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Health Canada

Fees Report - Fiscal Year 2020-21

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Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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Minister's message

On behalf of Health Canada, I am pleased to present the Departmental fees report for fiscal year 2020–21.

Throughout 2020-21, Health Canada implemented many measures to help lead a whole-of-government response to the COVID-19 pandemic. One such measure was the approval of several COVID-19 related Ministerial Orders. These Orders waived fees for applications and were key to allowing Health Canada to expedite the regulatory review and approval of personal protective equipment, drugs and medical devices needed by Canadians during the pandemic.

Effective April 1, 2020, as identified in last year's report, the majority of fees with respect to drugs and medical devices under the *Financial Administration Act* were repealed and set under the authority of the *Food and Drugs Act*. These fees are now regulated under the *Fees in Respect of Drugs and Medical Devices Order*, which include new fee mitigation measures for small businesses and penalty provisions related to service standards.

As per the *Service Fees Act* and the *Directive on Charging and Special Financial Authorities*, effective April 1, 2021, Health Canada implemented departmental and subordinate remission policies for fee regimes subject to the *Service Fees Act* (i.e. pesticides, hazardous materials and drug establishment licences - dealer's licences). These policies grant remissions to fee-payers for missed service standards.

Health Canada will continue to work towards continued 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], including 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 2020–21.[a]

Government of Canada departments may set fees for services, licences, permits, products, the use of facilities, for other authorizations of rights or privileges, or to recover, in whole or in part, costs incurred in relation to a regulatory scheme.

For reporting purposes, fees must be categorized under the following three fee-setting mechanisms:

1. Act, regulation or fees notice
    - An act of Parliament delegates the fee-setting authority to a department, minister or Governor in Council.
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.

This report contains information about all fees that are under Health Canada's authority.

The information covers fees subject to the *Service Fees Act* and exempted from the *Service Fees Act*.

For fees set by act, regulation or fees notice, the report provides totals for fee groupings, as well as detailed information for each fee.

Although the fees that 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

[a]. All years presented in this manner refer to fiscal years.

access to information fees for 2020–21 can be found in our access to information report, which is posted on our Web page: Reports and Publications - About Health Canada[iv].

Remissions

This report does not include remissions issued under the authority of the *Service Fees Act*, since this requirement took effect on April 1, 2021. Remissions issued under the *Service Fees Act* will be reported for the first time, as applicable, in the 2021–22 Fees Report, which will be published in 2022–23.

The *Service Fees Act* requires departments to remit a fee, in part or in full, to a fee payer when a service standard is deemed not met. Under the *Service Fees Act* and the *Directive on Charging and Special Financial Authorities*, departments had to develop policies and procedures for determining:

- whether a service standard has been met
- how much of a fee will be remitted to a fee payer if a service standard is deemed not met

The Health Canada remission policy and procedures were made available to the public as of April 1, 2021, and can be found on the following web page: Health Canada's Remission Policy for Missed Service Standards[v].

The "Overall totals for 2020-21, by fee-setting mechanism" presents the total remissions by fee-setting mechanism. The "Total, by fee grouping, for fees set by act, regulation or fees notice" provides further details related to remissions that were issued under Health Canada's enabling legislation in 2020-21.

In addition to remissions reported in the report, Health Canada did not charge cost recovery fees for application/licences submitted under various COVID-19 related Ministerial Orders as follows:

- The *Interim Order Respecting the Importation and Sale of Medical Devices for use in Relation to COVID-19*[vi] (effective until March 18, 2021) established an expedited authorization pathway for the importation or sale of medical devices used in the diagnosis, treatment, mitigation, or prevention of COVID-19.

- The *Interim Order No. 2 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*[vii] extends the flexibilities of the first order so that COVID-19 medical devices can continue to be sold and imported in Canada.

- The *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*[viii] (effective until September 16, 2021) established an expedited authorization pathway for the importation, sale, and advertising of drugs used in relation to COVID-19 while taking into consideration urgent public health needs.

- *Regulations Amending the Food and Drug Regulations (Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19)*[ix] introduces amendments to the Food and Drug Regulations (FDR) to incorporate some of the elective flexibilities related to market authorization, drug establishment licensing, and pre-positioning of COVID-19 drugs that were made available under the Interim Order. The amendments allow for the continued sale of COVID-19 drugs authorized under the Interim Order. The amendments also allow manufacturers of COVID-19 drugs to use these flexibilities even if no application is made under the Interim Order.

- *The Order Amending the Fees in Respect of Drugs and Medical Devices Order (COVID-19 Drugs)*[x] allows the remittance of fees in respect of a submission for a COVID-19 drug that was previously applied for under an interim order to stakeholders who wish to sell their COVID-19 drug after the interim order ceases.

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 2020–21, by fee-setting mechanism.

Overall totals for 2020–21, by fee-setting mechanism

Fee-setting mechanism	Revenue ($)	Cost ($)	Remissions ($)
Fees set by contract	0	0	Remissions do not apply to fees set by contract.
Fees set by either market rate or auction	0	0	0
Fees set by act, regulation or fees notice	201,488,969	545,169,123	190,252
Total	**201,488,969**	**545,169,123**	**190,252**

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

The following tables present, for each fee grouping, the total revenue, cost and remissions for all fees that Health Canada had the authority to set in 2020-21 that are set by any of the following:

- act
- regulation
- fees notice

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

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 2020–21

Fee grouping

Fees for Right to Sell Drugs

Revenue ($)	Cost ($)	Remissions ($)
21,093,308	73,709,077	0

Fees for Right to Sell Licenced Class II, III, or IV Medical Devices: totals for 2020-21

Fee grouping

Fees for Right to Sell Licenced Class II, III, or IV Medical Devices

Revenue ($)	Cost ($)	Remissions ($) (note 1)
12,990,279	23,505,960	1,429

1) Remitted fees related to missed service standards as per the *Fees in Respect of Drugs and Medical Devices Order*[xi]

Fees for Examination of a Submission - Drugs for Human Use: totals for 2020-21

Fee grouping

Fees for Examination of a Submission - Drugs for Human Use

Revenue ($)	Cost ($)	Remissions ($) (note 1)
77,265,889	153,080,486	4,861

1) Remitted fees related to missed service standards as per the *Fees in Respect of Drugs and Medical Devices Order*[xi]

Certificate of Supplementary Protection Application Fees: totals for 2020-21

Fee grouping

Certificate of Supplementary Protection Application Fees

Revenue ($)	Cost ($)	Remissions ($)
210,780	245,591	0

Fees for Examination of Medical Device Licence Applications: totals for 2020-21

Fee grouping

Fees for Examination of Medical Device Licence Applications

Revenue ($)	Cost ($)	Remissions ($) (note 1)
7,598,061	22,741,660	3,704

1) Remitted fees related to missed service standards as per the *Fees in Respect of Drugs and Medical Devices Order*[xi]

Fees for Examination of a Submission - Drugs for Veterinary Use Only: totals for 2020-21

Fee grouping

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

Revenue ($)	Cost ($)	Remissions ($)
1,009,016	9,581,773	0

Drug Establishment Licensing Fees: totals for 2020-21

Fee grouping

Drug Establishment Licensing Fees

Revenue ($)	Cost ($)	Remissions ($)
17,510,606	34,542,183	0

Drug Establishment Licensing Fees - Dealer's Licences: totals for 2020-21

Fee grouping

Drug Establishment Licensing Fees - Dealer's Licences

Revenue ($)	Cost ($)	Remissions ($)
208,425	4,995,045	0

Medical Devices Establishment Licensing Fees: totals for 2020-21

Fee grouping

Medical Devices Establishment Licensing Fees

Revenue ($)	Cost ($)	Remissions ($) (note 1)
12,185,289	14,356,144	134,258

1) Remitted fees related to missed service standards as per the *Fees in Respect of Drugs and Medical Devices Order*[xi]

Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product: totals for 2020-21

Fee grouping

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

Revenue ($)	Cost ($)	Remissions ($)
5,170,413	48,751,758	0

Annual Charge (for a registered Pest Control Product): totals for 2020-21

Fee grouping

Annual Charge (for a registered Pest Control Product)

Revenue ($)	Cost ($)	Remissions ($)
8,040,175	31,774,274	0

Fees Charged for Filing a Claim for Exemption under the Hazardous Materials Information Review Act: totals for 2020-21

Fee grouping

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

Revenue ($)	Cost ($)	Remissions ($)
377,437	4,396,433	0

Cannabis Fees: totals for 2020-21

Fee grouping

Cannabis Fees

Revenue ($) (note 1)	Cost ($)	Remissions ($) (note 2)
29,914,490	112,728,368	46,000

1) The *Order Amending the Cannabis Fees Order (Extension of Deadline for Payment of 2020–2021 Annual Fee)*[xii] 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 are being reported in 2020-21. The remaining outstanding revenues will be reported in 2021-22.
2) Remitted fees paid by certain stakeholders due to an oversight with how the Cannabis Fees Order was worded, which resulted in some otherwise eligible licence holders not qualifying for the exemption in the year they were first licenced to sell cannabis for medical purposes (*Cannabis for Medical Purposes Remission Order*)[xiii].

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 2020-21

Fee grouping

National Dosimetry Products and Services Fees

Revenue ($)	Cost ($)	Remissions ($)
6,798,141	8,782,621	0

Master File Fees: totals for 2020-21

Fee grouping

Master File Fees

Revenue ($)	Cost ($)	Remissions ($)
926,890	1,364,478	0

Certificate of Pharmaceutical Product Fee: totals for 2020-21

Fee grouping

Certificate of Pharmaceutical Product Fee

Revenue ($)	Cost ($)	Remissions ($)
189,770	613,272	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 2020-21 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)[xiv]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[xi]

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% completed within service standard

Application of *Low-Materiality Fees Regulations*

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Human drugs - Disinfectant (item 1)	1,285	1,192,421	April 1, 2022	1,449
Human drugs - Non-prescription (item 2)	1,623	4,360,505	April 1, 2022	2,500
Human drugs - Prescription (drug other than one referred to in item 1 or 2)	1,836	14,467,646	April 1, 2022	4,211

Fee
Veterinary Drugs

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

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Veterinary Drugs	312	282,791	April 1, 2022	437

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)[xiv]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[xi]

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
99.96% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Medical Device Right to Sell	381	12,990,279	April 1, 2022	394

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)[xiv]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[xi]

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
New Active Substance	400,288	18,829,121	April 1, 2022	490,666

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

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

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
100% 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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Clinical or non-clinical data and chemistry and manufacturing data	204,197	14,753,574	April 1, 2022	253,015

Fee
Clinical or non-clinical data only

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

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
100% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Clinical or non-clinical data only	90,864	16,656,746	April 1, 2022	104,339

Fee
Comparative studies

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

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
100% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Comparative studies	53,836	8,017,619	April 1, 2022	59,708

Fee
Chemistry and manufacturing data only

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

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
100% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Chemistry and manufacturing data only	27,587	10,270,033	April 1, 2022	34,831

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)[xiv]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[xi]

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% 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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Clinical or non-clinical data only, in support of safety upgrades to the labelling	19,442	4,288,905	April 1, 2022	20,064

Fee
Labelling only

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

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Labelling only	3,816	2,594,453	April 1, 2022	4,997

Fee
Labelling only (generic drugs)

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

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Labelling only (generic drugs)	2,010	552,951	April 1, 2022	2,075

Fee
Administrative submission

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
45 calendar days to review

Performance result
- Pharmaceuticals – 99.6% completed within service standard
- Biologics – 66.7% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Administrative submission	432	225,176	April 1, 2022	698

Fee
Disinfectant - full review

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

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
100% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Disinfectant - full review	5,712	744,497	April 1, 2022	9,211

Fee
Labelling only (disinfectants)

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

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Labelling only (disinfectants)	2,507	269,252	April 1, 2022	2,588

Fee
Drug identification number application - labelling standards

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

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Drug identification number application - labelling standards	1,616	662,459	April 1, 2022	1,668

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)[xvi]
- *Certificate of Supplementary Protection Regulations* (SOR/2017-165)[xvii]

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Certificate of Supplementary Protection Application Fees	5,394	210,780	April 1, 2022	5,613

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)[xiv]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[xi]

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Applications for Class II licence	450	590,708	April 1, 2022	522

Fee
Applications for Class II licence amendment

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
15 calendar days to review

Performance result
98.1% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Applications for Class II licence amendment	272	196,132	April 1, 2022	282

Fee
Applications for Class III licence

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

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Applications for Class III licence	7,477	2,023,726	April 1, 2022	10,679

Fee
Applications for Class III licence (near patient)

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

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Applications for Class III licence (near patient)	12,851	197,889	April 1, 2022	20,723

Fee
Applications for Class III licence amendment - changes in manufacturing

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

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% 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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Applications for Class III licence amendment - changes in manufacturing	1,903	55,025	April 1, 2022	3,070

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

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

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
98.5% 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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Applications for Class III licence amendment - significant changes not related to manufacturing	6,608	2,454,511	April 1, 2022	8,780

Fee
Applications for Class IV licence

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

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
97.7% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Applications for Class IV licence	24,345	1,292,805	April 1, 2022	25,955

Fee
Applications for Class IV licence amendment - changes in manufacturing

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

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% 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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Applications for Class IV licence amendment - changes in manufacturing	1,903	60,690	April 1, 2022	3,070

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

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

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% 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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Applications for Class IV licence amendment - significant changes not related to manufacturing	8,057	846,204	April 1, 2022	12,128

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)[xiv]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[xi]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
15 calendar days to review

Performance result
97.9% 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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Applications for Class II, III or IV licence or licence amendment - private label medical device	147	32,156	April 1, 2022	152

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)[xiv]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[xi]

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 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	918	8,998	April 1, 2022	1,483
2) Published references or other data	638	0	April 1, 2022	1,031

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 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	320	1,056	April 1, 2022	516

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

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

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
100% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 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	83,835	April 1, 2022	503

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

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

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 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.)	20,375	126,511	April 1, 2022	32,855
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	12,342	49,465	April 1, 2022	19,903

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 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	29,631	0	April 1, 2022	47,780
8) Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species	40,125	0	April 1, 2022	64,700
9) Comparative (pharmacodynamics, clinical or bioavailability) data to support an additional route of administration	3,698	1,482	April 1, 2022	5,965
10) Comparative (pharmacodynamics, clinical or bioavailability) data to support each additional strength	612	0	April 1, 2022	989
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	27,783	22,269	April 1, 2022	44,800
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	37,040	14,845	April 1, 2022	59,724

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
13) For food-producing animals, residue depletion studies to establish a withdrawal period for an additional dosage form, dosage or route of administration	3,698	0	April 1, 2022	5,965
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	18,513	0	April 1, 2022	29,853
15) Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug	6,171	34,548	April 1, 2022	9,953
16) Chemistry and manufacturing data to support one strength of a single dosage form	6,171	44,441	April 1, 2022	9,953
17) Chemistry and manufacturing data to support an additional strength of a single dosage form submitted at the same time as item 16	3,086	14,733	April 1, 2022	4,978
18) Documentation to support a change of manufacturer	320	22,271	April 1, 2022	516

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
240 calendar days to complete Review 1

Performance result
100% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
19) Efficacy data to support an additional indication in one animal species	16,053	16,053	April 1, 2022	25,886
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	12,342	12,342	April 1, 2022	19,903
21) Efficacy and safety data (in the intended species) to support an indication in another animal species	20,375	16,332	April 1, 2022	32,855

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 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.	29,631	83,129	April 1, 2022	47,780
23) Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species	40,125	0	April 1, 2022	64,700
24) Efficacy and safety data (in the intended species) to support the concurrent use of two drugs approved for the same animal species	9,869	0	April 1, 2022	15,915
25) Comparative (pharmacodynamics, clinical or bioavailability) data to support an additional route of administration	3,698	0	April 1, 2022	5,965
26) Comparative (pharmacodynamics, clinical or bioavailability) data to support each additional strength	612	0	April 1, 2022	989
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	3,698	0	April 1, 2022	5,965
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	18,513	7,420	April 1, 2022	29,853

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
29) For food-producing animals, toxicity studies to support a change of an established acceptable daily intake, maximum residue limit and withdrawal period	9,257	0	April 1, 2022	14,927
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	7,409	0	April 1, 2022	11,946
31) Chemistry and manufacturing data to support a change in the source of a medicinal ingredient or its manufacturing process	6,171	77,138	April 1, 2022	9,953
32) Chemistry and manufacturing data to support a change in formulation or dosage form	3,086	3,086	April 1, 2022	4,978
33) Chemistry and manufacturing data to support a change in packaging or in the sterilization process	2,462	0	April 1, 2022	3,972
34) Chemistry and manufacturing data to support an extension of the expiry dating	1,850	925	April 1, 2022	2,985
35) Chemistry and manufacturing data to support the concurrent use of two drugs	1,850	0	April 1, 2022	2,985
36) Chemistry and manufacturing data to support a change in the manufacturing site for parenteral dosage forms	612	1,224	April 1, 2022	989
37) Documentation to support a change to the name of a manufacturer or the brand name of a drug	320	0	April 1, 2022	516

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
300 calendar days to complete Review

Performance result
100% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
38) Comparative (pharmacodynamics, clinical or bioavailability) data to support a single route of administration and dosage form	3,698	12,603	April 1, 2022	5,965
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	3,698	13,310	April 1, 2022	5,965
40) Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug	6,171	65,472	April 1, 2022	9,953
41) Chemistry and manufacturing data to support a single dosage form	6,171	72,606	April 1, 2022	9,953

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
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	320	960	April 1, 2022	516

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)[xiv]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[xi]

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2021

Service standard
240 calendar days to complete Review 1

Performance result
100% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
38) Comparative (pharmacodynamics, clinical or bioavailability) data to support a single route of administration and dosage form	3,698	12,603	April 1, 2022	5,965
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	3,698	13,310	April 1, 2022	5,965
40) Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug	6,171	65,472	April 1, 2022	9,953
41) Chemistry and manufacturing data to support a single dosage form	6,171	72,606	April 1, 2022	9,953

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
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	320	960	April 1, 2022	516

Fee
Preclinical submission (Schedule 2 items 43 to 50)

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

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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 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	6,171	0	April 1, 2022	9,953
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	4,935	0	April 1, 2022	7,959

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 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	18,513	0	April 1, 2022	29,853
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	27,783	0	April 1, 2022	44,800
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	37,040	0	April 1, 2022	59,724
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	9,257	0	April 1, 2022	14,927
49) Chemistry and manufacturing data to support a single dosage form containing a non-compendial medicinal ingredient	6,171	0	April 1, 2022	9,953

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
50) Chemistry and manufacturing data to support a single dosage form containing a compendial medicinal ingredient	3,086	0	April 1, 2022	4,978

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)[xiv]
- *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124)[xi]

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 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	12,422	April 1, 2022	53
52) Information to support the sale of a drug to be used in the emergency treatment of a food-producing animal	102	7,142	April 1, 2022	106

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

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

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 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	980	31,852	April 1, 2022	1,013
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	1,471	April 1, 2022	507
55) Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a food-producing animal	2,958	20,718	April 1, 2022	3,054

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
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	1,478	April 1, 2022	507

Fee
Notifiable change (Schedule 2 item 57)

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

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
57) Information and material to support an application for Notifiable Change	1,658	92,730	April 1, 2022	2,674

Fee
Protocol (Schedule 2 item 58)

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

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% completed within service standard

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 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	1,658	5,803	April 1, 2022	2,674

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, reinstatement of a suspended DEL, or re-activation of a cancelled or withdrawn DEL.

Fee
Human Drug Establishment Licence Fees

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

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% (221/221) 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	2020–21 fee amount ($)	2020–21 total fee revenue ($) (note 1)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Fabrication - Sterile dosage form	41,626	559,349	April 1, 2022	43,171
Importation	27,359	2,566,616	April 1, 2022	31,688

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($) (note 1)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Fabrication - non-sterile dosage form	27,000	627,750	April 1, 2022	30,677
Distribution	12,560	295,945	April 1, 2022	15,691
Wholesaling	4,937	263,204	April 1, 2022	7,962
Packaging/labelling	6,061	101,522	April 1, 2022	6,255
Testing	2,560	65,718	April 1, 2022	4,129
Building outside Canada (each)	918	1,612,238	April 1, 2022	949

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 $11.5M was collected under the old fee structure.

Fee
Veterinary Drug Establishment Licence Fees

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

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% (221/221) 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	2020–21 fee amount ($)	2020–21 total fee revenue ($) (note 1)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Fabrication - Sterile dosage form	40,198	0	April 1, 2022	42,080
Importation	10,715	126,571	April 1, 2022	17,278
Fabrication - non-sterile dosage form	8,782	13,173	April 1, 2022	14,161
Distribution	4,835	8,461	April 1, 2022	7,797
Wholesaling	1,933	11,115	April 1, 2022	3,117
Packaging/labelling	6,061	0	April 1, 2022	6,255
Testing	1,315	0	April 1, 2022	2,121
Building outside Canada (each)	765	112,120	April 1, 2022	949

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 $0.3M was collected under the old fee structure.

Drug Establishment Licensing Fees - Dealer's Licences

Fees for the examination of an application for a new dealer's licence 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)[xviii]

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

Year fee-setting authority was introduced

1998

Last year fee-setting authority was amended

- Human Drugs: 2020
- Veterinary Drugs: 2019

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**: 87% of applications were processed within the service standard
- **Renew:** 98% of applications were processed within the service standard

Application of *Low-Materiality Fees Regulations*

Material (>$151): All fees listed below

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Dealer's Licence Fees - Human Drugs	5,394.00	198,539	April 1, 2022	5,613.00
Dealer's Licence Fees - Veterinary Drugs	1,824.27	9,886	April 1, 2022	1,882.52

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[b]. 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
Application for new licence and annual review of licence

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

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
80% (4,645 / 5,820) 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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Application for new licence and annual review of licence	4,590	12,185,289	April 1, 2022	4,737

[b] 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.

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 2020-21 fee revenue by individual fee.

Fee	2020–21 total fee revenue ($)
Processing	1,181,130
Applications not Mentioned in Schedules	248,030
Renewal	88,846
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	571,408
Product Chemistry – end-use product or manufacturing concentrate	277,139
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	321,233
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains an registered active ingredient	100,256
Toxicology data-acute toxicity studies	149,342
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	105,324
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	63,283
Exposure data-other	38,984
Metabolism data	111,847

Fee	2020–21 total fee revenue ($)
Residue data	324,044
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	94,794
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	144,067
Environmental fate data-other	17,027
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	208,499
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	101,649
Environmental toxicology data-other	10,471
Value and effectiveness data for a pest control product	151,297
Identification of compensable data	316,369
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	13,056
Registration of a new active ingredient – non-food use	0
Amendment of registration – new risk assessment necessary-environmental fate data, environmental toxicity data or exposure data	4,915
Amendment of registration – data required, label changes	24,499
Amendment of registration – data required, other	11,054
Amendment of registration – no data required	2,472
Registration of new active ingredient	0
Amendment of registration	2,156
Schedule 3: Fees for Other Applications in Respect of a Pest Control Product	

Fee	2020–21 total fee revenue ($)
Research authorization – major crops, other than research authorizations set out in paragraphs (c) and (d)	160,362
Research authorization – minor use crops, other than research authorizations set out in paragraphs (c) and (d)	48,528
Research authorization – microbial agents, semiochemicals and any substance listed in subparagraph 1(d) (ii) of these regulations	25,730
Research authorization – greenhouse crops and non-agricultural uses	12,852
Research notifications	3,150
Registration of active ingredient to be used in pest control product manufactured only for export	33,228
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	216,323
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	159,351

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 $172K.

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
655 days of Review

Performance result
0% (0/4 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Product Chemistry - active ingredient	5,173	See the total fee revenue table	April 1, 2022	5,383
Product Chemistry - end-use product or manufacturing concentrate	2,881		April 1, 2022	2,998
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	80,449		April 1, 2022	83,700
Toxicology data accompanying an application to register a pest control product -or to amend a pest control product -that contains an registered active ingredient	16,800		April 1, 2022	17,479
Toxicology data - acute toxicity studies	3,137		April 1, 2022	3,264

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	18,570		April 1, 2022	19,321
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	6,112		April 1, 2022	6,360
Metabolism data	30,716		April 1, 2022	31,958
Residue data	16,809		April 1, 2022	17,489
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	45,299		April 1, 2022	47,130
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	25,085		April 1, 2022	26,099
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	39,560		April 1, 2022	41,160
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	25,141		April 1, 2022	26,157

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Value and effectiveness data for a pest control product	963		April 1, 2022	1,003
Specification of maximum residue limit for a previously unexamined pest control product	133,142		April 1, 2022	138,522
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	16,809		April 1, 2022	17,489
Processing	1,204		April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9) [xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
555 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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Product Chemistry - active ingredient	5,173	See the total fee revenue table	April 1, 2022	5,383
Product Chemistry - end-use product or manufacturing concentrate	2,881		April 1, 2022	2,998
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	80,449		April 1, 2022	83,700
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that	16,800		April 1, 2022	17,479

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
contains an registered active ingredient				
Toxicology data - acute toxicity studies	3,137		April 1, 2022	3,264
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	18,570		April 1, 2022	19,321
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	6,112		April 1, 2022	6,360
Metabolism data	30,716		April 1, 2022	31,958
Residue data	16,809		April 1, 2022	17,489
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	45,299		April 1, 2022	47,130
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,	25,085		April 1, 2022	26,099

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
when a new risk assessment is necessary				
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	39,560		April 1, 2022	41,160
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	25,141		April 1, 2022	26,157
Value and effectiveness data for a pest control product	963		April 1, 2022	1,003
Registration of a new active ingredient - food use	7,680		April 1, 2022	7,991
Registration of a new active ingredient - non-food use	4,608		April 1, 2022	4,796
Amendment of registration - new risk assessment necessary - environmental fate data, environmental toxicity data or exposure data	3,073		April 1, 2022	3,198
Processing	1,204		April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
470 days of Review

Performance result
38% (3/8 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Product Chemistry - active ingredient	5,173	See the total fee revenue table	April 1, 2022	5,383
Product Chemistry - end-use product or manufacturing concentrate	2,881		April 1, 2022	2,998
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	80,449		April 1, 2022	83,700
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product -that contains	16,800		April 1, 2022	17,479

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
an registered active ingredient				
Toxicology data - acute toxicity studies	3,137		April 1, 2022	3,264
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	18,570		April 1, 2022	19,321
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	6,112		April 1, 2022	6,360
Metabolism data	30,716		April 1, 2022	31,958
Residue data	16,809		April 1, 2022	17,489
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	45,299		April 1, 2022	47,130
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,	25,085		April 1, 2022	26,099

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
when a new risk assessment is necessary				
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	39,560		April 1, 2022	41,160
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	25,141		April 1, 2022	26,157
Value and effectiveness data for a pest control product	963		April 1, 2022	1,003
Registration of a new active ingredient - food use	7,680		April 1, 2022	7,991
Registration of a new active ingredient - non-food use	4,608		April 1, 2022	4,796
Amendment of registration - new risk assessment necessary - environmental fate data, environmental toxicity data or exposure data	3,073		April 1, 2022	3,198
Processing	1,204		April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

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 2020-21)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Registration of new active ingredient	616	See the total fee revenue table	April 1, 2022	642
Amendment of registration	309		April 1, 2022	323

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

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

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[xxiii]

Performance result
0% (0/15 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Product Chemistry - active ingredient	5,173	See the total fee revenue table	April 1, 2022	5,383
Product Chemistry - end-use product or manufacturing concentrate	2,881		April 1, 2022	2,998
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	80,449		April 1, 2022	83,700
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	16,800		April 1, 2022	17,479

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Toxicology data - acute toxicity studies	3,137		April 1, 2022	3,264
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	18,570		April 1, 2022	19,321
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	6,112		April 1, 2022	6,360
Metabolism data	30,716		April 1, 2022	31,958
Residue data	16,809		April 1, 2022	17,489
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	45,299		April 1, 2022	47,130
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	25,085		April 1, 2022	26,099
Environment toxicology data accompanying an application to register a pest control	39,560		April 1, 2022	41,160

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
product that consists of or that contains a new active ingredient				
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	25,141		April 1, 2022	26,157
Value and effectiveness data for a pest control product	963		April 1, 2022	1,003
Registration of a new active ingredient - food use	7,680		April 1, 2022	7,991
Registration of a new active ingredient - non-food use	4,608		April 1, 2022	4,796
Amendment of registration - new risk assessment necessary - environmental fate data, environmental toxicity data or exposure data	3,073		April 1, 2022	3,198
Registration of new active ingredient	616		April 1, 2022	642
Amendment of registration	309		April 1, 2022	323
Specification of maximum residue limit for a previously unexamined pest control product	133,142		April 1, 2022	138,522
Specification of maximum residue limit for an unregistered use of a	16,809		April 1, 2022	17,489

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
previously examined pest control product				
Processing	1,204		April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
425 days of Review

Performance result
80% (170/213 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Product Chemistry - active ingredient	5,173	See the total fee revenue table	April 1, 2022	5,383
Product Chemistry - end-use product or manufacturing concentrate	2,881		April 1, 2022	2,998
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	16,800		April 1, 2022	17,479
Toxicology data - acute toxicity studies	3,137		April 1, 2022	3,264

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Exposure data - other	5,535		April 1, 2022	5,759
Metabolism data	30,716		April 1, 2022	31,958
Residue data	16,809		April 1, 2022	17,489
Environmental fate data - other	12,254		April 1, 2022	12,750
Environmental toxicology data - other	2,618		April 1, 2022	2,725
Value and effectiveness data for a pest control product	963		April 1, 2022	1,003
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	16,809		April 1, 2022	17,489
Processing	1,204		April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
360 days of Review

Performance result
92% (11/12 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Product Chemistry - active ingredient	5,173	See the total fee revenue table	April 1, 2022	5,383
Product Chemistry - end-use product or manufacturing concentrate	2,881		April 1, 2022	2,998
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	16,800		April 1, 2022	17,479
Toxicology data - acute toxicity studies	3,137		April 1, 2022	3,264

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Exposure data - other	5,535		April 1, 2022	5,759
Metabolism data	30,716		April 1, 2022	31,958
Residue data	16,809		April 1, 2022	17,489
Environmental fate data - other	12,254		April 1, 2022	12,750
Environmental toxicology data - other	2,618		April 1, 2022	2,725
Value and effectiveness data for a pest control product	963		April 1, 2022	1,003
Amendment of registration - data required, label changes	1,537		April 1, 2022	1,600
Amendment of registration - data required, other	1,231		April 1, 2022	1,282
Processing	1,204		April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
240 days of Review

Performance result
87% (27/31 application met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Amendment of registration - data required, label changes	1,537	See the total fee revenue table	April 1, 2022	1,600
Amendment of registration - data required, other	1,231		April 1, 2022	1,282
Amendment of registration	309		April 1, 2022	323

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
158 days of Review

Performance result
98% (50/51 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Value and effectiveness data for a pest control product	963	See the total fee revenue table	April 1, 2022	1,003
Amendment of registration - data required, label changes	1,537		April 1, 2022	1,600
Amendment of registration - no data required, other	309		April 1, 2022	323
Processing	1,204		April 1, 2022	1,254

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

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

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[xxiii]

Performance result
38% (3/8 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Product Chemistry - active ingredient	5,173	See the total fee revenue table	April 1, 2022	5,383
Product Chemistry - end-use product or manufacturing concentrate	2,881		April 1, 2022	2,998
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	16,800		April 1, 2022	17,479
Toxicology data-acute toxicity studies	3,137		April 1, 2022	3,264
Exposure data-other	5,535		April 1, 2022	5,759

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Metabolism data	30,716		April 1, 2022	31,958
Residue data	16,809		April 1, 2022	17,489
Environmental fate data - other	12,254		April 1, 2022	12,750
Environmental toxicology data - other	2,618		April 1, 2022	2,725
Value and effectiveness data for a pest control product	963		April 1, 2022	1,003
Amendment of registration - data required, label changes	1,537		April 1, 2022	1,600
Amendment of registration - data required, other	1,231		April 1, 2022	1,282
Amendment of registration - no data required	309		April 1, 2022	323
Amendment of registration	309		April 1, 2022	323
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	16,809		April 1, 2022	17,489
Processing	1,204		April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
240 days of Review

Performance result
98% (558/571 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Amendment of registration - no data required	309	See the total fee revenue table	April 1, 2022	323
Amendment of registration	309		April 1, 2022	323
Processing	1,204		April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
180 days of Review

Performance result
95% (105/110 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Amendment of registration - no data required	309	See the total fee revenue table	April 1, 2022	323
Amendment of registration	309		April 1, 2022	323
Processing	1,204		April 1, 2022	1,254

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

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

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[xxiii]

Performance result
N/A (0 applications completed in 2020-21)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Amendment of registration - no data required	309	See the total fee revenue table	April 1, 2022	323
Amendment of registration	309		April 1, 2022	323
Processing	1,204		April 1, 2022	1,254

Fee
Category D Component Based - 255 days of Review (Registration Renewal)

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
255 days of Review

Performance result
100% (1039/1039 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Registration Renewal	86	See the total fee revenue table	April 1, 2022	90

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
46 days of Review

Performance result
80% (4/5 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Registration of active ingredient to be used in pest control product manufactured only for export	8,307	See the total fee revenue table	April 1, 2022	8,644
Amendment to Registration of active ingredient to be used in pest control product manufactured only for export	1,204		April 1, 2022	1,254

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
42 days of Review

Performance result
99% (72/73 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Processing	1,204	See the total fee revenue table	April 1, 2022	1,254

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
10 days of Review

Performance result
N/A (0 applications completed in 2020-21)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Processing	1,204	See the total fee revenue table	April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
159 days of Review

Performance result
74% (17/23 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Research authorization - major crops, other than research authorizations set out in paragraphs (c) and (d)	5,392	See the total fee revenue table	April 1, 2022	5,610
Research authorization - minor use crops, other than research authorizations set out in paragraphs (c) and (d)	5,392		April 1, 2022	5,610
Research authorization - microbial agents, semiochemicals and any substance listed in subparagraph 1(d) (ii) of these regulations	1,293		April 1, 2022	1,346
Research authorization - greenhouse crops and non-agricultural uses	1,293		April 1, 2022	1,346

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
69 days of Review

Performance result
74% (31/42 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Research authorization - major crops, other than research authorizations set out in paragraphs (c) and (d)	5,392	See the total fee revenue table	April 1, 2022	5,610
Research authorization - minor use crops, other than research authorizations set out in paragraphs (c) and (d)	5,392		April 1, 2022	5,610
Research authorization - microbial agents, semiochemicals and any substance listed in subparagraph 1(d) (ii) of these regulations	1,293		April 1, 2022	1,346
Research authorization - greenhouse crops and non-agricultural uses	1,293		April 1, 2022	1,346

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
30 days of Review

Performance result
97% (35/36 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Research notifications	264	See the total fee revenue table	April 1, 2022	276

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
45 days of Review

Performance result
99% (882/883 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Applications not mentioned in schedules	264	See the total fee revenue table	April 1, 2022	276

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
425 days of Review

Performance result
67% (29/43 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Product Chemistry - active ingredient	5,173	See the total fee revenue table	April 1, 2022	5,383
Product Chemistry - end-use product or manufacturing concentrate	2,881		April 1, 2022	2,998
Toxicology data accompanying an application to register a pest control product -or to amend a pest control product -that contains an registered active ingredient	16,800		April 1, 2022	17,479
Toxicology data-acute toxicity studies	3,137		April 1, 2022	3,264

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Exposure data - other	5,535		April 1, 2022	5,759
Metabolism data	30,716		April 1, 2022	31,958
Residue data	16,809		April 1, 2022	17,489
Environmental fate data - other	12,254		April 1, 2022	12,750
Environmental toxicology data - other	2,618		April 1, 2022	2,725
Value and effectiveness data for a pest control product	963		April 1, 2022	1,003
Identification of compensable data	2,297		April 1, 2022	2,390
Processing	1,204		April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
365 days of Review

Performance result
84% (92/110 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Product Chemistry - active ingredient	5,173	See the total fee revenue table	April 1, 2022	5,383
Product Chemistry - end-use product or manufacturing concentrate	2,881		April 1, 2022	2,998
Identification of compensable data	2,297		April 1, 2022	2,390
Processing	1,204		April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
360 days of Review

Performance result
0% (0/1 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Product Chemistry - active ingredient	5,173	See the total fee revenue table	April 1, 2022	5,383
Product Chemistry - end-use product or manufacturing concentrate	2,881		April 1, 2022	2,998
Toxicology data accompanying an application to register a pest control product -or to amend a pest control product -that contains an registered active ingredient	16,800		April 1, 2022	17,479
Toxicology data-acute toxicity studies	3,137		April 1, 2022	3,264

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Exposure data - other	5,535		April 1, 2022	5,759
Metabolism data	30,716		April 1, 2022	31,958
Residue data	16,809		April 1, 2022	17,489
Environmental fate data - other	12,254		April 1, 2022	12,750
Environmental toxicology data - other	2,618		April 1, 2022	2,725
Value and effectiveness data for a pest control product	963		April 1, 2022	1,003
Identification of compensable data	2,297		April 1, 2022	2,390
Amendment of registration - data required, label changes	1,537		April 1, 2022	1,600
Amendment of registration - data required, other	1,231		April 1, 2022	1,282
Processing	1,204		April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

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 2020-21)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Identification of compensable data	2,297	See the total fee revenue table	April 1, 2022	2,390
Amendment of registration - data required, label changes	1,537		April 1, 2022	1,600
Amendment of registration - data required, other	1,231		April 1, 2022	1,282
Amendment of registration	309		April 1, 2022	323
Processing	1,204		April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

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[xxiii]

Performance result
0% (0/1 applications met the service standard)

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Product Chemistry - active ingredient	5,173	See the total fee revenue table	April 1, 2022	5,383
Product Chemistry - end-use product or manufacturing concentrate	2,881		April 1, 2022	2,998
Toxicology data accompanying an application to register a pest control product -or to amend a pest control product -that contains an registered active ingredient	16,800		April 1, 2022	17,479
Toxicology data-acute toxicity studies	3,137		April 1, 2022	3,264

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Exposure data - other	5,535		April 1, 2022	5,759
Metabolism data	30,716		April 1, 2022	31,958
Residue data	16,809		April 1, 2022	17,489
Environmental fate data - other	12,254		April 1, 2022	12,750
Environmental toxicology data - other	2,618		April 1, 2022	2,725
Value and effectiveness data for a pest control product	963		April 1, 2022	1,003
Identification of compensable data	2,297		April 1, 2022	2,390
Amendment of registration - data required, label changes	1,537		April 1, 2022	1,600
Amendment of registration - data required, other	1,231		April 1, 2022	1,282
Amendment of registration	309		April 1, 2022	323
Processing	1,204		April 1, 2022	1,254

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[xxi]
- *Pest Control Products Fees and Charges Regulations* (SOR/2017-9)[xxii]

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, 2020

Performance result
100%

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Annual Charge	The lesser of $3,752.78 and 4% of the actual gross revenue during the registrant's preceding fiscal year, but not less than $100	8,040,175	April 1, 2022	The lesser of $3,872.61 and 4% of the actual gross revenue during the registrant's preceding fiscal year, but not less than $100

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)[xxiv]
- *Hazardous Materials Information Review Regulations* (SOR/88-456)[xxv]

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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Original Claim (up to 15)	1,876.39	356,569	April 1, 2022	1,936.31
Original Claim (between 16-25)	416.98		April 1, 2022	430.29
Original Claim (26+)	208.49		April 1, 2022	215.15

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Refiled Claims (up to 15)	1,501.11	20,868	April 1, 2022	1,549.05
Refiled Claims (between 16-25)	333.58		April 1, 2022	344.23
Refiled Claims (26+)	166.79		April 1, 2022	172.12

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)[xxvi]
- *Cannabis Fees Order* (SOR/2018-198)[xxvii]

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 84.5% of the time.

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Licence Application Screening Fee - Licence for micro-cultivation	1,709	664,184	April 1, 2022	1,765
Licence Application Screening Fee - Licence for standard cultivation	3,417		April 1, 2022	3,527

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Licence Application Screening Fee - Licence for a nursery	1,709		April 1, 2022	1,765
Licence Application Screening Fee - Licence for micro-processing	1,709		April 1, 2022	1,765
Licence Application Screening Fee - Licence for standard processing	3,417		April 1, 2022	3,527
Licence Application Screening Fee - Licence for sale for medical purposes	3,417		April 1, 2022	3,527

Fee
Application for a Security Clearance

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

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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Application for a Security Clearance	1,725	3,210,875	April 1, 2022	1,781

Fee
Application for Import or Export Permit

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

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 51% of the time

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Application for Import or Export Permit	637	546,214	April 1, 2022	658

Fee
Annual Regulatory Fee

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

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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Annual fee - Licence for micro-cultivation	as per *Cannabis Fees Order*[xxvii]	25,493,217 (note 1)	Exempt	as per *Cannabis Fees Order*[xxvii]
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)*[xii] 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 are being reported in 2020-21. The remaining outstanding revenues will be 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[xxviii]

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 (a regulatory standard set by the Canadian Nuclear Safety Commission (CNSC));
2. Dosimeters shipped 10 to 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 to 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. 91% 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. 98% completed within two business days;
5. 95% being addressed within one business day; and
6. 95% addressed within two business days.

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

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Annual support	82.50	Not available	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)	5.25 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
Overdue dosimeter (three months after wearing period ends)	55.00	Not available		55.00

Fee	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
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[xxix]

Year fee-setting authority was introduced
1996

Last year fee-setting authority was amended
2017

Service standard
30 calendar days

Performance result
100% 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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
New Master Files (file registration)	1,273	279,743	April 1, 2022	1,324
Drug Master Files – letter of access	180	241,862	April 1, 2022	188
Drug Master Files - Update	552	373,517	April 1, 2022	575

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[xxx]

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
94% (2,226 / 2,372) 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	2020–21 fee amount ($)	2020–21 total fee revenue ($)	Fee adjustment date in 2022–23	2022–23 fee amount ($)
Certificate of Pharmaceutical Product	92	189,770	April 1, 2022	96

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 Annual Reports, https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications.html

[v] Remission for Missed Service Standards Policies, https://www.canada.ca/en/health-canada/services/funding/cost-recovery-service-fees.html

[vi] Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, https://gazette.gc.ca/rp-pr/p1/2020/2020-03-28/html/notice-avis-eng.html#ne2

[vii] Order Approving Interim Order No. 2 Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19, https://gazette.gc.ca/rp-pr/p1/2021/2021-03-20/html/order-decret-eng.html

[viii] Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19, https://gazette.gc.ca/rp-pr/p1/2020/2020-10-03/html/notice-avis-eng.html#nb1

[ix] Regulations Amending the Food and Drug Regulations (Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19): SOR/2021-45, https://canadagazette.gc.ca/rp-pr/p2/2021/2021-03-31/html/sor-dors45-eng.html

[x] Order Amending the Fees in Respect of Drugs and Medical Devices Order (COVID-19 Drugs): SOR/2021-47, https://www.gazette.gc.ca/rp-pr/p2/2021/2021-03-31/html/sor-dors47-eng.html

[xi] Fees in Respect of Drugs and Medical Devices Order, https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-124/FullText.html

[xii] 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

[xiii] Cannabis for Medical Purposes Remission Order: SOR/2020-9, https://canadagazette.gc.ca/rp-pr/p2/2020/2020-01-22/html/sor-dors9-eng.html

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

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

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

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

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

[xix] 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

[xx] 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

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

[xxii] 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

[xxiii] 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/regulatory-directive/2017/dir2017-01-management-submissions-policy.html#ai

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

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

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

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

[xxviii] 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

[xxix] 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

[xxx] 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