

Pest Management Regulatory Agency



Annual Report 2004–2005

Our Mission

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



Health
Canada

Santé
Canada

Canada

Également offert en français sous le titre :
Rapport annuel 2004-2005

This publication is also available on the Internet at www.pmra-arla.gc.ca

This publication can also be made available in alternate format(s) upon request.

The Pest Management Regulatory Agency publications team was responsible for the translation, formatting and publication of this document.

For additional copies, please contact:

Publications
Pest Management Regulatory Agency
2720 Riverside Drive
Ottawa ON K1A 0K9

Telephone: 1 800 267-6315
Facsimile: 1 613 736-3758

ISBN: 0-662-43386-6
Catalogue number: H110-2005E-PDF

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2006

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Table of Contents

Message from the Executive Director	
1.0 Mission, Vision and Key Objectives	1
2.0 The PMRA's Pesticide Program in Action—Just the Facts	6
3.0 Results from Pesticide Registrations	9
4.0 Partnerships	15
Appendix I Tables	19
Appendix II Agency Contacts	20
Appendix III Organization of the PMRA as of 31 March 2005	21
Appendix IV Description of Submission Categories	25

Message from the Executive Director



I am pleased to present the Pest Management Regulatory Agency's (PMRA) Annual Report for 2004–2005. With the close of this year, the Agency has reached a significant milestone. April 1, 2005, marked the 10th anniversary of the creation of the PMRA as part of Health Canada and 10 years of progressive change to the Government of Canada's federal pesticide regulatory system. The new *Pest Control Products Act*, a clear mandate to protect the health and environment of Canadians, and an improved and more transparent approach to pesticide registration are just some of the positive changes.

The work related to bringing the new Act into force has been significant and is certainly a priority. Work on new regulations continues. Two sets of proposed regulations were published in the *Canada Gazette*, Part 1: Proposed Safety Information Regulations in July 2004; and Proposed Adverse Effects Reporting Regulations in October 2004. Comments received will help refine the proposals.

A critical element of the new Act is its impact on openness and transparency. Under the new Act, interested parties will have access to information on applications to register a pesticide, to reports on the evaluation of the health and environmental risks and the value of pesticides prepared by the PMRA as well as to the outcomes of the applications, including the conditions of registration. They will be able to comment on major decisions, view confidential test data used to support pesticide registrations, and request a re-examination of major decisions or a special review of registered products. These initiatives will help support confidence in the regulatory system by providing Canadians with substantive information and further opportunity to participate in the regulation of pesticides in Canada.

To support these transparency requirements and to increase the efficiency of our pesticide registration process, the PMRA has been a world leader in developing an electronic Pesticide Regulatory System (e-PRS). Part of the Government On-Line initiative, the PMRA's e-PRS is the first web-based national pesticide regulatory service of its kind. This service will allow applicants to submit applications, provide data and apply for and manage product registrations in a stable and secure on-line environment. The PMRA will be able to accept electronic submissions of pesticide applications, national pesticide sales data reports and adverse effect reports. Work to date has already allowed industry and the PMRA to realize efficiencies.

While the PMRA's mandate is clear, the regulation of pesticides is challenging and of interest to many sectors. For many users, such as the agriculture, forestry and lumber sectors, pesticides are critical tools. Many Canadians express concern over the health and environmental impacts of pesticides. Our requirements to consider health and environmental impacts and our support to sectors in reducing the risks of pesticides are interests we all share. We are keenly interested in working with Agriculture and Agri-Food Canada, Environment Canada, and other federal colleagues, with our provincial colleagues, farmers, industry and consumers.

This report documents our achievements in a number of areas, particularly in the fields of performance standards, re-evaluation work and progress on our collaboration with international colleagues. I invite comments both on our performance and on our reporting.

As the Agency begins its second decade, it does so with a common focus, a collegial, supportive atmosphere and an expert and dedicated staff. I am proud to have become part of this work and look forward to continued efforts with staff and stakeholders to address our challenges.

Karen L. Dodds, Ph.D.
Executive Director
Pest Management Regulatory Agency
Health Canada



Section 1 Mission, Vision and Key Objectives

Mission

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

Vision

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

Key Objectives

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

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

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

Overview

Health Canada's Pest Management Regulatory Agency (PMRA) protects human health and the environment by minimizing the risks associated with pesticides imported, sold or used in Canada and works to do so in an open and transparent manner. The PMRA registers pesticides and provides advice on sustainable pest management strategies. The Agency considers the environmental and human health risks associated with proposed products as well as product effectiveness and its contribution to sustainable development. As well, the PMRA sets maximum residue limits (MRLs) under the *Food and Drugs Act*. The *Pest Control Products Act* (PCPA) and Regulations allow the Agency to meet its commitment to protect human health and safety, while providing access to the best tools in Canadian and global pest management.

The Agency's approach to pesticide risk-reduction aims to reduce the risks associated with pesticides to the lowest level possible while effectively managing pest problems and enhancing sustainable pest management. The PMRA manages the risks associated with pesticide use by:

- carrying out detailed health and environmental risk and value assessments, and setting conditions of registration for new products;
- proposing MRLs under the *Food and Drugs Act* for pesticide levels in food commodities;
- re-evaluating products that are already on the market;
- monitoring compliance with conditions of registration;
- supporting the development of sustainable pest management strategies; and
- developing new policies and regulatory requirements that meet evolving science and international approaches to reduce pesticide risks.

Companies that wish to sell a pesticide in Canada must submit detailed information and data to the PMRA for evaluation. Scientific studies are necessary to determine if the risks associated with a product are acceptable. Based on the evaluation, the PMRA determines whether the product will be granted registration, allowing it to be sold and used in Canada. Pesticides are registered only if the human health and environmental risks associated with their use are acceptable and if the product is effective.

Once products are registered and on the market, the PMRA has, by policy, implemented a re-evaluation program to ensure that older pesticides meet current scientific standards with respect to human health and environmental risk.

Supporting Government Priorities

Health and the environment continued to be top priorities for the Government of Canada. The PMRA supports this and has established the following priorities over the next three years:

- ensure the health and environmental safety and efficacy of pesticides;
- ensure that pesticides are manufactured, sold and used in compliance with the PCPA; and
- promote sustainable pest management practices that help minimize the risks associated with pesticides.

As well, our business improvement initiatives are in line with government-wide initiatives. For example, the new PCPA is consistent with the principles of Smart Regulation and the PMRA's new electronic regulatory system is part of the Government On-Line initiative.

Benefits to Canadians

Refined science methodology, interpretation and data reporting expertise within the PMRA represent important contributions toward improving the impact of our programs and services, providing real and lasting benefits for Canadians.

The PMRA helps prevent unacceptable risks to people and the environment by:

- providing timely access to reduced-risk pesticides;
- working jointly with the United States Environmental Protection Agency (USEPA) to streamline a joint registration process;
- re-evaluating older pesticides and uses on a regular basis;
- encouraging sustainable pest management practices; and
- strengthening post-registration controls through compliance activities.

Management Agenda

The Treasury Board Secretariat's publications *Results for Canadians: A Management Framework for the Government of Canada* and *Management Accountability Framework* provided the PMRA with a clear vision as well as specific expectations with regards to its management agenda. While the Agency is pursuing the integration and implementation of the *Management Accountability Framework* requirements on a longer-term horizon, emphasis was placed this year on implementing:

- service improvement;
- the integration of performance information; and
- people and partnerships.

In articulating this management agenda the Agency remained committed to its Key Objectives. These objectives were integrated into the business framework of the Agency to address current and future organizational needs in the context of the *Management Accountability Framework* requirements.

The new PCPA reinforces health and environmental protection provided by the existing Act, makes the registration system more transparent and strengthens post-registration controls on pesticides. Collaborating with stakeholders in an open, transparent and participatory process for pesticide regulation is a fundamental part of our work in promoting sustainable pest management. The PMRA seeks the advice of its provincial/territorial partners and solicits public comment on new policies and programs, as well as on pesticide registration and re-evaluation decisions. In 2004–2005 we continued to work with our stakeholders through the Pest Management Advisory Council (PMAC), the Economic Management Advisory Committee (EMAC) and the Federal/Provincial/Territorial (FPT) Committee on Pest Management and Pesticides. A consultative meeting with stakeholders was also held prior to the annual meeting of the North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides that involves stakeholder participation.

The PMRA's mission is accomplished not only by preventing unacceptable risks, but also by minimizing all risks posed by pesticides. New methodologies and science policy documents have been developed by the PMRA scientists. They equip the Agency with the tools to conduct the most advanced and modern risk assessments that promote improvements in the handling and use of pesticides as well as optimal management of pest problems. Keeping the risks associated with pesticides to the lowest levels possible to manage pest problems enhances sustainable pest management.

The Agency continued to improve its electronic environment that allows information to be accessed and exchanged effectively and efficiently. The PMRA strove to provide a supportive, motivating and engaging work environment for PMRA staff and continued to practice sound financial management for both appropriations and revenues.

During the year, a number of innovations were introduced in publishing re-evaluation reviews and providing data on pesticide use to PMRA evaluators. The template for the value portion of re-evaluation review documents was streamlined to be clearer and more informative to the public. Another template that requires registrants to respond to questions pertaining to the use of pesticides was also developed and used. A database on pesticide use and related information was collated and made available to the evaluators at the PMRA. In addition, the PMRA developed an electronic expert opinion poll to collect information on agricultural practices.

Outreach and Education

Significant accomplishments related to outreach have been achieved in the re-evaluation program. Initiatives include initiation in May 2004 of ongoing teleconferences and meetings with a wide range of re-evaluation stakeholders to ensure that they are kept informed and that their views are heard. The PMRA has also revised the re-evaluation review process to allow for greater input from stakeholders with respect to preliminary risk and value assessments to ensure that the PMRA has the best available information for informed decision-making.

The PMRA Continuous Learning Program is responsible for the management, development and coordination of operational, scientific and professional learning and development for staff; staff orientation; staff and management development programs; and, internal communication, and learning activities for stakeholders including the pesticide industry, and provincial and territorial government officials.

The Agency Learning Plan for 2004–2005 resulted in the development and delivery of many learning events, for example, expert witness training, field tours of pesticide use scenarios, training on pesticide application in agriculture, a course on creating a respectful workplace, science team lead training, coaching sessions, a statistics refresher session, writing courses, a toxicokinetics course and media training.

Some of these events were shared with other branches of Health Canada and the USEPA. There were also a wide variety of information sessions fostering internal communications, such as round tables with senior management and PMRA Issue Discussions and seminars. Learning events were also held for PMRA stakeholders, including a technical session on the new PCPA for provincial pesticide colleagues.

In its second year, the development program for biologist and chemist groups continues to provide solid, on-the-job training and improvement opportunities. A first in the Public Service, this development program provides a learning environment that leads to career advancement for the participants in a planned and consistent manner. It is based on competencies for the different job levels, and promotions are based on individual merit, without competition, as the program participants meet the required competencies for the next level. In 2004–2005, 137 biologists and chemists participated in the program, resulting in 45 promotions over the year.

The PMRA continues to work with provincial pesticide regulators as federal co-chair of the FPT Working Group on Pesticide Education, Training, and Certification, which creates and maintains standards for pesticide applicators and vendors across the country. Planning was initiated to host industry training sessions on the impact of the new PCPA and on the new e-PRS. In addition, the PMRA regularly schedules a Canadian pesticide registration course to help registrants and other stakeholders understand the process of pesticide regulation in Canada as well as to understand how a submission should be put together.

As part of our outreach efforts, the PMRA website was redesigned to make information easier to find. The improved design, plain language and subject-based organization helped make the site more accessible to a greater number of Canadians.

More than 400 documents were processed in 2004–2005, with more than 200 documents being published via our website, including a wide variety of consumer information products, regulatory proposals, decision documents and re-evaluation reports.

PMRA Electronic Pesticide Regulatory System (e-PRS)

As part of the Government On-Line initiative, the PMRA launched the world's first web-based service for conducting pesticide regulatory transactions. This service will allow industry to submit applications, provide data and apply for product registration in a stable and secure on-line environment. As promised in the new PCPA, we have put into place the mechanisms necessary to complete the remainder of the work to enable us to fully accept electronic submissions, national pesticide sales data reports and adverse effects reports.

Development work for the PMRA's e-PRS focussed on the Access Management Module, which was released in September 2004. This module allows those planning to submit information to the Agency to manage their on-line accounts, passwords and the assignment of rights and privileges to others as necessary, based on business needs.



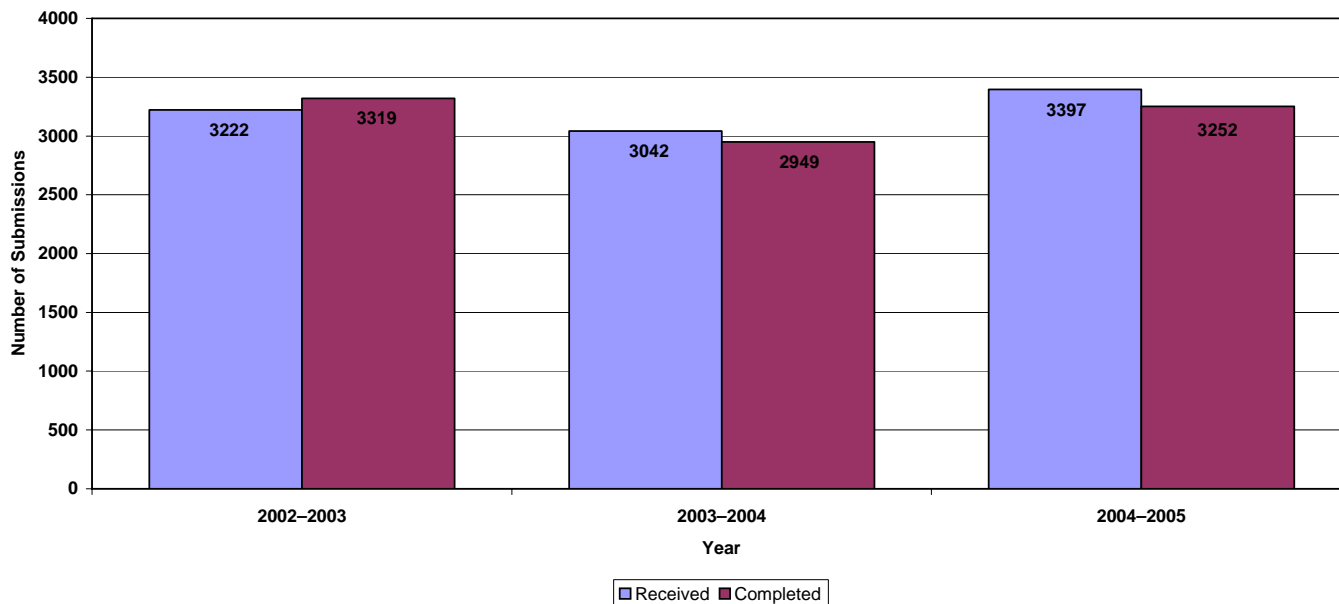
Section 2 The PMRA’s Pesticide Program in Action—Just the Facts

Financial Information (millions of dollars)

	2004-2005 Planned Spending	2004-2005 Total Authorities	2004-2005 Actual Spending
Gross expenditures	45.3	48.7	47.5
Revenues	-7	-7	-6.1
Net expenditures	38.3	41.7	41.4
FTEs*	541	546	475

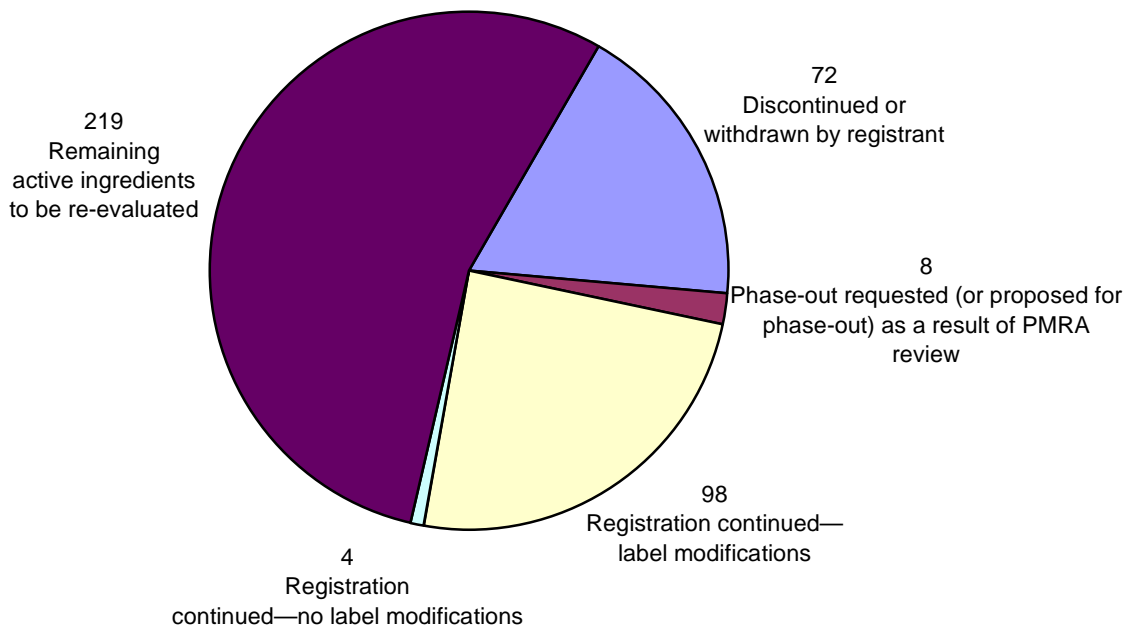
* Full time equivalents

Submission Overview 2004–2005

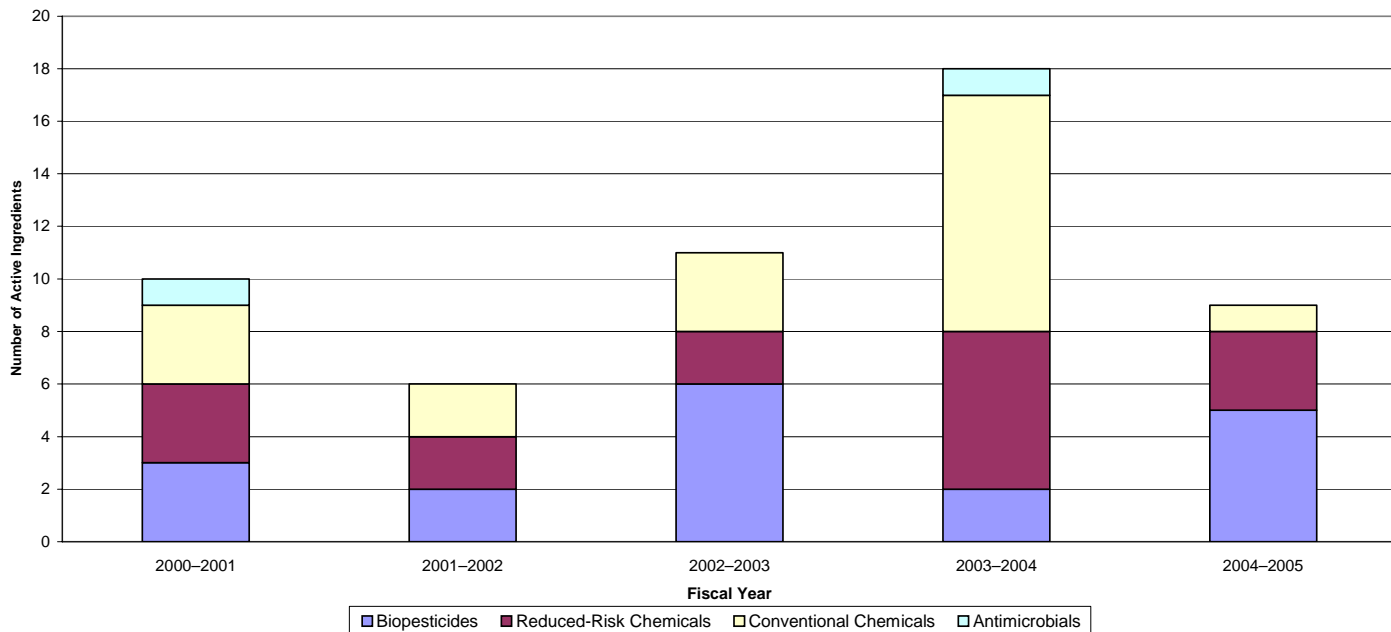


Re-evaluation Activities

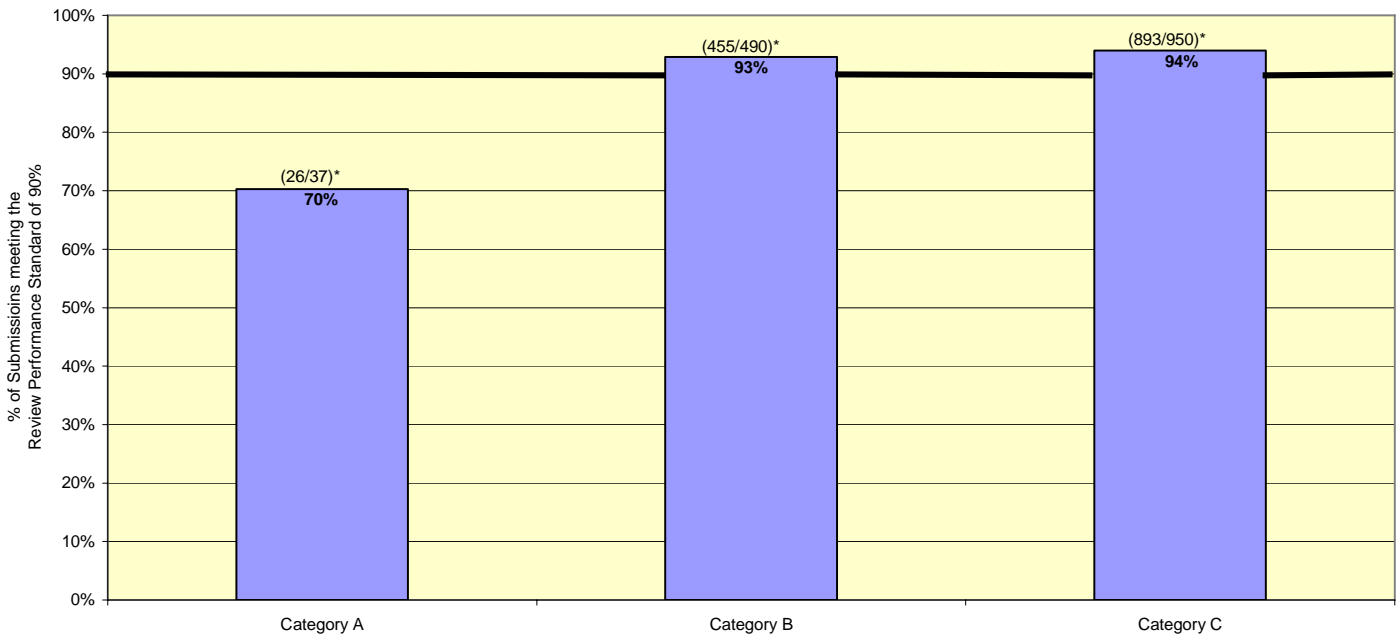
The PMRA has committed to re-evaluate all 401 pesticide active ingredients registered on or before 31 December 1994. As of 31 March 2005, 219 remain to be re-evaluated.



Number of Active Ingredients Registered by Type New Active Ingredients First Appearing in Registered Products



Performance Against the Review Performance Standards for Category A, B and C Submissions Completed in 2004–2005



* (# of submissions that met the standard / # of submissions reviewed)

The reduced-risk submissions in categories A and B met the 90% review performance standards 100% of the time.

For Category A submissions, 70% (26/37) met the applicable review time lines. To meet the 90% review performance standard, 8 of the 11 submissions that missed the review time lines needed to be completed faster, having missed the review time lines by 13 to 43 days.



Section 3 Results from Pesticide Registrations

Registration of New Products

Companies that wish to sell a pesticide in Canada must submit detailed information and data for evaluation to the PMRA. These scientific studies are needed to determine if the product is acceptable in terms of safety, merit and value. Depending on the complexity of the submission, a complete evaluation can take from several weeks to over a year.

Before making a registration decision on a new pesticide, the PMRA conducts a comprehensive assessment of the risk and value specific to the proposed use. The value assessment considers whether the product contributes to pest management and whether the application rates are the lowest possible to effectively control the target pest. The risk assessment considers the inherent toxicity, the persistence and the bioaccumulative nature of the pesticide as well as the potential hazards, including the level of exposure to humans and the non-target environment. Exposure estimates are a key component of the risk assessment process. As pesticides are deliberately introduced into the environment at quantifiable rates, potential short-term impacts on environmental exposures can be closely estimated. For long-term environmental exposure, the PMRA consults all available data on persistence and bioaccumulation.

The assessment determines whether the product will be granted registration and allowed for sale and use in Canada or whether it will be rejected. Pesticides are registered only if the human health and environmental risks are acceptable and if the product is effective.

Providing Canadians with improved timely access to new pest management tools includes increasing the efficiency of the registration process. Increased harmonization of data requirements; relevant test protocols; data submissions (dossiers) and study report formats; data review and risk assessment practices; approach to regulatory decision-making; and administrative processes and procedures with international regulatory authorities, through NAFTA and the Organisation for Economic Co-operation and Development (OECD), and facilitation of simultaneous registrations in participating countries are priorities for the PMRA.

To ensure the most efficient use of evaluator and registrant time, the PMRA offered applicants presubmission consultations. This ensured they were familiar with the data requirements and minimized the need to request additional data once the review began. For products evaluated under the Joint Review stream, the PMRA and the USEPA carried out joint presubmission consultations with applicants to ensure the registration requirements in both countries were met. In 2004–2005, a total of 67 presubmission consultation meetings were held. As a result of continued harmonization efforts, 10 out of 45 submissions

currently underway to register new active ingredients in 2004–2005 were handled through the Joint Review and Worksharing Program.

The PMRA's *Management of Submissions Policy* outlines the method by which we manage applications and material submitted for the notification, research, registration and amendment of pesticides.

The workload in 2004–2005 remained high, with more than 3250 regulatory decisions being made.

Our performance standard is to have 90% of submissions in all categories processed within the applicable review time frames established in the *Management of Submissions Policy* and subsequent documents.

Because of the complexity of the evaluations required for categories A, B and C, the majority of our evaluators time is spent reviewing submissions in these three categories.

2004–2005 Submissions

	Received	Completed
Category A	77	49
Category B	525	515
Category C	1186	955

Of the 49 submissions in Category A that were completed, 23 were withdrawn or rejected and 26 were registered/approved. Of the 37 reviewed, 26 were reviewed within the applicable performance standards.

Of the 515 submissions in Category B that were completed, 65 were withdrawn or rejected and 451 were registered/approved. Of the 490 reviewed, 455 were reviewed within the applicable performance standards.

Of the 955 submissions in Category C that were completed, 109 were withdrawn or rejected and 846 were registered. Of the 950 reviewed, 893 were reviewed within the applicable performance standards.

New Active Ingredients Registered During the Fiscal Year 2004–2005

1-Methylcyclopropene (MCP), a plant growth regulator, was given temporary registration¹ as a reduced-risk biopesticide for use on post-harvest apples (SmartFresh Technology).

Bifenazate, a selective miticide, was given temporary registration as a reduced-risk conventional chemical for use on indoor ornamentals (Floramite SC), apples and grapes (Acramite 50 WS).

Chondrostereum Purpureum (North American Strain; Pathovar: PFC2139), a biological herbicide that inhibits resprouting on cut stumps, was given temporary registration as a reduced-risk biopesticide through the Joint Review Program for use in forest vegetation management areas and rights-of-ways (Chontrol Paste).

Codling Moth and Leaf Roller Pheromone, a mating disruptor for codling moths and leafrollers, was given full registration as a reduced-risk biopesticide for use on apples, sweet cherries, tart cherries and pears (Isomate - CM/LR Pheromone).

¹ A temporary registration is granted for a period not exceeding one year. The purpose is to allow the registrant to endeavor to produce additional scientific or technical data in relation to the control product.

Kaolin, an insect repellent, was given full registration as a reduced-risk biopesticide for use on apples, crabapples, pears and quince (Surround WP Crop Protectant).

Mesotrione, an herbicide for broadleaf weeds, was given temporary registration as a reduced-risk conventional chemical for use on field corn, corn for seed and sweet corn (Callisto 480 SC Herbicide).

Methoxyfenozide, an insecticide for lepidopteran larvae (codling moth, oriental fruit moth, leafroller, leafminer), was given temporary registration as a reduced-risk conventional chemical for use on apples (Intrepid 240 F Insecticide).

Ophiostoma Piliferum Fungus, a wood preservative for control of blue-staining/sapstain fungi, was given temporary registration as a reduced-risk biopesticide for use on freshly felled lodgepole and red pines (Sylvanex Flakes).

Tepraloxydim, an herbicide for control of annual grasses and quackgrasses, was given full registration as a conventional chemical for use on flax, lentils and dry peas (Aramo EC Herbicide).

Re-evaluating Products Already on the Market

Today, close to 550 pesticide active ingredients are in more than 5000 products that are registered under the PCPA for use in Canada. When they were registered, these pesticides were considered acceptable on the basis of an assessment of their safety, merit and value. However, the scientific knowledge that forms the underpinning of these assessments is continually evolving, and new methodologies and tools are being integrated into regulatory risk assessments. These modern risk assessment approaches include application of additional safety factors for the protection of children as well as consideration of aggregate exposure from combined dietary, residential and drinking water exposure and cumulative risk for chemicals considered to exhibit a common mechanism of toxicity. The re-evaluation of older pesticides takes into consideration the full extent of the use patterns of the active ingredients, the diversity of their end-use products and their market penetration. For these reasons, the PMRA has developed a re-evaluation program that uses current scientific approaches to examine the continued acceptability of older active ingredients and their end-use products.

The PMRA's re-evaluation program is described in Regulatory Directive [DIR2001-03](#), *PMRA Re-evaluation Program*. The new approach to re-evaluation, recommended by stakeholders and supported by PMAC, builds on available foreign reviews and expands the extensive work-sharing arrangements with the USEPA. This internationally harmonized approach increases regulatory efficiency and helps to maintain a level playing field for Canada-U.S. trade of pesticide-treated products.

The PMRA has committed to re-evaluate all 401 pesticide active ingredients registered before 1995. The strong reliance of the Canadian re-evaluation program on the availability of American reviews ties the completion of the Canadian program to that of the American program. The PMRA aims to complete the current round of re-evaluations of older Canadian active ingredients within the same time frame as the USEPA in 2008–2009.

The PMRA's re-evaluation program work plan for April 2004 to June 2005 (REV2004-06) was published on December 2004. The re-evaluation of older pesticides was on target for 2004–2005. Added to the accomplishments of previous years, decisions have been made or proposed for 182 active ingredients. A total of 102 were granted continued registration, 72 were discontinued or withdrawn by the registrant, and 8 are being phased out. Publications providing details of most of these pesticides are available on the PMRA website.

Three common turf and lawn use herbicides were reviewed during the 2004–2005 fiscal year. A Proposed Acceptability for Continuing Registration (PACR series) document concerning uses of 2,4-D on lawn and turf was published, and documents for MCPA and dicamba were in the publications process. As well, the preliminary risk assessment for pentachlorophenol, a heavy duty wood preservative, was published in cooperation with the USEPA.

Beginning in 2004–2005, teleconferences were held every four months with re-evaluation stakeholders to enhance communications and to ensure stakeholders input into the re-evaluation program.

Once implemented, the new PCPA will set out specific conditions and schedules for the initiation of ongoing re-evaluations as well as conditions (or possible triggers) for special reviews.

Monitoring Compliance with Conditions of Registration

The 2004–2005 National Pesticides Compliance Program activities were selected for action using a risk management approach based on Health Canada's *Integrated Risk Management Framework*. This approach covered all three segments of the regulated community—registrants, distributors and users, with a particular focus on users. The risk to humans, to the environment and/or to the integrity of the regulatory process resulting from situations of non-compliance was assessed. User compliance was monitored in the following commodities/use areas: golf courses, greenhouse tomatoes, leaf lettuce, honey, apples and table beets. The remaining two user inspection programs focussed on an issue related to pesticide drift and the sale/use of a fumigant.

During this period, the Agency advanced work on four key projects related to revising compliance policy and guidance based on an integrated risk management model, enhancing federal/provincial/territorial coordination in the area of compliance and developing performance indicators for reporting the outcomes of the Agency's compliance efforts.

Under the 2004–2005 National Pesticides Compliance Program, 18 compliance inspections and 2 compliance promotion activities resulted in 1115 inspections.

In addition, the Agency conducted more than 570 investigations and delivered more than 900 enforcement responses. Most violations were minor in nature and were resolved by informing the delinquent companies or individuals of the regulatory requirements. As well, the PMRA laboratory conducted more than 650 analyses in support of compliance inspections and investigations.

Supporting the Development of Sustainable Pest Management Strategies

The PMRA contributed to Health Canada's *Sustainable Development Strategy in 2004–2007: Becoming the Change We Wish to See*. The strategy outlines an ambitious set of commitments designed to provide staff with information and practical tools that will assist them to integrate sustainable development thinking into all aspects of departmental operations. A complete report on Health Canada's third sustainable development strategy can be found on Health Canada's website.

Progress on sustainable development is not limited to the Strategy alone. The PMRA's commitment to sustainable development extends into all legislative, policy and program initiatives, well beyond the three-year lifetime of the Sustainable Development Strategy. In 2004–2005, the Agency sought public input on new regulations and processes to protect human health and safety as well as the environment when the new PCPA comes into force. For example, the proposed Adverse Effects Reporting Regulations were published

in the *Canada Gazette*, Part I, and draft reporting forms were posted on the PMRA website for comment. A related activity was the completion of a Privacy Impact Assessment for the program. Information on the Adverse Effects Reporting Program is available on the PMRA's website.

An information package on the Action Plan on Urban Use Pesticides was distributed to 1300 municipalities in March 2005. The Action Plan is designed to help reduce Canadians' reliance on pesticide use for lawn care and focusses on integrated pest management principles. As part of this action plan, The Healthy Lawns Strategy places particular emphasis on preventing pests, using reduced-risk products and applying pesticides only when necessary. To reduce reliance on pesticides and to better inform pesticide users of sustainable lawn practices, more than 18 000 copies of the Healthy Lawns Strategies were distributed to homeowners and municipalities in 2004. In addition, the Healthylawns.net website was updated regularly with information on lawn management with the principles of integrated pest management. In 2004, homeowners were surveyed to determine their use of healthy lawn practices.

Reducing Risk

Reduced-risk pesticides present an improved health or environmental risk scenario compared to existing products that have the same use pattern. To increase public awareness, the *Update on Reduced-Risk Pesticides in Canada* was developed during the 2004–2005 fiscal year to illustrate the reduced-risk designated active ingredients, end-use products and associated uses currently available in Canada.

The PMRA also began a partnership with the provinces and territories in 2004–2005 to develop a tool to assess trends in the potential risks posed by pesticide use in Canada. This tool will allow all partners to evaluate the performance of different activities, such as the risk reduction program, minor use program and sustainability program; various horizontal programs across several Federal departments; and various provincial/territorial programs. This harmonization effort will allow the Canadian public to understand more clearly what is happening on the pesticide scene in Canada today. As well, the various government program managers will be able to use the tool as a guide.

Through initiatives such as the Joint Review Program for Reduced-Risk Chemicals and the Initiative for Reduced-Risk Pesticides, 34 of the 49 reduced-risk chemical active ingredients that were registered or pending registration in the United States were registered or pending registration in Canada. Out of the nine new active ingredients registered in 2004–2005, eight were reduced-risk; one of these active ingredients was registered through the Joint Review Program.

Minor Use

Increased access to new pest management tools for use on minor/specialty crops is an ongoing priority for the PMRA; as a consequence, two dedicated user-sponsored programs were previously established—the User Requested Minor Use Label Expansion (URMULE) and the User Requested Minor Use Registration (URMUR) programs. These programs provide the Canadian agri-food sector access to improved pest control solutions for minor crops that would not have been otherwise available to them. In these cases, registrants may consider the Canadian market too small to make registration of products economically feasible.

Through the URMULE and URMUR programs and initiatives with Agriculture and Agri-Food Canada, Canadian farmers have improved access to newer, more cost-effective pesticides necessary for sustainable agriculture. In 2004–2005, the PMRA reviewed 117 presubmission consultation proposals received from Agriculture and Agri-Food Canada, the Provincial Minor Use Coordinators and Forestry Canada—6 of which were rejected or withdrawn. As well, the PMRA reviewed 43 formal submissions generated by

Agriculture and Agri-Food Canada and the provinces. In total, 65 new minor crop uses, including 42 reduced-risk uses, were registered through the user-requested and standard submission processes.

Emergency Registrations

Any request for emergency registration must be sponsored by the provincial or federal agency directly involved in the management of the pest problem (e.g., the provincial Ministry of Agriculture or the Canadian Food Inspection Agency). The sponsor must provide the PMRA with the necessary information to support the proposed emergency use and letters of support that indicate there are no concerns with the emergency use from the provincial department responsible for pesticide use and from the registrant.

In general, a request for emergency registration is initiated in the following situation:

- a pest outbreak or pest situation occurs that can cause significant economic, environmental or health problems;
- there is no effective product or application method registered in Canada for the control of the pest; and
- there is no effective alternative control method available.

Only new uses of currently registered products can be considered for an emergency registration because the active ingredients for these products have already been assessed. Under the emergency registration program, there is insufficient time available to conduct the full human and environmental health risk assessment needed for a previously unregistered product.

In 2004–2005, the PMRA received a total of 73 emergency registration requests, of which 11 were withdrawn or rejected. Of the 62 that were granted registration, 16 were repeat requests for emergency situations which had expanded into additional provinces. This left a total of 46 distinct emergency requests approved by the PMRA.

Commodity specific risk reduction strategies address technology gaps. Priority needs are identified and registration of risk reduction products are facilitated leading to the reduction in the need for emergency registration requests. An example is Endeavor 50WG Insecticide for aphids on greenhouse peppers.

The PMRA consulted with various commodity groups through stakeholder meetings to develop pesticide risk-reduction strategies for honey beekeeping and pulse crops. Risk reduction strategies have also been developed for several other commodities—apples, pulse crops, potatoes in eastern Canada, cranberries and canola. The work of the steering groups for these commodities has brought positive results to Canadian agricultural producers.

- The Apple Steering Committee identified and developed an action plan to facilitate the registration of two biopesticide products. Both of these was a reduced-risk alternative for fireblight management on apples and pears to become part of an integrated pest management strategy for reducing the use of streptomycin.
- A NAFTA work plan was developed and implemented to harmonize product registrations and MRLs for products used on pulse crops.

The PMRA and the commodity groups have developed criteria for prioritizing and have selected commodities for which pesticide risk reduction strategies will be developed in 2005–2006.



Section 4 Partnerships

Overview

The PMRA made important strides in accomplishing its mandate this year. Our preliminary focus has been on the implementation of the PCPA. However, we have also moved forward substantially in our goal to re-evaluate existing products. We continue to advance toward a more transparent and participatory regulatory process that will provide timely access to new pesticides.

Partnerships

The PMRA works in partnership with all levels of Canadian governments—including other parts of Health Canada—nationally and internationally on a number of projects. A few examples of these partnerships include collaboration with the Canadian Food Inspection Agency and provincial governments on compliance activities, work with Agriculture and Agri-Food Canada to develop risk reduction strategies and improve access to specialized pest control for the agricultural sector as well as work with our NAFTA partners and OECD members to harmonize regulatory approaches for evaluating pesticides.

International Cooperation

Pesticide regulatory agencies, growers and industry recognize that efficiency and effectiveness are maximized through international collaborative efforts. Encouraged by this recognition, information-sharing sessions and informal exchanges were held with our NAFTA counterparts in January and November 2004 in an effort to move toward a coherent electronic submission environment that facilitates harmonization and work sharing in North America and with OECD countries.

Canada met formally with NAFTA counterparts at semi-annual meetings of the Executive Board of the NAFTA Technical Working Group on Pesticides, held in June and December 2004. The meetings included discussion of joint reviews, labelling issues, MRL issues, re-evaluation of registered pesticides, minor use submissions, electronic data submission, guidance for conducting and evaluating specific studies, and applicator training. In addition, the December meeting provided an interactive forum for stakeholders to receive information and to provide comment on NAFTA activities.

In January and February 2005, formal OECD meetings were held to discuss registration and work sharing; biopesticides; risk reduction; techniques and electronic tools used to facilitate the collection, management, storage and dissemination of chemical safety data; and biocides. As well, the PMRA engaged several regulatory agencies in risk assessment methodologies and MRL setting processes.

Canada has ratified several international treaties regarding chemical management. The PMRA participated as the federal lead on issues related to pesticides and provided a share of Canada's financial contributions. In May 2004, the Stockholm Convention on Persistent Organic Pollutants came into force. The Rotterdam Convention on Prior Informed Consent held its first Conference of the Parties in September 2004, and its Chemical Review Committee held its first meeting in February 2005.

Public Participation

The Agency continues to meet our strategic objectives by maintaining timely and open communication within our organization as well as with other government departments, diverse stakeholders and the public at large through consultation and transparency of our actions. We have worked with PMAC, EMAC and the FPT Committee as part of our work to promote sustainable pest management.

The PMRA provides a 1-800 information service for enquiries on any issue related to the registration or use of pesticides. This information service responded to a total of 6834 calls in 2004–2005. Approximately 2800 calls came from registrants or applicants and approximately 2600 calls were from individuals. The remaining calls were from various levels of governments, media or special interest groups.

The **Pest Management Advisory Council (PMAC)**, formed in 1998, serves as a forum to foster communication and dialogue between stakeholders and the PMRA as well as to provide advice to the Minister of Health on policies and issues relating to the federal pest management regulatory system. To achieve a balanced representation of interests in pest management issues, membership includes environmental, health and consumer groups as well as academics and pesticide manufacturers and users.

At meetings held in May and November 2004, PMAC discussed various issues such as the implementation of the new PCPA, reduced-risk products and the PMRA's Electronic Regulatory System. Updates were also provided on the re-evaluation program, risk reduction strategies, harmonization and its working group on voluntary reporting of adverse effects. More information on PMAC, including meeting reports, is available on the PMRA's website.

The **Economic Management Advisory Committee (EMAC)** was established in April 1997 to provide strategic advice to the PMRA's Executive Director on specific ways to improve efficiency and cost effectiveness without compromising health or environmental protection while maintaining industry competitiveness. Membership includes pesticide industry representatives, grower groups and PMRA officials.

In November 2004, a work plan was completed and, at the April 2005 meeting, the Committee will address the following subjects:

- on-line submission (e-PRS) and electronic index;
- segregation of CBI under the new Act;
- international regulatory cooperation initiatives;
- submission statistics and performance in 2004–2005;
- the evaluation of the cost recovery initiative; and
- the Financial Report—a summary of PMRA resources allocated by business line for fiscal years 2001–2002 to 2003–2004.

Various updates were also provided on the PMRA's submission management efficiencies, re-evaluation program, the Globally Harmonized System of Classification and Labelling of Chemicals, the Formulants program, and the co-packaging formulation. Additional information about EMAC is available on the PMRA's website.

The **Federal/Provincial/Territorial (FPT) Committee on Pest Management and Pesticides**, formed in 1997, brings together provincial, territorial and federal representatives on pesticide use, regulation and management to exchange information and expertise. FPT Committee working groups address key pesticide issues—product classification, buffer zones, pesticide risk indicators, education training and certification, and healthy lawns.

In 2004–2005, the Committee addressed many of its priority issues through their working groups, such as the following:

- The Classification Implementation Working Group continued to work toward establishing a harmonized approach for the classification of domestic products.
- The Working Group on Pesticide Education, Training and Certification reported on the completion of priority items on their Workplan. The FPT Committee continues to place priority on the update of the basic knowledge requirements for applicators.
- The Healthy Lawns Working Group continued its efforts to reach homeowners with messages on integrated pest management practices with regard to lawn care and to improve labelling of household use products as well as addressed recommendations regarding what type of product should be available to homeowners. The FPT Committee was interested in pursuing discussions with the Canadian Food Inspection Agency to examine concerns related to fertilizer/herbicide combination products. The Healthy Lawns Working Group will work to finalize the remaining workplan commitments as quickly as possible.
- The PMRA Buffer Zone Working Group has prepared a new draft of the buffer zone regulatory proposal and will circulate it to the FPT working group for comment. The FPT Committee encouraged the group to host a teleconference call to advance communication on the proposal in the near future.
- The Pesticide Risk Indicator Working Group reported on their progress and highlighted the need to communicate with stakeholders on the recommendations of a pesticide risk indicator model. FPT supported the ongoing efforts of this group and wanted to ensure that any Canadian approach stayed current with international progress on risk indicators.

The stakeholder session included presentations by the Canadian Aerial Applicators Association, the Urban Pest Management Council of Canada, Syngenta Crop Protection Canada Inc., the Consumer Chemical Specialty Products Association, the World Wildlife Fund, the BC Landscape & Nursery Association, the Integrated Vegetation Management Association, CropLife Canada and the Forest Pest Management Caucus.

Federal Partners

A number of departments are involved with pest management at the federal level. The PMRA works with Environment Canada, Department of Fisheries and Oceans, Natural Resources Canada, the Canadian Food Inspection Agency, Agriculture and Agri-Food Canada and other branches within Health Canada to conduct pesticide research and monitoring. Agreements have been signed clarifying the roles and responsibilities of each agency and department to ensure there is no duplication of effort. These agreements also provide a mechanism for communication, transparency and accountability.

These horizontal efforts with other science-based departments at the federal government level are successfully improving the coordination of pesticide research and regulatory activities in the federal government.²

Our compliance activities often involve collaboration with the Canadian Food Inspection Agency and the provincial governments. The PMRA will continue to work with Agriculture and Agri-Food Canada to develop risk-reduction strategies for the agricultural sector and improve access to the specialized pesticides that are a priority for Canadian growers.

Science

To strengthen the science capacity at the PMRA, the Agency participated in five joint industry/regulator task forces related to the development of human exposure data. As well, we participated in the development of health criteria for a globally harmonized system for hazard classification. We also continued to revise aggregate and cumulative risk assessment methods to safeguard Canadians' health and safety.

To enhance science methodology, interpretation and data reporting, representatives from the PMRA participated in International Life Sciences Institute working groups and relevant OECD steering committees and working groups.

In 2004–2005, the Agency published a document that outlines how formulants (inert ingredients in registered pesticides) are regulated in Canada and as well launched a new series listing all the formulants found in registered pesticides with the Chemical Abstracts Service number. Updates on formulants that no longer appear in a registered pesticide will be published on a regular basis. These updates also flag those formulants that are allergens which must be reported on product labels. The PMRA requires all applicants to provide a Statement of Product Specification Form that lists all ingredients contained in the proposed pesticide.

Formulants determined to be of toxicological concern (List 1 formulants) have been virtually eliminated from pesticides. For the few remaining products containing formulants of concern, the PMRA has begun to review the safety data submitted when registration was requested. Pending the outcome of these reviews, these formulants must be disclosed on the labels of pesticides containing them.

² For further information, see www.tbs-sct.gc.ca/rma/eppi-ibdrp/hrdb-rhbd/bpcpr-rcprp/description_e.asp.

Appendix I Tables

Table 1 PMRA Registration Actions 2004–2005

	Totals ¹	Temporary Registration ²	New Active Ingredients of Agricultural Interest
Total New Active Ingredients Total New Uses ³ = 47	9	6	7
Conventional Chemicals New Uses ³ = 3	1	0	1
Total Reduced-Risk Active Ingredients New Uses ³ = 44	8 ===	6 ===	6 ===
• Conventional Reduced-Risk Chemicals	3	3	3
• Biopesticides	5 (1)	3 (1)	3
Antimicrobials	0	0	0

¹ The number in parentheses () represents registrations through joint reviews or work sharing with the USEPA.

² Temporary registrations are granted when the risks are considered acceptable, that is when the product meets current health and environmental safety standards and is efficacious, but when only confirmatory or conditional data are required. Pesticide regulators in the United States and Europe issue temporary registrations according to the same criteria.

³ A new use is defined as the addition of a new crop or site to the use pattern of an active ingredient and does not include the addition of new pests, tank mixes, etc.

Percentage of total registrations that are full registrations: 96%.

Percentage of total registrations that are temporary: 4%.

Table 2 Minor Crop Uses¹ Registered in 2004–2005

Total² Minor Crop Uses¹ Registered	65
• Food Crops	19
• Non-Food Crops	46
Total² Reduced-Risk Crop Uses¹ Registered	42
• Conventional Reduced-Risk Chemicals	32
• Biopesticides	10

¹ A new crop use is defined as the addition of a new crop to the use pattern of an active ingredient and does not include the addition of new pests, tank mixes, etc.

² This table includes all sources—joint review submissions and other submissions for new active ingredients and new uses, user-requested minor use label expansions.

Appendix II Agency Contacts

Pest Management Regulatory Agency

2720 Riverside Drive, Ottawa ON K1A 0K9

Information Service: 1 800 267-6315

Facsimile: 1 (613) 736-3799

e-mail: pmra_infoserv@hc-sc.gc.ca

Regional Offices



British Columbia Region
400 - 4321 Still Creek Drive
Burnaby BC V5C 6S7
Telephone: (604) 666-0741

1905 Kent Road
Kelowna BC V1Y 7S6
Telephone: (250) 470-4890

Alberta Region
220 - 4th Avenue SE
Calgary AB T2G 4X3
Telephone: (403) 292-4106

J.G. O'Donoghue Building
Room 205, 7000 - 113th Street
Edmonton AB T6H 5T6
Telephone: (780) 495-7014

3605 - 14th Avenue North
Lethbridge AB T1H 6P7
Telephone: (403) 382-4794

Saskatchewan Region
3085 Albert Street
P.O. Box 8060
Regina SK S4P 4E3
Telephone: (306) 780-7123

301 - 421 Downey Road
Saskatoon SK S7N 4L8
Telephone: (306) 975-5219

Manitoba Region
613 - 269 Main Street
Winnipeg MB R3C 1B2
Telephone: (204) 983-8662

Ontario Region
174 Stone Road West
Guelph ON N1G 4S9
Telephone: (519) 826-2895

1200 Commissioners Road East
Unit 19
London ON N5Z 4R3
Telephone: (519) 691-1300
Ext. 127

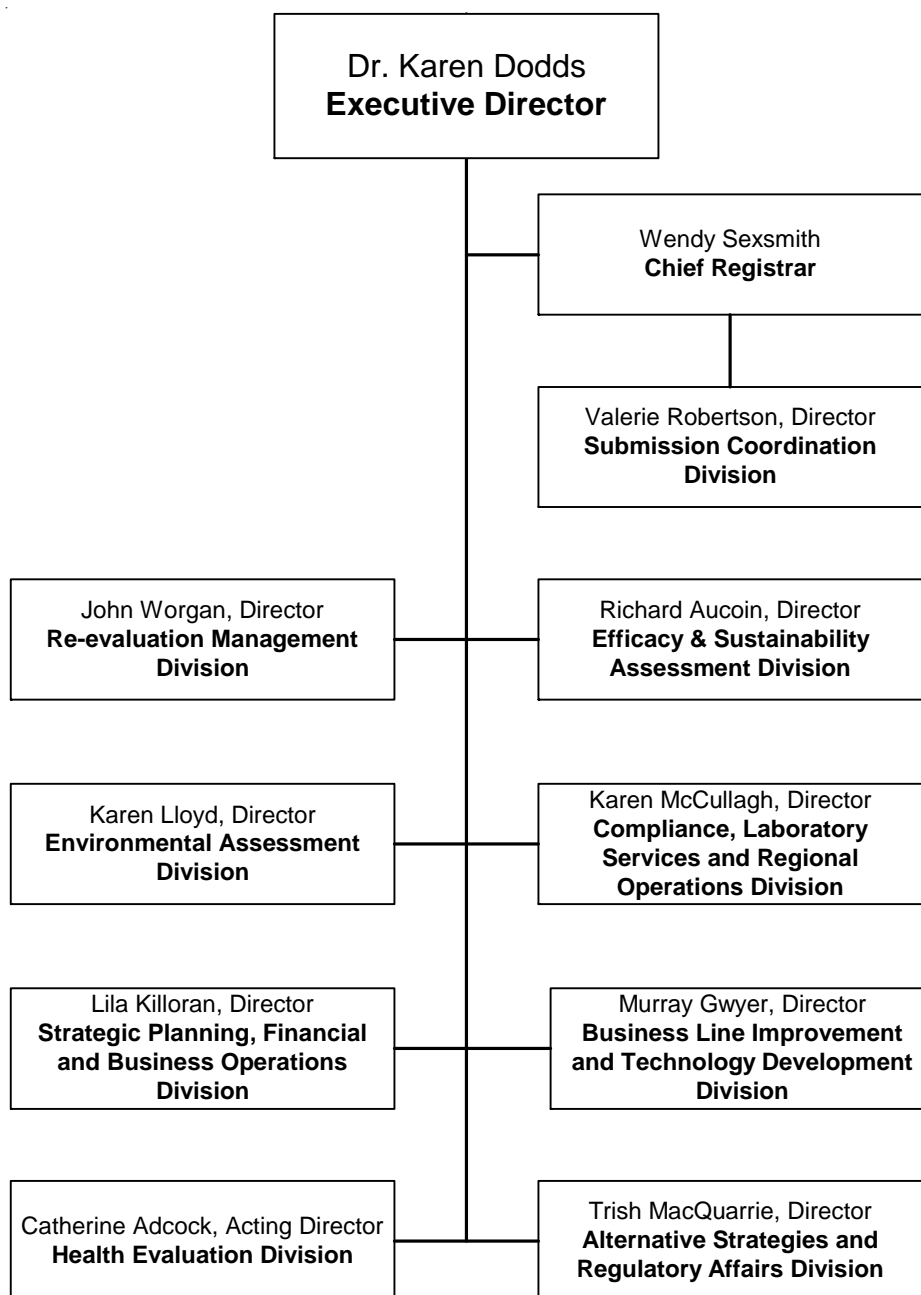
Quebec Region
200, René-Lévesque Blvd West
Montreal QC H2Z 1X4
Telephone: (514) 496-1672

Atlantic Region
1081 Main Street
P.O. Box 6088
Moncton NB E1C 8R2
Telephone: (506) 851-7876

690 University Avenue
Charlottetown PE C1E 1E3
Telephone: (902) 566-7201

Agriculture Centre
32 Main Street
Kentville NS B4N 1J5
Telephone: (902) 679-5304

Appendix III Organization of the PMRA as of 31 March 2005



During 2004–2005, the PMRA utilized 475 FTEs.

Description of Divisions Within the PMRA

Executive Director's Office

- oversees the operation of the PMRA; and
- chairs the Agency Management Committee (AMC), comprising the directors of all divisions.

Chief Registrar's Office

- ensures the PMRA makes integrated, science-based decisions in a timely fashion and in a global environment;
- manages registration, including minor use, and product related issues;
- chairs Science Management Committee meetings; and
- provides policy and strategic advice.

Submission Coordination Division

- manages and tracks submissions;
- conducts scientific screening of submissions;
- maintains electronic and paper records for registration activities;
- manages databases; and
- provides information services.

Business Line Improvement and Technology Development Division

- directs business line improvement projects, including electronic environment initiatives; and
- provides information technology support.

Efficacy and Sustainability Assessment Division

- provides expertise on the use of antimicrobials, fungicides, herbicides, insecticides and other pesticides;
- houses a team of scientific evaluators that conducts efficacy assessments, sustainability evaluations and value assessments for pesticides;
- collects and analyzes information pertaining to usage of pesticides for use in risk assessments; and
- supports various user groups in developing and implementing sustainable pest management practices, tools and long-term strategies and facilitating the registration of reduced-risk products.

Health Evaluation Division

- provides expertise on human health hazards, risk assessments and risk mitigation;
- houses a team of scientific evaluators that conducts toxicology evaluation and exposure assessment of new and registered pesticides; and
- participates in national and international activities to develop and harmonize testing and evaluation procedures.

Environmental Assessment Division

- provides expertise on environmental hazards, risk assessments and risk mitigation;
- houses a team of scientific evaluators that conducts assessments of the environmental fate and effects of pesticides; and
- participates in national and international activities to harmonize testing and evaluation procedures.

Alternative Strategies and Regulatory Affairs Division

- develops and coordinates policy and regulation, strategic planning and reporting, response to government reports and audits; is responsible for liaison with other government departments and issue management;
- minimizes health/environment risk associations with pesticide use in urban settings through/by promoting access to sustainable pest management strategies;
- acts as primary information resource on all major PMRA communications matters, provides strategic advice and guidance to management on communications issues and delivers on all aspects of media relations;
- manages the translation, publication and distribution of PMRA regulatory documents and consumer information products; manages the Agency Web site and reference centre;
- manages, develops and coordinates operational, scientific and professional learning and development for staff; staff orientation; staff and management development programs; internal communication, and learning activities for stakeholders including the pesticide industry, and provincial and territorial government officials;
- develops, maintains and communicates about the federal legislative framework for pesticides and coordinates the Agency's responses to access to information/privacy requests related to this framework;
- co-chairs, with a provincial representative, the Federal/Provincial/Territorial Committee on Pest Management and Pesticides; and
- supports the working of the Pest Management Advisory Council.

Compliance, Laboratory Services and Regional Operations Division

- conducts investigations and enforces the PCPA and Regulations;
- promotes, inspects and verifies compliance through national pesticide compliance programs;
- represents the PMRA at the regional and local level;
- conducts product chemistry evaluations;
- provides expertise on the chemistry of pesticides and analytical testing; and
- conducts analytical testing of samples associated with investigation and inspection programs.

Strategic Planning, Financial and Business Operations Division

- leads strategic management activities for the Agency;
- coordinates the Agency's planning and accountability processes;
- manages administration and business operations including material management, health, safety, security, facilities, and information management;
- plans and manages financial administration and cost recovery services;
- manages and prepares financial planning and analysis; and
- manages the integration of relevant government-wide initiatives.

Re-evaluation Management Division

- ensures the PMRA makes integrated, science-based decisions for older chemicals in a timely fashion and in a global environment;
- manages the re-evaluation program and issues;
- co-ordinates special reviews of specific aspects of older pesticides when needed;
- coordinates the Agency's re-evaluation activities with other countries to harmonize the timing and nature of decisions whenever possible;
- houses a team of scientific evaluators that interpret international reviews as the basis of re-evaluation for Canadian products, where appropriate; and
- provides input regarding impact of re-evaluation decisions on sustainability.

Our science professionals evaluate every aspect of pesticides: from their chemistry, efficacy, and health and environmental effects to their place in Canadian forestry, agricultural and domestic sectors. Our scientists are members of dozens of professional associations and institutes, and are recognized nationally and internationally as experts in their fields. They provide a wealth of experience in many disciplines, including human and environmental toxicology, biology, microbiology, chemistry, entomology, agronomy, parasitology, zoology, weed science, occupational hygiene and agriculture. Their research has been widely published in scientific journals and has garnered many awards.

Our support staff make the day-to-day operations of the Agency possible: managing communications, administrative services, training, human resources, financial administration and information systems.

The Agency's laboratory has been accredited by the Standards Council of Canada under stringent ISO/IEC 17025 requirements for the eleventh consecutive year. The Laboratory hosted representatives of the Standards Council of Canada (SCC) in June 2005. They conducted an audit to verify the level of conformity of the PMRA Laboratory's quality assurance procedures to the ISO 17025 standards. The laboratory's high level of achievement has been recognized with two awards of excellence.

Appendix IV Description of Submission Categories

Category A submissions include new active ingredients and their companion end-use product(s) as well as major new uses, or submissions to establish an MRL for a new active ingredient. User Requested Minor Use Registrations (URMURs) and joint reviews are also included in this category.

Category B submissions include submissions for new uses or new formulations.

Category C submissions are based on previously established precedents or that have reduced data requirements.