# Pest Management Regulatory Agency



# Annual Report 2006–2007

## 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.

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

For additional copies, please contact:

Facsimile: 1-613-736-3758

Telephone: 1-800-267-6315

Pest Management Regulatory Agency

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# Message of the Executive Director



I am pleased to present Health Canada Pest Management Regulatory Agency's Annual Report for 2006–2007.

The past year marked an important milestone in the history of pesticide regulation in Canada with the coming into force of the new *Pest Control Products Act* on 28 June 2006. Highlights of the new Act include additional authorities to protect human health and the environment, greater postmarket controls and increased transparency. In 2006–2007, beyond our core work of reviewing pesticides, we focussed on implementation of the new Act, effective communication, opportunities for international collaboration and stakeholder engagement. Our objective is to increase the public confidence in the Canadian pesticide regulatory process through effective communication and by implementing various transparency initiatives for increased public participation in our decision making process. By engaging our stakeholders, we are working to better understand the needs and concerns of all Canadians with respect to pesticides and pesticide regulation.

In the area of international collaboration, we have been working closely with our international counterparts such as the OECD and NAFTA to create a harmonized registration process for pesticides and treated commodities while guarding the Canadian legislative requirements and protecting human health and the environment. Our formulants policy, which we implemented in May 2006, is based on the approach followed by the Unites States. The first NAFTA label was completed this fiscal year, which will allow movement of a jointly labelled herbicide between Canada and the United States.

Science continues to evolve rapidly. Our improved relations with stakeholders and the international scientific and regulatory community are critical in keeping our scientists informed of new issues.

Canadians expect their government to be responsive to their needs, and to work toward removing regulatory barriers that have the potential to hinder their livelihood without compromising the protection of human health and environment. I believe that our efforts in the areas of international collaboration and stakeholder engagement are addressing these expectations.

Through the above-mentioned efforts, the Agency has had a successful year in meeting our commitments to protect human health and the environment, and increase public understanding of the Canadian pesticide regulatory process.

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

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# Section 1 Mission, Vision and Final Outcomes

### 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.

## **Final Outcomes**

- Protected health and environment.
- Increased use of reduced-risk pest management practices and products.
- Increased public and stakeholder confidence in pesticide regulation.

#### Overview

Health Canada's Pest Management Regulatory Agency (PMRA) contributes to the health and environmental agenda of the Government of Canada. This is achieved by regulating pesticides under the *Pest Control Products Act*, thereby protecting human health and environment from unacceptable risks associated with pesticides. A significant achievement has been the coming into force of the new Act in June 2006, which is based on three key principles—strengthening health and environmental protection, strengthening the postregistration control of pesticides that are already in the market and making the pesticide regulatory system more transparent. The Pest Control Products Sales Information Reporting Regulations came into force in October 2006. The Pest Control Products Incident Reporting Regulations were published in October 2006 and will come into force in April 2007.

In 2006–2007, the Agency increased its focus on effective communication and stakeholder engagement for knowledge sharing and to understand the pesticide-related issues of different sectors including growers, other government and non-government organizations, health and environmental groups, industry and the public. In addition, we implemented various transparency initiatives to increase public participation in our pesticide regulatory process. We strengthened stakeholder engagement by creating a new work unit dedicated to stakeholder engagement, made regional visits to consult with local stakeholders, provided training/information sessions and worked with various stakeholders in developing new policies, strategies and programs. Many transparency initiatives were undertaken such as improving the electronic Pesticide Regulatory System (e-PRS) and establishing a reading room to increase public confidence and participation in the pesticide regulatory process.

We have continued to work toward international regulatory cooperation in many areas to increase the availability of reduced-risk pesticides for Canadian growers and to gain regulatory efficiency without compromising the protection of human health and the environment. In 2006–2007, the Agency continued to make progress toward closing the technology gap between Canada and the United States through joint reviews, workshares and minor use programmes as well as by harmonizing the data requirements. The first NAFTA label was completed in 2006–2007, which will allow movement of a jointly labelled herbicide product between the United States and Canada. We have also increased international harmonization and work sharing by working closely with international bodies and our counterparts in other countries.

## The New Pest Control Products Act and Regulations

On 28 June 2006, the new *Pest Control Products Act* came into effect along with updated Pest Control Products Regulations. These two pieces of legislation constitute the core of the federal regulatory framework for pesticides as they give the basis for approving pesticides for use in Canada before they can be sold or used. As well, they provide for more transparency and for public participation opportunities before and after decisions are made. The public can access information about the substances on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern and the test data on which evaluations are based. The new legislation is an example of how the Government of Canada is applying the Smart Regulation principles of transparency and accountability, and is supporting international regulatory cooperation for increased efficiency in achieving common desired results while respecting Canadian legislation requirements.

In 2006–2007, we continued our work on developing new regulations pertaining to data protection, review panels, material safety data sheets and own-use imports. Incident and sales reports will enable us to monitor adverse impacts and provide us with greater information on the risks of pesticides when conducting our evaluations and to take timely regulatory action when needed to protect Canadians' health and their environment. The Pest Control Products Sales Information Reporting Regulations require registrants to submit an annual report to the Minister of Health indicating the quantity of each of their registered products that was made available for sale in each province and territory during the previous calendar year. The first report is due to the Minister on 1 June 2008.

We took a proactive communications approach to the coming into force of the new Act. Communications materials such as information notes, fact sheets and questions and answers were available for the public on our website. Also, e-mail notification of the Act coming into force was sent to the Pest Management Advisory Council, the Economic Management Advisory Committee, the Federal, Provincial, Territorial Committee on Pest Management and Pesticides, other government departments and agencies, stakeholder associations and user groups. In addition, targeted guidance documents were prepared to support various aspects of the Act and targeted training and/or information sessions were given to registrants on incident reporting, sales information reporting and transparency aspects of the new *Pest Control Products Act*. In 2006–2007, training of our staff was also a priority to ensure that all staff understand the general implications of the new Act and the specific areas where it impacts their day-to-day work. General interest in and support for the new Act has been expressed. On the day the new Act came into effect, the PMRA website received 10 000 hits in a 3-hour window.



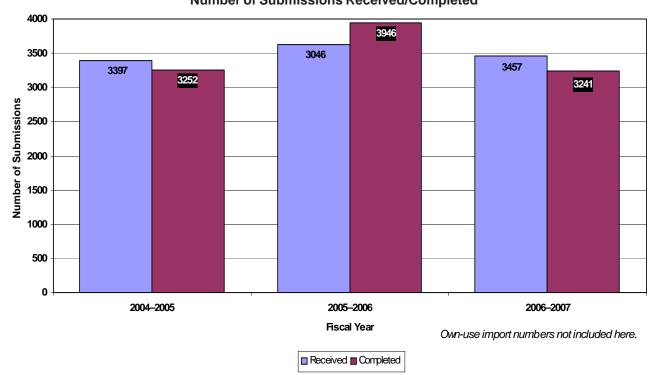
# Section 2 The PMRA's Pesticide Program in Action

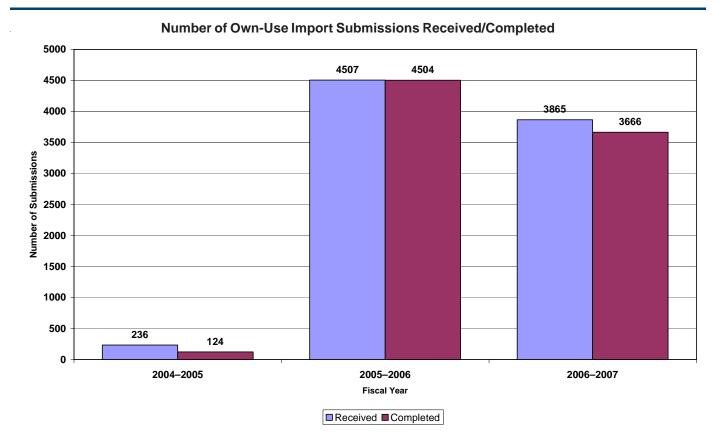
#### Financial Information (millions of dollars)

	2006–2007 Planned Spending	2006–2007 Total Authorities	2006–2007 Actual Spending
Gross expenditures	47.2	52.0	47.7
Revenues	-7.0	-7.0	-7.4
Net expenditures	40.2	45.0	40.3
FTEs*	550	550	473

<sup>\*</sup> Full-time equivalent staff

#### **Number of Submissions Received/Completed**





Number of Submissions Received/Completed Broken Down by Category

	Received	Completed
Category A	66	69
Category B	495	459
Category C	927	884
Category D	5725	5407
Category E	102	84
Miscellaneous	-	4
Total	7315	6907

Of the 69 submissions in Category A that were completed, 29 were withdrawn or rejected and 40 were registered/approved. Of the 62 submissions reviewed in 2006–2007, 58 were reviewed within the applicable performance standards.

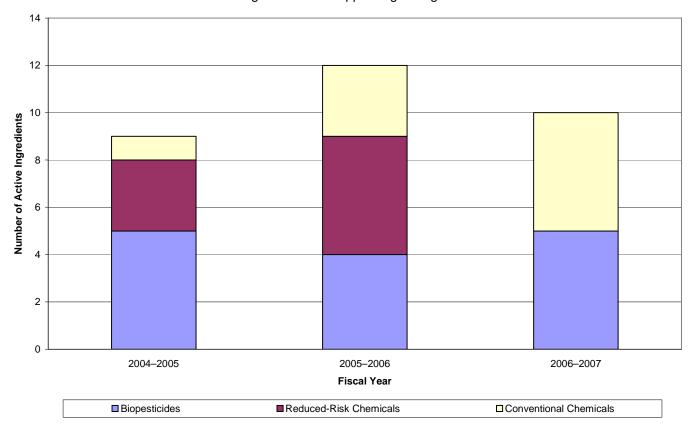
Of the 459 submissions in Category B that were completed, 58 were withdrawn or rejected and 401 were registered/approved. Of the 428 submissions reviewed in 2006–2007, 401 were reviewed within the applicable performance standards.

Of the 884 submissions in Category C that were completed, 108 were withdrawn or rejected and 776 were registered. Of the 883 submissions reviewed in 2006–2007, 755 were reviewed within the applicable performance standards.

Of the 5407 submissions in Category D that were completed, 214 were withdrawn or rejected and 5193 were registered/approved. Of the 5406 submissions reviewed in 2006–2007, 4880 were reviewed within the applicable review performance standards. This includes 3517/3666 own-use import (OUI) permit submissions reviewed within the 30-day performance timeline in 2006–2007.

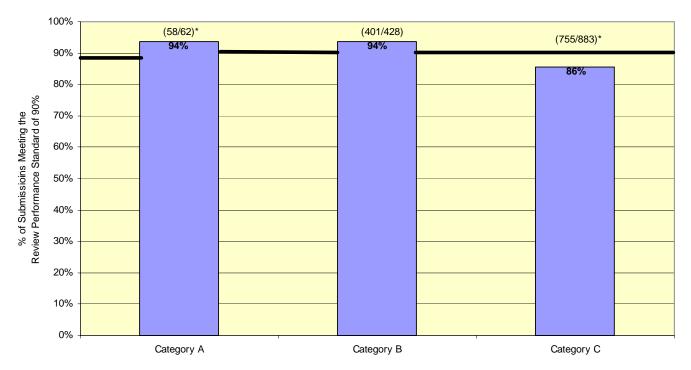
Of the 84 submissions in Category E that were completed, 10 were withdrawn or rejected and 74 were registered/approved. Of the 82 submissions reviewed in 2006–2007, 41 were reviewed within the applicable review performance standards.

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



Submissions received by the PMRA fall into one of five categories explained in Appendix I.

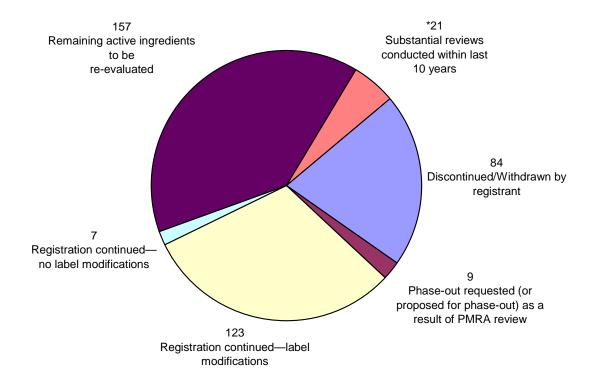
## Performance Against the Review Performance Standard for Category A, B and C Submissions Reviewed in 2006–2007



<sup>\* (#</sup> of submissions that met the standard / # of submissions review ed)

#### **Re-evaluation Activities**

We have committed to re-evaluate all 401 pesticide active ingredients registered on or before 31 December 1994. As of 31 March 2007, 157 remain to be re-evaluated.



<sup>\*</sup> Adequacy of previous reviews to be confirmed in 2007–2008

#### PMRA Registration Actions 1 April 2006-31 March 2007

	Totals <sup>1</sup>	Conditional Registration <sup>2</sup>	New Active Ingredients of Agricultural Interest
Total New Active Ingredients Total New Uses <sup>3</sup> = 361	10 (4)	7 (3)	6 (4)
• Conventional Chemicals New Uses <sup>3</sup> = 261	5 (2)	4 (1)	4 (2)
Total Reduced-Risk Active Ingredients     New Uses <sup>3</sup> = 11	5 (2)	3 (2)	2 (2)
Conventional Reduced-Risk Chemicals	0	0	0
Biopesticides New Uses <sup>3</sup> = 11	5 (2)	3 (2)	2 (2)
Antimicrobials	0	0	0

The number in parenthesis () is the number that was registered through joint reviews or work sharing with the United States Environmental Protection Agency (USEPA).

Percentage of total registrations that are full registrations: 95%.

Percentage of total registrations that are conditional: 5%.

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.

#### Minor Crop Uses<sup>1</sup> Registered 1 April 2006–31 March 2007

Total <sup>2</sup> Minor Crop Uses <sup>1</sup> Registered	663
Food Crops	546
Non-Food Crops	117
Total <sup>2</sup> Reduced-Risk Crop Uses <sup>1</sup> Registered	59
Reduced-Risk Chemical Crop Uses Registered	46
Biopesticide Crop Uses Registered	13

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.

Conditional 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. Conditional registrations are also issued by pesticide regulators in the same way in the United States and in Europe.

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



# Section 3 Pesticide Registrations

The workload in 2006–2007 remained high, with more than 6900 regulatory decisions being made.

#### New Active Ingredients Registered During the Fiscal Year 2006–2007

Active Ingredient	End-Use Product(s)	Product Type	Registration Status	Chemical Type	Pest Control
Carfentrazone-ethyl <sup>1</sup>	Aim EC	Agricultural herbicide	Conditional	Conventional chemical	Listed weeds in Crop Group 1 - Root and Tuber Vegetables, Crop Group 3 - Bulb Vegetables, Crop Group 4 - Leafy Vegetables, Crop Group 5 - Brassica (Cole) Leafy Vegetables, Crop Group 6 - Legume Vegetables, Crop Group 8 - Fruiting Vegetables, Crop Group 9 - Cucurbit Vegetables, Crop Group 11 - Pome Fruit, Crop Group 12 - Stone Fruit, Crop Group 13 - Berries, Crop Group 15 - Cereal Grains, Crop Group 20 - Oilseed
Neodiprion abietis nucleopolyhedrovirus	Abietiv Flowable Biological Insecticide	Insecticide	Conditional	Reduced-risk biopesticide	Balsam fir sawfly larvae in forestry
Novaluron <sup>2</sup>	Rimon 10 EC Novaluron Insecticide	Insect growth regulator, insecticide	Full	Conventional chemical	Listed foliar insects on apple and potato
Octenol	Multiple products/ devices	Attractant, insecticide	Full	Reduced-risk biopesticide	Mosquito trap
Pantoea agglomerans E325 <sup>3</sup>	Bloomtime Biological FD Biopesticide	Crop bactericide, fungicide	Conditional	Reduced-risk biopesticide	Fire blight on apple and pear
Pantoea agglomerans C9-1 <sup>3</sup>	BlightBan C9-1	Crop bactericide	Conditional	Reduced-risk biopesticide	Fire blight on apple and pear

Active Ingredient	End-Use Product(s)	Product Type	Registration Status	Chemical Type	Pest Control
Prothioconazole <sup>3</sup>	Proline 480 SC Foliar Fungicide	Agricultural fungicide	Conditional	Conventional chemical	Listed diseases on chickpea, lentils, canola, rapeseed, Oriental mustard, wheat (spring, durum, winter), and barley
Sodium chloride	Adios Ambros Water Soluble Granule	Herbicide	Full	Reduced-risk biopesticide	Common ragweed along roadsides, highways, walkways, vacant lots, and industrial sites
Spiromesifen <sup>1</sup>	Forbid 240 SC Miticide / Insecticide	Agricultural insecticide	Conditional	Conventional chemical	Mites and whiteflies on corn (field), ornamental plants, flowers and foliage plants, strawberry, greenhouse crops such as ornamentals, tomato, pepper, and cucumbers, Crop Group Subgroup 1C - Tuberous and corm vegetables subgroup, Crop Group Subgroup 4A - Leafy Greens subgroup, Crop Group 5 - Brassica (Cole) Leafy Vegetables, Crop Group 8 - Fruiting Vegetables, Crop Group 9 - Cucurbit Vegetables
Sulfuryl fluoride	Profume Gas Fumigant	Insecticide	Conditional	Conventional chemical	Stored product pests such as Indian meal moth, confused flour beetle, saw-toothed grain beetle, warehouse beetle and granary weevil in empty cereal grain mills, associated empty storage facilities, and empty food processing plants

- 1 Registered under the User Requested Minor Use Registration (URMUR) Program.
- Registered under the Workshare Program with the USEPA.
- 3 Registered under the Joint Review Program with the USEPA.

### **Presubmission Consultations**

The use of presubmission consultations continued to streamline the submission process so that decisions are reached with fewer delays. Thirty-eight consultations were held in 2006–2007. We anticipate that presubmission consultations will result in more biopesticide being registered and American registrants submitting relevant registration applications to Canada at the same time they submit to the USEPA. This will result in reducing the technology gap between Canada and the United States by increasing availability of reduced-risk pesticides.

### Low-Risk Biochemicals

The new Act provided a legislative foundation to facilitate the availability of new lower risk pesticides. To facilitate access to lower risk pesticides, we continued our low-risk initiative and developed a new registration guideline for low-risk biochemicals and other non-conventional pesticides, to be published for public consultation in 2007. Development of this guideline involved several consultations with the Pest Management Advisory Council Low Risk Working Group and presentations to several stakeholder groups, including CropLife, the Canadian Consumer Speciality Products Association and the Federal/Provincial/Territorial Committee on Pest Management and Pesticides over this past year. We also considered the USEPA's new proposed rule on data requirements for registration of biochemical pesticides (released in March 2006), harmonizing our requirements where applicable, and considered the regulatory requirements for biochemical-based pesticides of the European Union and other Organisation for Economic Co-operation and Development (OECD) countries, including Australia.

#### **Formulants**

A formulant is any substance other than the active ingredient that is intentionally added to a pesticide product to improve its physical characteristics, such as its sprayability, solubility, spreadability or stability. In May 2006, we published the *Formulants Policy and Implementation Guidance Document* (Regulatory Directive <u>DIR2006-02</u>), which outlines our policy on the regulation of formulants contained in pesticide products. The policy, based on the USEPA's approach, represents another step towards harmonization of pesticide regulations. The policy will ensure that the identifications are accurate, meet current standards and disclose allergens and preservatives. As well, we require the elimination of certain toxic formulants from products or data to support the safety of their continued use. We also encourage the use of the least toxic formulants available that are appropriate to the formulation.

Canada's new Chemicals Management Plan, which is discussed in more detail in Section 5, will increase progress in assessing health and environmental risks of formulants under our Formulants Program.

#### Maximum Residue Limits on Food

A maximum residue limit (MRL) represents the maximum amount of pesticide residue that might be expected in or on a food commodity. They are currently established under the *Food and Drugs Act*. In 2006–2007, we continued to develop an efficient process to establish the MRLs under the *Pest Control Products Act*. The Canadian Food Inspection Agency (CFIA) is responsible for monitoring domestic and imported foods as well as for carrying out enforcement activities to prevent the sale of food containing excessive residues. In 2005–2006, the Canadian Food Inspection Agency reported 99.1% of the domestic fruits and vegetables were below the established MRL and 88% had no detectable residues. They also reported 96.7% of imported fruits and vegetables were below the established MRL and 86% had no detectable residues. Canadian Food Inspection Agency data for 2006–2007 are currently being compiled. Analysis and continued consultation are being carried out on the several comments that were received as a result of Discussion Document <u>DIS2006-01</u>, *Revocation of 0.1 ppm as a General MRL for Food Pesticide Residues*, released in June 2006.



# Section 4 Postregistration Programs

## Re-evaluating Products Already in the Market

The re-evaluation process takes into consideration the current scientific assessment methods, the full extent of the use patterns of the active ingredients, the diversity of their end-use products and their market penetration. Some of the pressures of the ongoing commitments for re-evaluation include the complexity of some assessments, technology gaps, fewer alternatives, increased need for risk management, and transition strategies. As well, re-evaluation builds on the foreign reviews available to our reviewers 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 trade of products treated with pesticides in Canada and the United States. In 2006–2007, we commenced work with the USEPA to develop a cooperative work plan for harmonizing schedules and work sharing for the next round of re-evaluations.

The review of turf and lawn herbicides progressed with the publication of a Proposed Acceptability for Continued Registration (PACR) document on the turf use of the MCPA as well as a Re-evaluation Note (REV) on 2,4-D. This re-evaluation document outlined the interim mitigation measures consistent with the PACR for the lawn and turf uses of 2,4-D. As well, it responded to comments made during the PACR's consultation period.

We have begun work to develop a transition strategy for the phase out of azinphos-methyl. This process will address challenges encountered by growers as they move toward alternative pest control methods. Through stakeholder involvement, we will facilitate the move away from the use of azinphos-methyl, while attempting to minimize impacts on growers.

During 2006–2007, 29 re-evaluation documents were published. This included proposed and final decisions as well as updates on several active ingredients under re-evaluation.

## Monitoring Compliance With Conditions of Registration

We are also responsible for promoting, verifying and enforcing compliance with the *Pest Control Products Act* and its Regulations. In support of this mandate, our headquarters, regional and laboratory staff plan, develop and deliver compliance programs under the National Pesticide Compliance Program. These compliance programs are designed to promote (sector and stakeholder consultation programs) and verify (monitoring and surveillance inspection programs) compliance with the *Pest Control Products Act* and Regulations among registrants, distributors and

users of pesticide products. In addition to the compliance promotion and verification inspection programs conducted annually, we address suspected or known violations of the *Pest Control Products Act* and Regulations through investigative and enforcement activities. Information used to support the initiation of investigations and subsequent enforcement responses stems either from ongoing compliance program activities or from complaints.

The types of programs we decide to conduct in a given year depend on the nature and extent of the risks associated with compliance problems and issues. As described in Regulatory Proposal PRO2006-01, Compliance Policy, released in June 2006, managing risk in the context of compliance provides a basis to target and select the situations of most concern where non-compliance is either known or suspected to exist, i.e. integrating risk into decision-making in a systematic manner. Risk analysis includes impact characterization, likelihood analysis, and overall evaluation of risk level and tolerance. A final version of the compliance policy is expected to be published in 2007–2008.

Thirteen compliance programs were delivered in 2006–2007. Seven programs assessed levels of compliance in targeted and inspected sectors, including blueberry, grape and head lettuce growers; lawn care applicators; and importers of the OUI product. During these inspections, minor issues with label compliance were noted. Container disposal was also an issue that was identified during the delivery of one program. While we continue to encourage the recycling of product containers, work is underway to better coordinate regulatory efforts with provincial regulators. The six remaining programs assessed knowledge and capacity to comply with our Act and Regulations and provided information to help industry and users respect our regulatory requirements. These consultation programs addressed compliance knowledge gaps and provided motivation for compliance within the selected sectors, such as custom ground sprayers and agricultural consultants. Some programs collected information regarding a sector's willingness and ability to comply. Other programs collected important information that will be used to develop future compliance strategies and programs.

In 2006–2007, 437 investigations were initiated dealing with situations of non-compliance under the Act. A follow-up was conducted on all of these occurrences to assess the nature and severity of resulting harm and to decide whether to apply an enforcement response or other corrective measures. Most enforcement responses resulted in verbal warnings or letters explaining the problem, the requirement to be respected and the proposed corrective action, such as following label instructions. Some enforcement responses included the issuance of inspector's order to bring the situation into compliance. The primary difference between inspectors' orders and a verbal warning or a letter depends on the risk impact of the infraction and the intended effect of each enforcement response. The primary purpose of any enforcement response is to restore compliance. Hence, inspectors' orders are designed to immediately correct the problem associated with situations of non-compliance.

Our laboratory has maintained the stringent ISO/IEC 17025 accreditation requirements under the Standards Council of Canada for the twelfth consecutive year.

## Sustainable Pest Management and Risk-Reduction Strategies

In 2006–2007, we worked with several industrial sectors to integrate the concept of sustainable pest control into their respective pest control strategies. Such collaborations demonstrate the high level of interest of industries in adopting more sustainable pest management tools. Over the past year, efforts have focussed on the forestry sector, Richardson's ground squirrel control in the Prairies, invasive species control and ornamentals.

The forestry sector worked actively with us to register reduced-risk pesticides, including microbial pesticides and pheromones to control critical pests such as the mountain pine beetle. A research action plan that is part of the Canadian sustainable strategy in forestry is now incorporating pesticide regulations, allowing for greater efficiency.

The ground squirrel population in certain areas of the Prairies has recently reached levels not seen since the 1930s, highlighting the need for newer and more sustainable tools to improve the management of the ground squirrel population. Through discussions with growers, municipalities and universities, progress is being achieved toward developing more sustainable pest management control.

Efforts have also been placed on enhancing the sustainability of pest control approaches for invasive species. Where emergency registration was considered the only avenue of management in the past, the sector is developing strategies that allow for proactive registration applications and/or appropriate research component where a gap is identified.

Working with the ornamental sector, we helped growers find reduced-risk solutions for their pest management needs. One approach being pursued is the development, in collaboration with growers, of a grouping system for ornamentals to simplify the registration process while ensuring the level of safety the *Pest Control Products Act* requires.

As part of the joint Agriculture and Agri-Food Canada / Health Canada Pesticide Risk-Reduction Program, consultations with stakeholders for two new priority crops (blueberries and raspberries) took place to develop and implement commodity-specific risk-reduction strategies. These commodity-specific strategies are national in scope and are aimed at reducing the risk to health and the environment from the use of pesticides.

To measure our performance against the goal of reducing overall risk to Canadians and their environment, we have been working with our provincial and territorial partners to develop the Pesticide Risk Indicator. The model uses three separate sources of information to fulfill its purpose—health, environment and use data. In 2006–2007, the human health component was finalized, and a health database was created. The environmental risk database also was completed at the national level. Several regional and national pesticide use databases have been acquired through co-operative agreements and purchase of proprietary data.

To support and complement sustainable pest management and risk-reduction strategies, we participate in Health Canada's Sustainable Development Strategy as discussed in *A Path to Sustainability: Sustainable Development Strategy IV 2007–2010*. It 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 fourth sustainable development strategy, can be found at www.hc-sc.gc.ca/ahc-asc/pubs/sus-dur/strateg/sds2007-2010-sdd/index\_e.html. Progress on sustainable development is not limited to the strategy alone. Our policy commitment to sustainable development extends into all legislative, policy and program initiatives, well beyond the three-year lifetime of the Sustainable Development Strategy. We are committed to improving our process for making regulatory decisions for pest control products, including providing access to reduced-risk products and providing information on pest control products and on sustainable pest management practices.

### Urban Use

Through our public and stakeholder engagement activities in 2006–2007, we worked to increase the use of reduced-risk pest management practices and products. Information on reduced-risk pest management practices was made available to the general public and to stakeholder communities. Information and educational materials focusing on sustainable pest management in the urban environment were presented to municipal associations and at trade shows for homeowners.

## Own-Use Import Program

In November 2005, we assembled a stakeholder task force consisting of government groups and industry to consider issues concerning the Own-Use Import (OUI) Program and to identify possible solutions. In June 2006, the OUI Task Force presented us with a consensus package of recommendations that not only addressed the concerns raised from the OUI Program such as stewardship and data protection, but also included recommendations that addressed a broad range of agricultural issues—increased registration of generic pesticides and increased access to newer, safer pesticides available to the American agricultural sector.

In response to these recommendations, we have piloted the Grower Requested Own-Use (GROU) Program to allow growers to import the American version of a product registered in Canada if it is available at a lower price. Registrants have agreed to play an active role in identifying relevant products. As well, we have created an improved policy for the protection of intellectual property rights and the registration of generic pesticides. The new Protection of Proprietary Interests in Pesticide Data Policy is expected to be in place by July 2007. We have also created a list of priorities to further harmonize the Canadian and American pesticide regulatory systems. Two NAFTA labels have been approved, and the NAFTA Label Working Group is actively working on NAFTA labels for an additional eight products, with several other candidates in preliminary discussion.

These recommendations address several issues facing the agricultural sector beyond the narrow scope of the OUI Program. The Task Force's recommendations are viewed as an effective substitute for the OUI Program. We have committed to implement these recommendations.



# Section 5 Partnerships and Consultations

High priority has been placed on collaboration with stakeholders. A new work unit dedicated to stakeholder engagement was established as a centre of expertise in the Agency with the goal of fostering high quality stakeholder relations to ensure we are well informed on stakeholder views and to incorporate these considerations into our programming and planning. This new group was tasked with not only supporting existing collaborations but also exploring new opportunities to engage various stakeholder groups.

## **Our Advisory Bodies**

The PMRA seeks advise from its two formal advisory bodies—the Pest Management Advisory Council (PMAC) and the Economic Management Advisory Committee (EMAC).

PMAC met twice in the past year. Members of the Council have provided advice and input on various policy and program initiatives such as the transparency initiatives under the new *Pest Control Products Act* and on proposals concerning the revocation of the general pesticide maximum residue limit, the development of a pesticide risk indicator, regulation of low-risk pesticides and the harmonization of the classification of domestic class products across provinces. EMAC provided advice on specific ways to improve the efficiency and cost effectiveness of the pesticide regulatory process.

# The Federal/Provincial/Territorial Committee on Pest Management and Pesticides

The Federal/Provincial/Territorial Committee on Pest Management and Pesticides (FPT) was established to help strengthen federal/provincial/territorial relationships in the area of pest management and pesticides. Consultations with stakeholders have identified key issues with respect to pesticide use, particularly at the urban–rural interface. The Committee has agreed to hold further discussions regarding urban–rural pesticide issues.

## Federal Interdepartmental Cooperation

**6 Natural Resources Departments (6NR)**: The mandate of the 6NR Pesticides and Pest Management Working Group is to coordinate, promote and foster closer cooperation between the federal research and regulatory communities working on pesticides and pest management issues. We co-chair a multidepartmental project involving

six federal science-based departments and agencies that works to strengthen health and environmental protection and build public confidence in pesticide regulation. The Working Group focuses on identifying, prioritizing and coordinating pesticide research and monitoring activities and on facilitating the timely transfer of results to support decision making. This cooperation contributes to strengthening science-based decision making in the regulation of pesticides and the identification of effective risk mitigation strategies. Membership includes departments and agencies with a research, policy or regulatory capacity related to pesticides and/or pest management—Agriculture and Agri-Food Canada, the Canadian Food Inspection Agency, Environment Canada, Fisheries and Oceans Canada, Health Canada and Natural Resources Canada.

Chemicals Management Plan: Canada's new Chemicals Management Plan, announced in December 2006, establishes a clear roadmap for assessing and managing chemical substances that will better protect our health and environment. The initiative integrates and strengthens the coordination of federal statutes responsible for protecting health and environment—the *Canadian Environmental Protection Act* (1999), the *Pest Control Products Act*, the *Hazardous Products Act* and the *Food and Drugs Act*.

Under the *Canadian Environmental Protection Act*, Health Canada and Environment Canada reviewed 23 000 substances on the Domestic Substances List and identified 4300 that met *Canadian Environmental Protection Act* criteria for further assessment: greatest potential for human exposure or are persistent and/or bioaccumulative; and are inherently toxic to humans and non-human organisms.

Approximately 200 of the 4300 substances were identified as high priorities for action. Over the next three years, the government will collect information on the properties and uses of the high priority substances and make decisions regarding the best approach to protect Canadians and their environment from any risk these substances might pose. This initiative, known as the "Challenge", was announced on 9 December 2006 in the *Canada Gazette*, Part I, Vol. 140, No. 49.

Under the Challenge, batches of 15–30 substances will be released every three months, along with a profile of each chemical substance, a mandatory survey and a voluntary questionnaire for stakeholders to provide additional information in their possession. Pesticide registrants are obligated to respond to the mandatory survey if they meet the criteria for reporting.

From the list of substances subject to the Challenge, we identified 3 pesticide active ingredients, 35 pesticide formulants and 8 formulant impurities. The active ingredients identified in the Challenge will be re-evaluated under current Re-evaluation Program timelines. Any PMRA List 3 and 4B formulants subject to the Challenge will be reclassified to List 2 (potentially toxic) based on *Canadian Environmental Protection Act* categorization results. Registrants may be asked to amend product formulation at some point in the future. We will participate in the risk assessment and risk management of these substances in collaboration with other branches of Health Canada and Environment Canada.

Under the Chemicals Management Plan, we are also committing additional resources for the re-evaluation of older pesticides and to strengthen regulatory activities in order to facilitate access to newer and safer pesticide products.



# Section 6 Communication, Transparency and Public Involvement

In 2006–2007, increased focus was given to effective communication and various transparency initiatives. Proactive media relations continued to be a priority in 2006–2007 when handling highly visible files such as the OUI Task Force implementation of recommendations and the ongoing field research of control products for the Richardson's ground squirrels.

The new Act increased our ability to make the pesticide regulatory system more transparent, paving the way to establishing an electronic Public Registry. The Public Registry is a database of non-confidential information on pesticides or the pesticide regulatory system, accessible through the PMRA's website. The Act also provides for the establishment of a Reading Room, in which interested parties can inspect the confidential test data on which pesticide evaluations are based, and formalized into law the current practice of consultation on major registration decisions to ensure continued public participation in decision-making.

The new Act also allows for members of the public to make requests for reconsideration of registration decisions and for special reviews of registered products when new scientific information raises concerns.

**e-PRS**: Developments and improvements to the electronic Pesticide Regulatory System (e-PRS) continued through 2006–2007. The system now allows us to quickly disseminate decisions and documents to the public by extracting information from the different modules and automatically posting it to the Public Registry, which records all regulatory decisions regarding pesticide products. The system also puts public announcements on our website covering all current applications to register or amend pesticide products. As well, links were added, allowing the public to request a decision we have made be reconsidered or a special review.

The e-PRS will also allow us to manage information related to pesticide sales and incident reports. These two new programs will result in thousands of new records and documents every year. Ultimately, enhanced management of information in these programs will lead to timely decisions on the use of improved pest management practices and products. It now allows us to provide the full-text of the labels for pesticide products on our website, giving Canadians access to details on registered products.

Client usage of the existing electronic submission tools rose dramatically in 2006–2007. During that time we received 8262 submissions electronically containing more than 94 000 documents. This was 1974 more than the previous year. Over 80% of all applications are now received in electronic format.

**Reading Room**: Under the new Act, the public may use the Reading Room to inspect test data submitted by registrants in support of a decision made under the Act to register a product, to amend a registration or to continue a registration following a re-evaluation or special review. The Act also requires that confidential business information be protected. To help applicants better understand the segregation and designation of confidential business information, two documents were released in 2006 and are available on our web site. Regulatory Directive <a href="DIR2006-03">DIR2006-03</a> deals with the submission of new test data, and Regulatory Directive <a href="DIR2006-04">DIR2006-04</a> deals with previously provided test data.

**Reconsideration of Registration Decisions**: The new *Pest Control Products Act* provides a process for the reconsideration of major registration decisions whereby any person may file a notice of objection within 60 days of a major registration decision. A major registration decision is defined as a decision to grant or deny an application to register a new active ingredient, or to register or amend a major new use. A decision to maintain, amend or cancel a registration following a re-evaluation or special review is also considered a major registration decision. The proposed Review Panel Regulations would elaborate administrative matters concerning the process so as to make it predictable and transparent for the timely resolution of reconsideration questions. Comments have been received as a result of publishing these proposed Regulations in the *Canada Gazette*, Part I, and are in the process of being analysed. The Regulations are expected to be published in the *Canada Gazette*, Part II, in 2007–2008.

Pest Control Products Sales Reporting and Incident Reporting Regulations: The Pest Control Products Sales Information Reporting Regulations came into force in October 2006 and the first annual report must be provided to the Minister by 1 June 2008. The Pest Control Products Incident Reporting Regulations, which require pesticide companies to report incidents related to their products, will enable us to monitor adverse impacts on health and the environment and take any necessary actions in a timely fashion. To facilitate the coming into effect of these Regulations in April 2007 we developed a draft guidance document, mandatory reporting forms and a database for tracking the information.



## Section 7 International Affairs

International cooperation for pesticide regulation provides an essential framework to enhance the protection of human health and the environment by ensuring that international treaties and other agreements on pesticides are consistent with the high levels of protection afforded by Canadian laws. We actively participate in ongoing discussions with the USEPA and other OECD member countries, including the European Union countries, Australia, New Zealand and Japan, on the format of pesticide-related submissions, data requirements for registering pesticides, testing protocols and risk-assessment approaches. We also undertake work-sharing opportunities with these regulatory authorities. The benefits of our international collaboration include knowledge sharing, regulatory efficiency and higher standards for protecting human health and the environment while providing Canadians with greater access to reduced-risk pesticides. These efforts are also viewed as a way for Canada to influence the international community in a positive way, to press for more stringent health and environmental standards around the globe and to identify and adopt international best practices.

## North American Free Trade Agreement Activities

In 2006–2007, we continued to work closely with our partners from the United States and Mexico through the Technical Working Group on Pesticides, established under NAFTA. We addressed a number of specific issues with the goal of creating harmonized North American registration processes for pesticides and treated commodities while respecting legislative requirements in each country. The focus of our work was to develop both short- and long-term measures to facilitate trade in pesticide products and treated commodities across North America without compromising Canada's human health and environmental standards.

On numerous occasions, scientists in Canada, Mexico and the United States came together to compare approaches, share data and understand the pivotal studies for assessing the risks from specific pesticides in each country. These discussions helped ensure regulators are basing their decisions on the most current and relevant data. Along with our NAFTA partners, we completed residue zone maps that are based on scientifically defined common crop zones. The residue zone maps will facilitate the development of residue data for major and minor use crops as well as prevent the duplication of trials in each of the three countries, thereby reducing unnecessary testing.

The NAFTA Joint Review Program resulted in the registration of a significant number of new pesticide products in the United States and Canada. To date, the Technical Working Group has completed a total of 21 joint reviews and 7 workshares, thus facilitating access to 11 conventional and 17 reduced-risk chemicals. Canada and the United States continue to share resources and scientific expertise in reviewing data on many other pesticide products.

**Technology Gap:** Canadian grower organizations have primarily described the technology gap as the difference in access to pest management tools relative to their American counterparts. Canadian growers are at a significant competitive disadvantage, particularly as the registrations for new pesticides and uses (particularly minor uses) have not kept pace with crop diversification in Canada. It is to everyone's advantage to have Canadian growers using newer and safer technologies rather than continuing to rely on older chemistries. Re-evaluating and phasing out some older pesticides in Canada and the United States also means that newer chemistries and alternatives may not yet be available. The differences in registrations of pest control products between the two countries can be attributed to a number of factors including the smaller Canadian market size, business decisions and differences in the registration requirements between Canada and the United States.

In addition to the continued international joint reviews and work shares, the Agency explored various prospective and retrospective methods to reduce the technology gap while making regulatory decisions in accordance with Canadian legislation and in consultation with the Canadian public. These methods include developing an efficient review program in which active ingredients identified by the grower groups were reviewed with shorter time lines by making use of international reviews relevant to the Canadian use patterns, forward work planning and minor use programs.

**NAFTA Label:** Canadian and American regulators granted simultaneous approval for the first NAFTA pesticide label for Avadex MicroActiv Herbicide (Canada) and Far-GO Herbicide (United States). The expansion of products under NAFTA labels will help to strengthen competitiveness of North American growers without compromising Canada's high level standards of human health and the environment.

#### **International Treaties**

The United Nations Environment Program (UNEP) Stockholm Convention on Persistent Organic Pollutants (POPs) is an international agreement that establishes obligations aimed at restricting or eliminating global production and use of persistent organic pollutants. The PMRA supports Canada's commitments to the Stockholm Convention on Persistent organic pollutants. The Conference of the Parties held their second meeting in May 2006. Canada submitted its National Implementation Plan for the Stockholm Convention, and significant progress was made towards the development of an effectiveness evaluation for the Convention. The POP Review Committee held their second meeting in November 2006 and continued the review of five substances nominated in 2005, completing risk profiles and initiating a review of socioeconomic considerations for each substance. In addition, a further five newly nominated substances were found to meet screening criteria and will continue through the process for listing chemicals in the Convention.

The Rotterdam Convention on Prior Informed Consent (PIC) – The goal of the Rotterdam Convention is to promote shared responsibility for protecting health and the environment from potential harm through a prior informed consent procedure. Participating countries are obligated to provide information about regulatory actions and to prohibit the export of PIC chemicals when importing countries indicate that they do not want to receive shipments. The Conference of the Parties held their third meeting in October 2006. Participants, including Canada, continued to work towards a compliance mechanism for the Convention and encouraged everyone to take full advantage of the Convention's information exchange mechanisms to ensure that decisions are made on the most recent and comprehensive information available. The Chemical Review Committee met in March 2007, agreed that endosulfan and tributyl compounds met the criteria for addition to the Convention and finalized supporting documentation. A decision to add these substances to the Convention will be taken by Parties to the Convention at the next meeting.



# Section 8 People Development

The continuous learning and development of our employees is a priority for the Agency. Various training programs were offered to the employees such as management and leadership development, policy development, communications, project management, statistics, risk assessment methods, field tours of pesticide use scenarios and media training.

Our Science Development Program is in its fourth year of operation and acts as a key recruitment and retention tool. This competency-based program for biologists and chemists continued to provide structured progression within required scientific streams moving through the various biologist/chemist (BI/CH) levels. A comprehensive formative evaluation of the Program was completed and fine tuning of the program is underway. As of 31 March 2007, the Program had 160 participants with 14 graduates at the BI-03 level and 52 graduates at the BI-04 level. We have launched new recruitment processes that will provide development opportunities for current and new biologists at the PMRA.

# Appendix I Definitions for 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.

Category D includes submissions to register or amend products within particular programs, such as the Import for Manufacture and Export, Own-Use Import/Grower Requested Own-Use, Master Copy, Private Label, User Requested Minor Use Label Expansion (URMULE) and renewals.

Category E includes submissions for research permits and research notifications concerning research carried out in Canada.

## 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



#### **Atlantic Region**

1081 Main Street, P.O. Box 6088 Moncton NB E1C 8R2 Telephone: 506-851-7876

#### Manitoba Region

613 - 269 Main Street Winnipeg MB R3C 1B2 Telephone: 204-983-8662

#### **British Columbia Region**

400 - 4321 Still Creek Drive Burnaby BC V5C 6S7 Telephone: 604-666-0741

#### **Quebec Region**

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

#### Saskatchewan Region

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

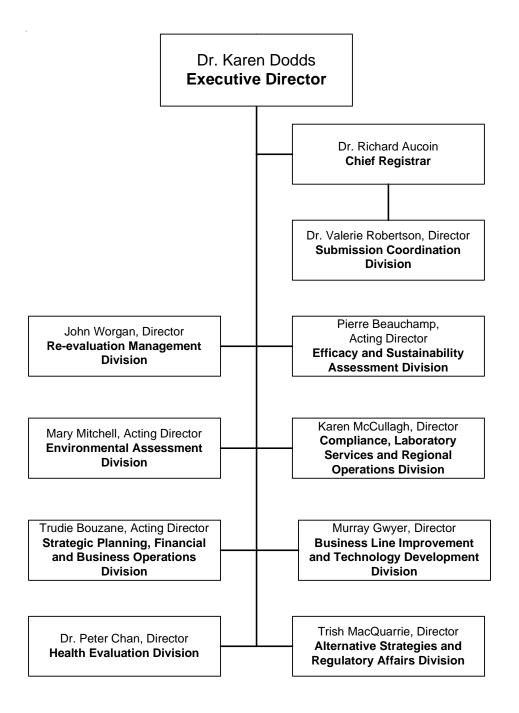
#### **Ontario Region**

174 Stone Road West Guelph ON N1G 4S9 Telephone: 519-826-2895

#### Alberta Region

220 - 4th Avenue SE Calgary AB T2G 4X3 Telephone: 403-292-4106

# Appendix III Organization of the PMRA as of 31 March 2007



# Appendix IV Index of Consultation Organizations/ Partnerships

6NR Agriculture and Agri-Food Canada, Canadian Food Inspection Agency, Environment Canada, Fisheries

and Oceans Canada, Health Canada, Natural Resources Canada

EMAC Economic Management Advisory Committee

FPT Federal/Provincial/Territorial Committee

MOU Memorandum of Understanding

NAFTA North American Free Trade Agreement

OECD Organisation of Economic Co-operation and Development

PMAC Pest Management Advisory Council

USEPA United States Environmental Protection Agency



