Pesticide Cost Recovery Consultation

A Consultation Document in Advance of Parliamentary Proposal

(publié aussi en français)

14 March 2014

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

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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. Since that time, the fees have not changed.

The purpose of this consultation is to solicit comments on our proposal to modernize regulatory charges and user fees charged for pesticide regulation.

Before developing this proposal, a broad representation of stakeholders was consulted on their expectations for the regulatory system. Stakeholders recognized our achievements, particularly in the areas of international regulatory cooperation and our current performance against published timelines for processing complex applications. However, concerns were expressed 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.

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 recognized that we may not be able to meet their needs and expectations without additional resources. The proposed fee changes were developed in consultation with stakeholder groups and we will continue to work with stakeholders to refine possible changes to the regulatory system as this proposal evolves.

This consultation document was created to provide you with an opportunity to review the proposed new 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 user fees, a rationale for fee increases, the proposed changes to application fees and the annual regulatory charge. We welcome and encourage your feedback, and will consider it in the on-going development of our proposal to Parliament.

Table of Contents

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*. 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 meeting the needs of pesticide users and registrants, and helping protect Canadians by upholding rigorous and modern health and environmental standards. In order to continue to meet expectations in all areas, we need to ensure that the use of revenues from fees and other funding sources reflect the relative benefits to all stakeholders.

2.0 Objective of the Consultation

This consultation 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 user fees and an annual regulatory charge, a rationale for application fees and the annual regulatory charge increases and the proposed changes to the fees/charges.

We welcome and encourage your feedback, and will consider it in the development of the Pre-Proposal Notification as part of a multi-step consultation process to meet the requirements of the *User Fees Act* (2004).

[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)

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

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; and,
    - Relative allocation of priorities.
- How any of your concerns may be addressed; and,
- Any additional relevant information.

Input received by 28 April 2014 will be considered.

Input 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

4.0 Introduction

We are proposing amended fees and a new cost recovery regime for pesticide regulation that 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.

This document outlines in detail our proposed new cost recovery regime, including proposed application fees, the annual regulatory charge and performance timelines.

A modernized cost recovery regime would:

- Better reflect costs that have been affected by 17 years of changing regulatory processes and inflation;
- Fulfill the requirements of the *User Fees Act* and 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; and,
- Better reflect the relative benefits to all stakeholders such as strengthening health and environmental protection, and contributing to Canadian economic goals.

5.0 Legal and Policy Requirements

5.1 *The Financial Administration Act*

The *Financial Administration Act* 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*.

5.2 *The Pest Control Products Act*

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

The *Pest Control Products Act* will be the authority under which the amended regulations will be made.

5.3 The *User Fees Act*

The *User Fees Act*, enacted in 2004, established 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;
- 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; and,
- Provide detailed information on service descriptions, reasons for fee changes and how it compares to international levels, service standards, three year revenue and costs forecasts, how the independent advisory panel is to 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. Temporary reductions in user fees could result if service standards are not adequately met.

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 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.

[2] "User fee" in the *User Fees Act* 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.

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* and is discussed with stakeholders twice a year during meetings of PMRA's Economic Management Advisory Committee.

5.5 Treasury Board Costing Guidelines

The Treasury Board Guide to Costing (2008) 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.

5.6 Treasury Board Policy on Special Revenue Spending Authorities

The current 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;
- The authority sought to re-spend revenues previously deposited to the Consolidated Revenue Fund[4] will correspondingly reduce the A-base of the department so that there is no net increase; 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.

[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)

[4] 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)

6.0 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.

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 science-based risk assessment includes the following:
    - Health and environmental risk assessments that consider the potential for a pesticide to cause adverse health 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; and,
- A value assessment that considers the product's actual or potential contribution to pest management.

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, label clarifications, etc.) 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 food, 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 Guidance Document on Pest Control Product Cost Recovery Fees (16 April 1997) 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, environmental fate, etc.).

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 (i.e. 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 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, Screening);
- Review Stage (Science Evaluation, Label Review and Decision); and,
- 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

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 the relevant legislative authorities and policies guiding the establishment of user fees previously described;
- 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.

A key objective with new fees is to establish a 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. 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); the United Kingdom Chemicals Regulation Directorate of the Health and Safety Executive; and the Australian Pesticides and Veterinary Medicines Authority 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. Many of the clients are multinational companies 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 are proposing that the USEPA pesticide fee structure be used as the primary international benchmark for developing new Canadian fees because they are our largest trading partner and our regulatory systems are more closely aligned as demonstrated by the number of joint activities Canada and the United States undertake.

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.

The outcomes of this exercise are included in Tables 1, 2, and 3 below 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 (Tables 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 resulted in 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.

The proposed user fees are premised on current MoSP timeframes as summarized in Appendix II

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
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

Item	Component	Proposed Fee	Current Fee	Average Cost to Health Canada
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	Generation of a compensable data list	$21,617	$0	$21,617

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.

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.

Item 11 – Generation of a compensable data list: The generation of a list of compensable data related to an application for a pesticide subject to the data protection provisions of the *Pest Control Product Regulations* is considered a direct benefit to the requesting applicant. A fee based on the full cost to provide the relevant resources to meet applicants' expectations (120 days) is proposed.

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
2	Research authorization	$5,080	$150	$16,932
3	Processing research notification	$552	$0	$1,841
4a	Review of a manufacture for export application	$7,827	$4,601	$25,948
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	$377	$0	$1,257

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 estimated costs for processing following the implementation of efficiency measures.

Items 2 – Research authorization and **3 – Processing research notification:** Fees for research notifications and authorizations have been separated, given differences in average costs between these activities.

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 import 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 to reflect more robust data required for the application – currently only the residue data fee is charged.

Item 6 – Processing of notification: A new fee is proposed for notifications,[5] based on estimated costs for review and processing.

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.

[5] Regulatory Directive DIR2013-02, *Notification/Non-notification*, http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir2013-02/index-eng.php

In establishing these fees, we took into account the USEPA fee for similar activities and the fee mitigation available to American applicants. Given that most 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. Mitigation for application fees are set at a maximum of 10 per cent of the sales revenue of products containing new active ingredients to a minimum of 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.

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 if the application is submitted by Agriculture and Agri-Food Canada or a provincial minor use coordinator (However, the basic application fee would apply when registrants amend the label to add the new use);
- Importations for own use, both for the Grower Requested Own Use (GROU) Program equivalency and import certificates; and,
- 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 affects the behaviour of arthropoda would be subject to fees described in Table 3.

7.3.6 Annual Fee Adjustment

An annual fee adjustment will allow fees to be increased incrementally based upon an approved formula for calculating changes.

The current lack of adjustment capability has not allowed fees to keep up with inflationary increases to costs, resulting in significant unrealized revenues. Periodically increasing fees in small increments will allow for improved planning for both government and industry and lessen the sudden impact of substantial increases at a later time.

The USEPA has a mechanism to increase pesticide application fees by 5 per cent every second year.[6]

We propose to increase application fees (Tables 1–3) annually, based on a weighted average of the following factors:

- Public service average annual percentage wage adjustments[7]
- Core Consumer Price Index (CPI) (annual) – Weighted Index[8]

Table 4 illustrates how the average annual adjustment is derived by averaging the two indices over the past four years. In this case, the adjustment factor would be applied to fees annually on a particular day, for example April 1 of a given year, and each subsequent year on the same date.

The annual adjustment is not proposed to be applied until after the new fee regulations are in effect.

---

6 United States Environmental Protection Agency, Pesticide Registration Manual, Registration Fees (http://www.epa.gov/pesticides/bluebook/chapter5.html)

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/)

Table 4 Weighted Average Annual Adjustment

Data Source	2009	2010	2011	2012	2013 (projected)	Weight	Weighted Average Annual Increase
Public service average annual percentage wage adjustments, by year	2.5%	1.6%	1.7%	1.7%	1.8%	83%	1.54%
Core CPI (annual) – Weighted Index	1.76%	1.72%	1.71%	1.7%	1.7%	17%	0.29%
						100%	1.83%

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 in an efficient and effective manner.

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 cost of living increases 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 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 3 per cent of the previous year's sales to a minimum of $75.

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 are selling between $2500 and $90,000 per year and are therefore paying the equivalent of 3 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 does not exceed 4 per cent of sales and that the current minimum regulatory charge be increased only slightly to $100. This increase approximates the cost of living increase since the charge was last updated. This mitigation should continue to support niche products and small businesses in Canada.

7.5 Projected Revenues

Table 5 outlines the revenues for fiscal year 2011/12 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) described in Table 4.

Table 5 Projected Revenues (Millions of dollars)

Revenue Sources	Fiscal Year 2011–12	Projected Revenues – New Fees				
		Year 1	Year 2	Year 2	Year 3	Year 4
			Based on estimated annual increase of 1.83%			
Application Fees	3.441	7.16	7.29	7.43	7.56	7.70
Annual Regulatory Charge	5.072	6.62	6.62	6.62	6.62	6.62
Total Revenues	8.513	13.78	13.91	14.05	14.18	14.32

7.6 Potential Impact of Proposed Changes

The economic impact on stakeholders of amending the pest control product fee regulations depends substantially on whether the potential increase in application fees and the annual regulatory charge would discourage registrants from seeking to register new products or maintaining their current registrations. As long as the proposed changes do not act as a significant deterrent to applying for or maintaining product registration, the primary impact would be to shift a portion of the costs of the product registration process from federal taxpayers to the private sector. While this shift could increase the costs borne by pesticide registrants, distributors of pesticide products, and users such as growers or applicators – and potentially the costs borne by consumers of products who benefit from the use of pesticides – it would not in and of itself represent a net cost to society; it would simply represent a redistribution of costs that are already being incurred.

For example, the following findings are based on preliminary analysis of the proposed changes and potential impacts to registrants of agricultural pest control products, and the agricultural sector:

- 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; and,
- 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.

8.0 Preliminary Stakeholder Feedback

Despite the fact that 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.

In addition, stakeholders are concerned 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, international work to address developments in science and policy; and, 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.

9.0 Next Steps

Your input will be considered and if required, further discussions with interested parties will be coordinated before the development of the Pre-Proposal Notification.

The Pre-Proposal Notification is a requirement of the *User Fees Act* and will be published on the Health Canada website for public comment. It will closely resemble this document, taking into account any changes resulting from this consultation as well as additional information required by the *User Fees Act*.

Subsequent to the Pre-Proposal Notification and processes prescribed by the *User Fees Act* to address comments received, the user fee proposal for pesticides will be tabled in Parliament.

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* (i.e. 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.

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[4]		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[2], Other Biopesticides, NSCLP[3]		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[4]		240 (8)	
	New MRL for previously assessed active ingredient[5]		425 (14)	
	Emergency use (priority): Reduced-Risk[2], Other Biopesticides, NSCLP[3]		<360 (12)	

Category	Category Subdivision	Completeness Check in Days	Review Time in Days (Months)[1]	Public Consultation in Days
	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[4], NSCLP[3], Reduced-Risk[2], 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 outlines the impacts of fee changes to Table 1 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 Table 1 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 / label • 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 / label • 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 / label • 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 / label • Chemistry	$1,434	$4,095

Type of Applications	Current Fee	Proposed Fee
A **change in application method** (B3.4) is often charged the following components: • Basic application / label • Human exposure • Value	$10,910	$7,502
Adding a new pest to an end-use product label (B3.11) is typically charged the following components: • Basic application / label • Value	$1,168	$2,289

[1] Metabolism data not always required.