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Health Canada

Fees Report - Fiscal Year 2019-20

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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 our report on fees for fiscal year 2019-20, my organization's third annual report under the *Service Fees Act*.

The *Service Fees Act* provides a modern legislative framework that enables cost-effective delivery of services and, through better reporting to Parliament, improves transparency and oversight.

This year's report includes the revision of the fees with respect to drugs and medical devices. Effective April 1, 2020, where indicated, fees were repealed from the *Financial Administration Act* and set under the authority of the *Food and Drugs Act*.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.

Cannabis fees were introduced on October 17, 2018 in support of the legalization, strict regulation and restriction on access to cannabis under the *Cannabis Act*. This year's report is the first time a full year of collections related to cannabis fees is reported. The amount recovered is expected to increase year over year as the legal industry grows, matures and stabilizes. By 2021-22, Health Canada aims to recover as much as 100 percent of annual regulatory costs.

I welcome the increased transparency and oversight that the *Service Fees Act's* reporting regime embodies, and I am fully committed to transitioning my department to this modern framework. I will continue to advance my key mandate priorities through collaboration and evidence-based decision-making that will maintain and improve the health and safety of all Canadians.

The Honourable Patty Hajdu,
Minister of Health

About this report

This report, which is tabled under section 20 of the *Service Fees Act*[i] and section 4.2.8 of the *Directive on Charging and Special Financial Authorities*[ii], contains information about the fees that Health Canada had the authority to set in 2019–20.

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 or both
    - 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, including any that are collected by another department.

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

For fees set by contract, fees set by market-rate, auction or both, the report provides totals only. For fees set by act, regulation or fees notice, it 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* are subject to the *Service Fees Act*, they are not included in this report. Information on Health Canada's access to information fees for 2019–20 can be found in our access to information report, which is posted on our website.

Remissions

A remission is a partial or full return of a fee to a fee payer who paid for a service.

Under the *Service Fees Act*, departments must develop policies for determining whether a service standard has been met and for determining how much of a fee will be remitted to a fee payer if a service standard is not met. This requirement will not take effect until April 1, 2021, therefore this report does not include remissions issued under the *Service Fees Act.*

Under the *Cannabis Act*, the Minister may, by order, remit all or part of any fee fixed by the Minister under subsection 142(1) of the *Cannabis Act*. During 2019-20 the Minister of Health, pursuant to subsection 144(1) of the *Cannabis Act*, via the *Cannabis for Medical Purposes Remission Order*[iii], 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. Going forward, this oversight was corrected via the *Order Amending the Cannabis Fees Order (Exemptions — Sale for Medical Purposes)*[iv].

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 2019–20, by fee setting mechanism.

Overall totals for 2019–20, 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 market-rate, auction or both	0	0	Remissions do not apply to fees set by market base, auction or both.
Fees set by act, regulation or fees notice	178,300,057	529,140,037	69,000
Total	**178,300,057**	**529,140,037**	**69,000**

* National Dosimetry Services, Drug Master Files and Certificate of Pharmaceutical Products were reported under “Fees set by contract” in 2018-19. However according to TBS fees that are set and published (ie: in Canada Gazette) are known as “fees set by fees notice” and therefore are to be reported as “Fees set by act, regulation or fees notice”.

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 2019–20 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.

Fees for Right to Sell Drugs: totals for fiscal year 2019-20

Fee grouping	Fees for Right to Sell Drugs	
Revenue ($)	**Cost ($)**	**Remissions ($)**
12,376,389	85,021,505	0

Fees for Right to Sell Licensed Class II, III, or IV Medical Devices: totals for fiscal year 2019-20

Fee grouping	Fees for Right to Sell Licensed Class II, III, or IV Medical Devices	
Revenue ($)	**Cost ($)**	**Remissions ($)**
8,559,329	26,802,633	0

Fees for Examination of a Submission — Drugs for Human Use: totals for fiscal year 2019-20

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use	
Revenue ($)	**Cost ($)**	**Remissions ($)**
50,939,645	129,446,836	0

Certificate of Supplementary Protection Application Fees: totals for fiscal year 2019-20

Fee grouping	Certificate of Supplementary Protection Application Fees	
Revenue ($)	**Cost ($)**	**Remissions ($)**
149,832	420,333	0

Fees for Examination of Medical Device Licence Applications: totals for fiscal year 2019-20

Fee grouping	Fees for Examination of Medical Device Licence Applications	
Revenue ($)	**Cost ($)**	**Remissions ($)**
5,613,398	23,779,103	0

Fees for Examination of a Submission — Drugs for Veterinary Use Only: totals for fiscal year 2019-20

Fee grouping	Fees for Examination of a Submission — Drugs for Veterinary Use Only	
Revenue ($)	**Cost ($)**	**Remissions ($)**
817,043	10,109,721	0

Drug Establishment Licensing Fees: totals for fiscal year 2019-20

Fee grouping	Drug Establishment Licensing Fees	
Revenue ($)	**Cost ($)**	**Remissions ($)**
16,925,045	33,852,458	0

Drug Establishment Licensing Fees - Dealer's Licences: totals for fiscal year 2019-20

Fee grouping	Drug Establishment Licensing Fees - Dealer's Licences	
Revenue ($)	**Cost ($)**	**Remissions ($)**
1,140,548	4,032,761	0

Medical Devices Establishment Licensing Fees: totals for fiscal year 2019-20

Fee grouping	Medical Devices Establishment Licensing Fees	
Revenue ($)	**Cost ($)**	**Remissions ($)**
9,455,621	12,264,929	0

Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product: totals for fiscal year 2019-20

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product	
Revenue ($)	**Cost ($)**	**Remissions ($)**
4,632,274	43,284,542	0

Annual Charge (for a registered Pest Control Product): totals for fiscal year 2019-20

Fee grouping	Annual Charge (for a registered Pest Control Product)	
Revenue ($)	**Cost ($)**	**Remissions ($)**
8,654,696	33,817,537	0

Fees Charged for Filing a Claim for Exemption under the Hazardous Materials Information Review Act: totals for fiscal year 2019-20

Fee grouping	Fees Charged for Filing a Claim for Exemption under the Hazardous Materials Information Review Act	
Revenue ($)	**Cost ($)**	**Remissions ($)**
511,379	5,496,990	0

Cannabis Fees: totals for fiscal year 2019-20

Fee grouping	Cannabis Fees	
Revenue ($)	**Cost ($)**	**Remissions ($)** (note 1)
50,446,556	110,242,063	69,000

1) 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*[iii]).

The following fees are set under the Ministerial Authority to Enter into 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 fiscal year 2019-20

Fee grouping	National Dosimetry Products and Services Fees	
Revenue ($)	**Cost ($)**	**Remissions ($)**
6,957,396	8,444,108	0

Master File Fees: totals for fiscal year 2019-20

Fee grouping	Master File Fees	
Revenue ($)	**Cost ($)**	**Remissions ($)**
857,352	1,832,626	0

Certificate of Pharmaceutical Product Fee: totals for fiscal year 2019-20

Fee grouping	Certificate of Pharmaceutical Product Fee	
Revenue ($)	**Cost ($)**	**Remissions ($)**
263,554	291,892	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 2019–20 and that was set by any of the following:

- act
- regulation
- fees notice

In most cases, the Department does not currently report that revenues are collected at the individual fee level. Health Canada is in the process of implementing changes to the financial system to allow for the reporting of lower level fees in the future.

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 grouping	Fees for Right to Sell Drugs
Fee	Human Drugs
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi]
Year fee-setting authority was introduced	1995
Last year fee-setting authority was amended	2011
Service standard	120 days to update the Drug Product Database following receipt of a complete Annual Notification Package
Performance result	100% completed on time
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Human Drugs	1,200	12,376,389	Not applicable, fee discontinued as of April 1, 2020	Not applicable, fee discontinued as of April 1, 2020

Fee grouping	Fees for Right to Sell Drugs
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	**As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	2019
Last year fee-setting authority was amended	Not applicable
Service standard	20 days to update the Drug Product Database following receipt of a complete Annual Notification Package
Performance result	Not applicable, new fee as of April 1, 2020
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Human drugs - Disinfectant (item 1)	Not applicable, new fee as of April 1, 2020	Not applicable, new fee as of April 1, 2020	April 1, 2021	1,342
Human drugs - Non-prescription (item 2)			April 1, 2021	2,018
Human drugs - Prescription (drug other than one referred to in item 1 or 2)			April 1, 2021	2,749

Fee grouping	Fees for Right to Sell Drugs
Fee	Veterinary Drugs
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Authority to Sell Veterinary Drug Fees Regulations*[ix] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1995
Last year fee-setting authority was amended	2019
Service standard	120 days to update the Drug Product Database following receipt of a complete Annual Notification Package * As of April 1, 2020 will be 20 days
Performance result	100% completed on time
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Veterinary Drugs	255.50	Not available at this time	April 1, 2021	367

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 grouping	Fees for Right to Sell a Licensed Class II, III or IV Medical Device
Fee	Medical Device Right to Sell (if annual gross revenue medical device sales is less than $20,000)
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi]
Year fee-setting authority was introduced	1999
Last year fee-setting authority was amended	2011
Service standard	20 days from deadline for receipt of annual notification to update the Medical Devices License Listing database
Performance result	96% completed on time
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Medical Device Right to Sell (if annual gross revenue medical device sales is less than $20,000)	65	Not available at this time	Not applicable, fee discontinued as of April 1, 2020	Not applicable, fee discontinued as of April 1, 2020

Fee grouping	Fees for Right to Sell a Licensed Class II, III or IV Medical Device
Fee	Medical Device Right to Sell
Fee-setting authority	• *Financial Administration Act (FAA)*[vvi] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1999
Last year fee-setting authority was amended	2019
Service standard	20 days from deadline for receipt of annual notification to update the Medical Devices License Listing (MDALL) database
Performance result	96% completed on time
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Medical Device Right to Sell	391	Not available at this time	April 1, 2021	381

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 grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	New Active Substance
Fee-setting authority	• *Financial Administration Act (FAA)*[vvi] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1995
Last year fee-setting authority was amended	2019
Service standard	New Drug Submission (NDS) - 300 Days
Performance result	NDS – Pharmaceuticals (267 Days) Biologics (281 Days)
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
New Active Substance	355,579	Not available at this time	April 1, 2021	437,009

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	Clinical or non-clinical data and chemistry and manufacturing data
Fee-setting authority	• *Financial Administration Act (FAA)*[vvi] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1995
Last year fee-setting authority was amended	2019
Service standard	New Drug Submission (NDS) - 300 Days Supplement to a New Drug Submission (SNDS) - 300 Days Drug Identification Number Application (DIN A) - 210 Days
Performance result	NDS – Pharmaceuticals (276 Days) Biologics (274 Days) SNDS – Pharmaceuticals (300 Days) Biologics (273 Days) DIN A – Pharmaceuticals (207 Days) Biologics (209 Days)
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Clinical or non-clinical data and chemistry and manufacturing data	180,101	Not available at this time	April 1, 2021	224,242

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	Clinical or non-clinical data only
Fee-setting authority	• *Financial Administration Act (FAA)*[vvi] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1995
Last year fee-setting authority was amended	2019
Service standard	New Drug Submission (NDS) - 300 Days Supplement to a New Drug Submission (SNDS) - 300 Days Drug Identification Number Application (DIN A) - 210 Days
Performance result	NDS – Pharmaceuticals (n/a) Biologics (n/a) SNDS – Pharmaceuticals (252 Days) Biologics (266 Days) DIN A – Pharmaceuticals (n/a)
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Clinical or non-clinical data only	84,059	Not available at this time	April 1, 2021	95,796

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	Comparative studies
Fee-setting authority	• *Financial Administration Act (FAA)*[vvi] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1995
Last year fee-setting authority was amended	2019
Service standard	Abbreviated New Drug Submission (ANDS) - 180 Days New Drug Submission (NDS) - 180 Days Supplement to an Abbreviated New Drug Submission (SANDS) - 180 Days Supplement to a New Drug Submission (SNDS) - 180 Days Drug Identification Number Application (DIN A) - Pharmaceutical - 210 Days
Performance result	ANDS – Pharmaceuticals (168 Days) Biologics (n/a) NDS – Pharmaceuticals (n/a) Biologics (179) SANDS – Pharmaceuticals (161 Days) SNDS – Pharmaceuticals (176 Days) Biologics (180 Days) DIN A – Pharmaceuticals (n/a) Biologics (n/a)
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Comparative studies	50,808	Not available at this time	April 1, 2021	55,737

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	Chemistry and manufacturing data only
Fee-setting authority	• *Financial Administration Act (FAA)*[vvi] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1995
Last year fee-setting authority was amended	2019
Service standard	Abbreviated New Drug Submission (ANDS) - 180 Days New Drug Submission (NDS) - 180 Days Supplement to an Abbreviated New Drug Submission (SANDS) - 180 Days Supplement to a New Drug Submission (SNDS) - 180 Days Drug Identification Number Application (DIN A) - 210 Days
Performance result	ANDS – Pharmaceuticals (170 Days) Biologics (178 Days) NDS – Pharmaceuticals (n/a) SANDS – Pharmaceuticals (147 Days) Biologics (n/a) SNDS – Pharmaceuticals (158 Days) Biologics (148 Days) DIN A – Pharmaceuticals (183 Days) Biologics (n/a)
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Chemistry and manufacturing data only	24,023	Not available at this time	April 1, 2021	30,609

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	Clinical or non-clinical data only, in support of safety upgrades to the labelling
Fee-setting authority	**As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	2019
Last year fee-setting authority was amended	Not applicable
Service standard	120 Days
Performance result	Not applicable as new fee as of April 1, 2020
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Clinical or non-clinical data only, in support of safety upgrades to the labelling	Not applicable as new fee as of April 1, 2020	Not applicable as new fee as of April 1, 2020	April 1, 2021	19,404

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	Published data only
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi]
Year fee-setting authority was introduced	1995
Last year fee-setting authority was amended	2011
Service standard	Supplement to a new Drug Submission (SNDS) - 300 Days Supplement to an Abbreviated New Drug Submission (SANDS) - 300 Days Drug Identification Number Application (DIN A) - 210 Days
Performance result	SNDS – Pharmaceuticals (282 Days) Biologics (297 Days) SANDS – Pharmaceuticals (n/a) DIN A – Pharmaceuticals (n/a)
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Published data only	19,921	Not available at this time	Not applicable, fee discontinued as of April 1, 2020	Not applicable, fee discontinued as of April 1, 2020

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	Switch from prescription to non-prescription status
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi]
Year fee-setting authority was introduced	1995
Last year fee-setting authority was amended	2011
Service standard	New Drug Submission (NDS) - 180 Days Supplement to a New Drug Submission (SNDS) - 180 Days
Performance result	NDS Pharmaceuticals (n/a) SNDS – Pharmaceuticals (n/a)
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Switch from prescription to non-prescription status	48,370	Not available at this time	Not applicable, fee discontinued as of April 1, 2020	Not applicable, fee discontinued as of April 1, 2020

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	Labelling only
Fee-setting authority	• *Financial Administration Act (FAA)*[vvi] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1995
Last year fee-setting authority was amended	2019
Service standard	New Drug Submission (NDS) - 60 Days Supplement to a New Drug Submission (SNDS) - 60 Days Abbreviated New Drug Submission (ANDS) - 60 Days Supplement to an Abrreviated New Drug Submission (SANDS) - 60 Days Drug Identification Number Application (DIN A) - 180 Days * As of April 2020 will be 120 Days for all types
Performance result	NDS – Pharmaceuticals (54 Days) Biologics (59 Days) SNDS – Pharmaceuticals (50 Days) Biologics (54 Days) ANDS – Pharmaceuticals (39 Days) SANDS – Pharmaceuticals (38 Days) DIN A – Pharmaceuticals (153 Days) Biologics (179 Days)
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Labelling only	3,238	Not available at this time	April 1, 2021	4,320

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	Labelling only (generic drugs)
Fee-setting authority	**As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	2019
Last year fee-setting authority was amended	Not applicable
Service standard	120 Days
Performance result	Not applicable as new fee as of April 1, 2020
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Labelling only (generic drugs)	Not applicable, new fee as of April 1, 2020	Not applicable, new fee as of April 1, 2020	April 1, 2021	2,006

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	Administrative submission
Fee-setting authority	• *Financial Administration Act (FAA)*[vvi] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1995
Last year fee-setting authority was amended	2019
Service standard	Abbreviated New Drug Submisson (ANDS) - 45 Days New Drug Submission (NDS) - 45 Days Supplement to a New Drug Submission (SNDS) - 45 Days Supplement to an Abbreviated New Drug Submission (SANDS) - 45 Days Drug Identification Number Application (DIN) - 45 Days Drug Identification Number Application - Disinfectant (DIN Disinfectant) - 45 Days Drug Identification Number Application - Category (DIN Category IV) - 45 Days
Performance result	ANDS – Pharmaceuticals (22 Days) NDS – Pharmaceuticals (29 Days) Biologics (44 Days) SNDS – Pharmaceuticals (17 Days) SANDS – Pharmaceuticals (17 Days) DIN – Pharmaceuticals (31 Days) Biologics (43 Days) DIN Disinfectant – Pharmaceuticals (32 Days) DIN Category IV – Pharmaceuticals (38 Days)
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Administrative submission	338	Not available at this time	April 1, 2021	539

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	Disinfectant - full review
Fee-setting authority	• *Financial Administration Act (FAA)*[vvi] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1995
Last year fee-setting authority was amended	2019
Service standard	New Drug Submission (NDS) - 300 Days Supplement to a New Drug Submission (SNDS) – 300 Days Drug Identification Number Application (Disinfectant 210) (DIN D 210) - 210 Days Drug Identification Number Application (Disinfectant 180) (DIN D 180) - 180 Days
Performance result	NDS – Pharmaceuticals (300 Days) SNDS – Pharmaceuticals (n/a) DIN D 210 – Pharmaceuticals (204 Days) DIN D 180 – Pharmaceuticals (146 Days)
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Disinfectant - full review	4,480	Not available at this time	April 1, 2021	7,126

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	Labelling only (disinfectants)
Fee-setting authority	**As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	2019
Last year fee-setting authority was amended	Not applicable
Service standard	90 Days
Performance result	Not applicable as new fee as of April 1, 2020
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Labelling only (disinfectants)	Not applicable, new fee as of April 1, 2020	Not applicable, new fee as of April 1, 2020	April 1, 2021	2,502

Fee grouping	Fees for Examination of a Submission — Drugs for Human Use
Fee	Drug identification number application – labelling standards
Fee-setting authority	• *Financial Administration Act (FAA)*[vvi] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drug Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1995
Last year fee-setting authority was amended	2019
Service standard	Drug Identification Number Application (DIN A) - 45 Days Drug Identification Number Application - Disinifectant (DIN D) - 45 Days Drug Identification Number Application - Category IV (DIN F) - 45 Days * As of April 2020 it will be 60 Days for all types
Performance result	DIN A – Pharmaceuticals (40 Days) DIN D – Pharmaceuticals (38 Days) DIN F – Pharmaceuticals (36 Days)
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Drug identification number application – labelling standards	1,797	Not available at this time	April 1, 2021	1,613

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 grouping	Certificate of Supplementary Protection Application Fees
Fee	Certificate of Supplementary Protection Application Fees
Fee-setting authority	• *Patent Act*[x] • *Certificate of Supplementary Protection Regulations*[xi]
Year fee-setting authority was introduced	2017
Last year fee-setting authority was amended	Not applicable
Service standard	60 days for the first eligibility decision
Performance result	100% issued within 60 days
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Certificate of Supplementary Protection Application Fees	9,376	149,832	April 1, 2021	9,756

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; medical devices for investigational testing involving human subjects.

Fee grouping	Fees for Examination of an Application for a Medical Device Licence
Fee	Applications for Class II licence
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1998
Last year fee-setting authority was amended	2019
Service standard	15 Days to complete Review 1
Performance result	9 Days to complete Review 1
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Applications for Class II licence	414	Not available at this time	April 1, 2021	478

Fee grouping	Fees for Examination of an Application for a Medical Device Licence
Fee	Applications for Class II licence amendment
Fee-setting authority	**As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	2019
Last year fee-setting authority was amended	Not applicable
Service standard	15 Days to complete Review 1
Performance result	Not applicable, new fee as of April 1, 2020
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Applications for Class II licence amendment	Not applicable, new fee as of April 1, 2020	Not applicable, new fee as of April 1, 2020	April 1, 2021	272

Fee grouping	Fees for Examination of an Application for a Medical Device Licence
Fee	Applications for Class III licence
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1998
Last year fee-setting authority was amended	2019
Service standard	60 Days to complete Review 1
Performance result	45 Days to complete Review 1
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Applications for Class III licence	5,922	Not available at this time	April 1, 2021	8,895

Fee grouping	Fees for Examination of an Application for a Medical Device Licence
Fee	Applications for Class III licence (near patient)
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1998
Last year fee-setting authority was amended	2019
Service standard	60 Days to complete Review 1
Performance result	Not applicable
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Applications for Class III licence (near patient)	10,079	Not available at this time	April 1, 2021	16,032

Fee grouping	Fees for Examination of an Application for a Medical Device Licence
Fee	Applications for Class III licence amendment - changes in manufacturing
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1998
Last year fee-setting authority was amended	2019
Service standard	60 Days to complete Review 1
Performance result	41 Days to complete Review 1
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Applications for Class III licence amendment - changes in manufacturing	1,492	Not available at this time	April 1, 2021	2,375

Fee grouping	Fees for Examination of an Application for a Medical Device Licence
Fee	Applications for Class III licence amendment - significant changes not related to manufacturing
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1998
Last year fee-setting authority was amended	2019
Service standard	60 Days to complete Review 1
Performance result	44 Days to complete Review 1
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Applications for Class III licence amendment - significant changes not related to manufacturing	5,546	Not available at this time	April 1, 2021	7,543

Fee grouping	Fees for Examination of an Application for a Medical Device Licence
Fee	Applications for Class IV licence
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1998
Last year fee-setting authority was amended	2019
Service standard	75 Days to complete Review 1
Performance result	64 Days to complete Review 1
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Applications for Class IV licence	13,770	Not available at this time	April 1, 2021	24,699

Fee grouping	Fees for Examination of an Application for a Medical Device Licence
Fee	Class IV - Licence Application (Devices that contain Human- Animal Tissue)
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi]
Year fee-setting authority was introduced	1998
Last year fee-setting authority was amended	2011
Service standard	75 Days to complete Review 1
Performance result	68 Days to complete Review 1
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Class IV - Licence Application (Devices that contain Human- Animal Tissue)	12,846	Not available at this time	Not applicable, fee discontinued as of April 1, 2020	Not applicable, fee discontinued as of April 1, 2020

Fee grouping	Fees for Examination of an Application for a Medical Device Licence
Fee	Class IV - Licence Application (Near patient In Vitro Diagnostic Device)
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi]
Year fee-setting authority was introduced	1998
Last year fee-setting authority was amended	2011
Service standard	75 Days to complete Review 1
Performance result	Not applicable
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Class IV - Licence Application (Near patient In Vitro Diagnostic Device)	23,473	Not available at this time	Not applicable, fee discontinued as of April 1, 2020	Not applicable, fee discontinued as of April 1, 2020

Fee grouping	Fees for Examination of an Application for a Medical Device Licence
Fee	Applicatons for Class IV licence amendment - changes in manufacturing
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1998
Last year fee-setting authority was amended	2019
Service standard	75 Days to complete Review 1
Performance result	41 Days to complete Review 1
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Applicatons for Class IV licence amendment - changes in manufacturing	1,492	Not available at this time	April 1, 2021	2,375

Fee grouping	Fees for Examination of an Application for a Medical Device Licence
Fee	Applicatons for Class IV licence amendment - significange changes not related to manufacturing
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1998
Last year fee-setting authority was amended	2019
Service standard	75 Days to complete Review 1
Performance result	54 Days to complete Review 1
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Applicatons for Class IV licence amendment - significange changes not related to manufacturing	6,319	Not available at this time	April 1, 2021	9,964

Fee grouping	Fees for Examination of an Application for a Medical Device Licence
Fee	Applications for Class II, III or IV licence or licence amendment - private label medical device
Fee-setting authority	**As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	2019
Last year fee-setting authority was amended	Not applicable
Service standard	15 Days to complete Review 1
Performance result	Not applicable, new fee as of April 1, 2020
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Applications for Class II, III or IV licence or licence amendment - private label medical device	Not applicable, new fee as of April 1, 2020	Not applicable, new fee as of April 1, 2020	April 1, 2021	147

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 it efficacy and safety in the intended species as well as human safety. Fees are calculated on a component basis.

Fee grouping	Fees for Examination of a Submission — Drugs for Veterinary Use Only
Fee	Drug Identification Number
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Veterinary Drug Evaluation Fees Regulations*[xii] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1996
Last year fee-setting authority was amended	2019
Service standard	120 Days to complete Review 1
Performance result	78 Days to complete Review 1
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
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	735.84	Not available at this time	April 1, 2021	1,146
Published references or other data	511	Not available at this time	April 1, 2021	797
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	255.50	Not available at this time	April 1, 2021	400

Fee grouping	Fees for Examination of a Submission — Drugs for Veterinary Use Only
Fee	Notification – veterinary health product
Fee-setting authority	**As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	2019
Last year fee-setting authority was amended	Not applicable
Service standard	30 Days to process notification
Performance result	Not applicable, as this is a new fee as of April 1, 2020
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
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	Not applicable, as this is a new fee as of April 1, 2020	Not applicable, as this is a new fee as of April 1, 2020	April 1, 2021	486

Fee grouping	Fees for Examination of a Submission — Drugs for Veterinary Use Only
Fee	New drug submission
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Veterinary Drug Evaluation Fees Regulations*[xii] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1996
Last year fee-setting authority was amended	2019
Service standard	• 300 Days to complete Review 1 (other than Administrative New Drug Submission (NDS)) • 90 Days to complete review for Administrative New Drug Submission (NDS)
Performance result	• 194 Days to complete Review 1 (other than Administrative NDS) • 28 Days to complete review for Administrative NDS
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
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.)	16,331.56	Not available at this time	April 1, 2021	25,419
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	9,892.96	Not available at this time	April 1, 2021	15,398

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
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, dosage form and two indications in one animal species	23,751.28	Not available at this time	April 1, 2021	36,966
Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species	32,162.34	Not available at this time	April 1, 2021	50,057
Comparative (pharmacodynamics, clinical or bioavailability) data to support an additional route of administration	2,963.80	Not available at this time	April 1, 2021	4,614
Comparative (pharmacodynamics, clinical or bioavailability) data to support each additional strength	490.56	Not available at this time	April 1, 2021	764
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	22,269.38	Not available at this time	April 1, 2021	34,660
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	29,689.10	Not available at this time	April 1, 2021	46,208

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
For food-producing animals, residue depletion studies to establish a withdrawal period for an additional dosage form, dosage or route of administration	2,963.80	Not available at this time	April 1, 2021	4,614
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	14,839.44	Not available at this time	April 1, 2021	23,096
Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug	4,946.48	Not available at this time	April 1, 2021	7,700
Chemistry and manufacturing data to support one strength of a single dosage form	4,946.48	Not available at this time	April 1, 2021	7,700
Chemistry and manufacturing data to support an additional strength of a single dosage form submitted at the same time as the above item	2,473.24	Not available at this time	April 1, 2021	3,851
Documentation to support a change of manufacturer	255.50	Not available at this time	April 1, 2021	400

Fee grouping	Fees for Examination of a Submission — Drugs for Veterinary Use Only
Fee	Supplement to a new drug submission
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Veterinary Drug Evaluation Fees Regulations*[xii] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1996
Last year fee-setting authority was amended	2019
Service standard	240 Days to complete Review 1
Performance result	147 Days to complete Review 1
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Efficacy data to support an additional indication in one animal species	12,866.98	Not available at this time	April 1, 2021	20,027
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	9,892.96	Not available at this time	April 1, 2021	15,398
Efficacy and safety data (in the intended species) to support an indication in another animal species	16,331.56	Not available at this time	April 1, 2021	25,419
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.	23,751.28	Not available at this time	April 1, 2021	36,966

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species	32,162.34	Not available at this time	April 1, 2021	50,057
Efficacy and safety data (in the intended species) to support the concurrent use of two drugs approved for the same animal species	7,910.28	Not available at this time	April 1, 2021	12,312
Comparative (pharmacodynamics, clinical or bioavailability) data to support an additional route of administration	2,963.80	Not available at this time	April 1, 2021	4,614
Comparative (pharmacodynamics, clinical or bioavailability) data to support each additional strength	490.56	Not available at this time	April 1, 2021	764
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	2,963.80	Not available at this time	April 1, 2021	4,614
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	14,839.44	Not available at this time	April 1, 2021	23,096
For food-producing animals, toxicity studies to support a change of an established acceptable daily intake, maximum residue limit and withdrawal period	7,419.72	Not available at this time	April 1, 2021	11,548

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
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	5,937.82	Not available at this time	April 1, 2021	9,243
Chemistry and manufacturing data to support a change in the source of a medicinal ingredient or its manufacturing process	4,946.48	Not available at this time	April 1, 2021	7,700
Chemistry and manufacturing data to support a change in formulation or dosage form	2,473.24	Not available at this time	April 1, 2021	3,851
Chemistry and manufacturing data to support a change in packaging or in the sterilization process	1,972.46	Not available at this time	April 1, 2021	3,072
Chemistry and manufacturing data to support an extension of the expiry dating	1,481.90	Not available at this time	April 1, 2021	2,309
Chemistry and manufacturing data to support the concurrent use of two drugs	1,481.90	Not available at this time	April 1, 2021	2,309
Chemistry and manufacturing data to support a change in the manufacturing site for parenteral dosage forms	490.56	Not available at this time	April 1, 2021	764
Documentation to support a change to the name of a manufacturer or the brand name of a drug	255.50	Not available at this time	April 1, 2021	400

Fee grouping	Fees for Examination of a Submission — Drugs for Veterinary Use Only
Fee	Abbreviated new drug submission
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Veterinary Drug Evaluation Fees Regulations*[xii] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1996
Last year fee-setting authority was amended	2019
Service standard	300 Days to complete Review 1
Performance result	270 Days to complete Review 1
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Comparative (pharmacodynamics, clinical or bioavailability) data to support a single route of administration and dosage form.	2,963.80	Not available at this time	April 1, 2021	4,614
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.	2,963.80	Not available at this time	April 1, 2021	4,614
Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug.	4,946.48	Not available at this time	April 1, 2021	7,700
Chemistry and manufacturing data to support a single dosage form.	4,946.48	Not available at this time	April 1, 2021	7,700

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
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.	255.50	Not available at this time	April 1, 2021	400

Fee grouping	Fees for Examination of a Submission — Drugs for Veterinary Use Only
Fee	Supplement to an abbreviated new drug submission
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Veterinary Drug Evaluation Fees Regulations*[xii] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1996
Last year fee-setting authority was amended	2019
Service standard	240 Days to complete Review 1
Performance result	180 Days to complete Review 1
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Comparative (pharmacodynamics, clinical or bioavailability) data to support a single route of administration and dosage form.	2,963.80	Not available at this time	April 1, 2021	4,614
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.	2,963.80	Not available at this time	April 1, 2021	4,614
Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug.	4,946.48	Not available at this time	April 1, 2021	7,700
Chemistry and manufacturing data to support a single dosage form.	4,946.48	Not available at this time	April 1, 2021	7,700

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
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.	255.50	Not available at this time	April 1, 2021	400

Fee grouping	Fees for Examination of a Submission — Drugs for Veterinary Use Only
Fee	Preclinical new drug submission
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Veterinary Drug Evaluation Fees Regulations*[xii] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1996
Last year fee-setting authority was amended	2019
Service standard	60 Days to review application
Performance result	n/a for 2019-20
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Efficacy and safety (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	4,946.48	Not available at this time	April 1, 2021	7,700
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	3,955.14	Not available at this time	April 1, 2021	6,157

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
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	14,839.44	Not available at this time	April 1, 2021	23,096
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	22,269.38	Not available at this time	April 1, 2021	34,660
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	29,689.10	Not available at this time	April 1, 2021	46,208
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	7,419.72	Not available at this time	April 1, 2021	11,548
Chemistry and manufacturing data to support a single dosage form containing a non-compendial medicinal ingredient	4,946.48	Not available at this time	April 1, 2021	7,700

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Chemistry and manufacturing data to support a single dosage form containing a compendial medicinal ingredient	2,473.24	Not available at this time	April 1, 2021	3,851

Fee grouping	Fees for Examination of a Submission — Drugs for Veterinary Use Only
Fee	Sale of new drug for emergency treatment
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Veterinary Drug Evaluation Fees Regulations*[xii] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1996
Last year fee-setting authority was amended	2019
Service standard	2 business days to review application
Performance result	<2 business days to review application
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Information to support the sale of a drug to be used in the emergency treatment of a non-food-producing animal	51.10	Not available at this time	April 1, 2021	51
Information to support the sale of a drug to be used in the emergency treatment of a food-producing animal	102.20	Not available at this time	April 1, 2021	102

Fee grouping	Fees for Examination of a Submission — Drugs for Veterinary Use Only
Fee	Experimental studies certificate
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Veterinary Drug Evaluation Fees Regulations*[xii] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1996
Last year fee-setting authority was amended	2019
Service standard	60 Days to review application
Performance result	37 Days to review application
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a non-food-producing animal	981.12	Not available at this time	April 1, 2021	979
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	490.56	Not available at this time	April 1, 2021	490
Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a food-producing animal	2,963.80	Not available at this time	April 1, 2021	2,953

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
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	490.56	Not available at this time	April 1, 2021	490

Fee grouping	Fees for Examination of a Submission — Drugs for Veterinary Use Only
Fee	Notifiable change
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Veterinary Drug Evaluation Fees Regulations*[xii] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1996
Last year fee-setting authority was amended	2019
Service standard	90 Days to review application for Notifiable Changes
Performance result	64 Days to review application for Notifiable Changes
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Information and material to support an application for Notifiable Change	1,300	Not available at this time	April 1, 2021	2,069

Fee grouping	Fees for Examination of a Submission — Drugs for Veterinary Use Only
Fee	Protocol
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Veterinary Drug Evaluation Fees Regulations*[xii] **As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	1996
Last year fee-setting authority was amended	2019
Service standard	60 Days to review package *Modified to 90 Days as of April 1, 2020
Performance result	60 Days to review package
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
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	1,300	Not available at this time	April 1, 2021	2,069

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 component 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.

As of April 1, 2020, a more simplified DEL fee regime was introduced, as indicated in the tables below.

Fee grouping	Drug Establishment Licensing Fees
Fee	Human Drug Establishment Licence Fees
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi]
Year fee-setting authority was introduced	1998
Last year fee-setting authority was amended	2011
Service standard	250 Calendar days to issue/ renew license
Performance result	96% of licenses issued (human and veterinary) within 250 calendar days
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Fabrication - Basic Fee	18,107	Not available	Not applicable, fee discontinued as of April 1, 2020	Not applicable, fee discontinued as of April 1, 2020
Fabrication - Each Additional Category	4,538	Not available		
Dosage Form Classes:				
Fabrication - Two classes	9,061	Not available		
Fabrication - Three classes	18,107	Not available		
Fabrication - Four classes	22,642	Not available		
Fabrication - Five classes	27,162	Not available		
Fabrication - Six classes	31,686	Not available		
Fabrication - Each additional class	1,819	Not available		

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Fabrication - Sterile dosage forms	9,061	Not available		
Packaging/labelling - Basic Fee	12,107	Not available		
Packaging/labelling - Each Additional Category	3,026	Not available		
Packaging/labelling - Two classes	6,039	Not available		
Packaging/labelling - Three or more classes	9,061	Not available		
Importation/Distribution - Basic Fee	7,551	Not available		
Importation/Distribution - Each Additional Category	1,891	Not available		
Importation/Distribution - Two classes	3,778	Not available		
Importation/Distribution - Three or more classes	7,551	Not available		
Importation/Distribution - Each fabricator	1,819	Not available		
Importation/Distribution - Each additional dosage form class for each fabricator	917	Not available		
Distribution and Wholesaling Fee	4,538	Not available		
Testing - Testing Fee	3,026	Not available		
Drug Analysis Component - Vaccines	30,174	Not available		
Drug Analysis Component - Schedule D Drugs which are not vaccines or whole blood and its components	12,073	Not available		
Drug Analysis Component - Drugs for human use that are prescription drugs, controlled drugs or narcotics	9,061	Not available		
Drug Analysis Component - Drugs for human use, not included in any other item, for which a drug identification number has been assigned	4,538	Not available		

Fee grouping	Drug Establishment Licensing Fees
Fee	Human Drug Establishment Licence Fees
Fee-setting authority	**As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	2019
Last year fee-setting authority was amended	Not applicable
Service standard	250 Calendar days to issue/ renew license
Performance result	No performance result is available, since the new fees were introduced on April 1, 2020
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Fabrication - Sterile dosage form	Not applicable, as these are new fees as of April 1, 2020	Not applicable, as these are new fees as of April 1, 2020	April 1, 2021	41,647
Importation				28,975
Fabrication - non-sterile dosage form				28,308
Distribution				13,855
Wholesaling				6,159
Packaging/labelling				6,049
Testing				3,194
Building outside Canada (each)				917

Fee grouping	Drug Establishment Licensing Fees
Fee	Veterinary Drug Establishment Licence Fees
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Establishment Licensing Fees (Veterinary Drugs) Regulations*[xiii]
Year fee-setting authority was introduced	1998
Last year fee-setting authority was amended	Not applicable
Service standard	250 Calendar days to issue/ renew license
Performance result	96% of licenses issued (human and veterinary) within 250 calendar days
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Fabrication - Basic Fee	6,132	Not available	Not applicable, fee discontinued as of April 1, 2020	Not applicable, fee discontinued as of April 1, 2020
Fabrication - Each Additional Category	1,533	Not available		
Dosage Form Classes:				
Fabrication - Two classes	3,066	Not available		
Fabrication - Three classes	6,132	Not available		
Fabrication - Four classes	7,665	Not available		
Fabrication - Five classes	9,198	Not available		
Fabrication - Six classes	10,731	Not available		
Fabrication - Each additional class	613.20	Not available		
Fabrication - Sterile dosage forms	3,066	Not available		
Packaging/labelling - Basic Fee	4,088	Not available		
Packaging/labelling - Each Additional Category	1,022	Not available		
Packaging/labelling - Two classes	2,044	Not available		
Packaging/labelling - Three or more classes	3,066	Not available		
Importation/Distribution - Basic Fee	2,555	Not available		

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Importation/Distribution - Each Additional Category	638.75	Not available		
Importation/Distribution - Two classes	1,277.50	Not available		
Importation/Distribution - Three or more classes	2,555	Not available		
Importation/Distribution - Each fabricator	613.20	Not available		
Importation/Distribution - Each additional dosage form class for each fabricator	306.60	Not available		
Distribution and Wholesaling Fee	1,533	Not available		
Testing - Testing Fee	1,022	Not available		
Drug Analysis Component - Drug Identification Numbers for Veterinary Use	255.50	Not available		

Fee grouping	Drug Establishment Licence Fees
Fee	Veterinary Drug Establishment Licence Fees
Fee-setting authority	**As at April 1, 2020:** • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	2019
Last year fee-setting authority was amended	Not applicable
Service standard	250 Calendar days to issue/ renew license
Performance result	No performance result is available, since the new fees were introduced on April 1, 2020
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Fabrication - Sterile dosage form	Not applicable, as these are new fees as of April 1, 2020	Not applicable, as these are new fees as of April 1, 2020	April 1, 2021	40,407
Importation				13,367
Fabrication - non-sterile dosage form				10,957
Distribution				6,031
Wholesaling				2,412
Packaging/labelling				6,049
Testing				1,641
Building outside Canada (each)				917

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 grouping	Drug Establishment Licensing Fees - Dealer's Licences
Fee	• Dealer's Licence Fees - Human Drugs • Dealer's Licence Fees - Veterinary Drugs
Fee-setting authority	Human Drugs: • *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations* (until March 21 2019)[vi] • *Fees in Respect of a Dealer's Licences Regulations*[xiv] (beginning April 1, 2020) Veterinary Drugs: • *Financial Administration Act (FAA)*[v] • *Licensed Dealers for Controlled Drugs and Narcotics (Veterinary Use) Fees Regulations* [xv]
Year fee-setting authority was introduced	1998
Last year fee-setting authority was amended	Human Drugs: 2011 Veterinary Drugs: Not applicable
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**: 94% of applications were processed within the service standard **Renew:** 100% of applications were processed within the service standard
Application of *Low-Materiality Fees Regulations*	Material (>$151)

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Dealer's Licence Fees - Human Drugs	5,288	1,121,826	April 1, 2021	5,502
Dealer's Licence Fees - Veterinary Drugs	1,788.50	18,722	April 1, 2021	1,820.62

Medical Device Establishment Licensing Fees

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

Fee grouping	Medical Devices Establishment Licensing Fees
Fee	Application for new licence and annual review of licence
Fee-setting authority	• *Financial Administration Act (FAA)*[v] • *Fees in Respect of Drugs and Medical Devices Regulations*[vi] Beginning April 1, 2020: • *Food and Drugs Act (FDA)*[vii] • *Fees in Respect of Drugs and Medical Devices Order*[viii]
Year fee-setting authority was introduced	2000
Last year fee-setting authority was amended	2019
Service standard	120 Calendar days to issue/ renew licence
Performance result	100% of licences issued within 120 calendar days
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Application for new licence and annual review of licence	8,438	9,455,621	April 1, 2021	4,581

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

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.

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
Fee	Category A Component Based – 655 Days of Review (Conventional Chemicals and Import Maximum Residue Limits)
Fee-setting authority	• *Pest Control Products Act* [xvi] • *Pest Control Products Fees and Charges Regulations* [xvii]
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	655 Days of Review
Performance result	100% (5/5 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Product Chemistry – active ingredient	5,071	Not available at this time	April 1, 2021	5,277
Product Chemistry – end-use product or manufacturing concentrate	2,824	Not available at this time	April 1, 2021	2,939
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	78,871	Not available at this time	April 1, 2021	82,058

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains an registered active ingredient	16,470	Not available at this time	April 1, 2021	17,136
Toxicology data-acute toxicity studies	3,075	Not available at this time	April 1, 2021	3,200
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	18,205	Not available at this time	April 1, 2021	18,942
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	5,992	Not available at this time	April 1, 2021	6,235
Metabolism data	30,113	Not available at this time	April 1, 2021	31,331
Residue data	16,479	Not available at this time	April 1, 2021	17,146
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	44,410	Not available at this time	April 1, 2021	46,205
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	24,593	Not available at this time	April 1, 2021	25,587

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	38,784	Not available at this time	April 1, 2021	40,352
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	24,648	Not available at this time	April 1, 2021	25,644
Value and effectiveness data for a pest control product	944	Not available at this time	April 1, 2021	983
Specification of maximum residue limit for a previously unexamined pest control product	130,531	Not available at this time	April 1, 2021	135,805
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	16,479	Not available at this time	April 1, 2021	17,146
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	555 Days of Review
Performance result	82% (14/17 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Product Chemistry – active ingredient	5,071	Not available at this time	April 1, 2021	5,277
Product Chemistry – end-use product or manufacturing concentrate	2,824	Not available at this time	April 1, 2021	2,939
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	78,871	Not available at this time	April 1, 2021	82,058
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains an registered active ingredient	16,470	Not available at this time	April 1, 2021	17,136
Toxicology data-acute toxicity studies	3,075	Not available at this time	April 1, 2021	3,200
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	18,205	Not available at this time	April 1, 2021	18,942

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
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	5,992	Not available at this time	April 1, 2021	6,235
Metabolism data	30,113	Not available at this time	April 1, 2021	31,331
Residue data	16,479	Not available at this time	April 1, 2021	17,146
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	44,410	Not available at this time	April 1, 2021	46,205
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	24,593	Not available at this time	April 1, 2021	25,587
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	38,784	Not available at this time	April 1, 2021	40,352
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	24,648	Not available at this time	April 1, 2021	25,644
Value and effectiveness data for a pest control product	944	Not available at this time	April 1, 2021	983
Registration of a new active ingredient – food use	7,529	Not available at this time	April 1, 2021	7,834

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Registration of a new active ingredient – non-food use	4,517	Not available at this time	April 1, 2021	4,701
Amendment of registration – new risk assessment necessary-environmental fate data, environmental toxicity data or exposure data	3,012	Not available at this time	April 1, 2021	3,135
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	470 Days of Review
Performance result	N/A (0 applications completed in 2019-20)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Product Chemistry – active ingredient	5,071	Not available at this time	April 1, 2021	5,277
Product Chemistry – end-use product or manufacturing concentrate	2,824	Not available at this time	April 1, 2021	2,939
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	78,871	Not available at this time	April 1, 2021	82,058
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains an registered active ingredient	16,470	Not available at this time	April 1, 2021	17,136
Toxicology data-acute toxicity studies	3,075	Not available at this time	April 1, 2021	3,200
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	18,205	Not available at this time	April 1, 2021	18,942

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
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	5,992	Not available at this time	April 1, 2021	6,235
Metabolism data	30,113	Not available at this time	April 1, 2021	31,331
Residue data	16,479	Not available at this time	April 1, 2021	17,146
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	44,410	Not available at this time	April 1, 2021	46,205
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	24,593	Not available at this time	April 1, 2021	25,587
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	38,784	Not available at this time	April 1, 2021	40,352
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	24,648	Not available at this time	April 1, 2021	25,644
Value and effectiveness data for a pest control product	944	Not available at this time	April 1, 2021	983
Registration of a new active ingredient – food use	7,529	Not available at this time	April 1, 2021	7,834

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Registration of a new active ingredient – non-food use	4,517	Not available at this time	April 1, 2021	4,701
Amendment of registration – new risk assessment necessary-environmental fate data, environmental toxicity data or exposure data	3,012	Not available at this time	April 1, 2021	3,135
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	285 Days of Review
Performance result	N/A (0 applications completed in 2019-20)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Registration of new active ingredient	603	Not available at this time	April 1, 2021	629
Amendment of registration	302	Not available at this time	April 1, 2021	316

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
Fee	Category A Component Based – Submissions with atypical timelines and joint reviews
Fee-setting authority	• *Pest Control Products Act* [xvi] • *Pest Control Products Fees and Charges Regulations* [xvii]
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	Variable as per Management of Submission Policy [xviii] Appendix I, Table 1
Performance result	73% (8/11 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Product Chemistry – active ingredient	5,071	Not available at this time	April 1, 2021	5,277
Product Chemistry – end-use product or manufacturing concentrate	2,824	Not available at this time	April 1, 2021	2,939
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	78,871	Not available at this time	April 1, 2021	82,058
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains an registered active ingredient	16,470	Not available at this time	April 1, 2021	17,136
Toxicology data-acute toxicity studies	3,075	Not available at this time	April 1, 2021	3,200
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	18,205	Not available at this time	April 1, 2021	18,942

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
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	5,992	Not available at this time	April 1, 2021	6,235
Metabolism data	30,113	Not available at this time	April 1, 2021	31,331
Residue data	16,479	Not available at this time	April 1, 2021	17,146
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	44,410	Not available at this time	April 1, 2021	46,205
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	24,593	Not available at this time	April 1, 2021	25,587
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	38,784	Not available at this time	April 1, 2021	40,352
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	24,648	Not available at this time	April 1, 2021	25,644
Value and effectiveness data for a pest control product	944	Not available at this time	April 1, 2021	983
Registration of a new active ingredient – food use	7,529	Not available at this time	April 1, 2021	7,834

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Registration of a new active ingredient – non-food use	4,517	Not available at this time	April 1, 2021	4,701
Amendment of registration – new risk assessment necessary-environmental fate data, environmental toxicity data or exposure data	3,012	Not available at this time	April 1, 2021	3,135
Registration of new active ingredient	603	Not available at this time	April 1, 2021	629
Amendment of registration	302	Not available at this time	April 1, 2021	316
Specification of maximum residue limit for a previously unexamined pest control product	130,531	Not available at this time	April 1, 2021	135,805
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	16,479	Not available at this time	April 1, 2021	17,146
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	425 Days of Review
Performance result	86% (201/233 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Product Chemistry – active ingredient	5,071	Not available at this time	April 1, 2021	5,277
Product Chemistry – end-use product or manufacturing concentrate	2,824	Not available at this time	April 1, 2021	2,939
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains an registered active ingredient	16,470	Not available at this time	April 1, 2021	17,136
Toxicology data-acute toxicity studies	3,075	Not available at this time	April 1, 2021	3,200
Exposure data - other	5,426	Not available at this time	April 1, 2021	5,646
Metabolism data	30,113	Not available at this time	April 1, 2021	31,331
Residue data	16,479	Not available at this time	April 1, 2021	17,146
Environmental fate data - other	12,013	Not available at this time	April 1, 2021	12,500

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Environmental toxicology data - other	2,566	Not available at this time	April 1, 2021	2,671
Value and effectiveness data for a pest control product	944	Not available at this time	April 1, 2021	983
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	16,479	Not available at this time	April 1, 2021	17,146
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	360 Days of Review
Performance result	100% (5/5 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Product Chemistry – active ingredient	5,071	Not available at this time	April 1, 2021	5,277
Product Chemistry – end-use product or manufacturing concentrate	2,824	Not available at this time	April 1, 2021	2,939
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains an registered active ingredient	16,470	Not available at this time	April 1, 2021	17,136
Toxicology data-acute toxicity studies	3,075	Not available at this time	April 1, 2021	3,200
Exposure data - other	5,426	Not available at this time	April 1, 2021	5,646
Metabolism data	30,113	Not available at this time	April 1, 2021	31,331
Residue data	16,479	Not available at this time	April 1, 2021	17,146
Environmental fate data - other	12,013	Not available at this time	April 1, 2021	12,500
Environmental toxicology data - other	2,566	Not available at this time	April 1, 2021	2,671

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Value and effectiveness data for a pest control product	944	Not available at this time	April 1, 2021	983
Amendment of registration – data required, label changes	1,506	Not available at this time	April 1, 2021	1,568
Amendment of registration – data required, other	1,206	Not available at this time	April 1, 2021	1,256
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* [xvii]
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	240 Days of Review
Performance result	89% (16/18 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Amendment of registration – data required, label changes	1,506	Not available at this time	April 1, 2021	1,568
Amendment of registration – data required, other	1,206	Not available at this time	April 1, 2021	1,256
Amendment of registration	302	Not available at this time	April 1, 2021	316

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	158 Days of Review
Performance result	88% (35/40 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Value and effectiveness data for a pest control product	944	Not available at this time	April 1, 2021	983
Amendment of registration – data required, label changes	1,506	Not available at this time	April 1, 2021	1,568
Amendment of registration – no data required, other	302	Not available at this time	April 1, 2021	316
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
Fee	Category B Component Based – Submissions with atypical timelines and joint reviews
Fee-setting authority	• *Pest Control Products Act* [xvi] • *Pest Control Products Fees and Charges Regulations* [xvii]
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	Variable as per Management of Submission Policy[xviii] Appendix I, Table 2
Performance result	N/A (0 applications completed in 2019-20)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Product Chemistry – active ingredient	5,071	Not available at this time	April 1, 2021	5,277
Product Chemistry – end-use product or manufacturing concentrate	2,824	Not available at this time	April 1, 2021	2,939
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains an registered active ingredient	16,470	Not available at this time	April 1, 2021	17,136
Toxicology data-acute toxicity studies	3,075	Not available at this time	April 1, 2021	3,200
Exposure data-other	5,426	Not available at this time	April 1, 2021	5,646
Metabolism data	30,113	Not available at this time	April 1, 2021	31,331
Residue data	16,479	Not available at this time	April 1, 2021	17,146
Environmental fate data - other	12,013	Not available at this time	April 1, 2021	12,500
Environmental toxicology data - other	2,566	Not available at this time	April 1, 2021	2,671

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Value and effectiveness data for a pest control product	944	Not available at this time	April 1, 2021	983
Amendment of registration - data required, label changes	1,506	Not available at this time	April 1, 2021	1,568
Amendment of registration - data required, other	1,206	Not available at this time	April 1, 2021	1,256
Amendment of registration - no data required	302	Not available at this time	April 1, 2021	316
Amendment of registration	302	Not available at this time	April 1, 2021	316
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	16,479	Not available at this time	April 1, 2021	17,146
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	240 Days of Review
Performance result	97% (680/701 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Amendment of registration – no data required	302	Not available at this time	April 1, 2021	316
Amendment of registration	302	Not available at this time	April 1, 2021	316
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	180 Days of Review
Performance result	99% (122/123 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Amendment of registration – no data required	302	Not available at this time	April 1, 2021	316
Amendment of registration	302	Not available at this time	April 1, 2021	316
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
Fee	Category C Component Based – Submissions with atypical timelines and joint reviews
Fee-setting authority	• *Pest Control Products Act* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	Variable as per Management of Submission Policy[xviii], Appendix I, Table 3
Performance result	0% (0/1 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Amendment of registration – no data required	302	Not available at this time	April 1, 2021	316
Amendment of registration	302	Not available at this time	April 1, 2021	316
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
Fee	Category D Component Based – 247 Days of Review (Registration Renewal)
Fee-setting authority	• *Pest Control Products Act* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	247 Days of Review
Performance result	100% (970/970 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Low-materiality ($51–$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Renewal	84	Not available at this time	April 1, 2021	88

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	46 Days of Review
Performance result	33% (1/3 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Registration of active ingredient to be used in pest control product manufactured only for export	8,144	Not available at this time	April 1, 2021	8,474
Amendment to Registration of active ingredient to be used in pest control product manufactured only for export	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
Fee	Category D Component Based – 42 Days of Review (Master Copies)
Fee-setting authority	• *Pest Control Products Act* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	42 Days of Review
Performance result	100% (61/61 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
Fee	Category D Component Based – 10 Days of Review (Private Labels)
Fee-setting authority	• *Pest Control Products Act* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	10 Days of Review
Performance result	100% (5/5 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
Fee	Category E Component Based – 159 Days of Review (Research Authorizations for New Technical Grade Active Ingredients)
Fee-setting authority	• *Pest Control Products Act* [xvi] • *Pest Control Products Fees and Charges Regulations* [xvii]
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	159 Days of Review
Performance result	69% (20/29 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Research authorization – major crops, other than research authorizations set out in paragraphs (c) and (d)	5,286	Not available at this time	April 1, 2021	5,500
Research authorization – minor use crops, other than research authorizations set out in paragraphs (c) and (d)	5,286	Not available at this time	April 1, 2021	5,500
Research authorization – microbial agents, semiochemicals and any substance listed in subparagraph 1(d) (ii) of these regulations	1,267	Not available at this time	April 1, 2021	1,319
Research authorization – greenhouse crops and non-agricultural uses	1,267	Not available at this time	April 1, 2021	1,319

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	69 Days of Review
Performance result	79% (37/47 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Research authorization – major crops, other than research authorizations set out in paragraphs (c) and (d)	5,286	Not available at this time	April 1, 2021	5,500
Research authorization – minor use crops, other than research authorizations set out in paragraphs (c) and (d)	5,286	Not available at this time	April 1, 2021	5,500
Research authorization – microbial agents, semiochemicals and any substance listed in subparagraph 1(d) (ii) of these regulations	1,267	Not available at this time	April 1, 2021	1,319
Research authorization – greenhouse crops and non-agricultural uses	1,267	Not available at this time	April 1, 2021	1,319

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
Fee	Category E Component Based – 30 Days of Review (Research Notification for Research Carried out in Canada)
Fee-setting authority	• *Pest Control Products Act* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	30 Days of Review
Performance result	93% (27/29 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Research notifications	258	Not available at this time	April 1, 2021	270

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	45 Days of Review
Performance result	98% (926/945 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Applications not mentioned in schedules	258	Not available at this time	April 1, 2021	270

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	425 Days of Review
Performance result	76% (34/45 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Product Chemistry – active ingredient	5,071	Not available at this time	April 1, 2021	5,277
Product Chemistry – end-use product or manufacturing concentrate	2,824	Not available at this time	April 1, 2021	2,939
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains an registered active ingredient	16,470	Not available at this time	April 1, 2021	17,136
Toxicology data-acute toxicity studies	3,075	Not available at this time	April 1, 2021	3,200
Exposure data - other	5,426	Not available at this time	April 1, 2021	5,646
Metabolism data	30,113	Not available at this time	April 1, 2021	31,331
Residue data	16,479	Not available at this time	April 1, 2021	17,146
Environmental fate data - other	12,013	Not available at this time	April 1, 2021	12,500
Environmental toxicology data – other	2,566	Not available at this time	April 1, 2021	2,671

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Value and effectiveness data for a pest control product	944	Not available at this time	April 1, 2021	983
Identification of compensable data	2,251	Not available at this time	April 1, 2021	2,343
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	365 Days of Review
Performance result	90% (76/84 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Product Chemistry – active ingredient	5,071	Not available at this time	April 1, 2021	5,277
Product Chemistry – end-use product or manufacturing concentrate	2,824	Not available at this time	April 1, 2021	2,939
Identification of compensable data	2,251	Not available at this time	April 1, 2021	2,343
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	360 Days of Review
Performance result	100% (1/1 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Product Chemistry – active ingredient	5,071	Not available at this time	April 1, 2021	5,277
Product Chemistry – end-use product or manufacturing concentrate	2,824	Not available at this time	April 1, 2021	2,939
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains an registered active ingredient	16,470	Not available at this time	April 1, 2021	17,136
Toxicology data-acute toxicity studies	3,075	Not available at this time	April 1, 2021	3,200
Exposure data - other	5,426	Not available at this time	April 1, 2021	5,646
Metabolism data	30,113	Not available at this time	April 1, 2021	31,331
Residue data	16,479	Not available at this time	April 1, 2021	17,146
Environmental fate data - other	12,013	Not available at this time	April 1, 2021	12,500

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Environmental toxicology data – other	2,566	Not available at this time	April 1, 2021	2,671
Value and effectiveness data for a pest control product	944	Not available at this time	April 1, 2021	983
Identification of compensable data	2,251	Not available at this time	April 1, 2021	2,343
Amendment of registration – data required, label changes	1,506	Not available at this time	April 1, 2021	1,568
Amendment of registration – data required, other	1,206	Not available at this time	April 1, 2021	1,256
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	240 Days of Review
Performance result	N/A (0 applications completed in 2019-20)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Identification of compensable data	2,251	Not available at this time	April 1, 2021	2,343
Amendment of registration – data required, label changes	1,506	Not available at this time	April 1, 2021	1,568
Amendment of registration – data required, other	1,206	Not available at this time	April 1, 2021	1,256
Amendment of registration	302	Not available at this time	April 1, 2021	316
Processing	1,180	Not available at this time	April 1, 2021	1,229

Fee grouping	Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product
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* [xvi] • *Pest Control Products Fees and Charges Regulations* *xvii*
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	Variable as per Management of Submission Policy[xviii], Appendix I, Table 7
Performance result	100% (1/1 applications met the service standard)
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Product Chemistry – active ingredient	5,071	Not available at this time	April 1, 2021	5,277
Product Chemistry – end-use product or manufacturing concentrate	2,824	Not available at this time	April 1, 2021	2,939
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains an registered active ingredient	16,470	Not available at this time	April 1, 2021	17,136
Toxicology data-acute toxicity studies	3,075	Not available at this time	April 1, 2021	3,200
Exposure data - other	5,426	Not available at this time	April 1, 2021	5,646
Metabolism data	30,113	Not available at this time	April 1, 2021	31,331
Residue data	16,479	Not available at this time	April 1, 2021	17,146
Environmental fate data - other	12,013	Not available at this time	April 1, 2021	12,500
Environmental toxicology data – other	2,566	Not available at this time	April 1, 2021	2,671

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Value and effectiveness data for a pest control product	944	Not available at this time	April 1, 2021	983
Identification of compensable data	2,251	Not available at this time	April 1, 2021	2,343
Amendment of registration – data required, label changes	1,506	Not available at this time	April 1, 2021	1,568
Amendment of registration – data required, other	1,206	Not available at this time	April 1, 2021	1,256
Amendment of registration	302	Not available at this time	April 1, 2021	316
Processing	1,180	Not available at this time	April 1, 2021	1,229

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 grouping	Annual Charge (for a registered Pest Control Product)
Fee	Annual Charge
Fee-setting authority	• *Pest Control Products Act* [xvi] • *Pest Control Products Fees and Charges Regulations* [xvii]
Year fee-setting authority was introduced	1997
Last year fee-setting authority was amended	2017
Service standard	100% of all invoices were issued by April 30th 2019
Performance result	100%
Application of *Low-Materiality Fees Regulations*	Material (>$151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Annual Charge	The lesser of $3,679.20 and 4% of the actual gross revenue during the registrant's preceding fiscal year, but not less than $100	8,654,696	April 1, 2021	The lesser of $3,745.27 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 grouping	Fees Charged for Filing a Claim for Exemption under the Hazardous Materials Information Review Act
Fee	• Original Claims • Refiled Claims Note: A 50% fee reduction is available for small businesses that meets certain criteria
Fee-setting authority	• *Hazardous Materials Information Review Act* [xix] • *Hazardous Materials Information Review Regulations* [xx]
Year fee-setting authority was introduced	1988
Last year fee-setting authority was amended	2002
Service standard	Seven calendar days from the date of the receipt of a complete application, for the issuance of a registry number
Performance result	99% of claims (original and refiled) were registered within the service standard of seven days
Application of *Low-Materiality Fees Regulations*	Material (> $151): All fees

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Original Claim (up to 15)	1,839.60	Not available at this time	April 1, 2021	1,872.64
Original Claim (between 16-25)	408.80		April 1, 2021	416.14
Original Claim (26+)	204.40		April 1, 2021	208.07
Refiled Claims (up to 15)	1,471.68	Not available at this time	April 1, 2021	1,498.11
Refiled Claims (between 16-25)	327.04		April 1, 2021	332.91
Refiled Claims (26+)	163.52		April 1, 2021	166.46

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 grouping	Cannabis Fees
Fee	Licence Application Screening Fees
Fee-setting authority	• *Cannabis Act* [xxi] • *Cannabis Fees Order* [xxii]
Year fee-setting authority was introduced	2018
Last year fee-setting authority was amended	Not Applicable
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 78% of the time.
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Licence Application Screening Fee - Licence for micro-cultivation	1,675	No data available at this time	April 1, 2021	1,706
Licence Application Screening Fee - Licence for standard cultivation	3,350	No data available at this time	April 1, 2021	3,411
Licence Application Screening Fee - Licence for a nursery	1,675	No data available at this time	April 1, 2021	1,706
Licence Application Screening Fee - Licence for micro-processing	1,675	No data available at this time	April 1, 2021	1,706
icence Application Screening Fee - Licence for standard processing	3,350	No data available at this time	April 1, 2021	3,411
Licence Application Screening Fee - Licence for sale for medical purposes	3,350	No data available at this time	April 1, 2021	3,411

Fee grouping	Cannabis Fees
Fee	Application for a security Clearance
Fee-setting authority	• *Cannabis Act* [xxi] • *Cannabis Fees Order* [xxii]
Year fee-setting authority was introduced	2018
Last year fee-setting authority was amended	Not Applicable
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*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Application for a security Clearance	1,691	No data available at this time	April 1, 2021	1,722

Fee grouping	Cannabis Fees
Fee	Application for import or export permit
Fee-setting authority	• *Cannabis Act* [xxi] • *Cannabis Fees Order* [xxii]
Year fee-setting authority was introduced	2018
Last year fee-setting authority was amended	Not Applicable
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 82.46% of the time.
Application of *Low-Materiality Fees Regulations*	Not subject to *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Application for import or export permit	624	No data available at this time	April 1, 2021	636

Fee grouping	Cannabis Fees
Fee	Annual Regulatory Fee
Fee-setting authority	• *Cannabis Act* [xxi] • *Cannabis Fees Order* [xxii]
Year fee-setting authority was introduced	2018
Last year fee-setting authority was amended	Not Applicable
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*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Annual fee - Licence for micro-cultivation	as per Cannabis Fees Order [xxii]	No data available at this time	Exempt	as per Cannabis Fees Order [xxii]
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				

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 will be 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 grouping	National Dosimetry Products and Services Fees
Fee	National Dosimetry Products and Services Fees
Fee-setting authority	Ministerial Authority to Enter into Contract
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 working days prior to exchange date with clients; 3) Dose results for whole body and extremity services reported to clients within internal service standards of 20 to 30 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 CNSC regulatory standard; 2) Shipped out 99.97% of dosimeters 10 to 13 working days prior to exchange date; 3) 99.7% reported within the 20 to 30 business day internal standard, depending on the dosimetry service; 4) 97% completed within two business days; 5) 94% being addressed within one business day; and 6) 93% addressed within two business days.
Application of *Low-Materiality Fees Regulations*	Not subject to section 17 of the *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Core Fees:				
Annual support	80.00	Not available at this time	April 1, 2021	82.50
Annual support — multi-group discount (5+ groups)	50.00	Not available at this time	n/a	50.00
Shipping and handling (per shipment)	14.50	Not available at this time	n/a	14.50
Processing fees (per dosimeter	5.00 to 17.50	Not available at this time	April 1, 2021	5.25 to 17.50
Additional Fees:				
Ad hoc dosimeter request — add-on (per shipment)	65.00	Not available at this time	n/a	65.00
Priority processing request (per request)	95.00	Not available at this time	n/a	95.00
Pregnancy service (semi-monthly)	375.00	Not available at this time	n/a	375.00
Electronic personal dosimeter rental (per year)	415.00	Not available at this time	n/a	415.00
Specialized consultation (per hour)	125.00	Not available at this time	n/a	125.00
Customized reporting (per hour)	60.00	Not available at this time	n/a	60.00
NDR dose modifications (per hour)	60.00	Not available at this time	n/a	60.00
Reprinting reports (per report)	10.00	Not available at this time	n/a	10.00
Overdue dosimeter (three months after wearing period ends)	55.00	Not available at this time	n/a	55.00
Late dosimeter (six months after wearing period ends	55.00	Not available at this time	n/a	55.00
Lost/damaged dosimeter	82.50	Not available at this time	n/a	82.50
Damaged electronic personal dosimeter	415.00	Not available at this time	n/a	415.00
Credit upon returning overdue dosimeter	28.75	Not available at this time	n/a	28.75
Credit upon returning late or lost dosimeter	57.50	Not available at this time	n/a	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 grouping	Master File Fees
Fee	• New Master Files (file registration) • Drug Master Files - letter of access • Drug Master Files - Update
Fee-setting authority	Ministerial Authority to Enter into Contract
Year fee-setting authority was introduced	1996
Last year fee-setting authority was amended	2017
Service standard	30 calendar days
Performance result	99.86% issued within 30 calendar days
Application of *Low-Materiality Fees Regulations*	Not subject to section 17 of the *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
New Master Files (file registration)	1,248	Not available at this time	April 1, 2021	1,298
Drug Master Files – letter of access	176	Not available at this time	April 1, 2021	184
Drug Master Files - Update	541	Not available at this time	April 1, 2021	563

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 grouping	Certificate of Pharmaceutical Product Fee
Fee	Certificate of Pharmaceutical Product
Fee-setting authority	Ministerial Authority to Enter into Contract
Year fee-setting authority was introduced	1996
Last year fee-setting authority was amended	Not applicable
Service standard	10 calendar days to issue certificate
Performance result	87% of certificates issued within 10 calendar days
Application of *Low-Materiality Fees Regulations*	Not subject to section 17 of the *Service Fees Act*

Fee	2019–20 fee amount ($)	2019–20 total fee revenue ($)	Fee adjustment date	Adjusted fee amount in 2021–22 ($)
Certificate of Pharmaceutical Product	90	263,554	April 1, 2021	94

Endnotes

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

[ii] Directive on Charging and Special Financial Authorities, https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=32502

[iii] Cannabis for Medical Purposes Remission Order, https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=32502

[iv] Order Amending the Cannabis Fees Order (Exemptions — Sale for Medical Purposes), http://www.gazette.gc.ca/rp-pr/p2/2020/2020-01-22/html/sor-dors8-eng.html

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

[vi] Fees in Respect of Drugs and Medical Devices Regulations, https://laws-lois.justice.gc.ca/eng/acts/f-11/

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

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

[ix] Authority to Sell Veterinary Drugs Fees Regulations, https://laws-lois.justice.gc.ca/eng/regulations/sor-95-31/20110401/P1TT3xt3.html

[x] Patent Act, https://laws-lois.justice.gc.ca/eng/acts/p-4/index.html

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

[xii] Veterinary Drug Evaluation Fees Regulations, https://laws-lois.justice.gc.ca/eng/regulations/sor-96-143/20060322/P1TT3xt3.html

[xiii] Establishment Licensing Fees (Veterinary Drugs) Regulations, https://laws-lois.justice.gc.ca/eng/regulations/sor-98-4/page-1.html

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

[xv] 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

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

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

[xviii] Management of Submissions Policy, 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

[xix] Hazardous Materials Information Review Act, https://laws-lois.justice.gc.ca/eng/acts/H-2.7/

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

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

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