada.

e) Other (please describe).

Please describe specific instances and examples of impacts where possible.

13. Looking more broadly, do you believe that the direct impacts of applying cost recovery fees in the areas addressed in Question 12 has affected:

    a) The ability of industry sectors that rely upon the use of pest control products to:

        a.1 Sell their products in export markets.

        a.2 Compete with imported products in the Canadian market.

    b) The ability of government departments and agencies—federal, provincial and/or municipal—to achieve public policy and program goals related to public, occupational and/or environmental health?

    Once again, please describe specific instances and examples where possible.

14. Has the PMRA cost recovery initiative had any other impacts that you are aware of, either intended or unintended? Please describe the nature of these impacts.

3. Opportunities to improve the operation of cost recovery at PMRA

15. Do you have any suggestions for improving the operation of PMRA's cost recovery activities?

16. In your opinion, has the implementation of the PMRA's fees for applicants and registrants, and other elements of the Agency's cost recovery initiative, had any impact on PMRA registration decisions? In other words, has it increased or decreased the likelihood of a "Yes" or "No" for an application?

17. Do you have any other comments related to the assessment of the PMRA Cost Recovery Initiative?

B. Interviews with other pesticide regulatory agencies

KPMG LLP and ARC Applied Research Consultants (KPMG/ARC) have been commissioned by the Pest Management Regulatory Agency (PMRA), which administers Canada's *Pest Control Products Act*, to evaluate the impacts of the PMRA's Cost Recovery Initiative (CRI). This evaluation is examining the implementation of the CRI, effectiveness of the PMRA costing model, whether and how PMRA performance has been affected by the CRI, and the impact of the CRI on key stakeholders.

As part of this work, KPMG/ARC propose to conduct interviews with representatives of the Office of Pesticide Products at the U.S. Environmental Protection Agency, the U.K. Pesticides Safety Directorate at DEFRA, and the Australian Pesticides and Veterinary Medicines Authority to review:

- The extent to which cost recovery is applied.
- The impacts it has had on the regulatory agencies and the regulated users in each jurisdiction.

The following questions are intended to provide a guide to the aspects of interest to the project team, and to facilitate preparation for, and conduct of, these interviews. Any questions concerning these interviews or any other aspect of KPMG/Arc's work can be directed to the team's project manager, Geoff Golder, at 1-613-212-3660 or geoffgolder@kpmg.ca.

* * *

1. Features of your approach to cost recovery

18. Where did the impetus for introducing cost recovery in your organization come from? To what extent was it a function of:

    a) Legislation defining the mandate and roles of your organization, including requirements to impose fees and recover costs?

    b) Government-wide polices regarding the recovery of costs from direct beneficiaries of government programs and services?

19. When did your organization first introduce its cost recovery program? In what ways, if any, has it evolved—in terms of the level of cost recovery and/or structure and scope of fees charged—since that time?

20. What are the key features of your current approach in such areas as those listed below? We are also interested in gaining an understanding of situations where new fee structures or fee levels are pending, and the reasons for any changes that are being implemented.

    a) The general principles and structural features of the fee structure. For example, the relative significance of fees to review registration applications versus the use of levies on sales of registered products.

    b) The proportion of total funding generated from cost recovery fees from pesticide registrations and/or maintenance fees.

    c) Extent to which such cost elements as the following are included in, and captured by,

your fees:

- Direct costs to assess and register new active ingredients and uses (such as salaries and benefits of operational staff).
- Direct costs of compliance monitoring and enforcement activities.
- Direct costs to reregister existing active ingredients and products.
- Facility operation and maintenance.
- Development of policies, regulations and standards.
- Supporting research and development activities.
- Fee administration and revenue collection.
- General management of the organization.
- Other overhead costs and activities.
- Non-cash items, such as depreciation and cost of capital.

d) Methods used to measure and allocate costs between different activities, and formulate fee structures (e.g., time entry and coding systems, periodic Activity Based Costing studies).

21. To what extent do fees charged vary between different types of registrants, for example:

a) Do some applicants/registrants qualify for fee waivers? If so, on what basis are fees waived?

b) Do operators of small businesses qualify for lower registration fees or maintenance levies? If so,

- What is the definition of a "small business", and how do you verify the eligibility of claimants?
- How are the fee reductions determined? In the case of maintenance levies do they involve minimum and/or maximum fee levels?

c) Do certain types of products, such as biopesticides, qualify for lower registration fees compared to "conventional chemicals" seeking equivalent registration approvals? What is the rationale for providing these fee differentials?

22. When are fees payable, and what happens if a registration or maintenance fee is not paid?

23. How often do registrants dispute their registration or maintenance levy fees? How are these disputes resolved? For example, do you have a formal process for resolving such disputes?

24. How often are your fee structures reviewed and updated or modified?

25. What process(es) is (are) used to obtain stakeholder input and reaction to proposed changes in fees and fee structures? How long does this process typically take?

26. Do you also seek ongoing stakeholder feedback regarding fees and cost recovery, for example, through the work of stakeholder advisory committees?

2. Requirements to meet target timeframes for reviewing applications

27. For how long has your organization been required to complete registration reviews within pre-established time periods?

28. How are (were) these target times set? Do they incorporate progressive reductions over time, and if so, on what basis were these progressive reductions in the target time periods set?

29. Do you have to publicly report on your performance against these targets?

30. What are the consequences if you fail to meet the target times for registration reviews?

31. Are you experiencing difficulties, or do you expect to encounter difficulties in the future, in meeting these target review times with the resources available to you? If yes, what is the nature, and causes, of these difficulties?

32. How do the target times accommodate situations when applicants have to provide additional data to support their applications? Do applicants have to pay additional fees for the review of this additional data? What is the approximate incidence of these "partial re-submit" situations?

33. What actions have you taken (or are considering) to improve the efficiency of your review activities? What cost or time savings have you been able to achieve (or expect to achieve) as a result of such innovations?

3. Impacts of cost recovery on registrants and users of pesticides

34. To what extent has the application of your cost recovery fees had an impact on:

    a) The breadth of applicants' registration submissions? For example, it has been suggested that the fee structure in Canada has lead to the inclusion of a broader range of uses in submissions than would have been the case in the absence of fees.

    b) The rate of introduction and availability of new pest control products?

    c) The rate of replacement of older, less-safe products with safer equivalents?

    d) The price of pest control products to end-users?

    e) The rate of research and development of new pest control products undertaken in your country?

    Do you have, or are you aware of, any studies that support your views regarding these impacts? If yes, could we obtain a copy?

* * *

35. In summary, what aspects of your approach to cost recovery work best, and which pose the most significant ongoing difficulties, for:

    a) Your organization

    b) Registrants

    c) Other stakeholders, such as users of pesticides?

C. Interviews with international industry associations

KPMG LLP and ARC Applied Research Consultants (KPMG/ARC) have been commissioned by the Pest Management Regulatory Agency (PMRA), which administers Canada's *Pest Control Products Act*, to evaluate the impacts of the PMRA's Cost Recovery Initiative (CRI). This evaluation is examining the implementation of the CRI, effectiveness of the PMRA costing model, whether and how PMRA performance has been affected by the CRI, and the impact of the CRI on key stakeholders.

As part of this work, KPMG/ARC propose to conduct interviews with representatives of the Office of Pesticide Products at the U.S. Environmental Protection Agency, the Australian Pesticides and Veterinary Medicines Authority, the U.K. Pesticides Safety Directorate at DEFRA, and the European Commission's Health & Consumer Protection Directorate-General, as well as representatives of selected industry associations. These interviews will review the extent to which cost recovery is applied in each jurisdiction and the impacts of such programs.

The following questions are intended to provide a guide to the aspects of interest to the project team, and to facilitate preparation for, and conduct of, these interviews. Any questions concerning these interviews or any other aspect of KPMG/ARC's work can be directed to the team's project manager, Geoff Golder, at 1-613-212-3660 or geoffgolder@kpmg.ca or to PMRA's Project Authority, Robert Woods, at 1-613-736-3411.

* * *

1. To what extent has the application of cost recovery programs and the application of performance standards for the conduct of submission evaluations had an effect on your member companies':

   (a) Decisions to develop and/or introduce new products targeting:

      i) Major markets for pesticide products;

      ii) Minor use markets for pesticide products;

      iii) The replacement of existing, higher-risk pesticide products?

   (b) Approaches to the preparation of submissions for new or amended product registrations, and management of interactions with pesticide regulatory agencies regarding the evaluation of these submissions?

   (c) Approaches to the maintenance of existing product registrations?

2. In general terms, has the application of cost recovery policies had an impact on:

   a) The rate of introduction of new pesticide products;

   b) The rate of replacement of older, less-safe products with lower-risk equivalents;

   c) The prices paid by end-users for pesticide products;

   d) The level of pesticide research and development work performed in your country (or countries covered by your organization)?

3. What other factors have had a similar, or greater, impact on outcomes in each of the areas listed in Question 3?

4. Are you aware of any published studies that have investigated trends and causal factors in any of the areas listed in Question 2? If yes, can you provide us with a copy or tell us where we could obtain a copy?

5. What do you believe are the relative merits of fee based approaches to cost recovery versus the use of ongoing sales levies? And the weaknesses?

6. Is your organization, and its members, generally satisfied with the performance of the pesticide regulatory agency(ies) in your jurisdiction in conducting evaluations of new products and reviewing existing registrations, in terms of the timeliness, quality and cost of such work?

7. In what areas is the performance generally strong?

8. In what areas could it be improved?

9. What do you believe are the most significant challenges faced in:

   b) Bringing about a greater degree of international harmonization of pesticide registration processes;

   c) Increasing the efficiency of processes used to evaluate applications to register new active substances and pesticide products?

10. What actions or innovations offer the best apparent potential for bringing about improvements in the two areas listed in Question 9?

11. Are there any other aspects of cost recovery and the performance of the pesticide regulatory review process that you would like to comment on that have not been addressed by the above questions?

Appendix 6

Survey Questionnaire

(Confidential when completed)

Appendix 6

Survey Questionnaire

IMPACT ASSESSMENT STUDY
OF THE COST RECOVERY INITIATIVE
FOR THE PEST MANAGEMENT REGULATORY AGENCY

Conducted by

ARC Applied Research Consultants

COMPLETED QUESTIONNAIRES SHOULD BE RETURNED TO ARC AS NOTED BELOW

Please return this questionnaire no later than April 26

Introduction

The Pest Management Regulatory Agency (PMRA) has contracted with ARC Applied Research Consultants and KPMG to estimate the business impacts of the cost recovery initiative (CRI) for pest control products. **The PMRA Cost Recovery Initiative (CRI) is the process implemented by the PMRA to recover appropriate costs, in accordance and compliance with Treasury Board policy on external charging, for the regulation of pesticides, i.e. for the evaluation of applications for pest control products by charging application fees, and for the right and privilege to manufacture and sell a product in Canada by charging maintenance fees.**

Business impacts of the cost recovery initiative can take a variety of forms. The fees, for example, may increase costs of business to a varying degree as firms comply with the existing regulatory framework. As a result, this study focuses on the potential impacts of the cost recovery initiative on the activities of firms. Within the cost recovery initiative, the specific fees considered in this questionnaire are the Application Fees and the Maintenance Fees**. Note that the assessment is of the impact of the CRI, not the overall PMRA regulatory framework. This assessment requires the informed input of firms affected by the CRI and requires estimates that focus only on the impacts of the CRI.**

To provide an assessment of the impacts of the CRI, ARC Applied Research Consultants has developed this questionnaire. To assist us in this process, we would like you to provide answers to the following questions based on information on the operations of your firm. Please note that all information that you provide will be treated in complete confidence by ARC Applied Research Consultants. ARC has many years of experience in conducting studies of this kind that may involve confidential business information. The results of this impact study will include data that have been aggregated by ARC to ensure that the confidentiality of individual responses is preserved. Only aggregated data will be provided to the client as specified in our contract with them. The results of the study will be made available as a component of the overall evaluation of the CRI. Participating firms will be provided with a copy of the report.

The questions in this survey are based on the Business Impact Test (BIT), a tool developed by Treasury Board, Industry Canada and the Alliance of Manufacturers and Exporters, to analyse the impacts of regulation on business. The key topics and general structure of the BIT have been followed to meet the requirements of federal regulatory and cost recovery policies, but the questions have been targetted to the cost recovery initiative and simplified to minimize the response burden for you.

Returning the Questionnaire

The following pages provide the questionnaire that we are asking industry respondents to complete. If you have questions about the questionnaire or our data requirements, please contact Doug Smith at (613) 230-4394, or **1-800-663-6023**. If using e-mail, the address is Doug.Smith@tns-global.com

Completed forms in an envelope marked "CONFIDENTIAL" should be returned by mail or courier to the address provided at the end of this questionnaire. If you prefer, completed forms may also be sent by fax to ARC Applied Research Consultants at (613) 232-7102.

A. General Information

Respondent Name:_____

Respondent Title: _____

E-mail: _____

Telephone:_____

A1. Is the majority ownership of your firm: Canadian ☐[1] Other ☐[2]

A2. Does your firm produce or sell pest control products **in Canada only**?

Yes ☐[1] No ☐[2]

A3. For how many years has your firm operated in Canada? _____ years.

A4. Check the category in which sales for the Canadian operations of your firm should be classified for your most recent fiscal year. Sales should be gross sales less discounts and promotional rebates.

***Sales from CANADIAN* Operations**
DOMESTIC + EXPORTS

Less than $1,000,000
$1,000,000 to $3,249,999
$3,250,000 to $4,999,999
$5,000,000 to $9,999,999
$10,000,000 to $19,9999,999
$20,000,000 to $49,999,999
$50,000,000 to $79,999,999
$80,000,000 to $99,999,999
$100,000,000 to $149,999,999
$150,000,000 to 199,999,999
$200,000,000 to $249,999,999
$250,000,000 to $499,999,99
Over $500,000,000

Note: In categorising annual sales responses, this study will use the following firm size definitions:

- Small; up to $20M.
- Medium; $20M to $150M.
- Large; over $150M.

A5. What percentage of your sales in A4 is derived from selling pest control products regulated by PMRA to which the CRI applies?

_____ %

B. Estimated Impacts of the CRI: Jobs

B1. Please indicate the number of person years (PYs) that your firm had in Canada in 2003 in the following categories: (Note for example that one person, full time, for 6 months is 0.5 person years).

Note: Under **TOTAL**, count all employees in all of the Canadian operations of your firm. Under **PMRA Regulated**, count only employees in activities regulated by the PMRA to which the CRI applies (all registered products).

	TOTAL PYs	**PMRA Regulated PYs**
Scientific and Research	_____	_____
Management and Administration (includes Regulatory, Purchasing, Legal, Human Resources, Accounting, Tax, Payroll, Information Systems and General Administration)	_____	_____
Manufacturing/Operations (includes Quality Control, Distribution, and Freight)	_____	_____
Sales, Marketing and Other (includes Market Research, Sales Administration, Customer Services and New Business Development)	_____	_____
Total	_____	_____

B2. Has the CRI affected the extent of contract work carried out by your firm? If yes, please describe including the division between contracted work inside Canada and outside, if relevant.

_____

_____

_____

B3. What has been the impact of the PMRA CRI on ***domestic jobs*** (measured as person years as in B1) provided by your firm in Canada? [COMPLETE FOR EACH JOB TYPE]

				IF LOSS OR INCREASE IN JOBS: State change in numbers	
	Loss in jobs	Zero impact on jobs	Increase in jobs		Don't know
Scientific and Research	☐[1]	☐[2]	☐[3]	_____	☐[4]
Management and Administration (includes Regulatory, Purchasing, Legal, Human Resources, Accounting, Tax, Payroll, Information Systems and General Administration)	☐[1]	☐[2]	☐[3]	_____	☐[4]
Manufacturing/Operations (includes Quality Control, Distribution, and Freight)	☐[1]	☐[2]	☐[3]	_____	☐[4]
Sales, Marketing and Other (includes Market Research, Sales Administration, Customer Services and New Business Development)	☐[1]	☐[2]	☐[3]	_____	☐[4]
Total				_____	

Provide comments or explanations related to the numbers above.

_____

_____

_____

B4. In addition to the job impacts in Canada reported above, are there any employment impacts for your firm outside Canada that are attributable to the CRI?

_____

_____

_____

C. Estimated Impacts of the PMRA CRI

Application Fees

C1. Complete the following table relating to pest control product applications during the year 2003.

APPLICATIONS	Actual # of applications filed for the period January 1, 2003 to December 31, 2003. (1)	Estimated number of applications you would have made if these application fees had NOT been in place (2)	Number of applications for which fee reductions were granted (3)	Number of applications you would have made if no fee reductions were available (4)	Number of applications for which fee exemptions were granted (5)	Number of applications you would have made if no fee exemptions were available (6)
Category A						
Category B						
Category C						
Category D						
Category E						

Note: The table above refers to Application Fees. ***COMPLETE ALL PARTS OF THE SCHEDULE FOR WHICH YOU HAVE PAID FEES*** **from January 1, 2003 to December 31, 2003**.

C1a. If you identified changes in the number of applications due to cost recovery fees in the table above, please describe in detail how the fees affected these decisions.

_____

_____

_____

NOTE TO C1a: IF YOU WISH TO PROVIDE FURTHER COMMENTS RELATED TO YOUR ANSWER FOR C1, ATTACH ADDITIONAL SHEETS.

C1b. In column (2), if you report a change relative to column (1), to what extent is this the result of combining applications?

_____

_____

_____

C2. Has the CRI affected possible changes to existing pest control products that your firm sells in Canada? (Examples: Formulation changes, new uses).

Answer by selecting a number on the scale below.

Large decrease in changes		**No impact**		**Large increase in changes**	**Don't know**
1	**2**	**3**	**4**	**5**	
☐	☐	☐	☐	☐	☐

If fewer changes to existing products (box 1 or box 2 above), explain why this is the case and how many products have been affected.

_____
_____
_____

Fees for Maintenance of Product Licences

Note: The questions in this section refer to Maintenance Fees invoiced in April 2003.

C3. How many registered products did you have as of April 1, 2003? _____

C4. If the maintenance fees had not been put in place in **1997**, how many registered products would you have had as of April 1, 2003? _____

C5. If C4 is more than C3, how much of this difference is due to dropped registrations and how much is due to a decision not to register products because of the maintenance fees?

- Dropped registrations _____
- Products not registered_____

C6. Overall, what percentage of sales do you pay in maintenance fees? _____%

C7. Product maintenance fees are $2690. The fee reduction formula means that some firms pay 3% of sales (minimum $75) instead of $2690. Please describe the impact of this formula on your firm:

_____ Paying 3% instead of $2690 results in substantial saving in fees.

_____ Paying 3% instead of $2690 results in a moderate reduction in fees.

_____ Little impact.

Comments:

_____

_____

C8. In your opinion, should all firms pay the same percentage of registered product sales in maintenance fees?

Yes ____

No ____

Explain

_____

_____

_____

D. Estimated Impacts of the CRI: Prices and Exports

Please answer the following questions as they relate to *your firm*.

D1. Has the impact of the CRI on ***product prices*** for pest control products been a: [COMPLETE ONLY ONE CHOICE]

Reduction in prices	☐[1]	▶ ENTER %:	(-)_____% Don't know ☐
Zero impact on prices	☐[2]		
Increase in prices	☐[3]	▶ ENTER %:	(+)_____% Don't know ☐
Don't know	☐[4]		

The price change noted above (if indicated) refers to: (check one).

Retail price _____

Wholesale price _____

If you indicated a price change in D1, explain the factors underlying this decision.

_____

_____

_____

D2. Thinking of the total costs related to the CRI (not overall PMRA regulations), what proportion of these costs were passed on to your customers?

_____%

Please explain.

_____

_____

D3. Does your firm export regulated pest control products produced in Canada?

Yes ☐[1] No ☐ [2] Don't Know☐ [3]

IF YES, what has been the impact of the CRI on your export sales of regulated pest control products:

[COMPLETE ONLY ONE CHOICE]

Reduction in exports	☐[1]	▶ ENTER %:	(-)_____% Don't know ☐
Zero impact on exports	☐[2]		
Increase in exports	☐[3]	▶ ENTER %:	(+)_____% Don't know ☐
Don't know	☐[4]		

Note: In D3, exports include registered and unregistered end use products if the unregistered product contains a registered ingredient.

Provide the estimated dollar value of exports of pest control products from Canada in your most recent fiscal year.
$_____

Provide comments or explanations related to the numbers above.

_____

_____

_____

E. Effects of the Cost Recovery Initiative on the Availability of Specialty* Pest Control Products in Canada

(*): Specialty products refer to novel or niche products, minor use products, and products based on unique technologies. These factors tend to be associated with low sales volumes. Sales should be gross sales less discounts and promotional rebates.

E1. Has the existing CRI changed the number of these "specialty" pest control products made available by your firm in Canada?

Yes ☐[1] No ☐[2] Don't Know ☐[3]

E2. **If Yes** to E1:

- Reduced the number of products available by **(-)** _____

Please describe the uses of the number of specialty products not available.

_____

_____

_____

- Increased the number of products available by **(+)** _____

Please describe the uses of the increased number of specialty products.

_____

_____

_____

E3. Has the existing CRI changed the number of **uses of** these "specialty" pest control products made available by your firm in Canada?

Yes ☐[1] No ☐[2] Don't Know ☐[3]

E4. **If Yes** to E3:

- Reduced the number of **uses** of products available by **(-)** _____

Please describe these uses.

_____

_____

_____

- Increased the number of **uses** of products available by **(+)** _____

Please describe these uses.

_____

E5. What annual sales volume did you use in classifying products as "specialty pest control products"? $_____

E6. Have the fee reduction and exemption provisions affected your answer in E1? ___Yes ___ No

If YES, please describe.

F. Effects of the Cost Recovery Initiative on R&D, Manufacturing and Corporate Strategy

F1. Does your firm conduct R&D in Canada that relates to the introduction of new pest control products?

Yes ☐[1] No ☐[2] Don't Know ☐[3] ***go to F2***

F1b. How did the CRI affect the dollar amount of R&D conducted by your firm in Canada in your most recent fiscal year?

Decreased	☐[1]	▶ ENTER %:	(-)_____% Don't know ☐
No impact	☐[2]		
Increased	☐[3]	▶ ENTER %:	(+)_____% Don't know ☐
Don't know	☐[4]		

F1c. If you ***have*** indicated an impact, provide an estimate of the dollar amount of R&D conducted in Canada: $_____(most recent fiscal year)

F1d. If you answered "**Decreased"or "Increased"** in F1b, please explain:

_____

_____

F2. If yes to F1, please provide your firm's ratio of R&D to sales for 2003.

_____

F3. Has the CRI affected your firm's decision to manufacture technical active ingredients in Canada?

Yes ☐[1] No ☐[2] Don't Know ☐[3]

If yes, please describe:

_____

_____

_____

F4. Has the CRI affected your firm's decision to formulate pest control products in Canada? **Note**: Formulating includes the repackaging of end use products.

Yes ☐[1] No ☐[2] Don't Know ☐[3]

If yes, please describe:

_____

_____

_____

F5. Has the CRI affected your firm's product development plans?

Yes ☐[1] No ☐[2] Don't Know ☐[3]

Describe:

_____

_____

_____

F6. Has the CRI affected any strategic plans of your firm in Canada?

Yes ☐[1] No ☐[2] Don't Know ☐[3]

If yes, describe the extent to which this has been the case:

_____

_____

_____

F7. Are you aware of the existence elsewhere of any technical active ingredients or manufacturing concentrates that you are not able to buy in Canada because of the CRI?

Yes ☐[1] No ☐[2] Don't Know ☐[3]

If yes, please provide a list.

_____

_____

_____

G. Programme Services

G1. Has your firm observed any change in the availability or responsiveness of PMRA staff that you would attribute to the CRI for pest control products?

Please answer by selecting a number on the scale below.

Much less responsive			No impact		Much more responsive	Don't know
1	2	3	4	5		
☐	☐	☐	☐	☐		☐

G2. Has your firm observed any changes in PMRA efficiency or effectiveness that you would attribute to the introduction of the CRI for pest control products?

Much less efficient			No impact		Much more efficient	Don't know
1	2	3	4	5		
☐	☐	☐	☐	☐		☐

Please describe

_____

_____

_____

G3. Have there been any unintended impacts of the CRI on the performance of the PMRA?

Yes ☐[1] No ☐[2] Don't Know ☐[3]

If yes, please describe.

_____

_____

_____

G4. Have you disputed any of the fees applied by PMRA (since April, 1997) and submitted a formal appeal or complaint relating to:

- An application to register or amend a product registration

  Yes ☐[1] No ☐[2]

- Annual maintenance fees on your registered products

  Yes ☐[1] No ☐[2]

G5. If **YES** in G4. What was the outcome?

- Appeal/complaint was upheld and the fees payable were changed. _____
- Appeal/complaint was rejected and fees were not changed. _____
- Review still in process; PMRA response not yet received. _____
- Other (describe) _____

_____

_____

_____

G6. What aspects of the process used to review and respond to your complaint worked well and which could be improved?

_____

_____

_____

H. Cumulative Impacts and Other Issues

H1. Does your firm pay other federal government fees (not taxes) **for PMRA-regulated products and services**?

Yes ☐[1] No ☐[2] Don't Know ☐[3]

If yes, please describe:

_____

_____

H2. For products your firm may produce **other than PMRA-regulated products and services** is your firm subject to other (in addition to PMRA) Federal government fees (not taxes)? (For example, New Substance Notification fees.)

Yes ☐[1] No ☐ [2] Don't Know☐ [3]

If yes, please describe the other fees paid:

_____

_____

H3. Have there been any impacts of the cost recovery initiative that have not been identified in this questionnaire?

Yes ☐[1] No ☐ [2] Don't Know☐ [3]

Describe:

_____

_____

H4. Do you have any other comments you would like to make about the cost recovery initiative for pest control products?

_____

_____

Thank you for completing this questionnaire. Please return the completed form to ARC Applied Research Consultants. If you are returning the questionnaire by mail or courier, please address it as follows:

Dr. Douglas Smith
ARC Applied Research Consultants
Place de Ville Tower B
112 Kent Street, Suite 2010A
Ottawa, ON
K1P 5P2

Appendix 7

Participating Firms In The Business Impact Analysis

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Participating Firms In The Business Impact Analysis

FIRM	LOCATION
AFA Environment Inc.	Boischatel
Ashland Canada Corp.	Ajax
BASF	Toronto
Bayer Cropscience	Calgary
Can-Vet Animal Health	Guelph
Dow Agrosciences	Calgary
DuPont Canada	Streetsville
Engage Agro	Guelph
Environmental Factor Inc.	Oshawa
Exit Product License	Kamloops
Gustafson	Guelph
Hercules Canada	Mississauga
Interprovincial Co-operatives Ltd.	Saskatoon
SC Johnson	Brantford
King Home and Garden	Guelph
Monsanto Can	Winnipeg
Myco-forestis Corporation	L'Assomption
Nu-Gro	Brantford
Nufarm Ag	Calgary
Nalco Canada	Burlington
Parkland Aero-fillers	Spruce Grove
Plant Products Co.	Brampton
Recochem	Toronto
Swimco Canada	Georgetown
Syngenta Crop Protection	Guelph
United Agr-Products	Dorchester
Vetoquinol	Lavaltrie
Water Energy Technologies	Burlington
Wellmark International	Guelph
Western Industrial Clay Products	Kamloops
Woodstream Canada Corp	Scarborough

Note: One additional firm completed a questionnaire but it was received too late to include in the tabulations. A review of that questionnaire indicates that its responses are generally in line with the data shown in this report.

Appendix 8

Pest Management Sub-Committee (PMSC) Role And Membership

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A. Role

The assessment of the impact of the PMRA Cost Recovery Initiative (CRI) on the pest management industry was facilitated by a Pest Management Sub-Committee (PMSC).

The use of such a sub-committee reflects common practice in carrying out business impact tests. The PMSC provided the contractor with a vehicle for soliciting and considering the input of both industry and government. The PMSC reviewed ARC's work in designing and implementing a survey of industry respondents currently paying cost recovery fees to the PMRA.

The mandate of the PMSC was to provide input and feedback to the contractor on the structure, content and execution of the impact analysis so that it best identified the effects of the CRI on business. The members of the PMSC helped the contractor identify a group of potentially impacted organizations currently paying cost recovery fees. Members of the PMSC reviewed and provided comments regarding the methodology and preliminary findings of the contractor. In particular, PMSC members were invited to provide feedback on issues raised in the preliminary findings, which required additional clarification.

Membership of the PMSC was balanced between industry and government/PMRA representatives.

B. Membership

Mr. Michael Grant
President,
Can-Vet Animal Health Supplies Ltd.

Mr. Chris McCurdy
Director, Technical Support
S.C. Johnson and Son, Ltd.

Mr. Chris Warfield
Director, Regulatory Affairs - Canada
Bayer CropScience

Mr. Blair McRae
Project Manager
Pest Management Regulatory Agency

Ms. Valerie Robertson
Director, Submission Control Division
Pest Management Regulatory Agency

Mr. Robert Woods
Director, Management Planning and Coordination Division
Pest Management Regulatory Agency