Pesticide Cost Recovery Pre-Proposal Notice

A Consultation Document in Advance of Parliamentary Proposal

(publié aussi en français)

12 December 2014

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Foreword

Health Canada's Pest Management Regulatory Agency was established in 1995 in response to recommendations from stakeholders to consolidate pesticide regulation into one organization. Also in response to stakeholder recommendations, we established the current pesticide regulatory fees in 1997.

While the current pesticide regulatory fees have not changed since they were put in place in 1997, the work has become more complex and global in nature. The stakeholders consulted in the development of this fee proposal recognized that we may not be able to meet their needs and expectations without additional resources.

The purpose of this pre-proposal notification is to solicit comments on our proposal to modernize regulatory charges and user fees charged for pesticide regulation. In the development of this pre-proposal notification, stakeholders were consulted on their expectations for the regulatory system. The consultation process also included the publication of the Pesticide Cost Recovery proposal document for stakeholder/public input in March 2014.

Comments stemming from the March 2014 consultation indicate that stakeholders recognize our achievements, particularly in the areas of international regulatory cooperation and our performance against published timelines for processing complex applications. However, stakeholders have concerns regarding our ability to sustain and expand international regulatory cooperation, science policy, electronic infrastructure, and outreach. International work is important both to the competitiveness of Canadian industry and trade and to gain access to the best modern science to prevent unacceptable risk from the use of pesticides. Other comments focused on the proposed fees in support of generic registration, research permits, minor use registrations, and emergency registrations. All comments relevant to the March 2014 consultation are addressed in this document and its appendices.

This pre-proposal notification provides notice, as required under the *User Fees Act* 2004 that we are proposing revised fees, and their affiliated service standards and performance measures. This document also provides you with the information on how to comment on the proposed changes and information on next steps.

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1.0 Health Canada's Pest Management Regulatory Agency

The Pest Management Regulatory Agency (PMRA) is the branch of Health Canada responsible for regulating pest control products in Canada under the federal authority of the *Pest Control Products Act* 2002. Our mandate is to prevent unacceptable risks to people and the environment from the use of these products.

The Branch was formed in 1995 by consolidating expertise and resources from several different departments. In 1997, the current Regulations[1] prescribing fees for processing applications and supporting the regulatory system were introduced. Since that time, fees have not changed while the complexity and volume of pesticide regulatory activities and costs have increased.

We are committed to protecting Canadians by applying rigorous and modern health and environmental standards and committed to meeting the needs of pesticide users and registrants. Our goal is to ensure the appropriate use of revenues from fees and other funding sources in a way that meets the needs of all stakeholders.

2.0 Objective of the Pre-Proposal Notification

This document was created to provide you with an opportunity to review the proposed new pesticide cost recovery regime, and to consider how it might affect you as a registrant, a user, a supplier or a member of the public. This document outlines the regulatory requirements for establishing and updating user fees under the *User Fees Act* 2004 (UFA) and the proposed changes to the annual regulatory charge.

This pre-proposal notification is the mechanism to provide:

- Official notice that we are proposing a revised schedule of user fees.
- The proposed service standards and performance measures.
- The opportunity for stakeholders to comment on the proposed fees, service standards and performance measures.
- Information on next steps, including independent advisory panels and how we will incorporate your comments.
- Information on our obligations under the *User Fees Act*.

3.0 Providing Your Input

The following information is required when submitting your input:

- Your full name and organization.
- Your phone number.
- Your complete mailing address or email address.

[1] Regulations Prescribing the Fees to be Paid for a Pest Control Product Application Examination Service Provided by or on behalf of Her Majesty in Right of Canada, for a Right or Privilege to Manufacture or Sell a Pest Control Product in Canada and for Establishing a Maximum Residue Limit in Relation to a Pest Control Product (SOR/97-173) (http://laws-lois.justice.gc.ca/eng/regulations/SOR-97-173/page-1.html)

When submitting your input, please include:

- How this proposal might affect your interests, or those of the group you represent.
- Whether you are in support of:
    - The proposed rationale for application fees and annual regulatory charge changes.
    - The approach to determining application fees and the annual regulatory charge.
    - Relevance of international comparisons.
    - Criteria for application fees and annual regulatory charge mitigation.
    - Implementation of all new fees on publication of the regulations.
    - Relative allocation of priorities.
- How any of your concerns may be addressed.
- Any additional relevant information.

Input must be received between 12 December 2014 and 27 January 2015 to be considered within this process.

The deadline for input is midnight on 27 January 2015 and may be submitted electronically to cr_rc_pesticide@hc-sc.gc.ca or by post mail to:

Pesticide Cost Recovery
Health Canada, PMRA
Sir Charles Tupper Building
2720 Riverside Drive A.L. 6607D
Ottawa, ON K1A 0K9

3.1 What Happens When Your Input Is Received?

We will study your input while considering:

- Other stakeholder input on the same subject.
- Legal or policy implications of your proposals, if applicable.
- The cost of your proposals, as well as the source of funding, if applicable.
- Consistency with broader Government of Canada policies and priorities.

You will receive a written response from us before the end of the 30-day response and resolution period, which ends 26 February 2015. It will explain our position on the subject, and the rationale behind this position.

Our goal is to provide a response that you find satisfactory. However, if you feel that your complaint is not resolved to your satisfaction, you have the option of requesting that it be examined by an independent advisory panel.

To ensure an open and transparent process, your input will be summarized in a report available to the public. If you have submitted input as an individual and do not represent a business, group or organization, your name will be protected pursuant to the *Access to Information Act* 1985 and the *Privacy Act* 1985.

3.2 Independent Advisory Panels

If you believe that your complaint was not resolved you may ask that it be reviewed by an independent advisory panel. This is a higher-level resolution mechanism.

If an independent advisory panel is requested, its mandate is to provide an independent review of your complaint, as well as non-binding recommendations for its resolution. The panel consists of three members. You and Health Canada will each choose one panel member following certain guidelines. Then, the two panel members will select a neutral third member.

Independent advisory panels, if any, must be established no later than 9 March 2015. If you wish to request an independent advisory panel, submit to PMRA the reasons for which you feel the response you received from us was unsatisfactory. We will then contact you to provide you with more information on this process, including guidelines on how to select your panel member.

In accordance with the *User Fees Act*, we may group multiple complaints into one panel for reasons of economy or efficiency. In this case, a majority vote among the complainants will determine the panel member who will represent them.

The panel proceedings begin once all members have been selected. From this point, a maximum of 30 days is allotted for the panel to review the complaint and report its findings and would be considered complete when its final recommendations are received by Health Canada, or if you withdraw your complaint from the process. We will communicate the panel's recommendations to you at the end of the proceedings.

Please note that if, as per section 4.1 of the *User Fees Act*, in the opinion of the panel, your complaint is frivolous or vexatious, the complainant bears all the costs. The costs payable by the complainant become a debt due to Her Majesty and may be recovered as such in any court of competent jurisdiction.

3.3 Taking Your Input into Account

All input received, whether or not it is studied by a panel, will be documented and noted in our user fees proposal tabled in both Houses of Parliament.

3.4 Next Steps after the Pre-Proposal Notification

Following the conclusion of the official complaint period and any recommendations by an independent advisory panel, we will move forward with a formal proposal to change our user fees. The formal proposal will take stakeholders' input and any panel recommendations, if any, into consideration.

The projected next steps are:

- The Minister of Health tables the user fees proposal in the House of Commons and the Senate. This is a requirement of the *User Fees Act*, which also establishes that a Committee report recommending approval, rejection or amendment of the proposal be submitted within 20 sitting days.
- Stakeholders will have an opportunity to comment on the new fee schedule proposal when it appears in the *Canada Gazette*, Part I.
- After any necessary adjustments, begin implementation of the new fees through the *Canada Gazette*, Part II, as early as April 2016.

4.0 Introduction

The proposed fees and new cost recovery regime for pesticide regulation will better reflect current costs and help address priorities of both government and stakeholders. This modernized cost recovery regime will help us meet the needs of all Canadians through a pesticide regulatory system that continues to prevent unacceptable risks to human health and the environment and is modern, efficient and economically sustainable.

A modernized cost recovery regime would:

- Better reflect costs that have been affected by changing regulatory processes and inflation since 1997.
- Fulfil the requirements of the *User Fees Act* and to better align with relevant Government of Canada policies and guidelines, which have evolved since the current fees were established.
- Provide for appropriate fee mitigation, including removing exemptions that may no longer be justified.
- Better reflect the needs of all stakeholders such as strengthening health and environmental protection, and contributing to Canadian economic goals.

This pre-proposal notification document outlines in detail our proposed new cost recovery regime, including proposed application fees, the annual regulatory charge, performance timelines and our response to stakeholder comments received through previous consultation processes.

5.0 Legal and Policy Requirements

5.1 The *Financial Administration Act* 1985

The *Financial Administration Act* 1985 provides a statutory foundation for financial management activities undertaken by the Government of Canada. The government may establish fees or charges through regulation or by authorizing an appropriate Minister to do so via an order.

The current fee regulations for pest control products were made, in part, under the authority of the *Financial Administration Act* 1985.

5.2 The *Pest Control Products Act* 2002

The *Pest Control Products Act* 2002 contains a broad authority to make regulations respecting fees and charges in relation to the administration of the Act or the Regulations.

5.3 The *User Fees Act* 2004

The *User Fees Act* 2004 establishes specific requirements that federal regulating authorities must meet before fixing or increasing user fees.[2]

Under the *User Fees Act*, departments like Health Canada are required, among other things, to:

- Consult with stakeholders on the proposal and explain how the user fees are determined.
    - Conduct an impact assessment.
    - Establish an independent advisory panel to address complaints on the proposed user fees (if required).
    - Establish standards comparable to those established by other countries with which a comparison is relevant and against which the performance of the regulating authority can be measured.
    - Table, through their responsible Minister, a user fee proposal in each House of Parliament. Although not expressly required, the proposal should inform Parliament as to the department's compliance with the requirements set out above.
    - Provide detailed information on service descriptions, reasons for fee changes and how it compares to international levels, service standards, three year revenue and cost forecasts, how an independent advisory panel may be established and the complaints resolution process.

Under the *User Fees Act*, service standards must be published with other information in an annual report tabled before each House.

[2] "User fee" in the *User Fees Act* (http://laws-lois.justice.gc.ca/eng/acts/U-3.7/) is defined as a fee, charge or levy for a product, regulatory process, authorization, permit or licence, facility, or for a service that is provided only by a regulating authority, that is fixed pursuant to the authority of an Act of Parliament and which results in a direct benefit or advantage to the person paying the fee.

Further, pursuant to Section 5.1, where a regulating authority's performance in a particular fiscal year in respect of a user fee does not meet the standards established by it for that fiscal year by a percentage greater than ten per cent, the user fee shall be reduced by a percentage equivalent to the unachieved performance, to a maximum of fifty per cent of the user fee. The reduced user fee applies from the day on which the annual report for the fiscal year is tabled under subsection 7(1) of the *User Fees Act* until the day on which the next annual report is tabled.

New or increased user fees for pest control products would be subject to the requirements of the *User Fees Act*.

5.4 Treasury Board Policy on Service Standards for External Fees

The 2012 Treasury Board Policy on Service Standards for External Fees supports the *User Fees Act* in relation to service standards. The policy states that the provision of services external to the federal government, for which fees are collected, must have service standards that are measurable and relevant at the level of the paying stakeholder. These service standards must be developed in consultation with paying and non-paying stakeholders, and the service standards and consultation feedback must be reported to Parliament annually. Departments must have an auditable monitoring system in place to ensure that fee related activities are subject to audit.

Current service standards were made available for consultation in 2010 and are reflected in DIR2013-01, *Revised Management of Submission Policy*[3] (MoSP). Performance against service standards is included in the annual report to Parliament required by the *Pest Control Products Act* 2002 and is discussed with stakeholders twice a year during meetings of PMRA's Economic Management Advisory Committee.

5.5 Treasury Board Costing Guidelines

The 2008 Treasury Board *Guide to Costing* provides guidance for costing activities, including those to be cost recovered through fees. The guide indicates that the context of the costing should be considered carefully, including considerations of what other funding mechanisms are available, how common services are funded and how other indirect costs (for example, such as regional program costs, employee benefits and services provided without charge by other government departments) should be considered in a costing exercise.

The approach to activity based costing described more fully in later sections of this document is consistent with the Treasury Board *Guide to Costing*.

[3] Regulatory Directive 2013-01, *Revised Management of Submissions Policy* (http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir2013-01/index-eng.php)

5.6 Treasury Board Policy on Special Revenue Spending Authorities

The current July 2000 Treasury Board Policy on Special Revenue Spending Authorities guides departments seeking Parliamentary authority to use a certain portion of their revenues to finance their directly related expenditures. Some of the requirements of the policy include ensuring that:

- The expenses incurred to produce goods and services are directly related to the revenue produced through the sale of these goods and services. Revenues are spent on intended uses and there is no cross-subsidization;
- Authority would need to be sought for the program to re-spend revenues which would otherwise remain in the Consolidated Revenue Fund.[4] Additionally approval would be required to maintain existing government funding for the program; and,
- The objectives and activities of the unit, the conditions, as well as the commitments of the department governing the use of the mechanism are clearly described.

The current level of revenue is based on cost-sharing established when fees were implemented in 1997, and no longer reflects the current regulatory processes or workload.

6.0 Pesticide Regulation and the Current Cost Recovery System

6.1 Regulatory Activities

Much like the approach in other Organisation for Economic Co-operation and Development (OECD) countries, the Canadian pesticide regulatory system consists of pre-market assessments, post market re-evaluations, and compliance and enforcement activities. This system is supported by an electronic environment that simplifies the process for applications, manages the submission of those applications, and facilitates transparency. The electronic environment facilitates public access to relevant information and public participation in the decision-making process.

[4] Consolidated Revenue Fund: the account into which the government deposits taxes, tariffs, excises and other revenues, once collected, and from which it withdraws the money it requires to cover its expenditures. Parliament of Canada, House of Commons Procedure and Practice, Financial Procedures (http://www.parl.gc.ca/marleaumontpetit/DocumentViewer.aspx?Sec=Ch18&Seq=1&Language=E)

6.1.1 Registration of New Products

Before a pesticide can be sold in Canada, pesticide registrants are required to provide us with sufficient data to show that their product does not pose unacceptable risks to health and the environment and that the product has value. These data are thoroughly reviewed by our scientists before the product is accepted for registration in Canada. Our value assessment considers the product's actual or potential contribution to pest management, whereas our science-based risk assessment includes the following:

- Health and environmental risk assessments that consider the potential for a pesticide to cause adverse effects.
- An examination of all sources and routes (oral, dermal, inhalation) of potential human exposure to a given pesticide, including exposure through diet, from drinking water and from contact with treated areas like lawns and gardens.
- A human health risk assessment that considers risk to all potentially exposed sensitive subpopulations, including infants, children and pregnant women.
- An environmental risk assessment that considers fate in the environment and potential risks to plants, birds, mammals, beneficial insects and aquatic organisms.

Pesticide regulation is becoming an increasingly global collaboration, yielding benefits such as access to the best science available, same-time access to new technologies for Canadian users, and efficiencies for industry. To effectively participate in global collaboration, including global joint reviews, our science needs to be up-to-date and on par with regulatory partners.

Pesticide regulatory applications have continued to increase in size since 1997 from an average of 2000 pages to over 8000 pages. Contributing factors to this increase include registrants introducing new pesticides for a larger number of end uses within one application, developments in science, and combining multiple registration amendments (for example, changes to formulations, expansions of uses and label clarifications) into a single application.

The data required for registration depends on the nature of the product (for example, a chemical, a microbe, or a device); the purpose of the application (for example, full registration of a new product, or specification of an import maximum residue limit); and, the type of use (for example, industrial, forestry, agriculture, or domestic use).

6.1.2 Specification of Maximum Residue Limits

For pesticides that are used on imported or domestically produced foods, we specify the maximum amount of pesticide residue permitted to remain in or on any raw agricultural food commodity as well as to any processed food product that contains it. This is known as the maximum residue limit (MRL). The MRLs for each pesticide-crop combination are set at levels well below the amount that could pose a health concern.

6.1.3 Re-evaluation of Older Pesticide Products

The *Pest Control Products Act* requires that pesticides undergo a re-evaluation every 15 years so that registered products continue to meet evolving scientific requirements. Re-evaluation involves a review of pesticide active ingredients and their associated uses on the basis of updated science and data to determine whether, and under what conditions, their continued registration is acceptable. Pesticide incident reports can also provide valuable information that is taken into account during a product's re-evaluation.

Our re-evaluation program also involves collaboration with international partners to share work and address emerging health and environmental issues.

6.1.4 Compliance and Enforcement

We help protect the health of Canadians and their environment by facilitating, encouraging and maximizing compliance with the *Pest Control Products Act*. Compliance activities, conducted in collaboration with federal and provincial partners, include compliance promotion and monitoring inspection programs. When contraventions of the *Pest Control Products Act* occur, appropriate enforcement measures are taken.

Compliance programs may target users, distributors, registrants, manufacturers and formulators. Enforcement responses are carried out by regional pesticide compliance teams and can include denial of entry at the border, seizure and detention, notices of compliance, administrative monetary penalties and prosecutions.

6.2 Current Application Fees

The April 1997 Guidance Document on Pest Control Product Cost Recovery Fees describes the current fee structure and how it applies. For most types of applications, the fees are determined by the data requirements associated with the application. The scientific data requirements are determined by the nature of the pesticide, the purpose of the application, and the proposed use. A fee is charged for each type of scientific review required (for example, chemistry, toxicology or environmental fate).

If an application relies on previously assessed data, there would be no charge to applicants for the review of that data, although there are still some costs incurred by Health Canada. Applications to register products containing new active ingredients may also be eligible for reduced fees if the anticipated revenue from sales within the first three years is less than 10 times the calculated application fee. For other applications (in other words, those in Schedule II of the Regulations) a fixed or flat fee is charged.

As outlined in Appendix I, some pesticide products are currently exempt from application fees (other than the label review fee). These include, but are not limited to microbials and pheromones, food grade active ingredients, certain essential oils and minor use applications made under the User Requested Minor Use Label Expansion (URMULE) program.

6.3 Current Annual Regulatory Charge

Registrants are required to pay an annual regulatory charge (previously referred to as maintenance fees) in respect of each registered pest control product. The regulatory charge is set at the lower of $2,690 or three 3 per cent of annual sales of the pest control product, with a minimum fee of $75.

6.4 Current Performance Standards

The MoSP sets out the process for managing applications to register or amend the registration of pest control products. It also provides performance timelines for the review of applications as summarized in Appendix II. Recent updates refined the application submission processes, identified changes to the measurement of performance, and consolidated performance standards and timelines for all categories. The amendments reflect an application submission management process that is more efficient, effective, and predictable for applicants/registrants and Health Canada.

In general, applications follow the MoSP examination process outlined below:

- Completeness Check (Verification and Screening).
- Review Stage (Science Evaluation, Label Review and Decision).
- Public Consultation (applicable for new active ingredients and major new uses only).

The performance timeline associated with each step in the process varies according to category. For example, applications for new active ingredients or major new use expansions require significantly more review time than applications for amendments of registrations or registration of additional end-use products due to the extensiveness of the data package and level of review. Within each category there are further subdivisions that may have shorter performance timelines because they are conducted under specific programs (for example, joint reviews). The performance standard, as outlined in the MoSP, is to process 90 per cent of applications in all categories within the applicable review timelines.

7.0 Proposed User Fees and Annual Regulatory Charge

7.1 Principles for the New Cost Recovery Regime

A key objective with new fees is to establish a cost-sharing balance that would be acceptable to both government and fee payers, and provide adequate support for the regulatory system without unduly affecting the Canadian pesticide market or users.

In determining how user fees and regulatory charges should be applied under a renewed cost recovery regime, several key considerations were used in order to guide the development of this proposal:

- Any new application fee must be consistent with all relevant legislative authorities and policies guiding the establishment of user fees;
- Amendments to the current cost recovery regime should be minimized – early feedback from stakeholders indicated support for the current structure for fees (for example, fees based on application components rather than application types) and regulatory charges;
- Application fees and the annual regulatory charge should not exceed comparable fees and charges set by major trading partners to reflect Canada's relatively smaller market size and share; and,
- Mechanisms should be explored to adjust fees annually, based on economic indices, to provide more predictability for business planning purposes.

A range of important considerations were also taken into account in arriving at a new cost recovery regime, such as the public/private share of costs, potential impacts on small/medium-sized businesses, and impacts of user fees and annual regulatory charges on pesticide product prices. Appendix III provides examples of the cost of a few typical types of applications with the proposed fees.

7.2 International Comparison

Various countries with advanced pesticide regulatory systems collect fees, charges or levies. Following an analysis that identified relevant comparator jurisdictions, the United States Environmental Protection Agency (USEPA); United Kingdom Chemicals Regulation Directorate of the Health and Safety Executive (UK CRD); and the Australian Pesticides and Veterinary Medicines Authority (APVMA) were identified as comparable to Health Canada with respect to the level of scientific rigor regarding the pre-market application review processes, data requirements for registration and reviews, as well as similarities in the types of regulatory services offered.

Each jurisdiction has a similar fee paying clientele. By percentage of market share, most companies are multinationals that market/manufacture in all four countries. The balance of clients tends to be small- to medium-sized enterprises that have developed a niche product for a particular market.

There are variations in the rationale for charging fees, charges or levies and differences in the political, financial and business contexts that are unique to each jurisdiction. Additionally, there are varying market sizes, price modulation processes and market access issues between jurisdictions.

We propose that the USEPA pesticide fee structure serve as the primary international benchmark for developing new Canadian fees because the United States is our largest trading partner and our regulatory systems are closely aligned as demonstrated by the number of joint activities Canada and the United States undertake.

In addition to a comparison between proposed fees and equivalent USEPA fees for similar applications, our analysis includes comparisons in the following areas:

1. Fees for data compensation assessments.
2. Fees for import MRLs.
3. Fees for microbial and semiochemical pesticide applications.
4. Fees for notifications.
5. Fees for post-market fees and annual increases.
6. Exemptions, reductions, and refunds.

Overall, we note that while all four countries share similar regulatory processes in general, each country follows a distinct approach for recovering costs from applicants and registrants, and that we share the most commonalities with the USEPA. Given the latter, we acknowledge that most of our stakeholders have a keen interest in ensuring that our proposal is not out of step with the USEPA given that many registrants are active in both countries and benefit from the long history of regulatory cooperation between Canada and the United States (US). While there are certain areas that are different due to domestic characteristics, such as legislation, most of the fees proposed by HC are reasonably in line, if not lower, than fees currently charged by the USEPA. For more details of this analysis please see Appendix IV.

7.3 Application Fees

7.3.1 Approach for Determining Application Review Costs

An activity-based costing approach was used to identify the resources that are required to support each service or activity related to application examination services. The activity-based costing approach focuses on developing full costs consistent with Treasury Board guidance.

Costs were calculated using internal time tracking data collected through electronic systems and salary costs, for an 18-month period ending 31 December 2011. Full costing includes program support, program management, and corporate and administrative costs that support the examination services.

In addition, new cost projections to account for process changes since 2011 and stakeholder comments from the March 2014 consultation were conducted for generic pesticides, accelerated timelines for precedent based registrations and label amendments, the new notification/non notification policy and for value and effectiveness data (new approach implemented, costing to be quantified).

The outcomes of these exercises are included in Tables 1, 2, and 3 as the average cost to Health Canada for reviewing specific components of an application for the registration of a pest control product (Table 1), or other applications (Table 2 and Table 3).

7.3.2 Proposed Application Fees

The 1997 fee regulations had two fee schedules. Schedule I was for applications for issuance or amendment of a certificate of registration of a pest control product, and Schedule II was for other applications in relation to a pest control product. We propose to update these fee schedules, and to add a third schedule to establish fees for microbial and semiochemical pest control products.

In some cases, costs have increased due to greater application complexity and higher business costs. In other cases, efficiencies and changes in approach have contributed to decreased costs. This proposal establishes most fees at approximately 30 per cent of costs of individual review activities.

The proposed fees are listed in Tables 1, 2 and 3 below. Details are also provided where fees deviate from the 30 per cent level of cost recovery, represent a new approach from the 1997 fees, or require other explanation of rationale or change in fee as a result of stakeholder comments.

The proposed user fees are premised on current MoSP timeframes as summarized in Appendix II, unless otherwise noted.

Table 1 Application for Issuance or Amendment of a Certificate of Registration of a Pest Control Product

Item	Component	Proposed Fee	Current Fee	Average Cost to Health Canada
1	Basic application fee (label review and / or processing)	$1,133	$262	$3,777
2	Product chemistry – active ingredient	$4,873	$1,172	$16,244
3	Product chemistry – end-use product or manufacturing concentrate	$2,713	$1,172	$9,042
4a	Toxicology data accompanying an application for the registration of a pest control product consisting of, or containing a new active ingredient	$75,807	$98,248	$252,690
4b	Toxicology data accompanying a Category A application for a major new use of a registered pest control product or a Category B application	$15,830	$35,456	$52,768
4c	Toxicology data – Applications with acute studies only	$2,954	$4,274	$9,847

Item	Component	Proposed Fee	Current Fee	Average Cost to Health Canada
5a	Exposure data accompanying an application for the registration of a pest control product containing a new active ingredient	$17,498	$24,384	$58,325
5b	Exposure data accompanying an application for a major new use of a registered pest control product	$5,758	$24,384	$19,192
5c	Exposure data – other	$5,214	$9,742	$17,380
6	Metabolism data	$28,943	$6,034	$96,475
7	Residue data	$15,838	$8,448	$52,794
8a	Environmental fate data accompanying an application for the registration of a pest control product consisting of, or containing a new active ingredient	$42,685	$26,953	$142,284
8b	Environmental fate data accompanying an application for a major new use of a registered pest control product	$23,637	$26,953	$78,790
8c	Environmental fate data – other	$11,546	$6,738	$38,488
9a	Environmental toxicology data accompanying an application for the registration of a pest control product consisting of, or containing a new active ingredient	$37,277	$14,882	$124,257
9b	Environmental toxicology data accompanying an application for a major new use of a registered pest control product	$23,690	$14,882	$78,966
9c	Environmental toxicology data – other	$2,465	$3,720	$8,216
10	Value and effectiveness data for a pest control product	$906	$906	$35,042
11	Compensable data	$2,162	-	$ 6,486

Explanatory Notes:
General – Fees for issuance or amendment of a certificate of registration of a pest control product may be based on one or several of the components listed in this table. For examples of total fees for different types of applications please refer to Appendix III.

Item 1 – Basic application fee: Activities covered by this component are being expanded to cover processing activities as well as label review. Furthermore, costs across product types are similar enough to justify a single fee rather than three separate fees, as listed in the current Regulations. This includes work such as setting-up applications within our internal tracking system (e-PRS), coordination and management of applications through the review process, label and/or statement of product specifications form reviews, fee assessments, including fee reduction requests, preparation of decision letters and/or correspondence with applicants.

Item 10 – Value and effectiveness data for a pest control product: Since we have recently changed our approach to assessing value, and costs for this new approach have not been quantified, we propose to maintain the existing fee at this time. Any future changes to this fee will involve stakeholder consultation.

Item 11 – Compensable data (generation of a compensable data list): The compensable data assessment is a component of an application for a pesticide subject to the data protection provisions of the Pest Control Products Regulations. This is an activity for which a fee does not currently exist.

The PMRA has reconsidered this fee and through further discussions, consultation and development of this process, we propose to reduce the fee to $2,162 with a timeline of 365 days from the previously proposed $21,617 and 120 day timeline. This marks a considerable fee reduction and aligns with the timelines of other applications having similar data requirements. The fee is directly related to the average cost required by Health Canada to conduct a data compensation assessment within 365 days.

In addition, PMRA is committed to developing a generic on-line data base. This tool will ensure that greater information is shared with stakeholders. Upon its completion, the time required for the data compensation assessment will be less than it is currently. This will be considered in future re-assessments of the application fees.

The fee component is proposed to be charged for each application to which it relates.

Table 2 Other Applications in Relation to a Pest Control Product

Item	Activity	Proposed Fee	Current Fee	Average Cost to Health Canada
1	Renewal of certificate of registration	$80	$154	$268
2a	Research authorization - Major Crops	$5,080	$150	$16,932
2b	Research authorization - Minor use crops (except greenhouse uses)	$5,080	$150	$16,932
2c	Research authorization - Microbials/ semiochemicals/non-conventional products	$1,217	$150	$16,932
2d	Research authorization - Greenhouse crops and non-agricultural uses (in other words: domestic/residential areas, industrial premises, food handling areas, structural pest control, forest and aquatic uses)	$1,217	$150	$16,932
3	Processing research notification	$247	$0	$1,841
4a	Review of a manufacture for export application	$7,827	$4,601	$25,948

Item	Activity	Proposed Fee	Current Fee	Average Cost to Health Canada
4b	Review of an application to amend a manufacture for export registration	$1,133	$154	$7,498
5a	Specification of maximum residue limit for a previously unassessed pest control product	$125,461	$8,448	$259,520
5b	Specification of maximum residue limit for an unregistered use of a previously assessed pest control product	$15,838	$8,448	$58,113
6	Processing of notification	$247	$0	$825

Explanatory Notes

Item 1 – Renewal of certificate of registration: Procedures related to the renewal of a certificate of registration have changed since the costing analysis was completed. The proposed fee is based on updated estimated costs for processing following the implementation of efficiency measures.

Items 2a, 2b, 2c and 2d Research Authorizations

General Note:

Fees for research notifications and authorizations have been separated, given differences in average costs between these activities (an explanation of the specific revisions is provided below).

Based on stakeholder feedback, we have revised the proposed fee for some research authorizations and provided additional clarification. With the goal of fostering innovation, we revised the fees based on consideration of similar USEPA fees.

Research Authorizations are not normally required for studies conducted to support minor use registrations as the studies are usually less than five hectares and would normally fall under the research exemption[5] or research notification criteria (with the exception of operational/demonstration trials and research in greenhouses as described in Item 2d below).

Pursuant to paragraph 19 (3)(a) of the *Financial Administration Act* 1985, applications, including those for research authorizations and notifications, received from other federal departments are exempt from fees.

[5] Health Canada, PMRA. Overview of Requirements for Research Involving a Chemical Active Ingredient. (http://www.hc-sc.gc.ca/cps-spc/pest/registrant-titulaire/res-rech/guidance-exigences-chem-eng.php)

Revisions

Items 2b – Research authorization - Minor use crops (except greenhouse uses). This fee would be required only in limited circumstances as the size of trials needed to support a minor

use registration would normally fall under a research exemption or the research notification criteria.

Item 2c - Research authorization – Microbials/semiochemicals/non-conventional products. In order to continue to support low-volume, niche products and non-conventional products, the proposed fee would be comparable to the USEPA PRIA (*Pesticide Registration Improvement Extension Act* 2012) fee for Experimental Use Permit for Biopesticides (Straight Chain Lepidopteran Pheromones).

Item 2d - Research authorization - Greenhouse crops and Non-Agricultural Uses (in other words: domestic/residential areas, industrial premises, food handling areas, structural pest control, forest and aquatic uses). Research in these particular areas does not qualify for a fee exemption or for the research notifications fee. To support research in these minor uses which are typically submitted by smaller companies, PMRA proposes that the fee for research in these areas be reduced and aligned with the new proposal for Item 2c, based on the number of these types of submissions from small companies.

Item 3 – Processing research notification: This fee has been reduced to align with other notification fees.

Item 4a – Review of a manufacture for export application: Fees for manufacture for export registrations are based on relevant component costs from Table 1 (Items 1, 5b, and 10) to reflect more robust data used for the component based costs.

Item 4b – Review of an application to amend a manufacture for export registration: The activities associated with this type of amendment are similar to the basic application fee, and therefore set at the same level.

Items 5a – Specification of maximum residue limit for a previously unassessed pest control product and **5b – Specification of maximum residue limit for an unregistered use of a previously assessed pest control product:** Fees related to MRLs have been divided to better reflect the higher level of work required for previously unassessed active ingredients. Fees are now proposed to be based on all relevant component costs from Table 1 (basic application fee, chemistry, metabolism, human acute and chronic toxicology, and residue data) to reflect more robust data required for the application – currently only the residue data fee is charged for a previously assessed active ingredient.

Under the current cost recovery framework, MRLs for new active ingredients and previously registered ones are charged a fee of $8,448; however, this does not reflect the amount of work that is actually required to review these applications.

Following an examination of all import MRL applications received since 1996/1997, it was found that about half of the applications for previously registered pesticides eventually resulted in a domestic registration if they did not already come packaged in a Joint Review.

There is no economic rationale for not recovering a greater portion of the costs associated with the review effort required. The proposed fees take into account the fee components that comprise an import MRL review, and are significantly lower than the equivalent USEPA fee for an import tolerance (please see Section 7.2 and Appendix IV - International Comparison for additional details).

Item 6 – Processing of notification: As a result of the PMRA's experience with the new notifications/non notifications policy the fee for processing notifications has been reduced to $247 from the previously consulted proposed fee of $377. This amendment to the proposed fee is directly related to the average level of effort required by the PMRA to process a notification under the new Notifications program. The proposed fee reflects the fact that the Notifications program includes application types that are administrative in nature as well as those which require a label and/or statement of product specifications form (SPSF) review and database updates. Consistent with the current practice, multiple notifications may be submitted together and would be charged as a single application.

Table 3 Application for Issuance or Amendment of a Certificate of Registration of a Microbial or Semiochemical Pest Control Product

Item	Registration Decision	Proposed Fee	Current Fee	Average Cost to Health Canada
Microbials and semiochemicals (excluding straight chain lepidopteran pheromones):				
1	Registration of a new active ingredient; food use	$7,236	$262	$197,844
2	Registration of a new active ingredient; non-food use	$4,341	$262	$213,783
3	Amendment of registration – major new use	$2,894	$262	$176,897
4	Amendment of registration – new use	$1,447	$262	$107,983
5	Amendment of registration – new product or source of active ingredient	$1,158	$262	$79,369
6	Conversion from conditional registration to full registration	$1,158	$262	$7,990
7	Amendment of registration – no data required	$290	$154	$7,207
Straight chain lepidopteran pheromones:				
8	Registration of a new active ingredient	$579	$262	$39,239
9	Amendment of registration	$290	$262	$85,982

Explanatory Notes
In 1997, a lack of experience with assessing microbial and semiochemical pesticide applications led us to conclude that establishing user fees for data review was premature (only a label review fee is currently charged). Since that time, we gained considerable experience with these products, and included these activities in the costing exercise. These fees also take into account the continued need to encourage their registration in Canada, given their generally lower risk profile.

It is understood that for some of the fees/charges in Table 3, the percentage increase seems high, largely because these applications are no longer exempt; however the actual fee for these applications is very low compared to the cost to Health Canada.

Registrants are proposed to be charged on average three per cent of the cost to Health Canada, in other words, the Government would be subsidizing applications by 97 per cent.

In establishing these fees, we took into account the USEPA fee for similar activities and the fee mitigation available to American applicants. Given that many American applications for these types of products would be expected to apply for the maximum fee reduction (based on company size), and in order to facilitate their registration in Canada, the Canadian fees are proposed at a level equal to the minimum USEPA fee. No additional fee mitigation would be applied.

7.3.3 Basic Application Fee

The fee payable for the examination by the Minister of an application for amendment of a certificate of registration that does not include a component set out in Table 1 or an application referred to in Table 2 or 3 is proposed to be raised from $150 to $1,133, which represents approximately 30 per cent of costs ($3,990).

7.3.4 Mitigation for Application Fees

Fee mitigation offered by Health Canada was designed to facilitate access to the Canadian market for low-volume, niche products and to support small business in Canada. Application fees can be mitigated to not exceed 10 per cent of annual sales of the product(s) registered with a new active ingredient(s) during the first three years of registration. The fees payable under Table 1 cannot be reduced below 10 per cent of the total fee.

The USEPA also has a fee mitigation program but it applies to all application fees not just new active ingredients. In addition, the size of the enterprise, which takes into account both total global pesticide sales and number of employees, determines the possible percentage discount – from 50 to 75 per cent.

It is proposed that fee mitigation for the registration of new pest control products subject to fees listed in Table 1 will remain unchanged.

Fee mitigation is not proposed for other applications in relation to a pest control product (Table 2) consistent with the current Regulations. Since the March 2014 proposal, fees for some research applications, processing research notification and processing other applications have been reduced.

Should the PMRA revise the fee mitigation policy in the future, we will consider all relevant stakeholder comments and suggestions at that time. The current policy has evolved based on the needs of Canadian registrants and the Canadian regulatory system. Although applied slightly differently when compared to the USEPA, the main objective still applies, which is to facilitate access to the Canadian market for low-volume, niche products and to support small business in Canada.

7.3.5 Exemption from Application Fees

Currently, there are several types of applications to which the fee regulations do not apply. These exemptions are proposed to continue in the following cases:

- User-requested minor use label expansions funded through the Growing Forward 2 - Minor Use Program (however, the basic application fee would apply when registrants amend the label to add the new use).
- All requests under the Grower Requested Own Use (GROU) Program.
- Organisms (other than microbials) and substances that do not fall within the definition of "agricultural chemical" in the Food and Drug Regulations, except for the basic application fee and any item in Table 2.

We are proposing the following changes:

- Microbials would be subject to fees described in Table 3; and, naturally occurring semiochemical or identical synthetic substances that affect the behaviour of arthropoda would be subject to fees described in Table 3 (including naturally occurring substances used as personal insect repellents, essential oils and arthropod pheromones.)

7.3.6 Annual Fee Adjustment

Although there were a few stakeholder comments on the proposed approach presented in the March 2014 Consultation Document, no stakeholder objected to a predictable and incremental annual increase to fees or to the percentage increase. There was consensus from stakeholders that this was preferred over a large increase at irregular intervals. To reflect those comments, we have clarified the process for annual fee increases.

Annual fee adjustments are consistent with other international pesticide jurisdictions which make adjustments to their fees to reflect changing costs and workload. For example, the USEPA increases pesticide application fees by 5 per cent every second year.[6]

[6] United States Environmental Protection Agency, Pesticide Registration Manual, Registration Fees (http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees)

Also consistent with other policies already in place at Health Canada, we are proposing a flat percentage increase of two per cent based on a five-year weighted average of public service wage adjustments[7] and the Core Consumer Price Index - Weighted Index[8] (CPI).

The annual adjustment will remain stable for a three-year period and is not proposed to be applied until after the new fee regulations are in effect. A notification will be provided in the *Canada Gazette*, Part II annually with the revised application fees (Tables 1–3).

After three years, we will review costs and may propose new or amended fees.

7.4 Annual Regulatory Charge

7.4.1 Proposed Annual Regulatory Charge

The current annual regulatory charge is $2690 and is applied to each registered pest control product in Canada. The regulatory charge is used to offset the portion of regulatory costs which are not associated with application review. The proposed annual regulatory charge is necessary to ensure that registered products continue to meet evolving scientific requirements and are adequately regulated throughout their lifecycle.

The idea of an annual post market fee or regulatory charge is not unique to Canada. Both the United Kingdom and Australia apply annual charges in combination with annual levies based on a percentage of product sales for each registered pest control product. The USEPA charges each registrant an annual maintenance fee which is calculated by applying a per product charge to a maximum fee based on company size. The USEPA charge per registered product is adjusted annually to achieve predetermined revenue targets.

Our current approach for applying an annual regulatory charge is not proposed to change, however we are proposing to increase the charge by roughly one third to $3600 per product per year. This proposed increase was calculated based on applying a cost of living increase to the current fee.

7.4.2 Mitigation for the Annual Regulatory Charge

Similar to the mitigation for application fees, the annual regulatory charge can also be reduced recognizing there are a number of products registered for niche markets with low sales. Current mitigation allows for the regulatory charge to be reduced so that it does not exceed three per cent of the previous year's sales to a minimum of $75.

[7] Human Resources and Skills Development Canada, Average annual percentage wage adjustments by year (http://www.hrsdc.gc.ca/eng/labour/labour_relations/info_analysis/datas/wages/wage_adjustments_year.shtml)

[8] Bank of Canada, Consumer Price Index, 2000 to present (http://www.bankofcanada.ca/rates/price-indexes/cpi/)

The current mitigation system is used extensively, with only 23 per cent of registered products selling over $90,000 per year and therefore paying the full fee. Another 21 per cent of registered products have annual sales between $2500 and $90,000 and are therefore paying the equivalent of three per cent of sales. This leaves 56 per cent of registered products selling less than $2500 per year and paying the minimum fee.

The USEPA did not establish a mitigation program to address products with low sales, choosing instead to place a lower cap on the total value of regulatory charges that a small company would be required to pay.

Based on stakeholder input, we are proposing that the annual regulatory charge not exceed four per cent of sales and to increase the current minimum regulatory charge only slightly to $100. This increase approximates a cost of living increase since the charge was last updated. This mitigation would be expected to continue to support niche products and small businesses in Canada.

7.5 Projected Revenues

Table 4 outlines revenues averaged over eight fiscal years based on the current cost recovery fees and the forecasted revenues using the proposed cost recovery regime and the annual adjustment (for application fees only).

Table 4 Projected Revenues (Millions of Dollars)

Revenue Sources	Current Average Revenues	Projected Revenues – New Fees				
		Year 1	Year 2	Year 3	Year 4	Year 5
			Based on estimated annual increase of 2%			
Application Fees	3.6	6.3	6.4	6.6	6.7	6.8
Annual Regulatory Charge	5.4	7.0	7.0	7.0	7.0	7.0
Total Revenues	**9.0**	**13.3**	**13.4**	**13.6**	**13.7**	**13.8**

7.6 Cost Benefit Analysis

Initial Economic Impact Analysis
In 2012, a preliminary analysis was conducted in order to determine the economic impacts of possible amendments to the pest control product fee regulations. The cost recovery options tested were based on percentage increases of current fees (20, 40, 60, 80 and 100 per cent increases).

The analysis estimated the following impacts:

- If registrants of pest control products were to absorb the increase in application fees and the annual regulatory charge rather than increase prices, their net revenues would decline by approximately 0.68 per cent.
- If distributors were to absorb the full impact of the increase in application fees and the annual regulatory charge, net revenues are expected to decrease by 2.9 per cent. If distributors raise prices, the estimated impact on pest control products is estimated at 0.1 per cent.
- If growers were to absorb an increase in pesticide prices without an offsetting increase in crop prices, their net income would decline by less than 0.1 per cent.
- With respect to consumers, the magnitude of the potential impacts identified is also quite small. Even if the full impact of the increase were reflected in crop prices, the increase is likely to be less than 0.05 per cent.

Business Impact Test (BIT)

In March 2014, at the same time as the 2014 Pesticide Cost Recovery Consultation document was released, PMRA conducted a business impact test (BIT) in order to assess the potential impact on businesses as a result of proposed changes to the pest control product fee regulations.

The BIT was sent to 827 registrants/applicants and 20 usable responses were received, accounting for a 2.4 per cent response rate.

Based on the March 2014 proposal, the main findings were as follows:

- Of the twenty responses, a total of thirteen indicated that there would be a decrease in their Canadian annual pesticide gross revenue when considering all of the proposed changes to the cost recovery regime.
- Six out of twenty respondents indicated that there would be a decrease in the number of applications submitted during an average year and a decrease in the total number of products available for sale.
- Three out of fourteen respondents indicated that there would be a decrease in the number of applications that included a data compensation assessment.
- Four out of twelve respondents indicated that there would be a decrease in the number of applications for research authorizations; and two out of ten respondents indicated that there would be a decrease in the number of applications for research notifications;
- Two out of ten respondents indicated that there would be a decrease in the number of applications for microbials/semiochemicals; and two out of two respondents indicated that they did not know what the impact would be on the number of applications for straight chain lepidopteran pheromones.

Cost Benefit Analysis (CBA)

In August 2014, PMRA commissioned a Cost Benefit Analysis (CBA) in order to estimate the impacts of the fees and charges proposed in this Pre-proposal Notice (PPN), on pesticide registrants, manufacturers, distributors, and users. This exercise included a survey component to gauge the extent to which the proposed changes would affect the number of new pesticide applications received by PMRA, the number of product registrations maintained, as well as the degree to which costs would be passed on by manufacturers to the end users.

A total of 45 registrants representing a broad mix of enterprises (in terms of the number of employees, number of product registrations and types of products registered) were surveyed. Twenty-four responses to the detailed survey were received. Those who responded hold 25 per cent of current product registrations.

The overall anticipated effect of the regulatory proposal would be to transfer costs previously borne by taxpayers to industry. PMRA estimated in its previous consultation document that the proposed cost recovery regime would result in an annual shift of $5.5 million in costs from taxpayers to registrants of pest control products. Four million dollars (70 per cent) was attributable to proposed increases in fees and $1.5 million (30 per cent) was attributable to the proposed increase in the annual regulatory charge.

Industry respondents expressed differing views on the extent to which increased regulatory costs would be passed through the supply chain to pesticide users. For the purpose of analysis, the Cost Benefit Analysis assumed that 50 per cent of costs would be passed on to users. An analysis of the effects of the regulatory charge on pest control product prices suggests that an average price increase of 0.11 per cent would result, based on the 50 per cent pass-through estimate and an overall annual domestic pesticide market of $2.5 billion. This price increase is small and is not expected to significantly affect pesticide sales.

Other findings of the survey include the following:

- Proposed fee increases are expected to have a small effect on future registrations of both technical grade active ingredients (reduction of no more than two to six per cent) and end-use products (reduction of no more than five per cent).
- The introduction of fees to register or amend biological pest control products may reduce applications by 30 per cent (this estimate is driven largely by a response from one company).
- Extrapolating survey responses across all registered pest control products suggests that increases in the annual regulatory charge would lead to 150 currently registered products being discontinued or not renewed. Nearly all of these are expected to be dormant or low-sales products.

A number of non-quantifiable benefits are also expected: notably improved equity by shifting costs from taxpayers to the direct beneficiaries of cost recoverable pesticide submission review activities; improved fairness of application fees and regulatory charges that better reflect actual costs; and economic benefits of mitigation measures to support low volume products and small businesses. Furthermore, additional benefits would be realized if the increased revenue is re-spendable by PMRA to address stakeholder priorities.

7.7 Proposed Penalty Structure

It is proposed that penalties under the *User Fees Act* will be determined based on the average time to completion of all submission types falling under each performance timeline published in the MoSP. If average time exceeds the published time by greater than 10 per cent, a penalty equivalent to the amount by which the target is missed, up to a 50 per cent reduction in the fee will be applied to the relevant submission types in the following calendar year.

The PMRA will continue to make available performance statistics against currently published standards in order to facilitate the identification of trends.

8.0 Stakeholder Feedback

Even though we are now meeting most of our published application review timelines under standardized and efficient processes, stakeholders are concerned with the lack of stable funding for core activities and the PMRA's future ability to meet performance standards.

Stakeholders have reconfirmed their concerns with the PMRA's ability to participate in international regulatory cooperation activities for pesticides. Specifically, stakeholders want the PMRA to participate fully in global joint scientific reviews and international work to address developments in science and policy; and to maintain an e-environment capable of supporting international work. There is also pressure to advance Canadian approaches for establishing health standards for commodities treated with pesticides.

Stakeholders indicated that they would support a regulatory package that proposes reasonable increases provided that government addresses gaps related to pesticide regulation and provides stability to the program.

Specific comments stemming from the March 2014 consultation are summarized in Appendix V.

Appendix I Current Exemptions as Outlined in the Guidance Document on Pest Control Product Cost Recovery Fees

The Guidance Document on Pest Control Product Cost Recovery Fees provides guidance to applicants and registrants of pest control products with respect to the fees payable for the examination of applications for pest control products and for the right and privilege to manufacture or sell a pest control product in Canada, and for establishing a maximum residue limit in relation to a pest control product.

Listed below are substances that, if they are an active ingredient in an application for a certificate of registration of a pest control product, the pest control product will be exempt from application fees (except for Item 1) listed in Schedule I of the Pest Control Products Fee Regulations. This exemption from application fees is pursuant to paragraph 2(2)(*d*) of the Pest Control Products Fees Regulations. For applications for registration of a pest control product containing more than one active ingredient, all of the active ingredients must be eligible for the exemption in order for the application to be exempt from the application fees. Other active ingredients will be considered for addition to this list on a case-by-case basis.

1. a) Microbial pest control agents.
   b) Invertebrate biological pest control agents.

2. a) Plant extracts, regardless of use pattern, if they are foods as defined in the *Food and Drugs Act* 1985 (in other words, if the same substance is sold as food).

   Examples of these substances may include:
   - capsaicin
   - garlic extract and garlic oil
   - sesame and sesame oil
   - soybean oil
   - rosemary and rosemary oil
   - corn oil
   - lemon grass oil
   - mustard oil
   - thyme and thyme oil

   b) Substances, regardless of use pattern, if they have been regulated under the Food and Drug Regulations as:
   - food additives other than those listed in the tables to Division 15;
   - vitamin, mineral nutrient or amino acid;
   - spice, seasoning, flavouring preparation, essential oil, oleoresin or natural extractive;
   - food packaging material or component thereof, or
   - drug recommended for administration to animals that may be consumed as food.
     - Examples of these substances may include:
       - artificial grape extract
       - ergocalciferol – vitamin D2
       - sorbic acid

- menthol
- diatomaceous earth

c) Substances included in the Safety Universally Recognized (SURE) list (see Table I) if they are food grade, as specified in the Food Chemicals Codex, Fourth Edition and subsequent editions, as amended from time to time, and published on behalf of the National Academy of Sciences, Washington, D.C., United States.

3. a) Arthropod pheromones and other semiochemicals

b) Naturally occurring substances used as personal insect repellents (for example, plant extracts regardless of their suitability as food). Examples of these substances may include:

- cedar oil
- citronella, citronella oil, citronella turpine
- geranium oil
- geraniol mixture of oils
- lavender oil
- tea tree oil and lemon scented tea tree oil
- garlic extract and garlic oil
- lemon grass oil
- sesame and sesame oil
- mustard oil
- rosemary and rosemary oil
- soybean oil
- corn oil
- thyme and thyme oil

Appendix II Revised Management of Submissions Policy (MoSP) Performance Timelines for Pest Control Product Applications

The MoSP Performance Standard is for 90 per cent of applications to be processed within the applicable review timelines. This is consistent with Government of Canada guidance. The full Revised Management of Submissions Policy (DIR2013-01) is available at http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir2013-01/index-eng.php, and will be updated based on the approved cost proposal.

Table A-1 Revised Management of Submissions Policy (MoSP) Performance Timelines for Pest Control Product Applications

Category	Category Subdivision	Completeness Check in Days	Review Time in Days (Months)[1]	Public Consultation in Days
A	Conventional Chemical	37	655 (22)	45
	Reduced-Risk,[2] Other Biopesticides, NSCLP[3]		555 (18.5)	
	Microbials		470 (15.5)	
	Pheromones-SCLP[4]		285 (9.5)	
	Joint Reviews		Negotiated	
	URMUR		470 (15.5)	
	URMUR-SCLP		285 (905)	
	Program 914		Negotiated (<470d)	
	Import MRL[5]		655 (22)	n/a
B	Conventional Chemical	37	425 (14)	n/a
	Streamlined (application rate changes, tank mixes, new pests or changes to level of control)		158 (5)	
	Reduced-Risk, Other Biopesticides, NSCLP		360 (12)	
	Renewal or Conversion of Conditional Registration (with public consultation)		470 (15.5)	45
	Renewal or Conversion of Conditional Registration (without public consultation)		425 (14)	n/a
	Microbials		240 (8)	
	Pheromones-SCLP		240 (8)	
	New MRL for previously assessed active ingredient		425 (14)	
	Emergency use (priority): Reduced-Risk, Other		<360 (12)	

Category	Category Subdivision	Completeness Check in Days	Review Time in Days (Months)[1]	Public Consultation in Days
	Biopesticides, NSCLP			
	Emergency use (priority): Conventional Chemicals		<425 (14)	
	Joint Review		Negotiated	
C	Standard	37	240 (8)	n/a
D	IMEP	21	46	n/a
	OUI equivalency certificate	21	70	
	OUI permit	30 days total time		
	GROU equivalency certificate	To be determined	To be determined	
	GROU permit	30 days total time		
	URMULE presubmission	97 days total time		
	URMULE Standard Chemical	247 days total time		
	URMULE – Microbial, SCLP, NSCLP, Reduced-Risk, Other Biopesticide	217 days total time		
	URMULE Joint Review	Negotiated		
	Master Copy	7 verification	42 screen and review	
	Private Label	7 verification	10 screen and review	
	Registration Renewal	Complete by March 15th		
	Discontinuation	7 verification	45 screen and review	
E	Research Permit – new technical grade active ingredient (Food and Non-Food Use)	21	159	n/a
	Research Permit – New Use	21	69	
	Notification of Research	30 days total		

1 Review Time is equal to the time after the end of the completeness check to the final regulatory decision. The review time excludes: a 45-day public consultation period, if applicable; time when a submission is "on-hold" pending the applicant.

2 Reduced risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, The PMRA Initiative for Reduced-Risk Pesticides (http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir2002-02/index-eng.php).

3 Non Straight Chain Lepidopteran Pheromone

4 Straight Chain Lepidopteran Pheromone

5 Maximum Residue Limit

Appendix III How User Fees May Affect You

While some fees have decreased, other fees have increased. In order to help stakeholders understand the scope of the proposed changes, the following table provides a comparison of the current and proposed fees on a few typical types of applications. Total fees for other application scenarios can be calculated using Health Canada's Pesticide Fee Form.

Table A-2 Proposed Fee Changes – Selected Applications

Type of Applications	Current Fee	Proposed Fee
A **new technical grade active ingredient for a food use** is typically charged the following components: • Basic application fee • Chemistry • Human acute and chronic toxicology • Metabolism[1] • Eco – Fate • Eco – Toxicology	$147,551	$190,696
A **new end-use product for a food use (field crop)** is typically charged the following components: • Basic application fee • Chemistry • Human acute toxicology • Human exposure • Residue • Eco – Fate • Eco – Toxicology • Value	$81,281	$120,981
A **new end-use product for a food use (greenhouse)** is typically charged the following components: • Basic application fee • Chemistry • Human acute toxicology • Human exposure • Residue • Value	$39,466	$41,019
A **change in formulation type** (B2.5) is typically charged the following components: • Basic application fee • Chemistry	$1,434	$4,095
A **change in application method** (B3.4) is often charged the following components: • Basic application fee • Human exposure • Value	$10,910	$7,502

Type of Applications	Current Fee	Proposed Fee
Adding a new pest to an end-use product label (B3.11) is typically charged the following components: • Basic application fee • Value	$1,168	$2,289
New Source of Technical Grade Active Ingredient (TGAI) with data protection implications (B.1.2) is proposed to be charged the following components: • Basic application fee • Product chemistry • Compensable data • Notification following negotiations / arbitrations	$1,434	$8,415
A new end-use product with data protection implications is typically charged the following components: • Basic application fee • Compensable data • Notification following negotiations / arbitrations	$262	$3,539
A **new Material Preservative Technical Grade Active Ingredient (TGAI)** is typically charged the following components: • Basic application fee • Chemistry • Human acute and chronic toxicology • Eco-Fate	$130,909	$127,452
A **new Material Preservative end-use product** is typically charged the following components: • Basic application fee • Chemistry • Human acute toxicology • Human exposure • Value	$30,998	$13,464

[1] Metabolism data not always required.

Appendix IV International Comparison

Introduction

In accordance with sections 4.(1)(f) and 4.(3) of the *User Fees Act* 2004, the Pest Management Regulatory Agency (PMRA) has conducted an international comparison as part of the cost recovery initiative to ensure that proposed fees are not out of step with similar jurisdictions. The following regulators were identified as comparable to Health Canada with respect to the level of scientific rigor regarding the pre-market application review processes, data requirements for registration and reviews, as well as similarities in the types of regulatory services offered:

- The United States Environmental Protection Agency (USEPA).
- The United Kingdom Chemicals Regulation Directorate (UK CRD) of the Health and Safety Executive.
- The Australian Pesticides and Veterinary Medicines Authority (APVMA).

Each jurisdiction has a similar fee paying clientele:

- Multinational corporations that are active in all four countries.
- Small- to medium-sized enterprises that have developed a niche product for a particular market.

While there are many regulatory similarities between all four countries, there are also many factors that have resulted in four distinct cost recovery models, such as:

- Fundamentally different political, business and financial environments.
- Varying market sizes (the United States being the largest).
- Variations in how products are priced (for example, small vs. large economies of scale).
- Market access issues between jurisdictions (for example, tariff and nontariff barriers to trade).

For this analysis, the USEPA is our closest comparator and is serving as the primary benchmark.

Regulatory Structure

For the most part, the proposed cost recovery fees are aligned with, and in many cases below, the comparable fee currently charged by the USEPA. Our regulatory systems share many commonalities, however, not all fee categories are the same, and a meaningful one-to-one comparison is not always possible.

The USEPA *Pesticide Registration Improvement Extension Act* (PRIA 3) of October 2013 prescribes 189 distinct fee categories, while PMRA's proposed schedule totals 39 fee components, which are often combined into a final fee depending on the data we must review. In many cases, the sum of the fee components that comprise an application has an equivalent USEPA fee category (not necessarily the fee itself), such as in the registration of a new active ingredient and end-use products for traditional agricultural chemicals. In others, such as applications for substances the USEPA considers to be "reduced risk", there is no equivalent Canadian fee that can be readily compared.

Australia has implemented a levy system that charges low fees on the front end scientific evaluation but levies an annual percentage of sales once substances are registered. As a result, there is very little fee alignment between Canada and Australia.

The United Kingdom is somewhat of a hybrid model. First, fees are charged up front to ensure that the full economic costs of evaluating and processing applications are recovered. There are standard charges for the initial review of a dossier, and then the fees for the complete review depend on the data requirements for the substance. Second, the United Kingdom charges registrants an annual levy based on sales to support post-market regulatory activities.

Scope of the International Comparison

The scope of this international comparison will be covered in two parts.

1 - To the extent possible, we will provide a side-by-side comparison with a selection of USEPA PRIA 3 fees that show at a glance how our proposed fees measure up.

2 - We will spend some time on the areas that you may notice have changed from the current model, and how the other regulators approach these areas. Specifically, we will discuss approaches for:

a - Data Compensation Assessment
b - Import Maximum Residue Limits (Import MRLs)
c - Microbial and Semiochemical Pesticide Applications
d - Notifications
e - Post-Market Fees and Annual Increases
f - Exemptions, Reductions, and Refunds

Note: The exchange rates used throughout this section are CAN$1 = US$0.89, CAN$1 = GBP0.51, and CAN$1= AU$0.99.

1 - Comparison with the United States Environmental Protection Agency

While the proposed fees for some components have decreased, others have increased and overall the total fees for traditional applications have increased by roughly 30 per cent (see Tables 1, 2, 3 in the Pre-Proposal Notice). We have been careful in ensuring that proposed fees are not out of step with the USEPA.

Table A-3 Typical PMRA Fees Compared with USEPA Fees

Type of Application, Based on the USEPA PRIA 3 Fee Category	PMRA Fee (Typical)[1]	USEPA Fee (PRIA 3)[2] in CAN$
New Technical Grade Active Ingredient (TGAI) for food use and a maximum of 5 End-use Products (EP)	$399,969[3] Low: $239,466 High: $658,895	$672,124 (R010)
TGAI for seed treatment (food or feed) and EP for seed treatment (food or feed)	Up to $190,718 (TGAI) Up to $41,042 (EP)[4]	$500,374 (R123)[5]
New TGAI for an outdoor non-food use and EP for an outdoor non-food use (for example, Turf)	Up to $124,498 (TGAI) Up to $67,889 (EP)	$466,959 (R060)
New TGAI for an indoor non-food use and EP for an indoor non-food use (for example, Residential Indoor Plants and Plantscapes)	Up to $81,813 (TGAI) Up to $25,204 (EP)	$259,711 (R110)
Major new use for a TGAI for a first outdoor food use currently registered for indoor non-food only (for example, Terrestrial Food Crops)	$77,403	$205,035 (R130)
Chemistry amendments for a TGAI - food and non-food uses (outdoor and indoor)	$6,006[6]	$1,692 (R300) $2,029 (R301) $14,153 (R351) $303,065 (R332)
Chemistry amendments for an EP - food and non-food (outdoor and indoor)	Up to $3,846	$1,692 (R300) $2,029 (R301) $5,672 (R310) $14,153 (R320)

1 PMRA fees can vary widely due to varying data requirements. The fees in this column are an indication of the range of fees that an applicant could expect to pay if all data components of an application need to be reviewed (except for the first row, see note 3 below).

2 This column includes Registration Division "R***" codes in the FY 2014/15 fee schedule for ease of reference.

3 This number is the mean based on a review of 18 Joint Reviews of conventional chemicals with agricultural and food uses.

4 Fee typically decreases for each subsequent EP if the data is similar to the previous ones.

5 A maximum of five new products are covered by the base fee; additional new products are charged extra fees.

6 PMRA usually charges the basic application fee and chemistry, while in the United States it can be a variety of changes (see adjacent column for examples).

2a - Data Compensation Assessment

Pursuant to the regulations PMRA must, upon request from an applicant applying for a generic registration outside of the period of exclusive use, prepare a list of compensable data that they may use or rely on, and in respect of which they will need to enter into an agreement with the registrant.

None of the other regulators provide a compensable data list generation service, and leave that process to the innovator and third parties.

2b - Import Maximum Residue Limits (Import MRLs)

Under the current cost recovery framework, Import MRLs for new active ingredients and previously registered ones are charged a fee of $8,448.[9] This, however, does not reflect the amount of work that is actually required to review an Import MRL application.

PMRA receives few Import MRL applications and following an examination of all Import MRLs received since 1996/1997, it was found that about half of the registered Import MRLs eventually resulted in a domestic registration if they did not already come packaged in a Joint Review. There is, therefore, no reasonable economic rationale for not recovering a greater portion of the costs associated with the review effort required.

United States Environmental Protection Agency

The proposed fees take into account the fee components that comprise an Import MRL review, and are significantly lower than the equivalent USEPA fee for an import tolerance (see comparison below).

Table A-4 Proposed Import MRL Fees Compared to USEPA Fees

Type of Import MRL	Canada (Proposed)	USEPA (PRIA 3) in CAN$
New active ingredient or first food use	$125,461	$341,726 (R280)[1]
Previously assessed active ingredient or additional new food use	$15,838	$68,346 (R290)

[1] The fee covers an Import Tolerance for a new active ingredient with a maximum of five new products if they are submitted in one package with the new active ingredient.

United Kingdom Chemicals Regulation Directorate

The fees charged in the UK for Import Tolerances depend on the number of crops that are being treated and how much information needs to be evaluated (in other words, full human health evaluation, metabolism and residues evaluation, residues evaluation). As a result, the fees can range from approximately CAN$3,819 (residues evaluation only) to CAN$43,333 (similar to Canada's data requirements for a new active ingredient) for a single import tolerance. Applications can be accepted for multiple import tolerances for the same active substance, in which case there would be additional charges for each crop depending on any additional data requirements. All applicants are charged a sift fee of CAN$400.

[9] The fee is charged per application and can include setting MRLs for multiple crops or crop groups.

Australian Pesticides and Veterinary Medicines Authority

The APVMA does not currently charge fees for Import Tolerances. Applicants must apply to Food Standards Australia New Zealand (FSANZ) for an Import Tolerance, which charges fees if an applicant has an exclusive capturable commercial benefit or if the applicant requires work to start on the assessment immediately, rather than according to the anticipated timeframes established as part of the Administrative Assessment.[10]

Where FSANZ charges a fee, it does so on an hourly basis and the total fee varies depending on the complexity of the application. Fees can range between CAN$21,270 for a minor procedure[11] to CAN$146,417 for a major procedure.[12]

2c - Microbial and Semiochemical Pesticide Applications

In 1997, a lack of experience with assessing microbial and semiochemical pesticide applications led us to conclude that establishing user fees for data review was premature (only a label review fee is currently charged). Since that time, we gained considerable experience with these products, and included these activities in the costing exercise. These fees also take into account the continued need to encourage their registration in Canada, given their generally lower risk profile.

United States Environmental Protection Agency

In establishing these fees, we took into account the USEPA fee for similar activities and the fee mitigation available to American applicants. Given that many American applications for these types of products would be expected to apply for the maximum fee reduction (based on company size), and in order to facilitate their registration in Canada, the Canadian fees are proposed at a level equal to the minimum USEPA fee.

United Kingdom Chemicals Regulation Directorate

Similarly to Canada, the United Kingdom typically requires less extensive data for the scientific review of microbials than for chemical active substances, but must nevertheless take into account other factors such as pathogenicity/infectivity in humans and animals, sensitisation of users, the production of toxins and the potential for multiplication in the environment. Data requirements for microbials must follow OECD Guidance for Industry Data Submissions for Microbial Pest Control Products and their Microbial Pest Control Agents (Dossier Guidance for Microbials), Series on Pesticides No. 23.

The variability of microbial fees in the United Kingdom makes a one-for-one comparison challenging. While it is known that the fees are generally lower than for chemical active substances, the actual fee will depend on the data required for each particular product and is not listed in a fee table.

Australian Pesticides and Veterinary Medicines Authority

Australia does not treat microbial applications any differently than other chemicals. All active substances are subject to a standard set of low application fees.

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10 Food Standards Australia New Zealand Application Handbook, 1 September 2013 (amended 18 September 2013) Prepared by Food Standards Australia New Zealand, p.12.

11 *Cost recovery for applications (Final Report)*, p.15, Table 2A, http://www.foodstandards.gov.au/code/changes/applying/documents/Cost%20recovery%20FINAL.pdf.

12 Ibid, p.15, Table 2A.

2d - Notifications

On average, notifications cost $825 for PMRA to process and the proposed fee of $247 is 30 per cent of that in accordance with the proposed cost recovery rationale.

United States Environmental Protection Agency

PMRA and USEPA notification processes are not harmonized in the range of activities that are covered; for example, PMRA can issue new product registrations under a notification. The USEPA currently does not charge a fee for notifications.

United Kingdom Chemicals Regulation Directorate

The United Kingdom currently charges a fee of CAN$491-$673 for approvals that are of an administrative nature. This includes a standard sift fee of CAN$400, which applies to all applications that come in the door.

Australian Pesticides and Veterinary Medicines Authority

In Australia, the fee charged for a notification depends on the type of application and what kind of information is required. Notification fees can range from no charge to CAN$1,978 or more.

2e - Post-market Fees and Annual Increases

PMRA is proposing an annual regulatory charge for each registered product of $3,600 which can be reduced based on sales, as well as an annual increase to application fees of 2 per cent.

United States Environmental Protection Agency

Under FIFRA section 4(i)(5)(C), Maintenance Fees, the USEPA is authorized to collect an aggregate amount of US$27.8 million for each of fiscal years 2013 through 2017 to support certain activities. Maintenance fees are a yearly product registration renewal fee[13] and the amount of this fee varies from year to year depending on the authorizing legislation. The amount of the 2015 maintenance fee is US$3,375 (CAN$3,792) per product up to the pre-set limits determined by legislation.[14]

Maintenance fees are reduced by 25 per cent for the first registration only, if the applicant can show that:

1. The applicant has 500 or fewer employees globally.
2. During the 3-year period prior to the most recent maintenance fee billing cycle the applicant has average annual gross revenue from all sources that do not exceed US$10,000,000.
3. The applicant holds a total of five or fewer registrations subject to the maintenance fee.

There also are maintenance fee waivers for products that meet certain narrow criteria in two categories: minor agricultural use products and public health pesticides.

[13] Implementing the Pesticide Registration Improvement Act – Fiscal Year 2013 (http://www2.epa.gov/pria-fees/implementing-pesticide-registration-improvement-act-fiscal-year-2013)

[14] Pesticide Registration Manual: Chapter 5 - Registration Fees (http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees)

United Kingdom Chemicals Regulation Directorate

In the United Kingdom, under section 18 of the *Food and Environment Act* 1985, as amended by the *Pesticides (Fees and Enforcement) Act* 1989, Ministers are empowered to recover costs of running and monitoring the system for approving products under the Control of Pesticides Regulations (COPR).

The levy collection exercise commences each year in September with a request to approval holders to declare their sales turnover for a given 12-month period. The levy is expressed as a percentage of the declared sales turnover, and each year approval holders are invoiced for the appropriate amount. The percentage is not published and applicants must fill out a form or contact the Health and Safety Executive (HSE) directly. In recent years the levy was pegged at 0.80 per cent.

Australian Pesticides and Veterinary Medicines Authority

In Australia, registrants are required to pay levies based on the dollar value of sales (disposals) on their registered products. A levy is payable on all sales for each product greater than AUD $5,000. Each year, registrants are required to provide the APVMA with the dollar value of sales by completing a request for declaration of leviable values. The APVMA commissions independent audits of these declarations, which check reported sales against company financial records to ensure they are accurate.

Levies are imposed under the Agricultural and Veterinary Chemical Products Levy Imposition (General) Act 1994, the Agricultural and Veterinary Chemical Products Levy Imposition (Excise) Act 1994, and the Agricultural and Veterinary Chemical Products Levy Imposition (Customs) Act 1994.

Levies are collected under the *Agricultural and Veterinary Chemical Products (Collection of Levies) Act* 1994. Levy rates are prescribed in the Act's Regulations.
For sales made from 1 July 2013 the levy calculation is based on a tiered levy rate structure as follows:

- 0.63 per cent levy rate for up to AUD $1,000,000 in product sales.
- 0.35 per cent levy rate for additional sales from AUD $1,000,001 to $5,000,000.
- 0.25 per cent levy rate for additional sales above AUD $5,000,000.

2f - Exemptions, Reductions and Refunds

United States Environmental Protection Agency

The USEPA grants exemptions, reductions and refunds in specific circumstances:

- A reduction of up to 75 per cent can be granted for a small business with less than US$10 million in global gross sales. A portion of all fees (25 per cent) is non-refundable.
- A 50 per cent reduction in the fee may be granted for a small business with less than US$60 million in annual gross pesticide sales (global).
- All applications from federal or state agencies (for example, for public health related products) and for applications solely associated with a tolerance petition submitted in connection with the Inter-Regional Project Number 4 (IR-4) that are in the public interest are exempted.

- No exemptions or reductions are applied for conventional pesticide active ingredients or major new uses.
- Under the United States *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) the OPP has discretionary authority to issue a partial refund (up to 75 per cent) of the registration service fee if in reviewing the application it has considered data submitted in support of another pesticide registration application.

United Kingdom Chemicals Regulation Directorate

The UK CRD always applies full fees and does not apply exemptions or reductions. The one area of discretion is the application of the partial dossier fees (where a full dossier is not needed as the required data is on hand from a previous application). However, the UK CRD tends to charge at the upper end of the fee range and does not apply discounts. No reductions are placed on the levy since there are a very low percentage of sales and it applies equally to all registration approval holders.

Australian Pesticides and Veterinary Medicines Authority

The APVMA does not have any provisions for exemptions and reductions as the application fees are kept low through subsidization, some applications are based on modules where you pay only for required inputs to the review process, and the post market levy is tiered to allow for SMEs to pay proportionally lower fees than larger companies.

Conclusion

While Canada, the United States, the United Kingdom and Australia share similar regulatory processes in general, each country favours a distinct approach for collecting fees from applicants and registrants. This made an international comparison less an exercise about which regulator employs more efficient and effective processes, and more an exercise for ensuring that our proposed fees and cost recovery approach are not out of step with our counterparts. Early analysis clearly showed that the United Kingdom and Australia operate, from an economic perspective, very differently than Canada and the United States. In particular we noted their authority to tax the sales of registered products, which is not current practice here.

In addition, since we share a border with the United States, and have a long history of regulatory cooperation, we selected the USEPA as our primary benchmark. We caution that although we work closely with the USEPA, the differences in our organizational structures, operational requirements and size result in vastly different costs to the regulatory framework, and as a result the fees required to recover those costs will always be different.

That being said, given Canada’s small market size compared to the United States and the fact that Canadian fees have, to date, typically been lower, it was important to ensure that our proposed fees did not exceed the equivalent fee charged by the USEPA, to the extent possible.

Appendix V Summary of Comments – Cost Recovery Consultation

1.0 Principles for New Cost Recovery Regime

Comment
Most stakeholders were supportive of the fee increases, public good/private sector split and the approach to calculating costs over an 18 month time period.

PMRA response
PMRA acknowledges stakeholder support and for understanding that the general cost of doing business has increased since 1997.

2.0 *User Fees Act* 2004

Comment
A few stakeholders sought clarification concerning the penalties and other implications for the PMRA not meeting performance timelines as laid out in the *User Fees Act* 2004.

PMRA response
PMRA agrees with this suggestion and additional details have been included in Section 5.0 of the pre-proposal notice.

3.0 Base Funding and Increased Revenue

Comment
All stakeholders who commented on the use of the increased revenue supported PMRA reinvesting it. Furthermore, they preferred that the government's share of the funding not be eroded through further reductions in A-base funding or sun-setting initiatives such as Growing Forward II or the Chemicals Management Plan.

Suggestions for where new resources should be concentrated:

- PMRA's commitment to meet the MoSP submission timelines for all categories.
- Increased funds could improve the registration process and would make the fee increases more acceptable to end users.
- Apply funds to activities to reduce barriers to trade for Canadian agricultural commodities containing pesticide residues.
- Ensure PMRA is able to remain current with emerging science concepts and risk assessment techniques, maintain its current level of international cooperation with other regulatory authorities and employ modern electronic tools.
- Full transparency on submission review stages.
- Public access to relevant information, improved transparency.
- Additional stakeholder input (working groups) could better guide spending on an ongoing basis.
- To assist with education, training, communication, collaboration and awareness activities.

PMRA response
PMRA acknowledges stakeholder support for government to reinvest new revenues in PMRA programs. PMRA is in general agreement that the priorities identified by stakeholders would help to advance the goals of PMRA with respect to health and environmental protection while supporting Canadian competitiveness.

4.0 International Comparison

Comment
Several stakeholders requested additional details and analysis on international comparisons.

PMRA response
PMRA is in agreement with this suggestion. Additional information has been provided in Section 7.2 of the document and in Appendix IV.

5.0 Harmonization with the United States Environmental Protection Agency and Other International Regulators

Several stakeholders had varying comments related to harmonization with the USEPA and other international regulators:

Comment
One comment suggested that differences in data requirement between the USEPA and the PMRA should be taken into account when setting the PMRA fee structure.

PMRA response
All efforts are made to ensure that data requirements are harmonized to the extent possible to ensure a comparable registration process on both sides of the border.

Comment
Another suggested that the PMRA could modify registration practices to allow for domestic and commercial labeling on the same product.

PMRA response
This comment is noted and may be considered in any future reviews of the Pest Control Products Regulations. However, changes to the labeling requirements are beyond the scope of the current proposal.

Comment
A third comment suggested working towards better alignment of Global Joint Review timelines and costs.

PMRA response
PMRA acknowledges this comment. Global Joint Review timelines are negotiated in cooperation with partner countries. However, given the various legislative bases and fee structures as well as differences business costs from country to country, it is not possible to align costs at this time.

6.0 Annual Fee Adjustment

Comment
Most stakeholders were in agreement with regular incremental fee adjustments to eliminate the need for large increases. Some specific comments suggested conducting a periodic costing analysis to ensure all fees and charges take into account associated improvements, efficiencies and processes, and actual resources required. Other comments related to the use of the CPI and public employee wage increases. Some were supportive; one did not think wages should be recovered.

PMRA response
The PMRA acknowledges the comments related to the fee adjustment. Consistent with other policies already in place at Health Canada, we are proposing a flat percentage increase of two per cent based on a five-year weighted average of public service wage adjustments and the Core Consumer Price Index (CPI) – Weighted Index. The annual adjustment will remain stable for a three-year period and is not proposed to be applied until after the new fee regulations are in effect. A notification will be provided in the *Canada Gazette*, Part II annually with the revised application fees (Tables 1–3). After three years, we will review costs and may propose new or amended fees.

Section 7.3.6 of the pre-proposal notice provides greater details on this proposal.

7.0 Table 1: Application for Issuance or Amendment of a Certificate of Registration of a Pest Control Product

Comment
Item 1: Basic Application Fee (label review and/or processing)
There were three comments related to this fee. The first requested clarity on what activities are included. The others sought clarity on why the current label fees (three separate fees) are now proposed to be combined into one. This comment also suggested some applications be charged a lower rate.

PMRA response
PMRA acknowledges stakeholder feedback and provides the following for clarity. The basic application fee covers all work performed by the PMRA on an application that is not specifically addressed by other fee components. This includes work such as setting-up applications within our internal tracking system (e-PRS), coordination and management of applications through the review process, label and/or statement of product specifications form reviews, fee assessments (including fee reduction requests), preparation of decision letters and/or correspondence with applicant.

With respect to the comment that suggested some applications be charged a lower rate, the level of effort with the work is very similar across submission categories and types; therefore we propose to maintain one fee for simplicity.

As the notification policy is further developed, we anticipate that more application currently subject to the basic application fee (Category C and some Category B) will qualify as notifications, effectively reducing the fee required.

Comment
Item 10: Value and effectiveness data for a pest control product
One comment suggested that additional consultations be held for any future changes to this fee; another requested that the PMRA conduct a new activity-based costing to review this fee and other supported the fee remaining at $906.

PMRA response
PMRA agrees that any new future fee amendments would be determined by activity-based costing and be subject to consultation.

Please see the note following Table 1 of the pre-proposal notice for Item 10 for information related to this fee.

Comment
Item 11: Data compensation assessment
Several stakeholders objected to the initial proposed fee of $21,617 based on 100 per cent cost recovery of the average cost to Health Canada for the generation of a compensable data list. The majority of the comments relate to:

- The availability/accessibility of the list.
- The fee being more in line with the percentage of other fees being cost recovered.
- How the fee was derived including timelines.

PMRA response
The PMRA has reconsidered this fee (previously referred to as “generation of a compensable data list”) and through further discussions, consultation and development of the process for the data compensation assessment, we are proposing an amended fee of $2,162 with a timeline of 365 days. This marks a considerable fee reduction and aligns with the timelines of other applications having similar data requirements. The fee is directly related to the average cost required by Health Canada to conduct a data compensation assessment within 365 days.

Please see the note in Table 1 of the pre-proposal notice for Item 11 for further information related to this fee and how it will be charged.

8.0 Table 2: Other Applications in Relation to a Pest Control Product

Comment
Items 2a, 2b, 2c and 2d Research Authorizations and Items 3 and 6: Processing research notification and Processing of notification
Stakeholders expressed concern that the proposed fee increases for research authorizations and research notifications are too high and would have a negative impact on research in the areas of minor use, biopesticides, forestry and other non-agricultural research.

PMRA response
Please see the notes following Table 2 of the pre-proposal notice for information related to these fees.

Fees for research notifications and authorizations have been separated, given differences in average costs between these activities.

Research Authorizations - Based on stakeholder feedback, we have revised the proposed fee for some research authorizations and provided additional clarification. With the goal of fostering innovation, we lowered the fees based on a consideration of similar USEPA fees and recognizing that some types of research authorizations require less review work.

Research Authorizations are not normally required for studies conducted to support minor use registrations as the studies are usually less than 5 hectares and would normally fall under the research exemption or research notification criteria (with the exception of operational/demonstration trials and research in greenhouses as described in Table 2, Item 2d of the pre-proposal notice).

Processing research notification - The PMRA agrees with the comments concerning the research notification fee. We propose to reduce the fee from $552 to $247, making the fee consistent with other types of notification applications.

Pursuant to paragraph 19 (3)(a) of the *Financial Administration Act* 1985, applications, including those for research authorizations and notifications, received from other federal departments are exempt from fees.

Comment
Items 5a and 5b: Specification of MRL for a previously unassessed pest control product and for an unregistered use of a previously assessed pest control product
There were seven comments on these fees. In general, those from growers and government were supportive of the fee increase. Registrants generally thought that the fee was too high and might reduce the number of MRL applications, creating trade implications for other countries exporting their crops to Canada.

PMRA response
PMRA acknowledges stakeholder comments and is maintaining the proposal as presented.

Under the current cost recovery framework, MRLs for new active ingredients and previously registered ones are charged a fee of $8,448; however, this does not reflect the amount of work that is actually required to review these applications.

Following an examination of all Import MRLs received since 1996/1997, it was found that about half of the applications for previously registered pesticides eventually resulted in a domestic registration, meaning costs should be reduced for the domestic registration applications.

There is no economic rationale for not recovering a greater portion of the costs associated with the review effort required. The proposed fees take into account the fee components that comprise an Import MRL review, and are significantly lower than the equivalent USEPA fee for an import tolerance (see Appendix IV International Comparison for additional details).

Please see the note to Table 2 Item 5a and 5b of the pre-proposal notice for additional information related to this fee.

Comment
Item 6: Processing of notification
There were several comments from stakeholders related to the proposed fee for the processing of notifications. Some stakeholders indicated that multiple amendments to a single registration should be made in a single notification which would result in paying the fee for processing notifications only once.

PMRA response
PMRA agrees that if multiple product amendments apply to a single registration number and all amendments qualify as notifiable changes; these can be submitted under one notification application. Notifiable amendments can also be included in applications for one of the other submission categories (for example, Category B or Category C applications) when other product amendments are being proposed.

Please see the note to Table 2 Item 6 of the pre-proposal notice for additional information related to this fee.

Comment
Some stakeholders indicated that there should not be a fee for the processing of notifications in order to be consistent with the United States where a fee is not charged.

PMRA response
Because PMRA and USEPA notification programs are not fully harmonized in fee or activities, PMRA supports retaining the proposed difference in fees. The Canadian notification program can result in new product registrations under the registration of repackaged-relabelled products (repack-relabel) option which is equivalent to actions taken in the United States under the PRIA Fee Category- R300 ($1506). In addition, the proprietary formulant changes allowed under the PMRA notification program are more extensive than those permitted in the United States. The Phase II notification changes will also involve additional notification application types not available under the USEPA notification program.

Comment
Another comment indicated that the fee for the processing of notifications should be aligned with other administrative fees charged by the PMRA, namely the current fee for renewals which is set at $154.

PMRA response
Because the level of effort required to review and update notification applications is greater than that required under the current renewal process, PMRA supports retaining the current proposal. The renewal process is strictly administrative and there is no label or statement of product specifications form (SPSF) review. The notification program includes application types that require a label and/or SPSF review and resulting database updates. Furthermore, the Phase I notification update resulted in less complex Category C application types being reclassified as notifiable amendments. This results in a timeline and fee benefit for registrants. In addition, the Phase II notification updates will reclassify more Category C and some Category B application types to notifiable amendments resulting in further efficiencies for registrants.

9.0 Table 3: Application for Issuance or Amendment of a Certificate of Registration of a Microbial or Semiochemical Pest Control Product

Comment
Several stakeholders suggested that the annual regulatory fee and application fees for microbial and semiochemical pest control products should remain unchanged or be minimal for a variety of reasons:

- The biopesticide technology gap between the United States and Canada still exists.
- Fees would further discourage species specific products and alternative pesticides.
- Conventional and nonconventional or reduced risk pesticides should be charged at different rates, particularly for products that include active ingredients approved for food uses.

PMRA response
As per the explanatory note to Table 3 of the pre-proposal notice, a lack of experience with assessing microbial and semiochemical pesticide applications led us to conclude in 1997 that establishing user fees for data review was premature (only a label review fee is currently charged). Since that time, we gained considerable experience with these products, and included these activities in the costing exercise. These fees also take into account the continued need to encourage their registration in Canada, given their generally lower risk profile.

It is understood that for some of the fees/charges in Table 3 of the pre-proposal notice, the percentage increase seems high, largely because these applications are no longer exempt; however the actual fee for these applications is very low compared to the cost to Health Canada.

Registrants are proposed to be charged on average three per cent of the cost to Health Canada, in other words, government would be subsidizing applications by 97 per cent.

In establishing these fees, we took into account the USEPA fee for similar activities and the fee mitigation available to American applicants. Given that many American applications for these types of products would be expected to apply for the maximum fee reduction (based on company size), and in order to facilitate their registration in Canada, the Canadian fees are proposed at a level equal to the minimum USEPA fee. No additional fee mitigation would be applied.

10.0 Mitigation for Application Fees

Comment
Stakeholder comments on the mitigation for application fees were mixed. Some were satisfied with the proposed approach. Others would like the fee revised though the establishment of a working group and propose consistency with the USEPA (a tolerance petition submitted in connection with the IR-4 and if the exemption is in the public interest).

PMRA response
PMRA proposes that fee mitigation for the registration of new pest control products subject to fees listed in Table 1 of the pre-proposal notice will remain unchanged.

Fee mitigation is not proposed for other applications in relation to a pest control product (Table 2) consistent with the current regulations. Since the March 2014 proposal, fees for some research applications, processing research notification and processing other applications have been reduced.

Should the PMRA revise the fee mitigation policy in the future, we will consider all relevant stakeholder comments and suggestions at that time. The current policy has evolved based on the needs of Canadian registrants and the Canadian regulatory system. Although applied slightly differently when compared to the USEPA, the main objective still applies, which is to facilitate access to the Canadian market for low-volume, niche products and to support small business in Canada.

Comment
Others commenters contended that URMULE and URMUR submissions as well as emergency registrations (particularly for repeated emergency registrations) should not have a fee as the increase to the basic application fee may be a deterrent for a company to follow through with the full submission process, especially for low volume niche products

PMRA response
User Requested Minor Use Label Expansions (URMULEs) are already subsidized by the government through the work done by Agriculture and Agri-Food Canada and provincial minor use coordinators in support of URMULE applications. This approach would continue under the proposed fee structure.

For example, URMULEs are exempt from fees as the application is submitted by Agriculture and Agri-Food Canada or a provincial minor use coordinator. However, the registrant would be required to pay the basic application fee ($1133) in order to amend the label to add the new use. The basic application fee is the cost of maintaining their registration and as with other proposed fees represents a portion of the costs to government associated with the activity. This fee is paid by the registrant who will gain the benefit of having additional uses on their label and potentially increase the sale of their product. The same principle applies to User Requested Minor Use Registrations in that the registrant will be gaining the benefit of these registrations.

As well, application fees for new products may be eligible for a reduction through the fee mitigation program. Mitigation for application fees are set at a maximum of 10 per cent of sales during the sales verification period[15] of the product(s) registered with a new active ingredient(s). The fees payable under Table 1 cannot be reduced below 10 per cent of the total fee. The Fee mitigation program was developed to facilitate access to the Canadian market for low- volume, niche products, and to support small business in Canada.

The annual regulatory charge can also be mitigated. Please see the main document for details on the proposal.

Emergency Registrations -The level of effort required and the short timeline associated with these registrations justifies the basic application fee (proposed at $1,133).

11.0 Appendix I: Current Exemptions as Outlined in the Guidance Document on Pest Control Product Cost Recovery Fees

Comment
With the policy for the registration of non-conventional pesticides, one stakeholder would support the introduction of fees for the review of all currently exempted products.

PMRA response
PMRA acknowledges the stakeholder comment and we are maintaining the current proposal to remove the fee exemption for applications relating to microbials and naturally occurring semiochemical or identical synthetic substances that affects the behaviour of arthropoda (including naturally occurring substances used as personal insect repellents, essential oils and arthropod pheromones). These applications would be subject to fees described in Table 3 of the pre-proposal notice.

The exemption would continue for:

- User-requested minor use label expansions funded through the Growing Forward 2 - Minor Use Program (however, the basic application fee would apply when registrants amend the label to add the new use).
- All requests under the Grower Requested Own Use Program.
- Applications for organisms (other than microbials) and substances that do not fall within the definition of “agricultural chemical” in the *Food and Drug Regulations*, except for the basic application fee and any item in Table 2.

12.0 Appendix II: Revised Management of Submissions Policy (MoSP) Performance Timelines for Pest Control Product Applications

Precedent-based submissions / label amendments (Category C.2, C.7 and C.3 applications)
There were several comments related to these fees.

[15] The sales verification period is the period beginning on the date that the registered pest control product is first sold in Canada and ending three years after that date.

Comment
Some suggested that a fee is inappropriate if the label change is proposed by the PMRA rather than the registrant.

PMRA response
PMRA's re-evaluation of an active ingredient may require that product labels be updated to reflect changes to risk mitigation that are required for risks to be acceptable and to maintain registration.

PMRA must verify that the submission addresses the requirements identified and must expend resources. If a similar amendment was requested by the registrant, and not as a result of re-evaluation, much higher fees could be incurred to account for any scientific review that may be involved.

It should be noted that under the revised Notification/Non-notification Directive (DIR2013-02) a number of applications which were previously classified as Category C can now be processed through notifications and are subject to lower proposed fees ($247). As the notification policy is further developed, we anticipate that more applications currently subject to the basic application fee (Category C and some Category B) will also qualify as notifications.

Comment
One stakeholder proposed that the fee be split into two, as in the current regulations. Category A and B applications would be charged at one rate and Category C and D applications at another lower rate.

PMRA response
In considering this comment, we confirmed that the resources required to process applications of this nature are similar and we propose maintaining the single fee.

Comment
Other stakeholders suggested that timelines for these types of applications should be harmonized with the USEPA.

PMRA response
A full analysis was undertaken to compare USEPA and PMRA timelines and fees for precedent-based submissions. The comparison exercise is limited as the submission types don't directly align. This is because PMRA does not make a distinction between conventional, antimicrobial and biopesticide products for precedent-based submissions / label amendments whereas the USEPA does.

However, we do note that the PMRA timeline for these applications is currently nine months, versus some four-to-six month USEPA timelines. We therefore propose to reduce the PMRA review timeline to six months for Formulation amendments (C.2 applications). Historically, formulation amendment applications have made up approximately 40 per cent of these applications.

The current timeline will be applied for applications received with multiple submission types. For example, if an application includes both formulation amendments (C.2) and label amendments (C.3), the overall review time will be nine months (37 day completeness check plus 280 day review time).

The PMRA proposed fee is $1133 whereas the USEPA fee for similar applications range from $1200 to $4800 based on submission type. It should be noted that under the revised Notification/Non-notification Directive (DIR2013-02) a number of applications which were previously classified as Category C can now be processed through notifications. These submissions have shorter timelines (45 days) and lower proposed fees ($247).

13.0 Appendix III: How User Fees May Affect You

Comment
A few registrants indicated that:

- An increased fee structure for smaller registrants is non-competitive and the proposed regime supports larger/multinational organizations.
- Smaller crop groups are likely to see a larger increase in input costs compared to larger acre crops.
- Costing should be reconsidered and more in-depth analysis is needed to determine what segments are more affected.

PMRA response
It is understood that no fee increases have occurred since 1997 and the proposed readjustment may seem large, affecting some segments more than others. However, mitigation measures are still available for companies who do not expect high volumes of sales in the first three years of having a new active ingredient on the market.

It should also be noted that some fees have been lowered and others remain the same. There are also some application costs which will only increase marginally, recognizing newer and more efficient processes that have been put in place over time.

An additional cost benefit analysis has been undertaken to better understand the potential impact of the proposed fees on stakeholders. A summary is provided in the pre-proposal notice in Section 7.6.

14.0 Pre-Submission Consultations

Comment
There were a few suggestions from stakeholders relating to the pre-submission consultation process. They suggested that the PMRA should consider pre-submission fees for more detailed, senior level scientific feedback and sought improved preparation and outcome at pre-sub consultation meetings with specific performance standards.

PMRA response
Pre-submission consultations are a free service that provides an opportunity for PMRA to provide regulatory guidance to applicants on the requirements to register or amend a pest control product or guidance on a study protocol. Pre-submissions (pre-subs) are not currently a mechanism to seek regulatory decisions regarding proposed data packages. They were introduced over a decade ago to improve the quality of regulatory submissions and thereby create efficiencies for both government and industry. While pre-subs were originally targeted at smaller, first-time applicants, this opportunity to seek clarification on specific applications was also well received by larger, more experienced pesticide manufacturers.

PMRA has undertaken a number of initiatives over the years to help applicants better understand their regulatory requirements through guidance documents and training. PMRA regularly meets with stakeholders to discuss the pre-sub process and provides further guidance around meeting the regulatory requirements. In addition to this, the use of new electronic tools such as webinars and electronic decisions trees has made training more accessible for both government and industry.

Fees for enhanced pre-submission consultations are not being considered at this time.

In response to stakeholders' comments, we propose the following efforts to improve clarity and certainty in interpreting pesticide regulatory requirements:

- Administrative performance standards for pre-submission consultations will be established and clearly communicated to registrants.
- In recognizing applicants' desire for greater clarity and certainty in interpreting pesticide regulatory requirements, PMRA will explore ways to increase the use of enhanced tools and guidance (electronic tools such as webinars, publishing FAQs with additional information around regulatory requirements, etc.) and consult on ways to improve the pre-submission consultation process.

15.0 Annual Regulatory Charge

Comment
Several comments suggested that this charge be lowered.

PMRA response
At this time the PMRA is not considering changes to the proposed annual regulatory charge as this revenue is necessary to ensure that registered products continue to meet evolving scientific requirements and are adequately regulated throughout their lifecycle. Additionally, the idea of an annual post market fee or regulatory charge is not unique to Canada as the USEPA, United Kingdom and Australia apply annual charges. Further, the mitigation currently available to products with low sales will continue to be applied. Please see Section 7.4.2 of the pre-proposal notice for additional information related to this charge.

16.0 Fast Tracking Applications

Comment
A few stakeholders suggested portions of an application could be fast tracked if applicants have the option of paying a premium fee.

PMRA response
All registrations/regulatory services provided by the PMRA are provided at a set fee and within a set time frame. A fast track system would require the availability of skilled scientific expertise on an as needed and temporary basis. In our experience, it is unlikely that such expertise would be easily identified and attracted unless more permanent employment is available. Expedited timelines at normal fees may be available where significant health or environmental concerns justify addition resources. However, PMRA is not considering expedited timelines to facilitate quicker access to the market for business reasons.

17.0 Changes to Submission Category

Comment
One comment suggested converting selected submissions from one category type to another and adding different use site categories.

PMRA response
The PMRA acknowledges this suggestion, however the comment relates to the MoSP rather than fees.

18.0 Fee Implementation

Comment
Transition the new fees overtime and be transparent on when the fees will take effect

PMRA response
Only one comment, with no proposal, was received to transition new fees. It is proposed that all fees will be implemented at the same time following the regulatory process outlined in the *User Fees Act 2004*. It should be noted that through consultations over the past year, several fees have been reduced. To ensure transparency we will communicate to stakeholders the progress to date and next steps. As appropriate, information may be posted to the Health Canada website and through the *Canada Gazette* process for amending the regulations.

19.0 Charge Different Sectors Differently

Comment
There were a few conflicting comments that suggested applications for agricultural and domestic products be charged differently.

PMRA response
All applications, regardless of intended user will be charged consistently as per the proposed fees. Fee mitigation is available based on sales volume.

20.0 Continued Monitoring

Comment
One stakeholder suggested that the PMRA attempt to monitor the impact of any cost recovery adjustments on registrations.

PMRA response
As part of the periodic review of fees, PMRA will monitor the impact on all registrations

21.0 Age of Costing Data

Comment
Several stakeholders commented on the age of the costing data and the relatively short timeframe of the exercise. Others were satisfied with the approach taken by PMRA.

PMRA response
PMRA is satisfied that data used to determine costs is sufficient to support new fees. In addition to the activity-based costing approach, new cost projections were conducted for generic pesticides, accelerated timelines for precedent based registrations and label amendments, the new notification/non notification policy and for value and effectiveness data (new approach implemented, costing to be quantified). The projections account for process changes since 2011 and stakeholder comments from the March 2014 consultation. Please see Section 7.3.1 of the pre-proposal notice for additional information.

Furthermore, PMRA is implementing a program for activity-tracking on an ongoing basis that will facilitate future review of fees.