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Health Canada

Fees Report

Fiscal Year 2022-23

The Honourable Mark Holland, P.C., M.P.
Minister of Health

YOUR HEALTH AND SAFETY... OUR PRIORITY.

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Minister’s message

On behalf of Health Canada, I am pleased to present the department’s fees report for the 2022-23 fiscal year, that lists the fees that are under our authority. It includes fee amounts, service standards, performance results, revenues and remissions.

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We currently charge fees in the areas of drugs and medical devices, pesticides, hazardous materials, radiation protection and cannabis.

We continue to consult and engage with industry stakeholders to ensure transparency and accountability when setting fees.

This past fiscal year, we consulted the public on the proposed *Biocides Regulations*, fees and related guidance document. Placing disinfectants and surface sanitizers under one regulatory framework will simplify the market authorization process. We plan to publish the *Biocides Regulations* in the Canada Gazette, Part II, in the near future. Fees will take effect a year later.

On February 22, 2023, regulatory amendments to the *Medical Devices Regulations* took effect, introducing a permanent regulatory framework for COVID-19 medical devices. Changes to the *Fees in Respect of Drugs and Medical Devices Order* also came into effect, providing certain fee exemptions for companies manufacturing COVID-19 devices. This spring, we proposed broadening the scope of these regulatory changes and fee exemptions to include medical devices needed to address other public health emergencies beyond COVID-19.

In May 2023, we consulted the public on fees for natural health products. By charging fees, we would be able to recover some of our regulatory costs and improve the program.

The Department will continue to work hard to be transparent and accountable. By collaborating and making evidence-based decisions, I will continue to advance my mandate priorities to help keep Canadians healthy and safe.

The Honourable Mark Holland, P.C., M.P.
Minister of Health

About this report

This report, which is tabled under section 20 of the *Service Fees Act*[i], the *Low-Materiality Fees Regulations*[ii], and subsection 4.2.8 of the Treasury Board *Directive on Charging and Special Financial Authorities*[iii], contains information about the fees that Health Canada had the authority to set in 2022-23.

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

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

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

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

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

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

Although the fees Health Canada charges under the *Access to Information Act* were subject to the *Service Fees Act*, they are not included in this report. Information on Health Canada's access to information fees for 2022–23 is in our annual report[iv] to Parliament on the administration of the *Access to Information Act*.

Remissions

In 2022–23, Health Canada was subject to the requirements to issue remissions under section 7 of the *Service Fees Act* and subsection 4.2.4 of the Treasury Board *Directive on Charging and Special Financial Authorities* to remit a fee, in whole or in part, to a fee payer when a service standard was not met. Health Canada's remission policy and procedures, pursuant to the Service Fees Act, are on the following web page: Remissions for missed service standards[v]

In 2022-23, Health Canada also issued remissions under its enabling legislation. These remissions may have been for reasons other than not meeting a service standard.

The authority to remit is delegated in the *Food and Drugs Act,*[vi] 30.63(1)[vi], and is detailed in the *Fees in Respect of Drugs and Medical Devices Order* [vii] and the *Medical Device Establishment Licence Fees Remission Order (Expedited Examination of Applications During the COVID-19 Pandemic)*[xiii].

The other sections of this report provide detailed amounts on Health Canada's remissions for 2022–23.

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 2022–23, by fee-setting mechanism.

Overall totals for 2022–23, by fee-setting mechanism

Fee-setting mechanism	Revenue ($)	Cost ($)	Remissions ($)
Fees set by act, regulation or fees notice	268,369,104	616,018,366	2,492,108

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

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

This section presents, for each fee grouping, the total revenue, cost and remissions for all fees that Health Canada had the authority to set in 2022-23 that are set by any of the following:

- act
- regulation
- fees notice

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

Fees for Right to Sell Drugs: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
42,470,403	82,158,165	0

Fees for Right to Sell Licenced Class II, III, or IV Medical Devices: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
12,747,202	36,998,321	0

Fees for Examination of a Submission - Drugs for Human Use: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
77,348,705	167,648,822	82,020

Certificate of Supplementary Protection Application Fees: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
189,091	862,659	0

Fees for Examination of Medical Device Licence Applications: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
8,331,933	26,172,323	68

Fees for Examination of a Submission - Drugs for Veterinary Use Only: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
1,270,533	11,948,188	0

Drug Establishment Licensing Fees: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
27,474,467	35,477,416	0

Drug Establishment Licensing Fees - Dealer's Licences: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
810,430	5,993,762	0

Medical Devices Establishment Licensing Fees: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($) (note 1)
11,930,810	20,171,756	2,403,192

1) Remissions for 2022-23 were related to missed service standards ($2K) and to the *Medical Device Establishment Licence Fee Remission Order (Expedited Examination of Applications During the COVID-19 Pandemic)*($2.4M)[xiii]

Fees to be Paid for the Examination of an Application in Respect of a Pest Control Product: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
6,910,655	60,914,568	6,828

Annual Charge (for a registered Pest Control Product): totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
9,518,104	29,424,470	0

Fees Charged for Filing a Claim for Exemption under the *Hazardous Materials Information Review Act*: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
536,612	3,209,498	0

Cannabis Fees: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
60,196,034	123,864,676	0

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

National Dosimetry Products and Services Fees: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
7,489,532	9,621,698	0

Master File Fees: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
902,728	792,102	0

Certificate of Pharmaceutical Product Fee: totals for 2022-23

Revenue ($)	Cost ($)	Remissions ($)
241,865	759,942	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 2022-23 and that was set by any of the following:

- act
- regulation
- fees notice

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

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

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

Fees for Right to Sell Drugs

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

Fee

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

Fee-setting authority

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

Year fee-setting authority was introduced

2017

Last year fee-setting authority was amended

2023

Service standard

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

Performance result

100% (1,230/1,230 human and veterinary completed within service standard)

Application of *Low-Materiality Fees Regulations*

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Human drugs - Disinfectant (item 1)	1,449	1,505,330	0	April 1, 2024	1,684
Human drugs - Non-prescription (item 2)	2,500	5,702,098	0	April 1, 2024	3,246
Human drugs - Prescription (drug other than one referred to in item 1 or 2)	4,211	34,502,147	0	April 1, 2024	5,385

Fee
Veterinary Drugs

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

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

Performance result
100% (1,230/1,230 human and veterinary completed within the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Veterinary Drugs	437	391,261	0	April 1, 2024	552

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

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

Fee
Medical Device Right to Sell

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
20 days to update Medical Device Licence Listing database following receipt of a complete Annual Notification Package

Performance result
100% (33,985/33,985 were completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Medical Device Right to Sell	394	12,747,200	0	April 1, 2024	440

Fees for Examination of a Submission — Drugs for Human Use

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

Fee
New Active Substance

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
300 calendar days to complete Review 1

Performance result
100% (46/46 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
New Active Substance	490,666	19,353,304	0	April 1, 2024	590,346

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

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

Performance result
- 210 calendar days – N/A (0 completed in 2022-23)
- 300 calendar days – 100% (41/41 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Clinical or non-clinical data and chemistry and manufacturing data	253,015	10,795,378	0	April 1, 2024	305,690

Fee
Clinical or non-clinical data only

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

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

Performance result
- 210 calendar days – N/A (0 completed in 2022-23)
- 300 calendar days - 100% (147/147 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Clinical or non-clinical data only	104,339	13,319,587	0	April 1, 2024	122,232

Fee
Comparative studies

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

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

Performance result
- 210 calendar days - N/A (0 completed in 2022-23)
- 180 calendar days – 99.4% (162/163 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Comparative studies	59,708	8,858,805	13,934	April 1, 2024	68,889

Fee
Chemistry and manufacturing data only

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

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

Performance result
- 210 calendar days - 100% (35/35 completed within service standard)
- 180 calendar days - 99.1% (335/338 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Chemistry and manufacturing data only	34,831	12,833,858	59,899	April 1, 2024	42,384

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
120 calendar days to complete Review 1

Performance result
100% (286/286 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Clinical or non-clinical data only, in support of safety upgrades to the labelling	20,064	5,838,391	0	April 1, 2024	22,372

Fee
Labelling only

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
120 calendar days to complete Review 1

Performance result
99.7% (1023/1026 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Labelling only	4,997	4,724,915	4,489	April 1, 2024	6,161

Fee
Labelling only (generic drugs)

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
120 calendar days to complete Review 1

Performance result
100% (87/87 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Labelling only (generic drugs)	2,075	198,807	0	April 1, 2024	2,315

Fee
Administrative submission

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
45 calendar days to review

Performance result
99.9% (696/697 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Administrative submission	698	419,662	135	April 1, 2024	975

Fee
Disinfectant - full review

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

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

Performance result
- 210 calendar days - 100% (51/51 completed within service standard)
- 300 calendar days - 50% (1/2 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Disinfectant - full review	9,211	604,700	3,563	April 1, 2024	12,839

Fee
Labelling only (disinfectants)

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
90 calendar days to complete Review 1

Performance result
100% (31/31 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Labelling only (disinfectants)	2,588	93,364	0	April 1, 2024	2,886

Fee
Drug identification number application - labelling standards

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
60 calendar days to complete Review 1

Performance result
98.7% (152/154 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Drug identification number application - labelling standards	1,668	253,141	0	April 1, 2024	1,861

Certificate of Supplementary Protection Application Fees

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

Fee
Certificate of Supplementary Protection Application Fees

Fee-setting authority

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
60 days for the first eligibility decision

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

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Certificate of Supplementary Protection Application Fees	9,952	189,091	This fee was not subject to remissions	April 1, 2024	10,356

Fees for Examination of an Application for a Medical Device Licence

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

Fee
Applications for Class II licence

Fee-setting authority

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
15 calendar days to review

Performance result
99.9% (1,514/1,515 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Applications for Class II licence	522	566,577	0	April 1, 2024	615

Fee
Applications for Class II licence amendment

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
15 calendar days to review

Performance result
99.9% (987/988 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Applications for Class II licence amendment	282	233,437	68	April 1, 2024	316

Fee
Applications for Class III licence

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
60 calendar days to complete Review 1

Performance result
100% (260/260 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Applications for Class III licence	10,679	2,404,865	0	April 1, 2024	13,559

Fee
Applications for Class III licence (near patient)

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
60 calendar days to complete Review 1

Performance result
100% (8/8 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Applications for Class III licence (near patient)	20,723	110,250	0	April 1, 2024	28,884

Fee
Applications for Class III licence amendment - changes in manufacturing

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
60 calendar days to complete Review 1

Performance result
100% (28/28 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Applications for Class III licence amendment - changes in manufacturing	3,070	67,442	0	April 1, 2024	4,279

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
60 calendar days to complete Review 1

Performance result
99.0% (306/309 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Applications for Class III licence amendment - significant changes not related to manufacturing	8,780	2,330,146	0	April 1, 2024	10,884

Fee
Applications for Class IV licence

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
75 calendar days to complete Review 1

Performance result
98.0% (50/51 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Applications for Class IV licence	25,955	1,325,619	0	April 1, 2024	29,405

Fee
Applications for Class IV licence amendment - changes in manufacturing

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
75 calendar days to complete Review 1

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

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Applications for Class IV licence amendment - changes in manufacturing	3,070	84,653	0	April 1, 2024	4,279

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
75 calendar days to complete Review 1

Performance result
100% (108/108 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Applications for Class IV licence amendment - significant changes not related to manufacturing	12,128	1,132,241	0	April 1, 2024	15,558

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
15 calendar days to review

Performance result
100% (434/434 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Applications for Class II, III or IV licence or licence amendment - private label medical device	152	48,479	0	April 1, 2024	171

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

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

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

Fee-setting authority

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
120 calendar days to complete Review 1

Performance result
100% (12/12 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
1) Information, other than that referred to in item 2, to support an application for a number, including the submission of labelling material for a second review, if required	1,483	18,216	0	April 1, 2024	2,257
2) Published references or other data	1,031	0	0	April 1, 2024	1,569

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
3) Documentation to support a change of manufacturer, a change to the name of a manufacturer or a change to the brand name of a drug	516	774	0	April 1, 2024	786

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
30 calendar days to process notification

Performance result
100% (805/805 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
4) Information contained in a notification filed under subsection C.01.615(1) of the Food and Drug Regulations in respect of a veterinary health product	503	123,118	0	April 1, 2024	562

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

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

Performance result
- 300 calendar days - 100% (4/4 completed within service standard)
- 90 calendar days - 100% (1/1 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
5) Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in one animal species. (In the case of an antiparasitic drug, several indications in one food animal species.)	32,855	194,968	0	April 1, 2024	50,015
6) Efficacy and safety data (in the intended species) to support a single route of administration and dosage form for an antiparasitic drug in one non-food animal species	19,903	19,903	0	April 1, 2024	30,298

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
7) Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in two animal species, or a single route of administration, dosage form and two indications in one animal species	47,780	0	0	April 1, 2024	72,735
8) Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species	64,700	0	0	April 1, 2024	98,491
9) Comparative (pharmacodynamics, clinical or bioavailability) data to support an additional route of administration	5,965	0	0	April 1, 2024	9,079
10) Comparative (pharmacodynamics, clinical or bioavailability) data to support each additional strength	989	0	0	April 1, 2024	1,505
11) For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	44,800	17,330	0	April 1, 2024	68,199

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
12) For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of less than 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	59,724	59,724	0	April 1, 2024	90,918
13) For food-producing animals, residue depletion studies to establish a withdrawal period for an additional dosage form, dosage or route of administration	5,965	0	0	April 1, 2024	9,079
14) For food-producing animals (once an acceptable daily intake with a safety factor of 1,000 or less has been established), metabolism and residue depletion studies to establish a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in an additional species	29,853	0	0	April 1, 2024	45,446
15) Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug	9,953	45,259	0	April 1, 2024	15,150
16) Chemistry and manufacturing data to support one strength of a single dosage form	9,953	78,968	0	April 1, 2024	15,150

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
17) Chemistry and manufacturing data to support an additional strength of a single dosage form submitted at the same time as item 16	4,978	49,780	0	April 1, 2024	7,578
18) Documentation to support a change of manufacturer	516	516	0	April 1, 2024	786

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

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

Performance result
- 240 calendar days - 100% (26/26 completed within service standard)
- 90 calendar days - N/A (0 completed in 2022-23)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
19) Efficacy data to support an additional indication in one animal species	25,886	45,913	0	April 1, 2024	39,406
20) Efficacy and safety data (in the intended species) to support a single route of administration and dosage form for an antiparasitic drug in one non-food animal species	19,903	218,933	0	April 1, 2024	30,298

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
21) Efficacy and safety data (in the intended species) to support an indication in another animal species	32,855	0	0	April 1, 2024	50,015
22) Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in two animal species, or a single route of administration and dosage form and two indications in one animal species.	47,780	0	0	April 1, 2024	72,735
23) Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species	64,700	0	0	April 1, 2024	98,491
24) Efficacy and safety data (in the intended species) to support the concurrent use of two drugs approved for the same animal species	15,915	0	0	April 1, 2024	24,225
25) Comparative (pharmacodynamics, clinical or bioavailability) data to support an additional route of administration	5,965	0	0	April 1, 2024	9,079
26) Comparative (pharmacodynamics, clinical or bioavailability) data to support each additional strength	989	0	0	April 1, 2024	1,505

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
27) For food-producing animals, residue depletion studies to establish a new withdrawal period for a change in the dosage or route of administration of an approved dosage form in one species	5,965	5,965	0	April 1, 2024	9,079
28) For food-producing animals, metabolism and residue depletion studies to establish a maximum residue limit and a withdrawal period for a single dosage and route of administration of an approved dosage form in an additional species	29,853	0	0	April 1, 2024	45,446
29) For food-producing animals, toxicity studies to support a change of an established acceptable daily intake, maximum residue limit and withdrawal period	14,927	0	0	April 1, 2024	22,724
30) For the concurrent use of two drugs in a species of food-producing animals, residue depletion studies to determine if an extension to existing withdrawal periods is required	11,946	0	0	April 1, 2024	18,187
31) Chemistry and manufacturing data to support a change in the source of a medicinal ingredient or its manufacturing process	9,953	82,868	0	April 1, 2024	15,150

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
32) Chemistry and manufacturing data to support a change in formulation or dosage form	4,978	12,680	0	April 1, 2024	7,578
33) Chemistry and manufacturing data to support a change in packaging or in the sterilization process	3,972	14,988	0	April 1, 2024	6,043
34) Chemistry and manufacturing data to support an extension of the expiry dating	2,985	4,478	0	April 1, 2024	4,541
35) Chemistry and manufacturing data to support the concurrent use of two drugs	2,985	0	0	April 1, 2024	4,541
36) Chemistry and manufacturing data to support a change in the manufacturing site for parenteral dosage forms	989	989	0	April 1, 2024	1,505
37) Documentation to support a change to the name of a manufacturer or the brand name of a drug	516	0	0	April 1, 2024	786

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

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

Performance result
- 300 calendar days - 100% (17/17 completed within service standard)
- 90 calendar days - N/A (0 completed in 2022-23)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
38) Comparative (pharmacodynamics, clinical or bioavailability) data to support a single route of administration and dosage form	5,965	19,807	0	April 1, 2024	9,079
39) For food-producing animals, residue depletion studies to confirm that the withdrawal period(s) for each species falls within the conditions of use for the Canadian reference product	5,965	21,158	0	April 1, 2024	9,079

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
40) Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug	9,953	33,499	0	April 1, 2024	15,150
41) Chemistry and manufacturing data to support a single dosage form	9,953	77,842	0	April 1, 2024	15,150
42) Documentation to support (a) a change of manufacturer, in the case of an abbreviated new drug submission; or (b) a change to the name of a manufacturer or the brand name of a drug, in the case of a supplement to an abbreviated new drug submission	516	258	0	April 1, 2024	786

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

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

Performance result
- 240 calendar days - 100% (6/6 completed within service standard)
- 90 calendar days - 100% (1/1 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
38) Comparative (pharmacodynamics, clinical or bioavailability) data to support a single route of administration and dosage form	5,965	19,807	0	April 1, 2024	9,079
39) For food-producing animals, residue depletion studies to confirm that the withdrawal period(s) for each species falls within the conditions of use for the Canadian reference product	5,965	21,158	0	April 1, 2024	9,079

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
40) Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug	9,953	33,499	0	April 1, 2024	15,150
41) Chemistry and manufacturing data to support a single dosage form	9,953	77,842	0	April 1, 2024	15,150
42) Documentation to support (a) a change of manufacturer, in the case of an abbreviated new drug submission; or (b) a change to the name of a manufacturer or the brand name of a drug, in the case of a supplement to an abbreviated new drug submission	516	258	0	April 1, 2024	786

Fee
Preclinical submission (Schedule 2 items 43 to 50)

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
60 calendar days to complete Review 1

Performance result
Not applicable - no applications received

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
43) Efficacy and safety data (in the intended species) and protocol to support the conduct of clinical studies relative to a single dose form, route of administration and indication in one species	9,953	0	0	April 1, 2024	15,150
44) Efficacy data and protocol to support the conduct of clinical studies relative to a single route of administration and indication with a dosage form for which a notice of compliance has been issued for use in the species to be treated	7,959	0	0	April 1, 2024	12,114

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
45) For food-producing animals, toxicity, metabolism and residue depletion studies to establish a temporary acceptable daily intake, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	29,853	0	0	April 1, 2024	45,446
46) For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	44,800	0	0	April 1, 2024	68,199
47) For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of less than 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	59,724	0	0	April 1, 2024	90,918
48) For food-producing animals (once an acceptable daily intake with a safety factor of 1,000 or less has been established), metabolism studies to establish a withdrawal period for a single dosage form, dosage and route of administration in an additional species	14,927	0	0	April 1, 2024	22,724

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
49) Chemistry and manufacturing data to support a single dosage form containing a non-compendial medicinal ingredient	9,953	0	0	April 1, 2024	15,150
50) Chemistry and manufacturing data to support a single dosage form containing a compendial medicinal ingredient	4,978	0	0	April 1, 2024	7,578

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
2 business days to review application

Performance result
100% (493/493 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
51) Information to support the sale of a drug to be used in the emergency treatment of a non-food-producing animal	53	15,508	0	April 1, 2024	60
52) Information to support the sale of a drug to be used in the emergency treatment of a food-producing animal	106	12,869	0	April 1, 2024	120

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

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
60 calendar days to review application

Performance result
100% (118/118 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
53) Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a non-food-producing animal	1,013	27,705	0	April 1, 2024	1,130
54) Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that for a previously authorized experimental studies certificate for a drug to be administered to a non-food-producing animal	507	507	0	April 1, 2024	566

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
55) Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a food-producing animal	3,054	4,581	0	April 1, 2024	3,406
56) Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that for a previously authorized experimental studies certificate for a drug to be administered to a food-producing animal	507	0	0	April 1, 2024	566

Fee
Notifiable change (Schedule 2 item 57)

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
90 calendar days to review application

Performance result
100% (81/81 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
57) Information and material to support an application for Notifiable Change	2,674	146,260	0	April 1, 2024	4,072

Fee
Protocol (Schedule 2 item 58)

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
90 calendar days to review package

Performance result
100% (1/1 completed within service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
58) A protocol that is filed with the Minister and may support a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or abbreviated new drug submission, a preclinical submission or information and material that is filed for the purpose of obtaining an experimental studies certificate	2,674	10,696	0	April 1, 2024	4,072

Drug Establishment Licensing Fees

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

Fee
Human Drug Establishment Licence Fees

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
250 calendar days to issue/ renew license

Performance result
100% (769/769) of licences issued (human and veterinary) within 250 calendar days

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Fabrication - Sterile dosage form	43,171	1,900,683	0	April 1, 2024	48,255
Importation	31,688	10,046,066	0	April 1, 2024	37,259

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Fabrication - non-sterile dosage form	30,677	1,646,488	0	April 1, 2024	35,774
Distribution	15,691	672,397	0	April 1, 2024	19,017
Wholesaling	7,962	958,976	0	April 1, 2024	11,098
Packaging/labelling	6,255	550,691	0	April 1, 2024	6,975
Testing	4,129	201,664	0	April 1, 2024	5,757
Building outside Canada (each)	949	10,483,059	0	April 1, 2024	1,059

Fee
Veterinary Drug Establishment Licence Fees

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
250 calendar days to issue/ renew license

Performance result
100% (769/769) of licences issued (human and veterinary) within 250 calendar days

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Fabrication - Sterile dosage form	42,080	42,080	0	April 1, 2024	47,588
Importation	17,278	390,650	0	April 1, 2024	30,099
Fabrication - non-sterile dosage form	14,161	21,578	0	April 1, 2024	24,671
Distribution	7,797	30,230	0	April 1, 2024	13,583
Wholesaling	3,117	58,305	0	April 1, 2024	5,431
Packaging/labelling	6,255	0	0	April 1, 2024	6,975
Testing	2,121	1,231	0	April 1, 2024	3,695
Building outside Canada (each)	949	481,853	0	April 1, 2024	1,059

Drug Establishment Licensing Fees – Dealer's Licences

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

Fee

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

Fee-setting authority

Financial Administration Act (FAA)[x]

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

Year fee-setting authority was introduced

1998

Last year fee-setting authority was amended

- Human Drugs: 2020
- Veterinary Drugs: 2022

Service standard:

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

Performance result

- **New**: 40% (21/52) of applications were processed within the service standard
- **Renew:** 96% (165/171) of applications were processed within the service standard

Application of *Low-Materiality Fees Regulations*

Material (>$151): All fees listed below

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Dealer's Licence Fees - Human Drugs	5,613	808,410	0	April 1, 2024	5,841
Dealer's Licence Fees - Veterinary Drugs	1,882.52	14,692	0	April 1, 2024	2,098.99
Dealer's Licence Fees - Veterinary Drugs – First Year	941.26	1,789	0	April 1, 2024	1,049.50

Medical Device Establishment Licensing Fees

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

Fee
Medical Device Establishment Licensing Fees

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

Year fee-setting authority was introduced
2017

Last year fee-setting authority was amended
2023

Service standard
120 calendar days to issue/ renew licence

Performance result
99.87% (3,170 / 3,174) of licenses issued within 120 calendar days

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

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Application for new licence and annual review of licence	4,737	11,930,812	2,403,192 (note 1)	April 1, 2024	5,283

1)Remissions for 2022-23 were related to missed service standards ($2K) and to the *Medical Device Establishment Licence Fee Remission Order (Expedited Examination of Applications During the COVID-19 Pandemic)*[xiii] ($2.4M)

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

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

The following table reflects the total 2022-23 fee revenue by individual fee.

Fee	2022-23 total fee revenue ($)
Processing	1,326,482
Applications not Mentioned in Schedules	218,914
Renewal	120,942
Schedule 1: Fees for Applications to Register, or to Amend the Registration of, a Pest Control Product Other Than a Semiochemical or Microbial Agent	
Product Chemistry – active ingredient	723,149
Product Chemistry – end-use product or manufacturing concentrate	404,131
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	517,450
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains a registered active ingredient	143,163
Toxicology data-acute toxicity studies	236,659
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	186,141
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	74,295
Exposure data-other	92,221
Metabolism data	230,751

Fee	2022-23 total fee revenue ($)
Residue data	343,236
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	386,142
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	174,382
Environmental fate data-other	57,932
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	347,248
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	158,333
Environmental toxicology data-other	15,455
Value and effectiveness data for a pest control product	183,357
Identification of compensable data	365,484
Schedule 2: Fees for Applications in Respect of a Pest Control Product that is a Semiochemical or Microbial Agent	
Registration of a new active ingredient – food use	23,973
Registration of a new active ingredient – non-food use	1,645
Amendment of registration – new risk assessment necessary-environmental fate data, environmental toxicity data or exposure data	12,729
Amendment of registration – data required, label changes	22,116
Amendment of registration – data required, other	17,564
Amendment of registration – no data required	6,455
Registration of new active ingredient	2,047
Amendment of registration	2,347
Schedule 3: Fees for Other Applications in Respect of a Pest Control Product	

Fee	2022-23 total fee revenue ($)
Research authorization – major crops, other than research authorizations set out in paragraphs (c) and (d)	289,373
Research authorization – minor use crops, other than research authorizations set out in paragraphs (c) and (d)	17,160
Research authorization – microbial agents, semiochemicals and any substance listed in subparagraph 1(d) (ii) of these regulations	30,796
Research authorization – greenhouse crops and non-agricultural uses	8,022
Research notifications	14,056
Registration of active ingredient to be used in pest control product manufactured only for export	0
Amendment to Registration of active ingredient to be used in pest control product manufactured only for export	0
Specification of maximum residue limit for a previously unexamined pest control product	0
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	124,697

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
655 calendar days of Review

Performance result
92% (34/37 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Product Chemistry - active ingredient	5,383	See the total fee revenue table	0	April 1, 2024	5,601
Product Chemistry - end-use product or manufacturing concentrate	2,998			April 1, 2024	3,120
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	83,700			April 1, 2024	87,082

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Toxicology data accompanying an application to register a pest control product -or to amend a pest control product - that contains an registered active ingredient	17,479			April 1, 2024	18,186
Toxicology data - acute toxicity studies	3,264			April 1, 2024	3,397
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	19,321			April 1, 2024	20,103
Exposure data accompanying an application to register a pest control product -or to amend the registration of a pest control product -that contains a registered active ingredient, when a new risk assessment is necessary	6,360			April 1, 2024	6,618
Metabolism data	31,958			April 1, 2024	33,250
Residue data	17,489			April 1, 2024	18,196
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	47,130			April 1, 2024	49,035

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Environmental fate data accompanying an application to register a pest control product,or to amend the registration of a pest control product, that contains a registered active ingredient, when a new risk assessment is necessary	26,099			April 1, 2024	27,154
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	41,160			April 1, 2024	42,824
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	26,157			April 1, 2024	27,215
Value and effectiveness data for a pest control product	1,003			April 1, 2024	1,045
Specification of maximum residue limit for a previously unexamined pest control product	138,522			April 1, 2024	144,119
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	17,489			April 1, 2024	18,196

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
555 calendar days of Review

Performance result
100% (10/10 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Product Chemistry - active ingredient	5,383	See the total fee revenue table	0	April 1, 2024	5,601
Product Chemistry - end-use product or manufacturing concentrate	2,998			April 1, 2024	3,120
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	83,700			April 1, 2024	87,082

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	17,479			April 1, 2024	18,186
Toxicology data - acute toxicity studies	3,264			April 1, 2024	3,397
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	19,321			April 1, 2024	20,103
Exposure data accompanying an application to register a pest control product - or to amend the registration of a pest control product - that contains a registered active ingredient, when a new risk assessment is necessary	6,360			April 1, 2024	6,618
Metabolism data	31,958			April 1, 2024	33,250
Residue data	17,489			April 1, 2024	18,196
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	47,130			April 1, 2024	49,035

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Environmental fate data accompanying an application to register a pest control product, or to amend the registration of a pest control product, that contains a registered active ingredient, when a new risk assessment is necessary	26,099			April 1, 2024	27,154
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	41,160			April 1, 2024	42,824
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	26,157			April 1, 2024	27,215
Value and effectiveness data for a pest control product	1,003			April 1, 2024	1,045
Registration of a new active ingredient - food use	7,991			April 1, 2024	8,315
Registration of a new active ingredient - non-food use	4,796			April 1, 2024	4,990

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Amendment of registration - new risk assessment necessary - environmental fate data, environmental toxicity data or exposure data	3,198			April 1, 2024	3,328
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
470 calendar days of Review

Performance result
100% (4/4 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Product Chemistry - active ingredient	5,383	See the total fee revenue table	0	April 1, 2024	5,601
Product Chemistry - end-use product or manufacturing concentrate	2,998			April 1, 2024	3,120
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	83,700			April 1, 2024	87,082

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product -that contains an registered active ingredient	17,479			April 1, 2024	18,186
Toxicology data - acute toxicity studies	3,264			April 1, 2024	3,397
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	19,321			April 1, 2024	20,103
Exposure data accompanying an application to register a pest control product - or to amend the registration of a pest control product - that contains a registered active ingredient, when a new risk assessment is necessary	6,360			April 1, 2024	6,618
Metabolism data	31,958			April 1, 2024	33,250
Residue data	17,489			April 1, 2024	18,196
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	47,130			April 1, 2024	49,035

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Environmental fate data accompanying an application to register a pest control product, or to amend the registration of a pest control product, that contains a registered active ingredient, when a new risk assessment is necessary	26,099			April 1, 2024	27,154
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	41,160			April 1, 2024	42,824
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	26,157			April 1, 2024	27,215
Value and effectiveness data for a pest control product	1,003			April 1, 2024	1,045
Registration of a new active ingredient - food use	7,991			April 1, 2024	8,315
Registration of a new active ingredient - non-food use	4,796			April 1, 2024	4,990

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Amendment of registration - new risk assessment necessary - environmental fate data, environmental toxicity data or exposure data	3,198			April 1, 2024	3,328
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
285 calendar days of Review

Performance result
N/A (0 applications completed in 2022-23)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Registration of new active ingredient	642	See the total fee revenue table	0	April 1, 2024	669
Amendment of registration	323			April 1, 2024	337

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

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

Performance result
44% (11/25 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Product Chemistry - active ingredient	5,383	See the total fee revenue table	0	April 1, 2024	5,601
Product Chemistry - end-use product or manufacturing concentrate	2,998			April 1, 2024	3,120
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	83,700			April 1, 2024	87,082

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	17,479			April 1, 2024	18,186
Toxicology data - acute toxicity studies	3,264			April 1, 2024	3,397
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	19,321			April 1, 2024	20,103
Exposure data accompanying an application to register a pest control product - or to amend the registration of a pest control product - that contains a registered active ingredient, when a new risk assessment is necessary	6,360			April 1, 2024	6,618
Metabolism data	31,958			April 1, 2024	33,250
Residue data	17,489			April 1, 2024	18,196
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	47,130			April 1, 2024	49,035

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Environmental fate data accompanying an application to register a pest control product, or to amend the registration of a pest control product, that contains a registered active ingredient, when a new risk assessment is necessary	26,099			April 1, 2024	27,154
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	41,160			April 1, 2024	42,824
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	26,157			April 1, 2024	27,215
Value and effectiveness data for a pest control product	1,003			April 1, 2024	1,045
Registration of a new active ingredient - food use	7,991			April 1, 2024	8,315
Registration of a new active ingredient - non-food use	4,796			April 1, 2024	4,990

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Amendment of registration - new risk assessment necessary - environmental fate data, environmental toxicity data or exposure data	3,198			April 1, 2024	3,328
Registration of new active ingredient	642			April 1, 2024	669
Amendment of registration	323			April 1, 2024	337
Specification of maximum residue limit for a previously unexamined pest control product	138,522			April 1, 2024	144,119
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	17,489			April 1, 2024	18,196
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
425 calendar days of Review

Performance result
91% (172/189 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Product Chemistry - active ingredient	5,383	See the total fee revenue table	0	April 1, 2024	5,601
Product Chemistry - end-use product or manufacturing concentrate	2,998			April 1, 2024	3,120
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	17,479			April 1, 2024	18,186

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Toxicology data - acute toxicity studies	3,264			April 1, 2024	3,397
Exposure data - other	5,759			April 1, 2024	5,993
Metabolism data	31,958			April 1, 2024	33,250
Residue data	17,489			April 1, 2024	18,196
Environmental fate data - other	12,750			April 1, 2024	13,266
Environmental toxicology data - other	2,725			April 1, 2024	2,836
Value and effectiveness data for a pest control product	1,003			April 1, 2024	1,045
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	17,489			April 1, 2024	18,196
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
360 calendar days of Review

Performance result
98% (40/41 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Product Chemistry - active ingredient	5,383	See the total fee revenue table	0	April 1, 2024	5,601
Product Chemistry - end-use product or manufacturing concentrate	2,998			April 1, 2024	3,120
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	17,479			April 1, 2024	18,186

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Toxicology data - acute toxicity studies	3,264			April 1, 2024	3,397
Exposure data - other	5,759			April 1, 2024	5,993
Metabolism data	31,958			April 1, 2024	33,250
Residue data	17,489			April 1, 2024	18,196
Environmental fate data - other	12,750			April 1, 2024	13,266
Environmental toxicology data - other	2,725			April 1, 2024	2,836
Value and effectiveness data for a pest control product	1,003			April 1, 2024	1,045
Amendment of registration - data required, label changes	1,600			April 1, 2024	1,665
Amendment of registration - data required, other	1,282			April 1, 2024	1,335
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
240 calendar days of Review

Performance result
94% (16/17 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Amendment of registration - data required, label changes	1,600	See the total fee revenue table	0	April 1, 2024	1,665
Amendment of registration - data required, other	1,282			April 1, 2024	1,335
Amendment of registration	323			April 1, 2024	337

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
158 calendar days of Review

Performance result
96% (53/55 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Value and effectiveness data for a pest control product	1,003	See the total fee revenue table	1,106	April 1, 2024	1,045
Amendment of registration - data required, label changes	1,600			April 1, 2024	1,665
Amendment of registration - no data required, other	323			April 1, 2024	337
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

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

Performance result
43% (3/7 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Product Chemistry - active ingredient	5,383	See the total fee revenue table	0	April 1, 2024	5,601
Product Chemistry - end-use product or manufacturing concentrate	2,998			April 1, 2024	3,120
Toxicology data accompanying an application to register a pest control product - or to amend a pest control product - that contains an registered active ingredient	17,479			April 1, 2024	18,186
Toxicology data-acute toxicity studies	3,264			April 1, 2024	3,397

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Exposure data-other	5,759			April 1, 2024	5,993
Metabolism data	31,958			April 1, 2024	33,250
Residue data	17,489			April 1, 2024	18,196
Environmental fate data - other	12,750			April 1, 2024	13,266
Environmental toxicology data - other	2,725			April 1, 2024	2,836
Value and effectiveness data for a pest control product	1,003			April 1, 2024	1,045
Amendment of registration - data required, label changes	1,600			April 1, 2024	1,665
Amendment of registration - data required, other	1,282			April 1, 2024	1,335
Amendment of registration - no data required	323			April 1, 2024	337
Amendment of registration	323			April 1, 2024	337
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	17,489			April 1, 2024	18,196
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
240 calendar days of Review

Performance result
99% (332/334 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Amendment of registration - no data required	323	See the total fee revenue table	392	April 1, 2024	337
Amendment of registration	323			April 1, 2024	337
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
180 calendar days of Review

Performance result
100% (127/127 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Amendment of registration - no data required	323	See the total fee revenue table	0	April 1, 2024	337
Amendment of registration	323			April 1, 2024	337
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

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

Performance result
N/A (0 applications completed in 2022-23)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Amendment of registration - no data required	323	See the total fee revenue table	0	April 1, 2024	337
Amendment of registration	323			April 1, 2024	337
Processing	1,254			April 1, 2024	1,306

Fee
Category D Component Based - 287 days of Review (Registration Renewal**)**

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

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

Performance result
100% (1365/1365 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Registration Renewal	90	See the total fee revenue table	0	April 1, 2024	94

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
46 calendar days of Review

Performance result
75% (3/4 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Registration of active ingredient to be used in pest control product manufactured only for export	8,644	See the total fee revenue table	161	April 1, 2024	8,994
Amendment to Registration of active ingredient to be used in pest control product manufactured only for export	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
42 calendar days of Review

Performance result
99% (68/69 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Processing	1,254	See the total fee revenue table	151	April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
10 calendar days of Review

Performance result
67% (2/3 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Processing	1,254	See the total fee revenue table	314	April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
159 calendar days of Review

Performance result
72% (21/29 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Research authorization - major crops, other than research authorizations set out in paragraphs (c) and (d)	5,610	See the total fee revenue table	238	April 1, 2024	5,838
Research authorization - minor use crops, other than research authorizations set out in paragraphs (c) and (d)	5,610			April 1, 2024	5,838
Research authorization - microbial agents, semiochemicals and any substance listed in subparagraph 1(d) (ii) of these regulations	1,346			April 1, 2024	1,401

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Research authorization - greenhouse crops and non-agricultural uses	1,346			April 1, 2024	1,401

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
69 calendar days of Review

Performance result
85% (40/47 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Research authorization - major crops, other than research authorizations set out in paragraphs (c) and (d)	5,610	See the total fee revenue table	1,196	April 1, 2024	5,838
Research authorization - minor use crops, other than research authorizations set out in paragraphs (c) and (d)	5,610			April 1, 2024	5,838
Research authorization - microbial agents, semiochemicals and any substance listed in subparagraph 1(d) (ii) of these regulations	1,346			April 1, 2024	1,401

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Research authorization - greenhouse crops and non-agricultural uses	1,346			April 1, 2024	1,401

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
30 calendar days of Review

Performance result
100% (58/58 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Research notifications	276	See the total fee revenue table	0	April 1, 2024	288

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
45 calendar days of Review

Performance result
99% (796/808 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Applications not mentioned in schedules	276	See the total fee revenue table	100	April 1, 2024	288

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
425 calendar days of Review

Performance result
93% (69/74 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Product Chemistry - active ingredient	5,383	See the total fee revenue table	3,170	April 1, 2024	5,601
Product Chemistry - end-use product or manufacturing concentrate	2,998			April 1, 2024	3,120
Toxicology data accompanying an application to register a pest control product -or to amend a pest control product -that contains an registered active ingredient	17,479			April 1, 2024	18,186

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Toxicology data-acute toxicity studies	3,264			April 1, 2024	3,397
Exposure data - other	5,759			April 1, 2024	5,993
Metabolism data	31,958			April 1, 2024	33,250
Residue data	17,489			April 1, 2024	18,196
Environmental fate data - other	12,750			April 1, 2024	13,266
Environmental toxicology data - other	2,725			April 1, 2024	2,836
Value and effectiveness data for a pest control product	1,003			April 1, 2024	1,045
Identification of compensable data	2,390			April 1, 2024	2,487
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
365 calendar days of Review

Performance result
85% (68/80 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Product Chemistry - active ingredient	5,383	See the total fee revenue table	0	April 1, 2024	5,601
Product Chemistry - end-use product or manufacturing concentrate	2,998			April 1, 2024	3,120
Identification of compensable data	2,390			April 1, 2024	2,487
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
360 calendar days of Review

Performance result
100% (2/2 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Product Chemistry - active ingredient	5,383	See the total fee revenue table	0	April 1, 2024	5,601
Product Chemistry - end-use product or manufacturing concentrate	2,998			April 1, 2024	3,120
Toxicology data accompanying an application to register a pest control product -or to amend a pest control product -that contains an registered active ingredient	17,479			April 1, 2024	18,186

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Toxicology data-acute toxicity studies	3,264			April 1, 2024	3,397
Exposure data - other	5,759			April 1, 2024	5,993
Metabolism data	31,958			April 1, 2024	33,250
Residue data	17,489			April 1, 2024	18,196
Environmental fate data - other	12,750			April 1, 2024	13,266
Environmental toxicology data - other	2,725			April 1, 2024	2,836
Value and effectiveness data for a pest control product	1,003			April 1, 2024	1,045
Identification of compensable data	2,390			April 1, 2024	2,487
Amendment of registration - data required, label changes	1,600			April 1, 2024	1,665
Amendment of registration - data required, other	1,282			April 1, 2024	1,335
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
240 calendar days of Review

Performance result
N/A (0 applications completed in 2022-23)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Identification of compensable data	2,390	See the total fee revenue table	0	April 1, 2024	2,487
Amendment of registration - data required, label changes	1,600			April 1, 2024	1,665
Amendment of registration - data required, other	1,282			April 1, 2024	1,335
Amendment of registration	323			April 1, 2024	337
Processing	1,254			April 1, 2024	1,306

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

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

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

Performance result
100% (2/2 applications met the service standard)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Product Chemistry - active ingredient	5,383	See the total fee revenue table	0	April 1, 2024	5,601
Product Chemistry - end-use product or manufacturing concentrate	2,998			April 1, 2024	3,120
Toxicology data accompanying an application to register a pest control product -or to amend a pest control product -that contains an registered active ingredient	17,479			April 1, 2024	18,186

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Toxicology data-acute toxicity studies	3,264			April 1, 2024	3,397
Exposure data - other	5,759			April 1, 2024	5,993
Metabolism data	31,958			April 1, 2024	33,250
Residue data	17,489			April 1, 2024	18,196
Environmental fate data - other	12,750			April 1, 2024	13,266
Environmental toxicology data - other	2,725			April 1, 2024	2,836
Value and effectiveness data for a pest control product	1,003			April 1, 2024	1,045
Identification of compensable data	2,390			April 1, 2024	2,487
Amendment of registration - data required, label changes	1,600			April 1, 2024	1,665
Amendment of registration - data required, other	1,282			April 1, 2024	1,335
Amendment of registration	323			April 1, 2024	337
Processing	1,254			April 1, 2024	1,306

Annual Charge (for a registered Pest Control Product)

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

Fee
Annual Charge

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

Year fee-setting authority was introduced
2002

Last year fee-setting authority was amended
2018

Service standard
Invoice is issued by April 30th 2022 or within 30 days of submitting a completed form (if after April 30th)

Performance result
100% of invoices were issued on time

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Annual Charge	The lesser of $3,872.61 and 4% of the actual gross revenue during the registrant's preceding fiscal year, but not less than $107.57	9,518,104	0	April 1, 2024	The lesser of $4,317.93 and 4% of the actual gross revenue during the registrant's preceding fiscal year, but not less than $119.93

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

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

Fee

- Original Claims
- Refiled Claims

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

Fee-setting authority:

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

Year fee-setting authority was introduced
1988

Last year fee-setting authority was amended
2020

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

Performance result
100% of claims (original and refiled) were registered within the service standard of seven calendar days
Note: In-year process changes have resulted in the need to review the current service standard

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Original Claim (up to 15)	1,936.31	447,542	0	April 1, 2024	2,158.97
Original Claim (between 16-25)	430.29			April 1, 2024	479.78

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Original Claim (26+)	215.15			April 1, 2024	239.88
Refiled Claims (up to 15)	1,549.05	89,070	0	April 1, 2024	1,727.18
Refiled Claims (between 16-25)	344.23			April 1, 2024	383.82
Refiled Claims (26+)	172.12			April 1, 2024	191.91

Cannabis Fees

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

Fee
Licence Application Screening Fees

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

Year fee-setting authority was introduced
2018

Last year fee-setting authority was amended
2020

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

Performance result
The non-binding administrative standard was met 94.9% of the time.

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Licence Application Screening Fee - Licence for micro-cultivation	1,765	410,180	This fee was not	April 1, 2024	1,969

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Licence Application Screening Fee - Licence for standard cultivation	3,527		subject to remissions	April 1, 2024	3,933
Licence Application Screening Fee - Licence for a nursery	1,765			April 1, 2024	1,969
Licence Application Screening Fee - Licence for micro-processing	1,765			April 1, 2024	1,969
Licence Application Screening Fee - Licence for standard processing	3,527			April 1, 2024	3,933
Licence Application Screening Fee - Licence for sale for medical purposes	3,527			April 1, 2024	3,933

Fee
Application for a Security Clearance

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

Year fee-setting authority was introduced
2018

Last year fee-setting authority was amended
2020

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

Performance result
Not applicable

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Application for a Security Clearance	1,781	2,945,335	This fee was not subject to remissions	April 1, 2024	1,987

Fee
Application for Import or Export Permit

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

Year fee-setting authority was introduced
2018

Last year fee-setting authority was amended
2020

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

Performance result
The non-binding administrative standard was met 98.6% of the time

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Application for Import or Export Permit	658	946,464	This fee was not subject to remissions	April 1, 2024	734

Fee
Annual Regulatory Fee

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

Year fee-setting authority was introduced
2018

Last year fee-setting authority was amended
2020

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

Performance result
Not applicable

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Annual fee - Licence for micro-cultivation	as per *Cannabis Fees Order*[xx]	55,894,055	This fee was not subject to remissions	Exempt	as per *Cannabis Fees Order*[xx]
Annual fee - Licence for standard cultivation					
Annual fee - Licence for a nursery					
Annual fee - Licence for micro-processing					
Annual fee - Licence for standard processing					
Annual fee - Licence for sale for medical purposes					

National Dosimetry Products and Services Fees

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

Fee
National Dosimetry Products and Services Fees

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

Year fee-setting authority was introduced
2004

Last year fee-setting authority was amended
2017

Service standard
Provide timely, responsive and reliable dosimetry services:
1. Exposures reported to the National Dose Registry within 45 calendar days of receipt - Canadian Nuclear Safety Commission (CNSC) regulatory standard;
2. Dosimeters shipped 10-15 business days prior to exchange date with clients;
3. Dose results for whole body and extremity services reported to clients within internal service standards of 10- 20 business days, depending on the dosimetry service;
4. Client account information updated within two business days;
5. Client voice mails responded to within one business day; and
6. Client emails responded to within two business days.

Performance result
1. 100% compliance within the 45 calendar day regulatory (CNSC) standard;
2. Shipped 94% of dosimeters within 10-15 business days prior to exchange date;
3. 97% reported within internal standard of 10-20 business days, depending on the dosimetry service.
4. 91% updated within two business days;

5. 89% addressed within one business day; and
6. 94% addressed within two business days.

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Annual support	85.00	Not available	This fee was not subject to remissions	Not subject to the *Service Fees Act* and therefore no automatic annual increase: All fees All fees currently under review.	85.00
Annual support - multi-group discount (5+ groups)	50.00	Not available			50.00
Shipping and handling (per shipment)	14.50	Not available			14.50
Processing fees (per dosimeter)	5.50 to 17.50	Not available			5.50 to 17.50
Ad hoc dosimeter request - add-on (per shipment)	65.00	Not available			65.00
Priority processing request (per request)	95.00	Not available			95.00
Pregnancy service (semi-monthly)	375.00	Not available			375.00
Electronic personal dosimeter rental (per year)	415.00	Not available			415.00
Specialized consultation (per hour)	125.00	Not available			125.00
Customized reporting (per hour)	60.00	Not available			60.00
NDR dose modifications (per hour)	60.00	Not available			60.00
Reprinting reports (per report)	10.00	Not available			10.00

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Overdue dosimeter (three months after wearing period ends)	55.00	Not available			55.00
Late dosimeter (six months after wearing period ends)	55.00	Not available			55.00
Lost/damaged dosimeter	82.50	Not available			82.50
Damaged electronic personal dosimeter	415.00	Not available			415.00
Credit upon returning overdue dosimeter	28.75	Not available			28.75
Credit upon returning late or lost dosimeter	57.50	Not available			57.50

Master File Fees

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

Fee

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

Fee-setting authority

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

Year fee-setting authority was introduced
1996

Last year fee-setting authority was amended
2017

Service standard
30 calendar days

Performance result
100% (1,485/1,485 issued within 30 calendar days)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
New Master Files (file registration)	1,324	255,336	This fee was not subject to remissions	April 1, 2024	1,379
Drug Master Files – letter of access	188	266,696		April 1, 2024	196

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Drug Master Files - Update	575	417,465		April 1, 2024	599

Certificate of Pharmaceutical Product Fee

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

Fee
Certificate of Pharmaceutical Product

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

Year fee-setting authority was introduced
1996

Last year fee-setting authority was amended
2012

Service standard
25 business days to issue certificate

Performance result
97.6% (2,284 / 2,341 of certificates issued within 25 business days)

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

Fee	2022–23 fee amount ($)	2022-23 total fee revenue ($)	2022-23 total remissions issued for the fee ($)	Fee adjustment date in 2024-25	2024-25 fee amount ($)
Certificate of Pharmaceutical Product	96	239,956	This fee was not subject to remissions	April 1, 2024	100

Endnotes

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

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

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

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

[v] Remissions for missed service standards https://www.canada.ca/en/health-canada/services/funding/cost-recovery-service-fees.html#a6
https://www.canada.ca/en/health-canada/services/funding/cost-recovery-service-fees.html
[vi] Food and Drugs Act, https://laws-lois.justice.gc.ca/eng/acts/f-27/

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

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

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

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

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

[xii] 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

[xiii] Medical Device Establishment Licence Fees Remission Order (Expedited Examination of Applications During the COVID-19 Pandemic) (SOR/2023-36), https://lois-laws.justice.gc.ca/eng/regulations/SOR-2023-36/index.html

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

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

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

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

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

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

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

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

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

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