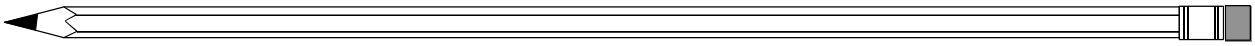
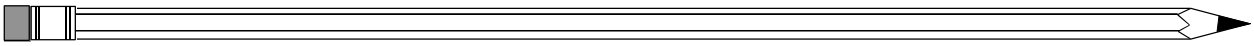


Guidance Document on Pest Control Product Cost Recovery Fees

April 16 1997



Guidance Document on Pest Control Product Cost Recovery Fees

1.0 Purpose and General Information Contacts

This document 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.

- For general information on the regulation of pest control products or questions related to specific applications, please contact the Pest Management Information Service at 1-800-267-6315 (outside Canada (613) 736-3799).
- For information on policy issues related to cost recovery contact Liz Javor at (613) 736-3703.
- For questions regarding invoices please contact the Accounts Receivable Unit at (613) 736-3402 and quote your invoice number.

Information on cost recovery including this document, the Fee Form, the *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 (Pest Control Product Fees Regulations)* and the Regulatory Impact Analysis Statement are available on the PMRA web page at http://www.hwc.ca/pmra. The regulations can also be found in Canada Gazette Part II. The application fees are listed in Schedule I and II of the fee regulations (see Appendix I of this guide).

2.0 Application Fees

2.1 Application Fee Procedures

2.1.1 Payment Schedule

Applications received before April 1, 1995

These applications are subject to the fees outlined in section 12 of the *Pest Control Products(PCP) Regulations*. While this section of the regulations has been repealed, the fees are still payable for applications received when the regulations were in effect. Invoices will be sent to the applicants of these applications when the registration is granted. If the application is withdrawn by the applicant or rejected by the PMRA, the old fee is not payable.

Applications received between April 1, 1995, and April 15, 1997

These applications fall into two categories: those applications subject to the old fees only and those subject to both the old fees and the new fees.

An application for which the evaluation of all components of the application has been started as of April 16, 1997 is subject to the old fee schedule only (section 12 of the *PCP Regulations*). Invoices will be sent to the applicant for these applications when the registration is granted. Exemptions or reduced fee provisions in the new regulations do not apply to the old fees.

For applications subject to the new fees and the old fees, an invoice will be sent to the applicant indicating the status of the evaluation of the application and the new fees payable. New fees will be charged on those components of the application for which the evaluation has not started. If the new fee is $1,000.00 or less, the total fee will be **payable on receipt of the invoice**. If the new fee is greater than $1,000.00, an invoice will be issued for 65% of the total fee. When the evaluation of the application is complete, an invoice will be issued for the remaining 25% of the new fee. Exemptions and reduced fee provisions of the new fee regulations may apply to the new fees for these applications. When the registration is granted, an invoice will be issued for the old fee payable under section 12 of the *Pest Control Product Regulations* (see Appendix II).

Applications received on or after April 16, 1997

For those applications that have a component outlined in Schedule I of the *Pest Control Product Fee Regulations* (see Appendix I) the fee payable is the sum of the fees for the required data components. If the amount payable is $1,000.00 or less, the total amount is payable at the time of application.

If the total amount payable is greater than $1,000.00, the fees are payable as follows:

- 10% is payable at the time of application;
- 25% is payable when the application has been accepted for preliminary review for deficiencies; and
- 65% is payable when the application has been accepted for evaluation.

The fees are payable before each step of the examination process of the application is started. Invoices will be issued if a fee installment is not received and the application will be kept on hold pending fee payment. Applicants will have 45 days to pay an invoice; if payment is not received within 45 days, the application will be rejected.

To avoid delays in the examination of the application, it would be advisable for the applicant to pay the entire fee at the time of application, provide postdated cheques for the 25% and the 65% amounts, or use a credit card. This would avoid the need for the PMRA to issue an invoice and invoke the 45 day on hold pending fees for the 25% and 65% payments.

The exemption and reduced fee provisions of the new fee regulations will apply as appropriate to these applications.

Schedule II of the *Pest Control Product Fee Regulations* (see Appendix I) lists the kinds of applications for which the total fee is payable on application. There are no reduced fee provisions for these applications.

Table 1 illustrates how the transition to cost recovery will be handled.

Table 1: Transition to Cost Recovery

Date Application Received	Application Status as of April 16, 1997	Stage of Application:				
		Screening	Accepted for Preliminary Review for Deficiencies	Accepted for Evaluation	Evaluation Completed	Accepted for Registration
		Percentage of Total Fee Payable				
before April 1, 1995	not yet registered	N/A	N/A	N/A	N/A	100% of old fee
April 1, 1995 to April 15, 1997	screening of application not yet started	0%	N/A	65%	25%	100% of old fee
April 1, 1995 to April 15, 1997	screening started or completed	0%	N/A	65%	25%	100% of old fee
April 1, 1995 to April 15, 1997	review not started on all data components	0%	N/A	65%	25%	100% of old fee
April 1, 1995 to April 15, 1997	review started on all data components	0%	N/A	0%	0%	100% of old fee
April 16, 1997 onwards	screening not started	10%	25%	65%	N/A	N/A

2.1.2 Withdrawn and Rejected Applications

If the applicant submits a written request to withdraw an application or an application is rejected by the PMRA, the fee payable for the application will be based on when the application was withdrawn/rejected. Refer to the summary table below.

Table 2: Fees Payable on Withdrawn or Rejected Applications

Timing of Withdrawal or Rejection:	Total Required Fee for Applications Received		
	before April 1, 1995	April 1, 1995 to April 15, 1997	on or after April 16, 1997
Before screening is started	N/A	0	0
Before screening has been completed	N/A	0	10%
After the application is accepted for preliminary review for deficiencies	N/A	N/A	10 + 25 = 35%
After the application is accepted for evaluation	N/A	65% of the new fees	10 + 25 + 65 = 100%
After the evaluation is complete	N/A	65 +25 = 90% of the new fees	100%
After evaluation is complete but before registration is granted	0% of the old fee	90% of the new fees but 0% of the old fee	100%

2.1.3 Payments

To avoid delays in the application examination process, applicants are encouraged to provide the PMRA with access to funds for the payment of the 25% and 65% amounts at the time of application. This can be done in three ways:

- (1) the applicant can pay the entire fee at the time of application. If the application is rejected or withdrawn before it reaches the point in the examination process where the fee is payable, the fee will be refunded.
- (2) postdated cheques can be provided to the PMRA. The 25% payment should be postdated 45 days from the date the application is made. The 65% payment should be postdated 105 days from the date the application is made.
- (3) Applicants can pay by credit card and give the PMRA permission to charge fees to the credit card as the application progresses and the 25% and 65% fees become payable.

If applicants do not arrange for payments through one of the methods outlined above, invoices will be issued as the 25% and 65% amounts become payable. Applicants should realize that this method of payment will result in delays in the application examination process because the examination of the application will be stopped for a 45-day period regardless of when the payment is received during the 45-day period.

When paying an invoice, all cheques should be in Canadian funds and made payable to the "**Receiver General for Canada**." As stated on the invoice, payment should be sent to:

Pest Management Regulatory Agency
Accounts Receivable
5th floor, Sir Charles Tupper Bldg.
A.L.6605C1
2250 Riverside Drive
Ottawa, Ontario
K1A 0K9

For questions regarding your invoice or your account balance, the staff in the Accounts Receivable Unit can assist you. They can be reached by phone at (613)-736-3402 or by fax at (613)-736-3410. Please have your invoice number available when you contact them.

2.1.4 Fee Form

A fee form has been developed to help identify submission data components and applicable fees for applicants. The form includes descriptions of the components along with the relevant fees outlined in the *Pest Control Product Fees Regulations*. Applicants are requested to fill in the appropriate boxes and total up the components, as applicable, to indicate the total application fee. The fee form must be signed by the applicant and submitted with the application and payment for the appropriate amount(s). The fee form must be completed for applications for reduced fees (see section 2.3 of this guide).

Fee forms are available from the PMRA or can be located on the PMRA web page. These forms may be updated periodically. A completed fee form should accompany each application unless the application is a User Requested Minor Use Label Expansion (URMULE) or Own Use Import (OUI) application. These applications are exempt from fees. If the application is missing a fee form or a request for an exemption from fees, it will be returned to the applicant at the applicant's expense. If the applicant is sending the application via courier service, please quote your courier account number. This is to ensure that the applicant receives their returned package the same way it was sent into the Agency. For a complete list of applications that are exempt from fees please refer to section 2.2.2 of this guide.

2.2 Application Fee Structure

2.2.1 Calculating the Applicable Fee

For the old fee structure which is applicable to all applications received before April 16, 1997, see Appendix II. For the new fee structure, which applies to all applications received on or after April 16, 1997, and applications received between April 1, 1995, and April 15, 1997, where the evaluation of a component of the application has not been started as of April 16, 1997, see Appendix I. Fees will not be refundable unless otherwise indicated.

Table 3 outlines all of the application categories and application types. Application categories are defined in the *Management of Submissions Policy*, June 1996. This document is available on the PMRA web page or by calling the Pest Management Information Service. The data components that may apply are also listed. For some application types such as a major new use there is a range of data components that may be required and, as a result, the fee will vary. For example, an outdoor food use will require more supporting data components than an indoor non-food use and the corresponding application fee will be higher.

To assess fees in an efficient manner, the fee for each component, outlined in Schedule I of the *Pest Control Product Fee Regulations*, is based on the amount of effort required to review an average package of supporting data making up the component. Therefore, the same fee is charged for a component regardless of the amount of information (e.g., number of studies) contained in that component.

The data requirements for some of the components will be less for a category B application in comparison to a category A application; therefore, the fee is lower. Because the label review for a category C application is generally less work than a label review for a category A or B application, the fee is lower.

For category A and B applications, there will be one or more possible data components (see Table 3). The total fee is the sum of the fees for each applicable data component. For example, an application to register a new technical grade active ingredient product would involve data components 1(a), 2, 4(a), 6, 8(a), 9(a). The fee would be the sum of the fees for these data components outlined in Schedule I of the *Pest Control Products Fee Regulations* (see Appendix I).

Table 3: Data Components for Pest Control Product Examination Service

Application Category	Application Type	Possible Data Components
Category A	New Technical Grade Active Ingredient (TGAI)	1(a), 2, (4a), 6, 8(a), 9(a)
	End-use Product Containing a New TGAI	1(a), 3, 4(c), 5(a), 6, 7, 8(a), 9(a), 10
	Major New Use	1(b), 3, 4(b), 4(c), 5(b), 6, 7, 8(b), 9(b), 10
	URMUR	same as new active and/or major new use
	Import MRL	See Schedule II of PCP Fee Regulations
Category B	New/Amended Formulation, New/Amended Labelling Conversion/Extension of Temporary Registration, New Source of TGAI, Import MRL for previously assessed TGAI.	1(b), 3, 4(b), 4(c), 5(c), 6, 7, 8(c), 9(c), 10
Category C	Registration Amendment	1(c)
Category D	IMEP	See Schedule II of PCP Fee Regulations
	Master Copy	1(c)
	Private Label	1(c)
	Registration Renewal	See Schedule II of PCP Fee Regulations
Category E	Research Permit	See Schedule II of PCP Fee Regulations

Applicants may request waivers for certain required studies or data parts. An acceptable waiver request consists of a scientific rationale with supporting documentation (e.g., literature search, surrogate data), all of which requires an assessment. Therefore, the fees will normally be charged for waiver requests.

There are several pieces of information that may be required in a complete data package that should not be included in the calculation of application fees. These pieces of information are basically a reorganization of information contained in other data components. Therefore, if a component consists only of the information listed in the right column of Table 4 (indexed according to PMRA data codes (DACOs)), there is no fee for reviewing the component listed in the left column of Table 4.

Table 4

Fee Regulation Schedule I Component	PMRA Data Code (DACO)
5 (a), (b), or (c) Exposure Data	5.2 Use Description/Scenario (Application and Post Application
8 (a), (b), or (c) Environmental Fate Data	8.2.1 Summary of Physicochemical Properties
8 (a), (b), or (c) Environmental Fate Data	8.2.3.2 Hydrolysis
8 (a), (b), or (c) Environmental Fate Data	8.4 Storage, Disposal and Decontamination
8 (a), (b), or (c) Environmental Fate Data	8.4.1 Summary

Fees for category C, D and E applications and fees for category A and B applications that are less than $1,000 are payable when the application is made. Please send payment together with the application to the Submission Management and Information Division. Applications will be returned to the applicant if the payment is missing.

In some situations an application may cross-reference or cite information in another file. If the cited information will be evaluated as part of the application, then the relevant fee will apply and should be indicated on the fee form. In addition, fees will not be charged for a component if all of the studies/data have been previously submitted and evaluated and are cited in a new application.

Applications for research permits and the establishment of maximum residue limits on unregistered products or uses (import MRLs) represent special cases in terms of fees charged. An administrative fee of $150.00 is charged for a research permit. Sometimes significant data are submitted and evaluated in support of a research permit application. These data are then cited in subsequent applications for registration of the product. The evaluation of the cited data will be charged for as part of the application for registration. Similarly, product chemistry, toxicology, residue and metabolism data are reviewed for applications for the establishment of import MRLs. The fee for an import MRL covers the review of residue data for the crops to be imported into Canada. The data submitted to support the establishment of the import MRL are often cited in subsequent applications to register the pest control product. The evaluation of the cited data, except for the residue data on the imported crops, will be charged for as part of the application for registration.

2.2.2 Exemptions

The following applications are exempt from some or all application fees:

(a) Proposals for user requested minor use label expansion (URMULE) prepared by sponsors and submitted to the PMRA via the Provincial or Forestry Minor Use Coordinators. If the proposed minor use is acceptable, the PMRA will contact the registrant of the pest control product for which the additional minor use is proposed. The registrant must then apply to amend the registered label of the pest control product. The fee for this application is $154.00.

(b) Pesticide own-use import (OUI) permits issued under the authority of section 5(1)(d)(iii) of the *Pest Control Products Regulations*. Applications for acceptance in the OUI program as specified in section 5(1)(d)(ii) and 5(3) are also exempt from fees.

(c) As specified in section 2(2)(c) of the *Pest Control Product Fee Regulations*, certain products are exempt from all of the application fees specified in Schedule I except the label fees under Item 1. This exemption applies to applications for a registration of a pest control product whose active ingredient is: i) an organism; ii) a substance that is not an agricultural chemical as defined in section B.01.001 of the *Food and Drugs Regulations*; or iii) a naturally occurring semiochemical or an identical synthetic substance that affects the behaviour of arthropoda. This exemption is temporary until the data requirements and anticipated evaluation costs to register these products are determined. Appendix III lists examples of applications for registration of pest control products that are exempt under this provision.

(d) Applications for research permits that are received from other federal departments are exempt from paying the $150 administration fee. This exemption is pursuant to paragraph 19 (3) (a) of the *Financial Administration Act*.

2.3 Application For Reduced Application Fees

This section provides guidance on how to apply for a reduction of the fee payable under Schedule I of the *Pest Control Product Fee Regulations* for applications for a new product (new PCP number). Applications for amendments to existing products are not eligible for reduced fees. Application types listed in Schedule II of the fee regulations are not eligible for reduced fees.

Reduced fees are being offered to facilitate access to the Canadian market for low volume, niche products. The onus is on the applicant to supply sufficient evidence to support the application for the reduced fee.

2.3.1 Eligibility for Reduced Application Fees

To be eligible for a reduced fee, a registrant's revenues from sales in Canada of the pest control product(s) during the sales verification period must be less than 10 times the applicable application fee. Sales are defined as the net sales of the product in Canada after all discounts (e.g., volume discounts and promotional rebates).

2.3.2 Application for Reduced Application Fees

The applicant must present information to support the anticipated revenue from sales of the pest control product in Canada during the sales verification period. 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. The information should provide the expected market situation for the proposed product. Information to support the anticipated revenue should include, as a minimum, the following:

- description of the product;
- target market(s) - description, size, demand;
- comparison with similar competitive products;
- expected market share for the 3 years of the sales verification period;
- expected average sale price/volume (for each submarket in the targeted group if applicable) for the 3 years of the sales verification period; and
- total expected sales for the 3 years of the sales verification period.

A request for a reduction of fees and the accompanying information must be included with the application as a separate section which can be detached from the application. This will facilitate the management of this Confidential Business Information and its separate review by a review committee. The applicant must include a completed fee form, indicating what the full fee would be and that the applicant has applied for a reduced fee.

The application for reduced fees will be reviewed during the 45-day screening period. The applicant will be notified in writing by the Screening Group if the application for reduced fees has been accepted or rejected, if deficiencies are identified, or if any fee adjustments are necessary. The applicant will be notified of the fees that will be charged at each phase of the examination process.

2.3.3 Calculation of Reduced Application Fees

Application fees are set at a maximum of 10% of the revenue from sales during the sales verification period of the product(s) registered as a result of the evaluation service. However, the fee reduction cannot reduce the fee payable under Schedule I of the fee regulations to below 10% of the total fee.

For the purposes of calculating the reduced fee for applications, the sales of all products that are registered based on the evaluation of the same data package must be added together. When calculating a reduced fee for an application for a pest control product containing a new active ingredient(s), the anticipated revenue calculation will include the anticipated revenue from sales of all products containing the new active ingredient registered during the sales verification period. These rules allow reduced application fees where the evaluation costs are high when compared to the potential benefit to the applicant (product sales).

If the reduced fee request is granted, certified sales records must be submitted to the Accounts Receivable Unit at the end of the sales verification period. Certified sales records are sales records that are certified on behalf of the registrant by a person designated by the registrant. If the revenue stated in the certified sales records is greater than the initially-projected sales, the balance payable will be due 60 days after the verification period ends.

The PMRA reserves the right to require the registrant to submit sales records, which have been audited by a qualified independent auditor, for any product for which a reduced fee is requested. If the audited sales records are not provided to the PMRA, the full maintenance fee will be payable. If the sales reported on the audited sales record are higher than the sales reported on the certified sales record, the fee payable will be based on the audited sales record.

The provision of an inaccurate certified sales record may constitute a contravention of the *Pest Control Products Regulations* and be a violation of the *Pest Control Products Act*.

Interest on amounts owing to the Crown as outlined in section 4 of this guide may be payable to the Crown where the sales reported in the certified sales record are lower than the sales reported in the audited sales record.

Reduced Fee Threshold

The reduced fee threshold (RFT) is the amount of projected sales below which an application qualifies for a reduced fee. The reduced fee threshold is ten (10) times the calculated application fee using Schedule I of the Fee Regulations.

RFT = 10 X Application Fee

Examples of Reduced Fee Calculations

A) Application for a new end-use product (EP) with low projected sales.

B) Applications for a new technical grade active ingredient (TGAI) and three (3) associated end-use products (EPs).

C) Applications for three (3) new end-use products (EP) applied for at the same time and based on substantially the same data package.

A) Application for a new end-use product (EP) with low projected sales

An application of a new EP product is made. The calculated application fee from Schedule I of the *Pest Control Product Fee Regulations* is $60,000. The projected sales of the product during the sales verification period are $380,000. Since this is less than the RFT (i.e., $600,000), this application qualifies for a reduced fee.

The fee payable is 10% of the projected sales (i.e., 10% x $380,000 = $38,000). Since the reduced application fee is greater than $1,000, a payment of 10% of the reduced application fee (i.e., $3,800) is payable upon application.

B) Calculation of fees payable for TGAI application and three (3) associated EPs

Definition of sales for a new TGAI: For an application to register a new TGAI, the revenue from sales is considered to include the gross sales of all products, excluding the TGAI, containing the new TGAI registered during the sales verification period.

Since all applications for EPs are received at the same time and share data components, the sales of all EPs must be added together when determining the projected sales.

Application	Application Fees	3 Year Projected Sales	Fee Payable
TGAI	$120,000.00	$0.00*	$100,000.00**
EP1	$60,000.00	$500,000.00	$60,000.00***
EP2	$6,000.00	$400,000.00	$6,000.00
EP3	$200.00	$100,000.00	$200.00
Total	$188,000.00	$1,000,000.00	$166,200.00

* There are no Canadian sales of the TGAI *(because the EP are imported into Canada or the TGAI is used only in the registrants own products, i.e., no external sales)*

** Based on maximum of 10% sales of all EPs containing the new TGAI

*** Based on total sales of all end use products submitted together and sharing data component(s)

C) Applications for three (3) new EP received at the same time and sharing data component(s).

Application	Application Fees	3 Year Projected Sales	Fee Payable
EP1	$60,000.00	$200,000.00	$40,000.00*
EP2	$6,000.00	$150,000.00	$6,000.00
EP3	$200.00	$50,000.00	$200.00
Total	$66,200.00	$400,000.00	$46,200.00

* Based on total sales of all end use products submitted together and sharing data component(s)

3.0 Maintenance Fees

An annual maintenance fee of $2,690.00 will be charged per registered product (per PCP number) for the right to manufacture or sell a product in Canada. All registered products including technical grade active ingredients, IMEPs, private label products and master copies must pay the maintenance fee. There are reduced fees for products with sales of less than $89,667.00 ($89,667.00 x 3% = $2,690.00). The reduced fee is 3% of sales. However, there is a minimum fee of $75.00. Sales are defined as the net sales of the product in Canada after all discounts (e.g., volume discounts and promotional rebates).

In February 1997, Health Canada agreed to the stakeholders' request to reduce regulatory burden by providing single window jurisdiction for the regulation of hard surface disinfectants. Responsibility for these products will rest with the Drugs Directorate, Health Protection Branch, Health Canada. The Department is currently working with stakeholders on the implementation of this change. Until responsibility for the regulation of hard surface disinfectants is effected through regulatory and legislative amendment, the PMRA is responsible for the regulation of these products and will be

charging maintenance fees. Transfer of this responsibility should be finalized by April 1998. In order to save companies from paying duplicate maintenance fees, the PMRA will reduce maintenance fees for products that have both a PCP number and a DIN by the amount of the annual DIN fee paid for each of these products in 1996-1997. The registrant will have to inform the PMRA of the amount of DIN fee paid in 1996-97. This reduction will only apply to maintenance fees for 1997.

3.1 Maintenance Fee Procedures

Four invoices will be issued in one mailing to each registrant for products registered in that registrant's name as of April 16, 1997, and April 1 of each year thereafter. Registrants have the choice of paying the total fee on receipt of the invoices or in four equal installments. Interest will be payable according to section 4 of this guide. For companies that choose to pay in four equal installments, the payments are payable quarterly.

Companies will receive with the April invoice an attachment listing the products registered to their company and the total fee payable. For each product listed on the invoice/attachment please indicate the maintenance fee ($2,690.00, reduced fee, DIN fee paid if applicable and/or the minimum fee of $75.00).

If you are in the process of transferring this product to another registrant and the transfer has not been completed as of April 1 of a given year, you are responsible for paying the maintenance fee for that product.

If you have discontinued the product and indicated that there is stock remaining in the marketplace, maintenance fees are still payable for the product for the years that the product remains registered while the stock is being exhausted. If a registrant wishes to discontinue the registration of a product to avoid paying the maintenance fee, the request to discontinue the product must be received by the PMRA prior to April 16, 1997, and April 1 each year thereafter, and the registrant must not have any stock remaining. If there is stock remaining in the marketplace and the registrant wishes to discontinue the registration immediately, the registrant will have to provide a plan along with the request to discontinue the registration of the product for approval by the PMRA, on recalling and disposing of unused stock. Alternatively, the PMRA may process the discontinuation but it will not take effect until the year in which the registrant has estimated that all stock in the marketplace will be exhausted. The registrant will be assessed maintenance fees for this interim period; however, the registrant may qualify for a reduced fee based on their sales.

It is not possible under the payment of maintenance fees process to amend the registration of products. All such proposed changes must be submitted via an Application for New or Amended Registration form or, if applicable, through the notification process.

Please submit one micro-encoded cheque (precoded with the transit number, institution number and account number) in Canadian funds and made payable to the Receiver General for Canada to cover the total cost of the maintenance fees for your company or provide your Visa or MasterCard number and expiry date..

All correspondence and inquiries regarding maintenance fees should quote the invoice number and be directed to the Accounts Receivable Unit.

On the invoice/attachment the registrant must check the products for which they are paying the maintenance fee. Nonpayment of maintenance fees will be considered a debt to the Crown and will be subject to the normal government collection procedures including the charging of interest and administrative fees as outlined in section 4 of this guide.

Private label products and master copy products also must pay the annual maintenance fee. For private label products and master copy products the invoices will be sent to the registrant of the product, not the initial product or master product registrant.

3.2 Application for Reduced Maintenance Fees

The registrant may apply for a reduced fee on any of the company's products. The reduced fee would be 3% of sales for the previous fiscal year. There is a minimum fee of $75.00.

3.2.1 Eligibility for Reduced Maintenance Fees

In order to be eligible for the reduced fee, a pest control product must have less than $89,667.00 sales (3% x $89,667.00 = $2,690.00). The registrant must submit the certified sales record for the previous fiscal year for the product with the first payment. The sales record must be certified on behalf of the registrant by a person designated for that purpose.

Applications for reduced fees will be accepted only if sales data for the previous fiscal year certified by a designated company official is provided. A letter will be sent to the registrant if the application for reduction is not accepted and interest will be charged to the company as outlined in section 4 of this guide. Sales data submitted in support of an application for reduced fees will be treated as Confidential Business Information and will not be used for any other program purposes by the PMRA.

The PMRA reserves the right to require the registrant to submit sales records, which have been audited by a qualified independent auditor, for any product for which a reduced fee is requested. If the audited sales records are not provided to the PMRA, the full maintenance fee will be payable. If the sales reported on the audited sales record are higher than the sales reported on the certified sales record, the fee payable will be based on the audited sales record.

The provision of an inaccurate certified sales record may constitute a contravention of the *Pest Control Products Regulations* and be a violation of the *Pest Control Products Act*.

Interest on amounts owing to the Crown as outlined in section 4 of this guide may be payable to the Crown where the sales reported in the certified sales record are lower than the sales reported in the audited sales record.

3.2.2 Calculation of Reduced Maintenance Fees

Example 1: The registrant has a product with $1 million in sales in the previous fiscal year. The company pays an annual maintenance fee of $2,690.00.

Example 2: The registrant has a product with $50,000.00 in sales in the previous fiscal year. The company pays an annual maintenance fee of 3% of $50,000.00 = $1,500.00.

Example 3: The registrant has a product with $2,000.00 in sales in the previous fiscal year. The company pays an annual maintenance fee of $75.00 because 3% of $2,000.00 = $60.00 (which is below the minimum fee of $75.00).

Example 4: The registrant has a product that is not manufactured in Canada and has zero sales. The company pays the minimum annual maintenance fee of $75.00 for the right and privilege to manufacture or sell a product in Canada.

Example 5: The registrant has three products with sales of $1 million, $50,000.00 and $2,000 respectively in the previous fiscal year. The company pays annual maintenance fees of $2,690.00 + $1,500.00 + $75.00 = $4,265.00.

Example 6: The registrant has five products with sales greater than $1 million in the previous fiscal year. The registrant has annual maintenance fees totalling 5 x $2,690.00 = $13,450.00.

Example 7: The registrant has a product with sales of $1 million in the previous fiscal year that has a DIN and a PCP number. The DIN fee paid in 1996-97 was $250.00. The fee payable to the PMRA is $2,690.00 - $250.00 = $2,440.00.

Example 8: The registrant has a product with sales of $10,000 in the previous fiscal year that has a DIN and a PCP number. The DIN fee paid in 1996-97 was $50.00. The reduced fee is $300.00 (3% x $10,000.00 = $300.00). The fee payable to the PMRA is $300.00 minus the $50.00 DIN fee paid = $250.00.

Example 9: The registrant has a product with sales of $2,000.00 that has a DIN and a PCP number. The DIN fee paid in 1996-97 was $50.00. The reduced fee is $75.00 because their is a minimum fee of $75.00. The fee payable to the PMRA is $75.00 minus the DIN fee paid of $50.00 = $25.00

Example 10: The registrant has a product with sales of $20,000 that has a DIN and a PCP number. The DIN fee paid in 1996-97 was $250.00 The reduced fee is $600.00 (3% x $20,000.00 = $600.00). The fee payable to the PMRA is $600.00 minus the DIN fee paid of $250.00 = $350.00.

4.0 Interest and Administrative Charges

Interest and administrative charges will be assessed as outlined below pursuant to the *Interest and Administrative Charges Regulations*.

4.1 Interest

Where an amount is owing to the government of Canada, interest calculated and compounded monthly at the average bank rate plus 3% is payable on that amount and accrues during the period beginning on the due date and ending on the day when payment is received by the government of Canada.

"Due Date" means the due date specified in a demand for payment. Where no date has been specified or included in the demand for payment, the due date is 30 days after the day on which a demand for payment is issued or any day on which payment is to be made in accordance with the applicable Act of Parliament, regulation, order, contract or arrangement.

4.2 Administrative Charges for Dishonoured Instruments

Where an instrument tendered in payment or settlement of an amount is, for any reason, dishonoured, an administrative charge of $15.00 is payable by the debtor.

Where a payment is made by the PMRA to a financial institution in order to reimburse that institution for an amount initially credited to the Receiver General on the basis of a dishonoured instrument, an administrative charge of $10.00 is payable by the debtor.

Where a financial institution charges an amount to the PMRA for monitoring the account of a debtor who has tendered a dishonoured instrument and for subsequently certifying or clearing that dishonoured instrument, an administrative charge in that amount is payable by the debtor, in addition to the charge referred to in the first paragraph of this section.

5.0 Complaint Mechanism and Appeals Procedure

The applicant or registrant may appeal decisions regarding the application of the *Pest Control Product Fee Regulations*. The first step which should be taken by the applicant is to get in touch with the appropriate contact person mentioned in section 1.0 of this Guide. These officers will assist the applicant in using the appeal/complaint process and will provide status on ongoing appeals/complaints.

The appeal must be received within 30 calendar days following issuance of the invoice. All appeals must be received in writing, by mail or facsimile. For application fees, the appeal or complaint should be directed to the Director, Submission Management and Information Division. The Director of the Submission Management and Information Division will review the decision in question in consultation with the Screening Group and the relevant review Division(s) and send the appellant a reply which will include the decision on the appeal and the rationale for the decision. The review of the application will not proceed until the dispute is resolved. For maintenance fees, the appeal or complaint should be directed to the Director, Management Planning and Coordination Division.

APPENDIX I

SCHEDULE I

(Sections 2 and 3 and subsection 8(4))

APPLICATION FOR ISSUANCE OR AMENDMENT OF A CERTIFICATE OF REGISTRATION OF A PEST CONTROL PRODUCT

Item	Column I Component	Column II Fee ($)
1.	(*a*) Label accompanying an application for the registration of a pest control product consisting of or containing a new active ingredient	262
	(*b*) Label accompanying an application in respect of a pest control product representing a new use	262
	(*c*) Label) other	154
2.	Product chemistry) active ingredient	1,172
3.	Product chemistry) end-use product or manufacturing concentrate	1,172
4.	(*a*) Toxicology data accompanying an application for the registration of a pest control product consisting of or containing a new active ingredient	98,248
	(*b*) Toxicology data accompanying an application in respect of a pest control product representing a new use	35,456
	(*c*) Toxicology data) acute studies only	4,274
5.	(*a*) Exposure data accompanying an application for the registration of a pest control product consisting of or containing a new active ingredient	24,384
	(*b*) Exposure data accompanying an application for a major new use of a registered pest control product	24,384
	(*c*) Exposure data) other	9,742
6.	Metabolism data	6,034
7.	Residue data	8,448
8.	(*a*) Environmental fate data accompanying an application for the registration of a pest control product consisting of or containing a new active ingredient	26,953
	(*b*) Environmental fate data accompanying an application for a major new use of a registered pest control product	26,953
	(*c*) Environmental fate data) other	6,738
9.	(*a*) Environmental toxicology data accompanying an application for the registration of a pest control product consisting of or containing a new active ingredient	14,882

Item	Column I Component	Column II Fee ($)
	(*b*) Environmental toxicology data accompanying an application for a major new use of a registered pest control product	14,882
	(*c*) Environmental toxicology data) other	3,720
10.	Value and effectiveness data for a pest control product	906

SCHEDULE II
(Sections 2 and 4)

OTHER APPLICATIONS IN RELATION TO A PEST CONTROL PRODUCT

Item	Column I Application	Column II Fee ($)
1.	Renewal of certificate of registration	154
2.	Research permit (administration fee)	150
3.	(*a*) Import for manufacture and export registration	4,601
	(*b*) Amendment to import for manufacture and export registration	154
4.	Establishment of maximum residue limit for an unregistered pest control product or for an unregistered use of a pest control product	8,448

APPENDIX II

Summary of fees payable pursuant to section 12 of the Pest Control Products Regulations (repealed April 16, 1997) for applications received before April 16, 1997

FEE CATEGORY	Fees ($)
PESTICIDES	
Registration Fees	
Registration of a new active ingredient	3,000
New crop/location	300
New product form	300
New application method	300
Antifouling paint	300
Re-evaluation of active ingredient	300
Other	300
New source of an active already registered in Canada	3,000
Amend application method or packaging	100
Amend formulation or chemistry specifications	100
New product	100
Add or delete pest	100
Add or delete crop/location	100
Master Product	100
Amend toxicological information or first aid statement	100
Initial Product	100
Extend/convert temporary registration	50
Other	100
Minor formulation correction (guarantee, proportions of inerts, change in fragrance/dye)	50
Amend label trade dress, layout, net contents or disposal	50
Amend source of active ingredient	100
Reinstatement of lapsed registration	100
Transfer of ownership	50
Amend product name	50
Amend name or address of registrant/agent/formulator	50
New Master Copy derived from Master Product	50
Amend label to improve clarity or as requested	50
Label Improvement Program	0
Minor Use label amendment:	
- Registrant request	50
- Agriculture and Agri-Food Canada request	0

APPENDIX III

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 Product Fee Regulations*. This exemption from application fees is pursuant to paragraph 2(2)(d) of the *Pest Control Product 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 Drugs 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 (e.g., 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

Table 1: Safety Universally Recognized List (SURE)

INS No.	Substance	INS No.	Substance
414	Acacia Gum	1403	Bleached Starch
260	Acetic Acid		Bovine Rennet
1422	Acetylated Distarch Adipate	1101	Bromelain
1414	Acetylated Distarch Phosphate	263	Calcium Acetate
472a	Acetylated Monoglycerides	404	Calcium Alginate
472e	Acetylated Tartaric Acid Esters of Mono & Diglycerides	556	Calcium Aluminum Silicate
1401	Acid-treated Starch (Thin-boiling Starch)	302	Calcium Ascorbate
406	Agar	170	Calcium Carbonate
400	Algin	333	Calcium Citrate
400	Alginic Acid	526	Calcium Hydroxide
1402	Alkaline-treated Starch	327	Calcium Lactate
403	Ammonium Alginate	529	Calcium Oxide
503	Ammonium Bicarbonate	282	Calcium Propionate
503	Ammonium Carbonate	552	Calcium Silicate
510	Ammonium Chloride		Calcium Stearate
380	Ammonium Citrate, Mono and Dibasic	516	Calcium Sulphate
527	Ammonium Hydroxide	150a	Caramel Class I
517	Ammonium Sulphate	290	Carbon Dioxide
1100	Amylase from *Aspergillus niger* var.	410	Carob Bean Gum
1100	Amylase from *Bacillus subtilis* var.		Catalase from Bovine (*Bos taurus*) Liver
1100	Amylase from Barley Malt		Cellulase from *Aspergillus niger* var.
1100	Amylase from *Rhizopus oryzae*	140	Chlorophyll
300	Ascorbic Acid	330	Citric Acid
408	Baker's Yeast Glycan	1400	Dextrin-roasted Starch
162	Beet Red	1412	Distarch Phosphate
315	Erythorbic Acid		Magnesium Fumarate
297	Fumaric Acid		Ethyl Alcohol
	Gelatin	528	Magnesium Hydroxide
	Glucanase from *Bacillus subtilis* var.	530	Magnesium Oxide
	Glucoamylase from *Rhizopus oryzae* var.	553	Magnesium Silicate
575	Glucono delta Lactone		Magnesium Stearate
422	Glycerin	518	Magnesium Sulphate (Epsom Salt)
	Glyceryl Diacetate	296	Malic Acid
	Glyceryl Mono Acetate		Milk Coagulating Enzyme from *Endothia parasitica*
	Glyceryl Triacetate		Milk Coagulating Enzyme from *Mucor pusillus Lindt*
412	Guar Gum	471	Mono and Diglycerides
	Hemicellulase from *Bacillus subtilis* var.		Monoglycerides
507	Hydrochloric Acid	1410	Monostarch Phosphate

INS No.	Substance	INS No.	Substance
1442	Hydroxypropyl Distarch Phosphate	941	Nitrogen
1440	Hydroxypropyl Starch	1404	Oxidized Starch
	Invertase from *Saccharomyces* sp.		Pancreas Extract
416	Karaya Gum		Pancreatin from the Pancreas of the Hog (*Sus scrofa*) or Ox (*Bos taurus*)
	Lactase from *Kluyveromyces lactis*	1101	Papain from the Fruit of the Papaya (*Carica papaya L.*, Fam. *Caricaceae*
	Lactase from *Saccharomyces* sp	160c	Paprika
270	Lactic Acid	440	Pectin
472b	Lactylated Mono and Diglycerides		Pectinase from *Rhizopus oryzae* var.
322	Lecithin		Pentosanase from *Aspergillus niger* var.
1104	Lipase from Animal Pancreatic Tissue		Pentosanase from *Bacillus subtilis* var.
1104	Lipase from edible forestomach tissue of calves, kids or lamb		Pepsin from Glandular Layer of Porcine Stomach
504	Magnesium Carbonate	1413	Phosphated Distarch Phosphate
511	Magnesium Chloride	261(i)	Potassium Acetate
402	Potassium Alginate	501(ii)	Potassium Bicarbonate
501(i)	Potassium Carbonate	1450	Starch Sodium Octenyl Succinate
508	Potassium Chloride		Stearic Acid
332(ii)	Potassium Citrate	553	Talc
	Potassium Fumarate	171	Titanium Dioxide
525	Potassium Hydroxide	413	Tragacanth Gum
326	Potassium Lactate		Trypsin from Pancreas of the Hog (*Sus scrofa*)
	Potassium Stearate	415	Xanthan gum
515	Potassium Sulphate		Zein
280	Propionic Acid		
1101	Protease from *Bacillus subtilis* var.		
1101	Protease from *Micrococcus caseolyticus* var.		
	Rennet from Aqueous Extracts from Fourth Stomach of Calves, Kids or Lambs		
551	Silicon Dioxide		
262(i)	Sodium Acetate		
401	Sodium Alginate		
554	Sodium Aluminum Silicate		
301	Sodium Ascorbate		
500	Sodium Bicarbonate		
500	Sodium Carbonate		
	Sodium Citrate		
262	Sodium Diacetate		
316	Sodium Erythorbate		
365	Sodium Fumarate		

INS No.	Substance	INS No.	Substance
524	Sodium Hydroxide		
325	Sodium Lactate		
281	Sodium Propionate		
	Sodium Stearate		
514	Sodium Sulphate		
1420	Starch Acetate		

INS - International Numbering System