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Health Canada

Fees Report

Fiscal Year 2021-22

The Honourable Jean-Yves Duclos, P.C., M.P.
Minister of Health

YOUR HEALTH AND SAFETY... OUR PRIORITY.

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Minister's message

On behalf of Health Canada, I am pleased to present the Departmental fees report for fiscal year 2021-22.

In 2021-22, Health Canada continued to ensure that Canadians had access to COVID-19 related medical devices. This was done by approving a third medical devices Ministerial Order which continues to allow Health Canada to waive related fees, expedite the authorization pathway for COVID-19 medical devices and provide flexibility and regulatory oversight to enable ongoing importation, sale and distribution of COVID-19 medical devices, including personal protective equipment.

In winter 2021, Health Canada held its first stakeholder information session since the new drugs and medical devices fees came into force on April 1, 2020. This was an opportunity for Health Canada to present the results of the 2020-21 Report on Fees, to discuss various business improvements initiatives the Department has put in place and to have an open dialogue with industry.

In spring 2022, Health Canada consulted on the proposed Biocides Regulations, related guidance document and proposed fees. The proposed regulations would bring disinfectants and surface sanitizers together under a single regulatory framework with a view to establishing a consistent simplified pathway to market authorization.

Health Canada conducted a review of the cannabis cost recovery framework and assessed the progress of cost recovery and the impact of the fee structure on the policy goals of the Cannabis Act and the cannabis industry. The review involved a series of internal analyses and consultations, as well as industry outreach in the form of a questionnaire and interviews. A summary report will be published in 2022-23.

Health Canada will continue to work towards ongoing transparency and accountability as it relates to fees. Through collaboration and evidence-based decision-making, I will continue to advance my key mandate priorities in order to maintain and improve the health and safety of all Canadians.

The Honourable Jean-Yves Duclos, P.C., M.P.
Minister of Health

About this report

This report, which is tabled under section 20 of the *Service Fees Act*[i], the *Low-Materiality Fees Regulations*[ii], and subsection 4.2.8 of the *Directive on Charging and Special Financial Authorities*[iii], contains information about the fees that Health Canada had the authority to set in 2021–22.

The report covers fees that are subject to the *Service Fees Act* and exempted from the *Service Fees Act*.

For reporting purposes, fees are categorized by fee-setting mechanism. There are three mechanisms:

1. Act, regulation or fees notice
   The authority to set these fees is delegated to a department, minister or Governor in Council pursuant to an act of Parliament.

2. Contract
   Ministers have the authority to enter into contracts, which are usually negotiated between the minister and an individual or organization, and which cover fees and other terms and conditions. In some cases, that authority may also be provided by an act of Parliament.

3. Market rate or auction
   The authority to set these fees is pursuant to an act of Parliament or regulation, and the minister, department or Governor in Council has no control over the fee amount.

For fees set by act, regulation or fees notice, the report provides totals for fee groupings, as well as detailed information for each fee. Health Canada did not have fees set by contract, market rate or auction.

Although the fees Health Canada charges under the *Access to Information Act* were subject to the *Service Fees Act*, they are not included in this report. Information on Health Canada's access to information fees for 2021–22 is in our annual report[iv] to Parliament on the administration of the *Access to Information Act*.

Remissions

In 2021–22, Health Canada was subject to the requirements to issue remissions under section 7 of the *Service Fees Act* and subsection 4.2.4 of the Treasury Board *Directive on Charging and Special Financial Authorities* to remit a fee, in whole or in part, to a fee payer when a service standard was deemed not met. Health Canada's remission policy and procedures, pursuant to the Service Fees Act, are on the following web page: Remissions for missed service standards[v]

In 2021–22, Health Canada also issued remissions under its enabling legislation. These remissions may have been for reasons other than not meeting a service standard.

The other sections of this report provide detailed amounts on Health Canada's remissions for 2021–22.

In addition to the remissions reported, Health Canada put in place a third COVID-19 medical devices interim order (effective until February 21, 2023) that maintains the same flexibilities as Interim Order No. 2 so that authorized COVID-19 medical devices can continue to be sold and imported in Canada. The first interim order was created on March 18, 2020, which was replaced by the second interim order on March 15, 2021.

Overall totals, by fee setting mechanism

The following table presents the total revenue, cost and remissions for all fees that Health Canada had the authority to set in 2021–22, by fee-setting mechanism.

Overall totals for 2021–22, by fee-setting mechanism

Fee-setting mechanism	Revenue ($)	Cost ($)	Remissions ($)
Fees set by act, regulation or fees notice	274,128,683	584,854,381	120,739

Totals, by fee grouping, for fees set by act, regulation or fees notice

A fee grouping is a set of fees relating to a single business line, directorate or program that a department had the authority to set for those activities.`

This section presents, for each fee grouping, the total revenue, cost and remissions for all fees that Health Canada had the authority to set in 2021-22 that are set by any of the following:

- act
- regulation
- fees notice

The revenue collections reported below may include: discontinued fees as of April 1, 2020; fees from previous years due to the timing of payments; and lower fees due to mitigation measures (as per the relevant regulations).

Fees for Right to Sell Drugs: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
28,571,438	82,280,531	0

Fees for Right to Sell Licenced Class II, III, or IV Medical Devices: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
13,114,294	31,621,930	18,860

Fees for Examination of a Submission - Drugs for Human Use: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
71,849,968	163,902,742	25,324

Certificate of Supplementary Protection Application Fees: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
156,096	229,964	0

Fees for Examination of Medical Device Licence Applications: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
7,459,566	21,897,541	1,600

Fees for Examination of a Submission - Drugs for Veterinary Use Only: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
1,078,567	10,994,275	222

Drug Establishment Licensing Fees: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
28,921,109	39,682,408	0

Drug Establishment Licensing Fees - Dealer's Licences: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
568,605	7,412,718	0

Medical Devices Establishment Licensing Fees: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
21,681,766	15,263,334	74,635

Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
6,962,776	51,494,952	98

Annual Charge (for a registered Pest Control Product): totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
9,148,686	29,570,501	0

Fees Charged for Filing a Claim for Exemption under the Hazardous Materials Information Review Act: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
432,522	3,625,445	0

Cannabis Fees: totals for 2021-22

Revenue ($) (note 1)	Cost ($)	Remissions ($)
75,683,891	114,949,669	0

1) The *Order Amending the Cannabis Fees Order (Extension of Deadline for Payment of 2020–2021 Annual Fee)*[vi] provided short-term economic relief to the cannabis industry by deferring the annual fee payment due date from September 30, 2020 to March 31, 2021. Only revenues received by March 31, 2021 were reported in 2020-21. The remaining outstanding revenues are being reported in 2021-22.

The following fees are set under the Ministerial Authority to Enter into a Contract. Health Canada strives to recover 100% of costs for these services, however since the fees were last set increases to costs have been incurred.

National Dosimetry Products and Services Fees: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
7,454,835	10,035,163	0

Master File Fees: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
814,556	1,065,333	0

Certificate of Pharmaceutical Product Fee: totals for 2021-22

Revenue ($)	Cost ($)	Remissions ($)
230,008	827,875	0

Details on each fee set by act, regulation or fees notice

This section provides detailed information on each fee that Health Canada had the authority to set in 2021-22 and that was set by any of the following:

- act
- regulation
- fees notice

The total of the revenue collections by fee grouping below may not equal the revenues reported in the "Totals, by fee grouping, for fees set by act, regulation or fees notice" section due to the following:

- Effective April 1, 2020, some fees were repealed from the *Financial Administration Act* and set under the authority of the *Food and Drugs Act*. In some instances, new fees were introduced and some fees were discontinued. Revenues collected after March 31, 2020 for discontinued fees are not included below; and

- A new report has been developed in the financial system to allow the reporting of revenue collections at the individual fee level, however, it is still being refined and therefore small discrepancies may exist.

Fees for Right to Sell Drugs

Health Canada monitors human and veterinary drugs on the Canadian market through post-market surveillance and compliance and enforcement activities. Industry pays an annual fee for the right to maintain and sell human and veterinary drugs in Canada.

Fee

- Human drugs - Disinfectant (item 1)
- Human drugs - Non-prescription (item 2)
- Human drugs - Prescription (drug other than one referred to in item 1 or 2)

Fee-setting authority

- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced

2017

Last year fee-setting authority was amended

2021

Service standard

20 calendar days to update the Drug Product Database following receipt of a complete Annual Notification Package

Performance result

100% (1,185/1,185 human and veterinary completed within service standard)

Application of *Low-Materiality Fees Regulations*

Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Human drugs - Disinfectant (item 1)	1,342	1,388,587	0	April 1, 2023	1,613
Human drugs - Non-prescription (item 2)	2,018	5,098,566	0	April 1, 2023	3,109
Human drugs - Prescription (drug other than one referred to in item 1 or 2)	2,749	21,926,783	0	April 1, 2023	5,158

Fee
Veterinary Drugs

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
20 calendar days to update the Drug Product Database following receipt of a complete Annual Notification Package

Performance result
100% (1,185/1,185 human and veterinary completed within the service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Veterinary Drugs

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Veterinary Drugs	367	345,214	0	April 1, 2023	528

Fees for Right to Sell a Licensed Class II, III or IV Medical Device

Health Canada monitors medical devices on the Canadian market through post-market surveillance and compliance and enforcement activities. There is an annual fee for the right to sell a Class II, III, IV medical device.

Fee
Medical Device Right to Sell

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
20 calendar days from deadline for receipt of annual notification to update the Medical Devices Licence Listing (MDALL) database

Performance result
99.34% (33,276/33,496 were completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Medical Device Right to Sell

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Medical Device Right to Sell	381	13,114,294	18,860	April 1, 2023	421

Fees for Examination of a Submission — Drugs for Human Use

Before a drug is authorized for sale in Canada, Health Canada reviews it to assess its safety, efficacy and quality. Drug products include prescription and non-prescription pharmaceuticals, biologics, disinfectants and sanitizers with disinfectant claims.

Fee
New Active Substance

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
300 calendar days to complete Review 1

Performance result
100% (52/52 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* New Active Substance

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
New Active Substance	437,009	19,401,161	0	April 1, 2023	565,465

Fee
Clinical or non-clinical data and chemistry and manufacturing data

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
- For drugs under Division 1 of the Food and Drug Regulations: 210 calendar days to complete Review 1
- For drugs under Division 8 of the Food and Drug Regulations: 300 calendar days to complete Review 1

Performance result
- 210 calendar days - 100% (1/1 completed within service standard)
- 300 calendar days - 100% (55/55 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Clinical or non-clinical data and chemistry and manufacturing data

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Clinical or non-clinical data and chemistry and manufacturing data	224,242	8,535,125	0	April 1, 2023	292,806

Fee
Clinical or non-clinical data only

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
- For drugs under Division 1 of the Food and Drug Regulations: 210 calendar days to complete Review 1
- For drugs under Division 8 of the Food and Drug Regulations: 300 calendar days to complete Review 1

Performance result
- 210 calendar days – 100% (1/1 completed within service standard)
- 300 calendar days - 100% (157/157 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Clinical or non-clinical data only

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Clinical or non-clinical data only	95,796	13,626,892	0	April 1, 2023	117,080

Fee
Comparative studies

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
- For drugs under Division 1 of the Food and Drug Regulations: 210 calendar days to complete Review 1
- For drugs under Division 8 of the Food and Drug Regulations: 180 calendar days to complete Review 1

Performance result
- 210 calendar days - 100% (4/4 completed within service standard)
- 180 calendar days - 100% (139/139 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Comparative studies

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Comparative studies	55,737	8,777,956	13,459	April 1, 2023	65,985

Fee
Chemistry and manufacturing data only

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
- For drugs under Division 1 of the Food and Drug Regulations: 210 calendar days to complete Review 1
- For drugs under Division 8 of the Food and Drug Regulations: 180 calendar days to complete Review 1

Performance result
- 210 calendar days - 100% (40/40 completed within service standard)
- 180 calendar days - 99.7% (312/313 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Chemistry and manufacturing data only

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Chemistry and manufacturing data only	30,609	10,123,957	6,897	April 1, 2023	40,597

Fee
Clinical or non-clinical data only, in support of safety upgrades to the labelling

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
120 calendar days to complete Review 1

Performance result
99.6% (277/278 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Clinical or non-clinical data only, in support of safety upgrades to the labelling

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Clinical or non-clinical data only, in support of safety upgrades to the labelling	19,404	5,472,991	4,861	April 1, 2023	21,429

Fee
Labelling only

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
120 calendar days to complete Review 1

Performance result
99.9% (899/900 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Labelling only

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Labelling only	4,320	4,098,833	0	April 1, 2023	5,901

Fee
Labelling only (generic drugs)

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
120 calendar days to complete Review 1

Performance result
100% (126/126 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Labelling only (generic drugs)

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Labelling only (generic drugs)	2,006	228,616	0	April 1, 2023	2,217

Fee
Administrative submission

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
45 calendar days to review

Performance result
99.6% (567/569 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Administrative submission

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Administrative submission	539	271,454	108	April 1, 2023	933

Fee
Disinfectant - full review

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
- For drugs under Division 1 of the Food and Drug Regulations: 180 or 210 calendar days to complete Review 1
- For drugs under Division 8 of the Food and Drug Regulations: 300 calendar days to complete Review 1

Performance result
- 180/210 calendar days - 100% (1/1 completed within service standard)
- 300 calendar days - 100% (134/134 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Disinfectant - full review

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Disinfectant - full review	7,126	908,127	0	April 1, 2023	12,297

Fee
Labelling only (disinfectants)

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
90 calendar days to complete Review 1

Performance result
100% (111/111 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Labelling only (disinfectants)

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Labelling only (disinfectants)	2,502	237,840	0	April 1, 2023	2,764

Fee
Drug identification number application - labelling standards

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
60 calendar days to complete Review 1

Performance result
100% (195/195 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Drug identification number application - labelling standards

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Drug identification number application - labelling standards	1,613	326,923	0	April 1, 2023	1,782

Certificate of Supplementary Protection Application Fees

In agreeing to provisionally apply the Canada-European Union Comprehensive Economic and Trade Agreement (CETA), Canada has committed to provide up to two years of sui generis (of its own kind) protection for new pharmaceutical products protected by an eligible patent, from the expiry of the patent. Canada has implemented this commitment by introducing Certificates of Supplementary Protection (CSPs) for medicinal ingredients, applicable for Canadian pharmaceuticals, biologics and veterinary drugs.

Fee
Certificate of Supplementary Protection Application Fees

Fee-setting authority
- *Patent Act*, 134(1)[ix]
- *Certificate of Supplementary Protection Regulations* (SOR/2017-165)[x]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2020

Service standard
60 days for the first eligibility decision

Performance result
100% (17/17 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Certificate of Supplementary Protection Application Fees

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Certificate of Supplementary Protection Application Fees	9,756	156,096	This fee was not subject to remissions	April 1, 2023	10,152

Fees for Examination of an Application for a Medical Device Licence

The Medical Device Licence Application Fees apply only to Class II, III and IV medical device licence applications. The following types of medical devices are exempt from medical device licensing and therefore no fees apply: Class I medical devices; custom-made medical devices; medical devices for special access; and medical devices for investigational testing involving human subjects.

Fee
Applications for Class II licence

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
15 calendar days to review

Performance result
99.1% (1,300/1,312 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Applications for Class II licence

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Applications for Class II licence	478	698,611	1,427	April 1, 2023	589

Fee
Applications for Class II licence amendment

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
15 calendar days to review

Performance result
99.6% (1,102/1,106 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Applications for Class II licence amendment

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Applications for Class II licence amendment	272	302,237	136	April 1, 2023	302

Fee
Applications for Class III licence

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
60 calendar days to complete Review 1

Performance result
99.6% (249/250 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Applications for Class III licence

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Applications for Class III licence	8,895	2,017,737	0	April 1, 2023	12,987

Fee
Applications for Class III licence (near patient)

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
60 calendar days to complete Review 1

Performance result
100% (2/2 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Applications for Class III licence (near patient)

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Applications for Class III licence (near patient)	16,032	129,586	0	April 1, 2023	27,666

Fee
Applications for Class III licence amendment - changes in manufacturing

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
60 calendar days to complete Review 1

Performance result
100% (18/18 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Applications for Class III licence amendment - changes in manufacturing

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Applications for Class III licence amendment - changes in manufacturing	2,375	39,477	0	April 1, 2023	4,098

Fee
Applications for Class III licence amendment - significant changes not related to manufacturing

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
60 calendar days to complete Review 1

Performance result
99.7% (301/302 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Applications for Class III licence amendment - significant changes not related to manufacturing

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Applications for Class III licence amendment - significant changes not related to manufacturing	7,543	2,425,033	0	April 1, 2023	10,425

Fee
Applications for Class IV licence

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
75 calendar days to complete Review 1

Performance result
100% (38/38 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Applications for Class IV licence

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Applications for Class IV licence	24,699	1,013,882	0	April 1, 2023	28,165

Fee
Applications for Class IV licence amendment - changes in manufacturing

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
75 calendar days to complete Review 1

Performance result
100% (36/36 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Applications for Class IV licence amendment - changes in manufacturing

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Applications for Class IV licence amendment - changes in manufacturing	2,375	74,736	0	April 1, 2023	4,098

Fee
Applications for Class IV licence amendment - significant changes not related to manufacturing

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
75 calendar days to complete Review 1

Performance result
100% (91/91 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Applications for Class IV licence amendment – significant changes not related to manufacturing

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Applications for Class IV licence amendment - significant changes not related to manufacturing	9,964	844,380	0	April 1, 2023	14,902

Fee
Applications for Class II, III or IV licence or licence amendment - private label medical device

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
15 calendar days to review

Performance result
99.5% (370/372 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Applications for Class II, III or IV licence or licence amendment - private label medical device

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Applications for Class II, III or IV licence or licence amendment - private label medical device	147	40,329	37	April 1, 2023	163

Fees for Examination of a Submission — Drugs for Veterinary Use Only

Before a veterinary drug is authorized for sale in Canada, Health Canada reviews it to assess its efficacy and safety in the intended species as well as human safety. Fees are calculated on a component basis.

Fee
Drug Identification Number (Schedule 2 items 1 to 3)

Fee-setting authority

- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
120 calendar days to complete Review 1

Performance result
100% (41/41 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
1) Information, other than that referred to in item 2, to support an application for a number, including the submission of labelling material for a second review, if required	1,146	11,577	0	April 1, 2023	1,891
2) Published references or other data	797	0	0	April 1, 2023	1,314

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
3) Documentation to support a change of manufacturer, a change to the name of a manufacturer or a change to the brand name of a drug	400	5,000	0	April 1, 2023	658

Fee
Notification - veterinary health product (Schedule 2 item 4)

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
30 calendar days to process notification

Performance result
99.6% (788/791 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
4) Information contained in a notification filed under subsection C.01.615(1) of the Food and Drug Regulations in respect of a veterinary health product	486	145,634	122	April 1, 2023	538

Fee
New drug submission (Schedule 2 items 5 to 18)

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
- 300 calendar days to complete Review 1 (items 5 to 17)
- 90 calendar days to complete Review 1 (item 18)

Performance result
- 300 calendar days - 100% (7/7 completed within service standard)
- 90 calendar days - 95% (19/20 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
5) Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in one animal species. (In the case of an antiparasitic drug, several indications in one food animal species.)	25,419	83,823	0	April 1, 2023	41,917
6) Efficacy and safety data (in the intended species) to support a single route of administration and dosage form for an antiparasitic drug in one non-food animal species	15,398	12,342	0	April 1, 2023	25,392

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
7) Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in two animal species, or a single route of administration, dosage form and two indications in one animal species	36,966	147,864	0	April 1, 2023	60,961
8) Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species	50,057	0	0	April 1, 2023	82,548
9) Comparative (pharmacodynamics, clinical or bioavailability) data to support an additional route of administration	4,614	0	0	April 1, 2023	7,610
10) Comparative (pharmacodynamics, clinical or bioavailability) data to support each additional strength	764	0	0	April 1, 2023	1,261
11) For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	34,660	86,650	0	April 1, 2023	57,158

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
12) For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of less than 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	46,208	0	0	April 1, 2023	76,201
13) For food-producing animals, residue depletion studies to establish a withdrawal period for an additional dosage form, dosage or route of administration	4,614	0	0	April 1, 2023	7,610
14) For food-producing animals (once an acceptable daily intake with a safety factor of 1,000 or less has been established), metabolism and residue depletion studies to establish a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in an additional species	23,096	0	0	April 1, 2023	38,088
15) Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug	7,700	19,250	0	April 1, 2023	12,697
16) Chemistry and manufacturing data to support one strength of a single dosage form	7,700	48,521	0	April 1, 2023	12,697

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
17) Chemistry and manufacturing data to support an additional strength of a single dosage form submitted at the same time as item 16	3,851	47,003	0	April 1, 2023	6,350
18) Documentation to support a change of manufacturer	400	3,640	100	April 1, 2023	658

Fee
Supplement to a new drug submission (Schedule 2 items 19 to 37)

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
- 240 calendar days to complete Review 1 (items 19 to 36)
- 90 calendar days to complete Review 1 (item 37)

Performance result
- 240 calendar days - 100% (20/20 completed within service standard)
- 90 calendar days - 100% (1/1 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
19) Efficacy data to support an additional indication in one animal species	20,027	60,081	0	April 1, 2023	33,026
20) Efficacy and safety data (in the intended species) to support a single route of administration and dosage form for an antiparasitic drug in one non-food animal species	15,398	30,796	0	April 1, 2023	25,392
21) Efficacy and safety data (in the intended species) to support an indication in another animal species	25,419	0	0	April 1, 2023	41,917

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
22) Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in two animal species, or a single route of administration and dosage form and two indications in one animal species.	36,966	0	0	April 1, 2023	60,961
23) Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species	50,057	0	0	April 1, 2023	82,548
24) Efficacy and safety data (in the intended species) to support the concurrent use of two drugs approved for the same animal species	12,312	0	0	April 1, 2023	20,305
25) Comparative (pharmacodynamics, clinical or bioavailability) data to support an additional route of administration	4,614	4,614	0	April 1, 2023	7,610
26) Comparative (pharmacodynamics, clinical or bioavailability) data to support each additional strength	764	764	0	April 1, 2023	1,261
27) For food-producing animals, residue depletion studies to establish a new withdrawal period for a change in the dosage or route of administration of an approved dosage form in one species	4,614	0	0	April 1, 2023	7,610

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
28) For food-producing animals, metabolism and residue depletion studies to establish a maximum residue limit and a withdrawal period for a single dosage and route of administration of an approved dosage form in an additional species	23,096	0	0	April 1, 2023	38,088
29) For food-producing animals, toxicity studies to support a change of an established acceptable daily intake, maximum residue limit and withdrawal period	11,548	0	0	April 1, 2023	19,045
30) For the concurrent use of two drugs in a species of food-producing animals, residue depletion studies to determine if an extension to existing withdrawal periods is required	9,243	0	0	April 1, 2023	15,243
31) Chemistry and manufacturing data to support a change in the source of a medicinal ingredient or its manufacturing process	7,700	48,521	0	April 1, 2023	12,697
32) Chemistry and manufacturing data to support a change in formulation or dosage form	3,851	3,851	0	April 1, 2023	6,350
33) Chemistry and manufacturing data to support a change in packaging or in the sterilization process	3,072	6,144	0	April 1, 2023	5,065

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
34) Chemistry and manufacturing data to support an extension of the expiry dating	2,309	0	0	April 1, 2023	3,807
35) Chemistry and manufacturing data to support the concurrent use of two drugs	2,309	0	0	April 1, 2023	3,807
36) Chemistry and manufacturing data to support a change in the manufacturing site for parenteral dosage forms	764	2,292	0	April 1, 2023	1,261
37) Documentation to support a change to the name of a manufacturer or the brand name of a drug	400	800	0	April 1, 2023	658

Fee
Abbreviated new drug submission (Schedule 2 items 38 to 42)

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
- 300 calendar days to complete Review (items 38 to 41)
- 90 calendar days to complete Review 1 (item 42)

Performance result
- 300 calendar days - 100% (15/15 completed within service standard)
- 90 calendar days - n/a (0/0 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
38) Comparative (pharmacodynamics, clinical or bioavailability) data to support a single route of administration and dosage form	4,614	4,614	0	April 1, 2023	7,610
39) For food-producing animals, residue depletion studies to confirm that the withdrawal period(s) for each species falls within the conditions of use for the Canadian reference product	4,614	2,321	0	April 1, 2023	7,610

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
40) Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug	7,700	44,671	0	April 1, 2023	12,697
41) Chemistry and manufacturing data to support a single dosage form	7,700	67,315	0	April 1, 2023	12,697
42) Documentation to support (a) a change of manufacturer, in the case of an abbreviated new drug submission; or (b) a change to the name of a manufacturer or the brand name of a drug, in the case of a supplement to an abbreviated new drug submission	400	0	0	April 1, 2023	658

Fee
Supplement to an abbreviated new drug submission (Schedule 2 items 38 to 42)

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
- 240 calendar days to complete Review 1 (items 38 to 41)
- 90 calendar days to complete Review 1 (item 42)

Performance result
- 240 calendar days - 100% (3/3 completed within service standard)
- 90 calendar days - n/a (0/0 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
38) Comparative (pharmacodynamics, clinical or bioavailability) data to support a single route of administration and dosage form	4,614	4,614	0	April 1, 2023	7,610
39) For food-producing animals, residue depletion studies to confirm that the withdrawal period(s) for each species falls within the conditions of use for the Canadian reference product	4,614	2,321	0	April 1, 2023	7,610

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
40) Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug	7,700	44,671	0	April 1, 2023	12,697
41) Chemistry and manufacturing data to support a single dosage form	7,700	67,315	0	April 1, 2023	12,697
42) Documentation to support (a) a change of manufacturer, in the case of an abbreviated new drug submission; or (b) a change to the name of a manufacturer or the brand name of a drug, in the case of a supplement to an abbreviated new drug submission	400	0	0	April 1, 2023	658

Fee
Preclinical submission (Schedule 2 items 43 to 50)

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
60 calendar days to complete Review 1

Performance result
Not applicable - no applications received

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
43) Efficacy and safety data (in the intended species) and protocol to support the conduct of clinical studies relative to a single dose form, route of administration and indication in one species	7,700	0	0	April 1, 2023	12,697
44) Efficacy data and protocol to support the conduct of clinical studies relative to a single route of administration and indication with a dosage form for which a notice of compliance has been issued for use in the species to be treated	6,157	0	0	April 1, 2023	10,153

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
45) For food-producing animals, toxicity, metabolism and residue depletion studies to establish a temporary acceptable daily intake, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	23,096	0	0	April 1, 2023	38,088
46) For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	34,660	0	0	April 1, 2023	57,158
47) For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of less than 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	46,208	0	0	April 1, 2023	76,201
48) For food-producing animals (once an acceptable daily intake with a safety factor of 1,000 or less has been established), metabolism studies to establish a withdrawal period for a single dosage form, dosage and route of administration in an additional species	11,548	0	0	April 1, 2023	19,045

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
49) Chemistry and manufacturing data to support a single dosage form containing a non-compendial medicinal ingredient	7,700	0	0	April 1, 2023	12,697
50) Chemistry and manufacturing data to support a single dosage form containing a compendial medicinal ingredient	3,851	0	0	April 1, 2023	6,350

Fee
Sale of new drug for emergency treatment (Schedule 2 items 51 and 52)

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
2 business days to review application

Performance result
100% (446/446 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
51) Information to support the sale of a drug to be used in the emergency treatment of a non-food-producing animal	51	11,577	0	April 1, 2023	57
52) Information to support the sale of a drug to be used in the emergency treatment of a food-producing animal	102	7,650	0	April 1, 2023	114

Fee
Experimental studies certificate (Schedule 2 items 53 to 56)

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
60 calendar days to review application

Performance result
100% (127/127 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
53) Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a non-food-producing animal	979	25,946	0	April 1, 2023	1,082
54) Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that for a previously authorized experimental studies certificate for a drug to be administered to a non-food-producing animal	490	2,450	0	April 1, 2023	542

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
55) Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a food-producing animal	2,953	29,540	0	April 1, 2023	3,262
56) Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that for a previously authorized experimental studies certificate for a drug to be administered to a food-producing animal	490	490	0	April 1, 2023	542

Fee
Notifiable change (Schedule 2 item 57)

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
90 calendar days to review application

Performance result
100% (62/62 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
57) Information and material to support an application for Notifiable Change	2,069	94,226	0	April 1, 2023	3,413

Fee
Protocol (Schedule 2 item 58)

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
90 calendar days to review package

Performance result
100% (6/6 completed within service standard)

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
58) A protocol that is filed with the Minister and may support a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or abbreviated new drug submission, a preclinical submission or information and material that is filed for the purpose of obtaining an experimental studies certificate	2,069	9,523	0	April 1, 2023	3,413

Drug Establishment Licensing Fees

Any person in Canada must obtain a Drug Establishment Licence (DEL) if they are engaged in any of the six regulated activities (fabricate, import, distribute, wholesale, package/label, and test) with respect to human and/or veterinary drugs. A fee is charged for the examination of a DEL application, including all compliance and enforcement and supporting activities needed to ensure that the applicant/licence holder conforms to all regulatory requirements. The DEL fee is calculated on a per-site basis, therefore, the fee amount varies by application. A DEL fee is charged for the application for a new DEL, an annual licence review of a DEL, certain amendments to a DEL, or reinstatement of a suspended DEL.

Fee
Human Drug Establishment Licence Fees

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
250 calendar days to issue/ renew license

Performance result
100% (851/851) of licences issued (human and veterinary) within 250 calendar days

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($) (note 1)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Fabrication - Sterile dosage form	41,647	2,071,287	0	April 1, 2023	46,221
Importation	28,975	10,809,999	0	April 1, 2023	35,688

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($) (note 1)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Fabrication - non-sterile dosage form	28,308	2,020,277	0	April 1, 2023	34,266
Distribution	13,855	704,508	0	April 1, 2023	18,215
Wholesaling	6,159	823,708	0	April 1, 2023	10,630
Packaging/labelling	6,049	625,628	0	April 1, 2023	6,681
Testing	3,194	178,492	0	April 1, 2023	5,514
Building outside Canada (each)	917	11,057,531	0	April 1, 2023	1,014

1) As of April 1, 2020, a new Drug Establishment Licencing fee structure was introduced, therefore the fee revenue reported above represents only those revenues collected based on the new fees. An additional amount of approximately $0.4M was collected under the old fee structure.

Fee
Veterinary Drug Establishment Licence Fees

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
250 calendar days to issue/ renew license

Performance result
100% (851/851) of licences issued (human and veterinary) within 250 calendar days

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($) (note 1)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Fabrication - Sterile dosage form	40,407	80,605	0	April 1, 2023	45,262
Importation	13,367	392,846	0	April 1, 2023	23,066
Fabrication - non-sterile dosage form	10,957	61,413	0	April 1, 2023	18,905
Distribution	6,031	19,327	0	April 1, 2023	10,409
Wholesaling	2,412	42,133	0	April 1, 2023	4,161
Packaging/labelling	6,049	0	0	April 1, 2023	6,681
Testing	1,641	2,630	0	April 1, 2023	2,833
Building outside Canada (each)	917	993,625	0	April 1, 2023	1,014

1) As of April 1, 2020, a new Drug Establishment Licencing fee structure was introduced, therefore the fee revenue reported above represents only those revenues collected based on the new fees. An additional amount of approximately $23K was collected under the old fee structure.

Drug Establishment Licensing Fees - Dealer's Licences

Fees for the examination of a new dealer's licence application (Human Drugs), a new dealer's licence (Veterinary Drugs) or the renewal of a dealer's licence; issued under the Narcotic Control Regulations and Part G of the Food and Drug Regulations. There is no fee associated with the application for a new or renewal of a controlled substances licence issued under the Benzodiazepines and Other Targeted Substances Regulations and Part J of the Food and Drug Regulations.

Fee

- Dealer's Licence Fees - Human Drugs
- Dealer's Licence Fees - Veterinary Drugs

Fee-setting authority

Financial Administration Act (FAA)[xi]

- Human Drugs: *Fees in Respect of a Dealer's Licences Regulations* (SOR/2011-79)[xii]
- Veterinary Drugs: *Licenced Dealers for Controlled Drugs and Narcotics (Veterinary Use) Fees Regulations* (SOR/98-5)[xiii]

Year fee-setting authority was introduced

1998

Last year fee-setting authority was amended

- Human Drugs: 2020
- Veterinary Drugs: 2022

Service standard:

- 270 Calendar days to issue a decision on an application for a **new** dealer's licence for controlled substances, from the receipt of a complete application
- 90 Calendar days to issue a decision on an application to **renew** a dealer's licence for controlled substances, from the receipt of a complete application

Performance result

- **New**: 20% (9/44) of applications were processed within the service standard
- **Renew:** 98% (158/162) of applications were processed within the service standard

Application of *Low-Materiality Fees Regulations*

Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Dealer's Licence Fees - Human Drugs	5,502.00	541,127	0	April 1, 2023	5,726.00
Dealer's Licence Fees - Veterinary Drugs	1,820.62	19,970	0	April 1, 2023	2,010.53
Dealer's Licence Fees - Veterinary Drugs – First Year	910.31	1,750	0	April 1, 2023	1,005.27

Medical Device Establishment Licensing Fees

A Medical Device Establishment Licence (MDEL) is required for the activities of importing or selling medical devices for human use in Canada with exceptions[a]. A fee is charged for the examination of an MDEL application, including all compliance and enforcement and supporting activities needed to ensure that the applicant/licence holder conforms to all regulatory requirements. The MDEL fee is a flat fee. The same fee is charged for an application for a new MDEL, an annual licence review of an MDEL, and the reinstatement of a suspended MDEL.

Fee
Medical Device Establishment Licensing Fees

Fee-setting authority
- *Food and Drugs Act (FDA),* 30.61(1)[vii]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[viii]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
120 calendar days to issue/ renew licence

Performance result
99.5% (4,277 / 4,298) of licenses issued within 120 calendar days

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Application for new licence and annual review of licence

[a] As per the Medical Devices Regulations, an MDEL is not required for: a retailer, a health care facility, a manufacturer of Class II, III or IV medical devices who only sells either medical devices for which they hold a valid licence, or medical devices subject to Parts 2 and 3 of the Regulations, a manufacturer of a Class I medical device who imports or distributes solely through a licensed establishment, a person solely selling medical devices subject to Parts 2 and 3 of the Regulations, or a dispenser.

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Application for new licence and annual review of licence	4,581	21,681,766 (note 1)	74,636	April 1, 2023	5,060

1)Revenue for 2021-22 was exceptionally high due to various reasons, however it is expected that this is a single-year phenomenon, and revenue figures will normalize starting in 2022-23.

Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product

No person shall manufacture, possess, handle, store, transport, import, distribute or use a pest control product that is not registered under the *Pest Control Products Act*, except as otherwise authorized under the Act or unless specifically exempted by the *Pest Control Products Regulations*. Fees for applications to register or to amend the registration of a pest control product are payable by component submitted. The fee payable is the sum of the fees for the submitted components in addition to the basic processing fee.

The following table reflects the total 2021-22 fee revenue by individual fee.

Fee	2021-22 total fee revenue ($)
Processing	1,212,854
Applications not Mentioned in Schedules	264,536
Renewal	131,992
Schedule 1: Fees for Applications to Register, or to Amend the Registration of, a Pest Control Product Other Than a Semiochemical or Microbial Agent	
Product Chemistry – active ingredient	653,601
Product Chemistry – end-use product or manufacturing concentrate	393,442
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	667,906
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains a registered active ingredient	34,262
Toxicology data-acute toxicity studies	198,719
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	215,893
Exposure data accompanying an application to register a pest control product –or to amend the registration of a pest control product –that contains a registered active ingredient, when a new risk assessment is necessary	87,479
Exposure data-other	74,188
Metabolism data	201,286

Fee	2021-22 total fee revenue ($)
Residue data	394,997
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	514,741
Environmental fate data accompanying an application to register a pest control product ,or to amend the registration of a pest control product, that contains a registered active ingredient , when a new risk assessment is necessary	35,174
Environmental fate data-other	70,401
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	398,295
Environmental toxicology data accompanying an application to register a pest control product ,or to amend the registration of a pest control product, that contains a registered active ingredient , when a new risk assessment is necessary	9,608
Environmental toxicology data-other	1,668
Value and effectiveness data for a pest control product	191,149
Identification of compensable data	346,402
Schedule 2: Fees for Applications in Respect of a Pest Control Product that is a Semiochemical or Microbial Agent	
Registration of a new active ingredient – food use	17,818
Registration of a new active ingredient – non-food use	3,312
Amendment of registration – new risk assessment necessary-environmental fate data, environmental toxicity data or exposure data	0
Amendment of registration – data required, label changes	12,701
Amendment of registration – data required, other	7,536
Amendment of registration – no data required	4,733
Registration of new active ingredient	134
Amendment of registration	2,823
Schedule 3: Fees for Other Applications in Respect of a Pest Control Product	

Fee	2021-22 total fee revenue ($)
Research authorization – major crops, other than research authorizations set out in paragraphs (c) and (d)	255,884
Research authorization – minor use crops, other than research authorizations set out in paragraphs (c) and (d)	51,425
Research authorization – microbial agents, semiochemicals and any substance listed in subparagraph 1(d) (ii) of these regulations	20,952
Research authorization – greenhouse crops and non-agricultural uses	17,121
Research notifications	4,842
Registration of active ingredient to be used in pest control product manufactured only for export	59,318
Amendment to Registration of active ingredient to be used in pest control product manufactured only for export	0
Specification of maximum residue limit for a previously unexamined pest control product	0
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	128,301

Note: A new report has been developed in the financial system to allow reporting collections per fee, however, it is still being refined. Therefore, the total of the revenues listed above does not equal the revenues reported in the *Totals, by fee grouping, for fees set by act, regulation or fees notice* section by $277K.

Fee
Category A Component Based - 655 days of Review (Conventional Chemicals and Import Maximum Residue Limits)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
655 days of Review

Performance result
64% (9/14 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Product Chemistry - active ingredient	5,277	See the total fee revenue table	0	April 1, 2023	5,491
Product Chemistry - end-use product or manufacturing concentrate	2,939			April 1, 2023	3,058
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	82,058			April 1, 2023	85,374

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Toxicology data accompanying an application to register a pest control product -or to amend a pest control product - that contains an registered active ingredient	17,136			April 1, 2023	17,829
Toxicology data - acute toxicity studies	3,200			April 1, 2023	3,330
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	18,942			April 1, 2023	19,708
Exposure data accompanying an application to register a pest control product -or to amend the registration of a pest control product -that contains a registered active ingredient, when a new risk assessment is necessary	6,235			April 1, 2023	6,488
Metabolism data	31,331			April 1, 2023	32,598
Residue data	17,146			April 1, 2023	17,839
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	46,205			April 1, 2023	48,073

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Environmental fate data accompanying an application to register a pest control product,or to amend the registration of a pest control product, that contains a registered active ingredient, when a new risk assessment is necessary	25,587			April 1, 2023	26,621
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	40,352			April 1, 2023	41,984
Environmental toxicology data accompanying an application to register a pest control product,or to amend the registration of a pest control product, that contains a registered active ingredient, when a new risk assessment is necessary	25,644			April 1, 2023	26,681
Value and effectiveness data for a pest control product	983			April 1, 2023	1,024
Specification of maximum residue limit for a previously unexamined pest control product	135,805			April 1, 2023	141,293
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	17,146			April 1, 2023	17,839

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Processing	1,229			April 1, 2023	1,280

Fee
Category A Component Based - 555 days (Reduced risk, other biopesticides, non-conventionals, non-straight-chain lepidopteran pheromone)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
555 days of Review

Performance result
100% (9/9 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Product Chemistry - active ingredient	5,277	See the total fee revenue table	0	April 1, 2023	5,491
Product Chemistry - end-use product or manufacturing concentrate	2,939			April 1, 2023	3,058
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	82,058			April 1, 2023	85,374

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	17,136			April 1, 2023	17,829
Toxicology data - acute toxicity studies	3,200			April 1, 2023	3,330
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	18,942			April 1, 2023	19,708
Exposure data accompanying an application to register a pest control product - or to amend the registration of a pest control product - that contains a registered active ingredient, when a new risk assessment is necessary	6,235			April 1, 2023	6,488
Metabolism data	31,331			April 1, 2023	32,598
Residue data	17,146			April 1, 2023	17,839
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	46,205			April 1, 2023	48,073

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Environmental fate data accompanying an application to register a pest control product, or to amend the registration of a pest control product, that contains a registered active ingredient, when a new risk assessment is necessary	25,587			April 1, 2023	26,621
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	40,352			April 1, 2023	41,984
Environmental toxicology data accompanying an application to register a pest control product,or to amend the registration of a pest control product, that contains a registered active ingredient, when a new risk assessment is necessary	25,644			April 1, 2023	26,681
Value and effectiveness data for a pest control product	983			April 1, 2023	1,024
Registration of a new active ingredient - food use	7,834			April 1, 2023	8,151
Registration of a new active ingredient - non-food use	4,701			April 1, 2023	4,892

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Amendment of registration - new risk assessment necessary - environmental fate data, environmental toxicity data or exposure data	3,135			April 1, 2023	3,262
Processing	1,229			April 1, 2023	1,280

Fee
Category A Component Based - 470 days of Review (Microbials including User Requested Minor Use Registration (URMUR), and URMUR for conventional chemical, reduced risk, other biopesticides, non-conventionals, non-straight-chain lepidopteran pheromone)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
470 days of Review

Performance result
100% (8/8 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Product Chemistry - active ingredient	5,277	See the total fee revenue table	0	April 1, 2023	5,491
Product Chemistry - end-use product or manufacturing concentrate	2,939			April 1, 2023	3,058
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	82,058			April 1, 2023	85,374

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product -that contains an registered active ingredient	17,136			April 1, 2023	17,829
Toxicology data - acute toxicity studies	3,200			April 1, 2023	3,330
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	18,942			April 1, 2023	19,708
Exposure data accompanying an application to register a pest control product - or to amend the registration of a pest control product - that contains a registered active ingredient, when a new risk assessment is necessary	6,235			April 1, 2023	6,488
Metabolism data	31,331			April 1, 2023	32,598
Residue data	17,146			April 1, 2023	17,839
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	46,205			April 1, 2023	48,073

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Environmental fate data accompanying an application to register a pest control product, or to amend the registration of a pest control product, that contains a registered active ingredient, when a new risk assessment is necessary	25,587			April 1, 2023	26,621
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	40,352			April 1, 2023	41,984
Environmental toxicology data accompanying an application to register a pest control product, or to amend the registration of a pest control product, that contains a registered active ingredient, when a new risk assessment is necessary	25,644			April 1, 2023	26,681
Value and effectiveness data for a pest control product	983			April 1, 2023	1,024
Registration of a new active ingredient - food use	7,834			April 1, 2023	8,151
Registration of a new active ingredient - non-food use	4,701			April 1, 2023	4,892

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Amendment of registration - new risk assessment necessary - environmental fate data, environmental toxicity data or exposure data	3,135			April 1, 2023	3,262
Processing	1,229			April 1, 2023	1,280

Fee
Category A Component Based - 285 days of Review (Straight-chain lepidopteran pheromones, including User Requested Minor Use Registration)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
285 days of Review

Performance result
N/A (0 applications completed in 2021-22)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Registration of new active ingredient	629	See the total fee revenue table	0	April 1, 2023	655
Amendment of registration	316			April 1, 2023	330

Fee
Category A Component Based - Submissions with atypical timelines and joint reviews

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
Variable as per Management of Submission Policy Appendix I, table 1[xvi]

Performance result
79% (15/19 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Product Chemistry - active ingredient	5,277	See the total fee revenue table	0	April 1, 2023	5,491
Product Chemistry - end-use product or manufacturing concentrate	2,939			April 1, 2023	3,058
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	82,058			April 1, 2023	85,374

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	17,136			April 1, 2023	17,829
Toxicology data - acute toxicity studies	3,200			April 1, 2023	3,330
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	18,942			April 1, 2023	19,708
Exposure data accompanying an application to register a pest control product - or to amend the registration of a pest control product - that contains a registered active ingredient, when a new risk assessment is necessary	6,235			April 1, 2023	6,488
Metabolism data	31,331			April 1, 2023	32,598
Residue data	17,146			April 1, 2023	17,839
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	46,205			April 1, 2023	48,073

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Environmental fate data accompanying an application to register a pest control product, or to amend the registration of a pest control product, that contains a registered active ingredient, when a new risk assessment is necessary	25,587			April 1, 2023	26,621
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	40,352			April 1, 2023	41,984
Environmental toxicology data accompanying an application to register a pest control product,or to amend the registration of a pest control product, that contains a registered active ingredient, when a new risk assessment is necessary	25,644			April 1, 2023	26,681
Value and effectiveness data for a pest control product	983			April 1, 2023	1,024
Registration of a new active ingredient - food use	7,834			April 1, 2023	8,151
Registration of a new active ingredient - non-food use	4,701			April 1, 2023	4,892

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Amendment of registration - new risk assessment necessary - environmental fate data, environmental toxicity data or exposure data	3,135			April 1, 2023	3,262
Registration of new active ingredient	629			April 1, 2023	655
Amendment of registration	316			April 1, 2023	330
Specification of maximum residue limit for a previously unexamined pest control product	135,805			April 1, 2023	141,293
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	17,146			April 1, 2023	17,839
Processing	1,229			April 1, 2023	1,280

Fee
Category B Component Based - 425 days of Review (Conventional Chemicals including emergency use and New Import Maximum Residue Limits for previously assessed active ingredient)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
425 days of Review

Performance result
94% (154/163 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Product Chemistry - active ingredient	5,277	See the total fee revenue table	0	April 1, 2023	5,491
Product Chemistry - end-use product or manufacturing concentrate	2,939			April 1, 2023	3,058
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	17,136			April 1, 2023	17,829

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Toxicology data - acute toxicity studies	3,200			April 1, 2023	3,330
Exposure data - other	5,646			April 1, 2023	5,875
Metabolism data	31,331			April 1, 2023	32,598
Residue data	17,146			April 1, 2023	17,839
Environmental fate data - other	12,500			April 1, 2023	13,005
Environmental toxicology data - other	2,671			April 1, 2023	2,780
Value and effectiveness data for a pest control product	983			April 1, 2023	1,024
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	17,146			April 1, 2023	17,839
Processing	1,229			April 1, 2023	1,280

Fee
Category B Component Based - 360 days of Review (Reduced risk, other biopesticides, non-conventionals, non-straight chain lepidopteran pheromone including emergency use)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
360 days of Review

Performance result
95% (21/22 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Product Chemistry - active ingredient	5,277	See the total fee revenue table	0	April 1, 2023	5,491
Product Chemistry - end-use product or manufacturing concentrate	2,939			April 1, 2023	3,058
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	17,136			April 1, 2023	17,829

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Toxicology data - acute toxicity studies	3,200			April 1, 2023	3,330
Exposure data - other	5,646			April 1, 2023	5,875
Metabolism data	31,331			April 1, 2023	32,598
Residue data	17,146			April 1, 2023	17,839
Environmental fate data - other	12,500			April 1, 2023	13,005
Environmental toxicology data - other	2,671			April 1, 2023	2,780
Value and effectiveness data for a pest control product	983			April 1, 2023	1,024
Amendment of registration - data required, label changes	1,568			April 1, 2023	1,632
Amendment of registration - data required, other	1,256			April 1, 2023	1,308
Processing	1,229			April 1, 2023	1,280

Fee
Category B Component Based - 240 days of Review (Microbials and straight chain lepidopteran pheromones including emergency use)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
240 days of Review

Performance result
100% (17/17 application met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Amendment of registration - data required, label changes	1,568	See the total fee revenue table	0	April 1, 2023	1,632
Amendment of registration - data required, other	1,256			April 1, 2023	1,308
Amendment of registration	316			April 1, 2023	330

Fee
Category B Component Based - 158 days of Review (Streamlined; application rate changes, tank mixes, new pests or changes to level of control)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
158 days of Review

Performance result
98% (55/56 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Value and effectiveness data for a pest control product	983	See the total fee revenue table	0	April 1, 2023	1,024
Amendment of registration - data required, label changes	1,568			April 1, 2023	1,632
Amendment of registration - no data required, other	316			April 1, 2023	330
Processing	1,229			April 1, 2023	1,280

Fee
Category B Component Based - Submissions with atypical timelines and joint reviews

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
Variable as per Management of Submission Policy Appendix I, table 2[xvi]

Performance result
100% (7/7 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Product Chemistry - active ingredient	5,277	See the total fee revenue table	0	April 1, 2023	5,491
Product Chemistry - end-use product or manufacturing concentrate	2,939			April 1, 2023	3,058
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	17,136			April 1, 2023	17,829
Toxicology data-acute toxicity studies	3,200			April 1, 2023	3,330

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Exposure data-other	5,646			April 1, 2023	5,875
Metabolism data	31,331			April 1, 2023	32,598
Residue data	17,146			April 1, 2023	17,839
Environmental fate data - other	12,500			April 1, 2023	13,005
Environmental toxicology data - other	2,671			April 1, 2023	2,780
Value and effectiveness data for a pest control product	983			April 1, 2023	1,024
Amendment of registration - data required, label changes	1,568			April 1, 2023	1,632
Amendment of registration - data required, other	1,256			April 1, 2023	1,308
Amendment of registration - no data required	316			April 1, 2023	330
Amendment of registration	316			April 1, 2023	330
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	17,146			April 1, 2023	17,839
Processing	1,229			April 1, 2023	1,280

Fee
Category C Component Based - 240 days of Review (New/Changes to Product Labels, Addition of Approved Minor Use, Similar Product)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
240 days of Review

Performance result
98% (347/353 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Amendment of registration - no data required	316	See the total fee revenue table	0	April 1, 2023	330
Amendment of registration	316			April 1, 2023	330
Processing	1,229			April 1, 2023	1,280

Fee
Category C Component Based - 180 days of Review (New/Changes to TGAI, ISP, MA or EP Product Chemistry, Administrative Changes, Administrative Re-instatement)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
180 days of Review

Performance result
100% (94/94 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Amendment of registration - no data required	316	See the total fee revenue table	0	April 1, 2023	330
Amendment of registration	316			April 1, 2023	330
Processing	1,229			April 1, 2023	1,280

Fee
Category C Component Based - Submissions with atypical timelines and joint reviews

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
Variable as per Management of Submission Policy Appendix I, table 3[xvi]

Performance result
N/A (0 applications completed in 2021-22)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Amendment of registration - no data required	316	See the total fee revenue table	0	April 1, 2023	330
Amendment of registration	316			April 1, 2023	330
Processing	1,229			April 1, 2023	1,280

Fee
Category D Component Based - 253 days of Review (Registration Renewal)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
253 days of Review (The number of days from the issuance of the renewal notice to March 15 of the following year)

Performance result
100% (1,061/1,061 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Low-materiality ($51-$151) : Registration Renewal

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Registration Renewal	88	See the total fee revenue table	0	April 1, 2023	92

Fee
Category D Component Based – 46 Days of Review (Registration/Amendment to Registration of active ingredient to be used in pest control product manufactured only for export)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
46 days of Review

Performance result
100% (7/7 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Registration of active ingredient to be used in pest control product manufactured only for export	8,474	See the total fee revenue table	0	April 1, 2023	8,817
Amendment to Registration of active ingredient to be used in pest control product manufactured only for export	1,229			April 1, 2023	1,280

Fee
Category D Component Based - 42 days of Review (Master Copies)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
42 days of Review

Performance result
99% (66/67 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Processing	1,229	See the total fee revenue table	0	April 1, 2023	1,280

Fee
Category D Component Based - 10 days of Review (Private Labels)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
10 days of Review

Performance result
100% (5/5 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Processing	1,229	See the total fee revenue table	0	April 1, 2023	1,280

Fee
Category E Component Based - 159 days of Review (Research Authorizations for New Technical Grade Active Ingredients)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
159 days of Review

Performance result
84% (16/19 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Research authorization - major crops, other than research authorizations set out in paragraphs (c) and (d)	5,500	See the total fee revenue table	0	April 1, 2023	5,723
Research authorization - minor use crops, other than research authorizations set out in paragraphs (c) and (d)	5,500			April 1, 2023	5,723
Research authorization - microbial agents, semiochemicals and any substance listed in subparagraph 1(d) (ii) of these regulations	1,319			April 1, 2023	1,373

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Research authorization - greenhouse crops and non-agricultural uses	1,319			April 1, 2023	1,373

Fee
Category E Component Based - 69 days of Review (Research Authorizations for New Uses of Registered Active Ingredients)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
69 days of Review

Performance result
97% (56/58 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Research authorization - major crops, other than research authorizations set out in paragraphs (c) and (d)	5,500	See the total fee revenue table	0	April 1, 2023	5,723
Research authorization - minor use crops, other than research authorizations set out in paragraphs (c) and (d)	5,500			April 1, 2023	5,723
Research authorization - microbial agents, semiochemicals and any substance listed in subparagraph 1(d) (ii) of these regulations	1,319			April 1, 2023	1,373

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Research authorization - greenhouse crops and non-agricultural uses	1,319			April 1, 2023	1,373

Fee
Category E Component Based - 30 days of Review (Research Notification for Research Carried out in Canada)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
30 days of Review

Performance result
100% (65/65 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Research notifications	270	See the total fee revenue table	0	April 1, 2023	282

Fee
Category F Component Based - 45 days of Review (Registration and amendments to registered pest control products via notification)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
45 days of Review

Performance result
99% (927/931 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Applications not mentioned in schedules	270	See the total fee revenue table	98	April 1, 2023	282

Fee
Category L Component Based - 425 days of Review (Equivalency and data compensation assessment of end-use product and manufacturing concentrate with partial data package - conventional chemical)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
425 days of Review

Performance result
83% (66/80 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Product Chemistry - active ingredient	5,277	See the total fee revenue table	0	April 1, 2023	5,491
Product Chemistry - end-use product or manufacturing concentrate	2,939			April 1, 2023	3,058
Toxicology data accompanying an application to register a pest control product -or to amend a pest control product -that contains an registered active ingredient	17,136			April 1, 2023	17,829

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Toxicology data-acute toxicity studies	3,200			April 1, 2023	3,330
Exposure data - other	5,646			April 1, 2023	5,875
Metabolism data	31,331			April 1, 2023	32,598
Residue data	17,146			April 1, 2023	17,839
Environmental fate data - other	12,500			April 1, 2023	13,005
Environmental toxicology data - other	2,671			April 1, 2023	2,780
Value and effectiveness data for a pest control product	983			April 1, 2023	1,024
Identification of compensable data	2,343			April 1, 2023	2,438
Processing	1,229			April 1, 2023	1,280

Fee
Category L Component Based - 365 days of Review (Equivalency and data compensation assessment of active ingredient, end-use product and manufacturing concentrate with no data)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
365 days of Review

Performance result
85% (82/97 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Product Chemistry - active ingredient	5,277	See the total fee revenue table	0	April 1, 2023	5,491
Product Chemistry - end-use product or manufacturing concentrate	2,939			April 1, 2023	3,058
Identification of compensable data	2,343			April 1, 2023	2,438
Processing	1,229			April 1, 2023	1,280

Fee
Category L Component Based – 360 days of Review (Equivalency and data compensation assessment of end-use product and manufacturing concentrate with partial data package - reduced risk, other biopesticides, non-conventionals, non-straight chain lepidopteran pheromone)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
360 days of Review

Performance result
N/A (0 applications completed in 2021-22)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Product Chemistry - active ingredient	5,277	See the total fee revenue table	0	April 1, 2023	5,491
Product Chemistry - end-use product or manufacturing concentrate	2,939			April 1, 2023	3,058
Toxicology data accompanying an application to register a pest control product -or to amend a pest control product -that contains an registered active ingredient	17,136			April 1, 2023	17,829

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Toxicology data-acute toxicity studies	3,200			April 1, 2023	3,330
Exposure data - other	5,646			April 1, 2023	5,875
Metabolism data	31,331			April 1, 2023	32,598
Residue data	17,146			April 1, 2023	17,839
Environmental fate data - other	12,500			April 1, 2023	13,005
Environmental toxicology data - other	2,671			April 1, 2023	2,780
Value and effectiveness data for a pest control product	983			April 1, 2023	1,024
Identification of compensable data	2,343			April 1, 2023	2,438
Amendment of registration - data required, label changes	1,568			April 1, 2023	1,632
Amendment of registration - data required, other	1,256			April 1, 2023	1,308
Processing	1,229			April 1, 2023	1,280

Fee
Category L Component Based 240 days of Review (Equivalency and data compensation assessment of end-use product and manufacturing concentrate with partial data package - microbials and straight chain lepidopteran pheromone)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
240 days of Review

Performance result
N/A (0 applications completed in 2021-22)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Identification of compensable data	2,343	See the total fee revenue table	0	April 1, 2023	2,438
Amendment of registration - data required, label changes	1,568			April 1, 2023	1,632
Amendment of registration - data required, other	1,256			April 1, 2023	1,308
Amendment of registration	316			April 1, 2023	330
Processing	1,229			April 1, 2023	1,280

Fee
Category L Component Based – Applications with atypical timelines (Tailgaters, renegotiated timelines, synchronized timelines, coordination with Re-Evaluation)

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
Variable as per Management of Submission Policy Appendix I, table 7[xvi]

Performance result
100% (3/3 applications met the service standard)

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Product Chemistry - active ingredient	5,277	See the total fee revenue table	0	April 1, 2023	5,491
Product Chemistry - end-use product or manufacturing concentrate	2,939			April 1, 2023	3,058
Toxicology data accompanying an application to register a pest control product -or to amend a pest control product -that contains an registered active ingredient	17,136			April 1, 2023	17,829

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Toxicology data-acute toxicity studies	3,200			April 1, 2023	3,330
Exposure data - other	5,646			April 1, 2023	5,875
Metabolism data	31,331			April 1, 2023	32,598
Residue data	17,146			April 1, 2023	17,839
Environmental fate data - other	12,500			April 1, 2023	13,005
Environmental toxicology data - other	2,671			April 1, 2023	2,780
Value and effectiveness data for a pest control product	983			April 1, 2023	1,024
Identification of compensable data	2,343			April 1, 2023	2,438
Amendment of registration - data required, label changes	1,568			April 1, 2023	1,632
Amendment of registration - data required, other	1,256			April 1, 2023	1,308
Amendment of registration	316			April 1, 2023	330
Processing	1,229			April 1, 2023	1,280

Annual Charge (for a registered Pest Control Product)

A registrant must pay each year, in respect of every pest control product that is registered in their name on April 1 of the year, an annual charge. All registered products including technical grade active ingredients (TGAI), import for manufacturing and export program (IMEPs), private label products and master copies must pay the annual charge.

Fee
Annual Charge

Fee-setting authority
- *Pest Control Products Act*, 63[xiv]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xv]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
100% of all invoices were issued by April 30, 2021

Performance result
100%

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Annual Charge	The lesser of $3,745.27 and 4% of the actual gross revenue during the registrant's preceding fiscal year, but not less than $104.03	9,148,686	0	April 1, 2023	The lesser of $4,135.95 and 4% of the actual gross revenue during the registrant's preceding fiscal year, but not less than $114.88

Fees Charged for Filing a Claim for Exemption under the Hazardous Materials Information Review Act

When a supplier or employer wants to be exempt from having to disclose confidential business information (CBI), such as the chemical identity of one or more trade-secret hazardous ingredients, they must file a claim for exemption with Health Canada.

Fee

- Original Claims
- Refiled Claims

Note: A 50% fee reduction is available for small businesses that meet certain criteria

Fee-setting authority:

- *Hazardous Materials Information Review Act,* 48(2)[xvii]
- *Hazardous Materials Information Review Regulations* (SOR/88-456)[xviii]

Year fee-setting authority was introduced
1988

Last year fee-setting authority was amended
2020

Service standard
Seven calendar days from the date of the receipt of a complete application, for the issuance of a registry number

Performance result
100% of claims (original and refiled) were registered within the service standard of seven calendar days

Application of *Low-Materiality Fees Regulations*
Material (>$151): All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Original Claim (up to 15)	1,872.64	412,455	0	April 1, 2023	2,067.98
Original Claim (between 16-25)	416.14			April 1, 2023	459.56
Original Claim (26+)	208.07			April 1, 2023	229.77

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Refiled Claims (up to 15)	1,498.11	20,067	0	April 1, 2023	1,654.39
Refiled Claims (between 16-25)	332.91			April 1, 2023	367.64
Refiled Claims (26+)	166.46			April 1, 2023	183.82

Cannabis Fees

Fees are charged for the following transactional activities: application screening, security clearances, and import/export permits. In addition, an Annual Regulatory Fee is charged which covers costs associated with a range of regulatory activities including regulatory inspections, compliance and enforcement, program management and oversight. These activities are carried out by Health Canada, the Canada Border Services Agency, the Public Health Agency of Canada and Public Safety Canada to support the objectives of the *Cannabis Act* with respect to the legislation and regulations of cannabis.

Fee
Licence Application Screening Fees

Fee-setting authority
- *Cannabis Act,* 142(1)[xix]
- *Cannabis Fees Order* (SOR/2018-198)[xx]

Year fee-setting authority was introduced
2018

Last year fee-setting authority was amended
2020

Service standard
Health Canada is committed to a non-binding administrative service standard of 30-business-days for the screening of new licence applications. The standard excludes time spent awaiting additional information from applicants.

Performance result
The non-binding administrative standard was met 94% of the time.

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Licence Application Screening Fee - Licence for micro-cultivation	1,706	498,125	This fee was not	April 1, 2023	1,886

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Licence Application Screening Fee - Licence for standard cultivation	3,411	(note 1)	subject to remissions	April 1, 2023	3,767
Licence Application Screening Fee - Licence for a nursery	1,706			April 1, 2023	1,886
Licence Application Screening Fee - Licence for micro-processing	1,706			April 1, 2023	1,886
Licence Application Screening Fee - Licence for standard processing	3,411			April 1, 2023	3,767
Licence Application Screening Fee - Licence for sale for medical purposes	3,411			April 1, 2023	3,767

1)The revenues are significantly lower than previous fiscal years due to an increase in the number of micro and nursery licence holders in 2021-22 compared to the other years. These licence holders pay a lower fee, however, the cost of screening is the same for all licence classes.

Fee
Application for a Security Clearance

Fee-setting authority
- *Cannabis Act,* 142(1)[xix]
- *Cannabis Fees Order* (SOR/2018-198)[xx]

Year fee-setting authority was introduced
2018

Last year fee-setting authority was amended
2020

Service standard
No administrative service standard for this fee as outlined during the 2018 consultation on the Proposed Approach to Cost Recovery for the Regulation of Cannabis and the subsequent Regulatory Impact Analysis Statement for the *Cannabis Fees Order*.

Performance result
Not applicable

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Application for a Security Clearance

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Application for a Security Clearance	1,722	3,466,560	This fee was not subject to remissions	April 1, 2023	1,903

Fee
Application for Import or Export Permit

Fee-setting authority
- *Cannabis Act,* 142(1)[xix]
- *Cannabis Fees Order* (SOR/2018-198)[xx]

Year fee-setting authority was introduced
2018

Last year fee-setting authority was amended
2020

Service standard
Health Canada commits to a non-binding administrative service standard of 30 business days from the date that payment is received for the application to the issuance or rejection of the permit. The standard excludes time spent awaiting additional information from applicants.

Performance result
The non-binding administrative standard was met 95% of the time

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* Application for Import or Export Permit

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Application for Import or Export Permit	636	597,340	This fee was not subject to remissions	April 1, 2023	703

Fee
Annual Regulatory Fee

Fee-setting authority
- *Cannabis Act,* 142(1)[xix]
- *Cannabis Fees Order* (SOR/2018-198)[xx]

Year fee-setting authority was introduced
2018

Last year fee-setting authority was amended
2020

Service standard
No administrative service standard for this fee as outlined during the 2018 consultation on the Proposed Approach to Cost Recovery for the Regulation of Cannabis and the subsequent Regulatory Impact Analysis Statement for the *Cannabis Fees Order*.

Performance result
Not applicable

Application of *Low-Materiality Fees Regulations*
Not subject to *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Annual fee - Licence for micro-cultivation	as per *Cannabis Fees Order*[xx]	71,121,867 (note 1)	This fee was not subject to remissions	Exempt	as per *Cannabis Fees Order*[xx]
Annual fee - Licence for standard cultivation					
Annual fee - Licence for a nursery					
Annual fee - Licence for micro-processing					
Annual fee - Licence for standard processing					
Annual fee - Licence for sale for medical purposes					

1)The *Order Amending the Cannabis Fees Order (Extension of Deadline for Payment of 2020–2021 Annual Fee)*[vi] provided short-term economic relief to the cannabis industry by deferring the annual fee payment due date from September 30, 2020 to March 31, 2021. Only revenues received by March 31, 2021 were reported in 2020-21. The remaining outstanding revenues are being reported in 2021-22.

National Dosimetry Products and Services Fees

National Dosimetry Services (NDS) provides radiation monitoring services to Canadians who are exposed to radiation in their work environment. NDS provides commercial dosimetry services to over 100,000 individuals working in over 12,500 organizations and operates on a cost-recovery basis. There are a number of components to NDS that are billed on a regular basis. These fees include the annual support fee, the shipping and handling fee and the processing fee. Other fees are billed depending on whether additional services are requested or if a dosimeter is overdue, late, lost or damaged.

Fee
National Dosimetry Products and Services Fees

Fee-setting authority
- Minister's Authority
- Fees notice published in Canada Gazette[xxi]

Year fee-setting authority was introduced
2004

Last year fee-setting authority was amended
2017

Service standard
Provide timely, responsive and reliable dosimetry services:
1. Exposures reported to the National Dose Registry within 45 calendar days of receipt - Canadian Nuclear Safety Commission (CNSC) regulatory standard;
2. Dosimeters shipped 10-13 business days prior to exchange date with clients;
3. Dose results for whole body and extremity services reported to clients within internal service standards of 10- 20 business days, depending on the dosimetry service;
4. Client account information updated within two business days;
5. Client voice mails responded to within one business day; and
6. Client emails responded to within two business days.

Performance result
1. 100% compliance with the 45 day regulatory (CNSC) standard;
2. Shipped out 99% of dosimeters within 10 to 13 business days prior to exchange date;
3. 83% reported within internal standard of 10-20 business days, depending on the dosimetry service. Reduction due to COVID-19 pandemic impact on operations. CNSC regulatory standard prioritized over internal standards.;
4. 97% completed within two business days;
5. 92% being addressed within one business day; and
6. 92% addressed within two business days.

Application of *Low-Materiality Fees Regulations*
Not subject to section 17 of the *Service Fees Act*

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Annual support	85.00	Not available	This fee was not subject to remissions	Not subject to the *Service Fees Act* and therefore no automatic annual increase: All fees All fees currently under review.	85.00
Annual support - multi-group discount (5+ groups)	50.00	Not available			50.00
Shipping and handling (per shipment)	14.50	Not available			14.50
Processing fees (per dosimeter)	5.50 to 17.50	Not available			5.50 to 17.50
Ad hoc dosimeter request - add-on (per shipment)	65.00	Not available			65.00
Priority processing request (per request)	95.00	Not available			95.00
Pregnancy service (semi-monthly)	375.00	Not available			375.00
Electronic personal dosimeter rental (per year)	415.00	Not available			415.00
Specialized consultation (per hour)	125.00	Not available			125.00
Customized reporting (per hour)	60.00	Not available			60.00
NDR dose modifications (per hour)	60.00	Not available			60.00
Reprinting reports (per report)	10.00	Not available			10.00

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Overdue dosimeter (three months after wearing period ends)	55.00	Not available			55.00
Late dosimeter (six months after wearing period ends)	55.00	Not available			55.00
Lost/damaged dosimeter	82.50	Not available			82.50
Damaged electronic personal dosimeter	415.00	Not available			415.00
Credit upon returning overdue dosimeter	28.75	Not available			28.75
Credit upon returning late or lost dosimeter	57.50	Not available			57.50

Master File Fees

A Master File (MF) is a reference that provides information about specific processes or components used in the manufacturing, processing, or packaging of a drug. The MF is a useful vehicle for providing information to Health Canada, where that information is confidential business information (CBI) and is not available to the manufacturer of the dosage form or to the sponsors of a drug submission, DIN (Drug identification Number) application or clinical trial application (CTA).

Fee

- New Master Files (file registration)
- Drug Master Files - letter of access
- Drug Master Files - Update

Fee-setting authority

- Minister's Authority
- Fees notice published in Canada Gazette[xxii]

Year fee-setting authority was introduced
1996

Last year fee-setting authority was amended
2017

Service standard
30 calendar days

Performance result
99.6% (2,014/2,022 issued within 30 calendar days)

Application of *Low-Materiality Fees Regulations*
Not subject to section 17 of the *Service Fees Act:* All fees listed below

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
New Master Files (file registration)	1,298	372,326	This fee was not subject to remissions	April 1, 2023	1,351
Drug Master Files – letter of access	184	219,469		April 1, 2023	192

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Drug Master Files - Update	563	257,823		April 1, 2023	587

Certificate of Pharmaceutical Product Fee

A certificate issued establishing the status of the pharmaceutical, biological, radiopharmaceutical or veterinary product listed and the Good Manufacturing Practice status of the fabricator of the product.

Fee
Certificate of Pharmaceutical Product

Fee-setting authority
- Minister's Authority
- Fees notice published in Canada Gazette[xxiii]

Year fee-setting authority was introduced
1996

Last year fee-setting authority was amended
2012

Service standard
25 business days to issue certificate

Performance result
96.6% (2,407 / 2,492 of certificates issued within 25 business days)

Application of *Low-Materiality Fees Regulations*
Not subject to section 17 of the *Service Fees Act:* Certificate of Pharmaceutical Product

Fee	2021–22 fee amount ($)	2021-22 total fee revenue ($)	2021-22 total remissions issued for the fee ($)	Fee adjustment date in 2023-24	2023-24 fee amount ($)
Certificate of Pharmaceutical Product	94	230,008	This fee was not subject to remissions	April 1, 2023	98

Endnotes

[i] Service Fees Act, https://laws-lois.justice.gc.ca/eng/acts/S-8.4/index.html

[ii] Low Materiality Regulations, https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-109/index.html

[iii] Directive on Charging and Special Financial Authorities, https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-109/index.html

[iv] Access to Information and Privacy https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications.html#atip

[v] Remissions for missed service standards https://www.canada.ca/en/health-canada/services/funding/cost-recovery-service-fees.html#a6

[vi] Order Amending the Cannabis Fees Order (Extension of Deadline for Payment of 2020–2021 Annual Fee): SOR/2020-170, https://gazette.gc.ca/rp-pr/p2/2020/2020-08-05/html/sor-dors170-eng.html

[vii] Food and Drugs Act, https://laws-lois.justice.gc.ca/eng/acts/f-27/

[viii] Fees in Respect of Drugs and Medical Devices Order, Fees in Respect of Drugs and Medical Devices Order (justice.gc.ca)

[ix] Patent Act, https://laws-lois.justice.gc.ca/eng/acts/p-4/page-28.html#docCont

[x] Certificate of Supplementary Protection Regulations (SOR/2017-165), https://laws-lois.justice.gc.ca/eng/regulations/SOR-2017-165/FullText.html

[xi] Financial Administration Act, https://laws-lois.justice.gc.ca/eng/acts/f-11/

[xii] Fees in Respect of Dealer's Licences Regulations (SOR/2011-79), https://laws-lois.justice.gc.ca/eng/regulations/sor-2011-79/page-1.html

[xiii] Licensed Dealers for Controlled Drugs and Narcotics (Veterinary Use) Fees Regulations, https://laws-lois.justice.gc.ca/eng/regulations/SOR-98-5/page-1.html

[xiv] Pest Control Products Act, https://laws-lois.justice.gc.ca/eng/acts/p-9.01/

[xv] Pest Control Products Fees and Charges Regulations (SOR/2017-9), https://laws-lois.justice.gc.ca/eng/regulations/SOR-2017-9/page-1.html#h-843512

[xvi] Performance Timelines for Pest Control Product Applications, https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/management-submissions-policy.html#a5

[xvii] Hazardous Materials Information Review Act, https://laws-lois.justice.gc.ca/eng/acts/h-2.7/index.html

[xviii] Hazardous Materials Information Review Regulations (SOR/88-456), https://laws-lois.justice.gc.ca/eng/regulations/sor-88-456/

[xix] Cannabis Act, https://laws-lois.justice.gc.ca/eng/acts/c-24.5/

[xx] Cannabis Fees Order (SOR/2018-198), https://laws-lois.justice.gc.ca/eng/regulations/SOR-2018-198/page-1.html

[xxi] Notice amending Health Canada's National Dosimetry Services Products, Services and Fee Schedule, https://gazette.gc.ca/rp-pr/p1/2017/2017-01-28/html/notice-avis-eng.html

[xxii] Notice of changes to Health Canada's Master File fees, https://canadagazette.gc.ca/rp-pr/p1/2017/2017-04-22/html/notice-avis-eng.html

[xxiii] Notice amending Health Canada's Drug Master Files and Certificate of a Pharmaceutical Product fees, https://www.gazette.gc.ca/rp-pr/p1/2012/2012-02-18/html/notice-avis-eng.html#d104