Guidance on Biocide Annual Confirmation and the Right to Sell Biocides

Health Canada Santé Canada

Canada

Date adopted: 2025/05/31
Date posted: 2025/08/15
Effective date: 2025/05/31

Health Canada is responsible for helping the people of Canada maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre:
Lignes directrices – Confirmation annuelle des biocides et frais pour le droit de vendre des biocides

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Publication date: November 2025

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Cat.: H164-391/1-2025E-PDF
ISBN: 978-0-660-79603-1
Pub.: 250313

Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

Please note that this guidance document is in effect as of May 31, 2025 and should be used for products under the *Biocides Regulations* on or after that date.

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Introduction

Once a biocide is authorized for sale in Canada, industry must pay an annual fee to retain the right to sell the biocide in Canada. Health Canada has charged fees since 1995 to recover some of the associated costs with post-market regulatory activities such as assessing safety signals and trends and communicating about risks.

Objective

This document provides guidance on how fees for the right to sell biocides will be administered in accordance with the *Food and Drugs Act* and as stipulated in the *Fees in Respect of Drugs and Medical Devices Order*.

Policy statements

A market authorization holder will be charged a fee for the right to sell a biocide each year that the biocide is on the market in Canada. For the purposes of this document, a market authorization holder is any entity or person who holds a market authorization issued for a biocide under section 11 of the *Biocides Regulations*. Fees are charged for a 12-month period which begins October 1 and ends September 30 of the following year.

Unpaid fees are subject to collection procedures in accordance with the federal government's directive on public money and receivables. Health Canada has the authority to withhold services, approvals or rights and privileges for unpaid fees.

As of May 31, 2025, new fees for biocides will be in effect. See section on Applicable fees for further details. Further, as of May 31, 2025, Health Canada:

- Will offer fee mitigation in specific circumstances. Fees may be waived or reduced for small businesses, publicly funded health care institutions and those owned by federal, provincial or territorial governments. See section on Mitigation measures for further details.
- Will charge a reduced fee in the event that a performance standard is missed. See section on Missed performance standards for further details.

Scope and application

This guidance document applies to all biocides for which a market authorization is issued and the sale of the biocide has commenced in Canada.

Guidance

This section provides detailed information on regulatory requirements, invoicing and fee payment, mitigation measures, missed performance standards, and applicable fees.

Regulatory requirements

Once an applicant has been issued a market authorization by Health Canada, the biocide is considered to be authorized for sale in Canada. However, market authorization holders must submit a first sale notification with a complete Biocide Application Form (BAF) within 30 days after commencing the sale of the biocide in Canada. For more information on how to fill out the First Sale part of the Sales-Related Information section in the BAF, please consult the BAF user guide.

Annual notification

Before October 1 of each year, biocide market authorization holders must confirm whether they are selling the biocide in Canada or have sold it in Canada in the 12 months preceding that date. In June of every year, Health Canada sends each market authorization holder the following information:

- A Biocide Annual Confirmation of Marketing Status, listing biocides with a market authorization and their respective identification numbers that, according to Health Canada records as of the date of printing, have been marketed for sale in Canada
- Instructions on how to complete the annual confirmation
- Instructions on how to apply for small business fee mitigation
- Any other information deemed necessary

Market authorization holders should submit the completed Biocide Annual Confirmation of Marketing Status and any other applicable documents by mid-August to allow Health Canada sufficient time to update information in its regulatory and financial databases prior to issuing invoices on October 1st.

Note that payment is only due upon receipt of an invoice. See section on Invoicing and fee payment for further details.

Permanent discontinuance of sale

Products deemed discontinued as of October 1, resulting from a permanent discontinuance of sale, will not be subject to Right to Sell fees. If the sale of a product has been permanently discontinued and Health Canada has not been informed before October 1, the market authorization holder is still liable for payment of the right to sell fee. For more information on how to fill out the Permanence Discontinuance of Sale part of the Sales-Related Information section in the BAF, please refer to the BAF user guide.

Invoicing and fee payment

Every October 1, Health Canada sends invoices for the upcoming year based on the information market authorization holders have provided in the Biocide Annual Confirmation of Marketing Status. The person on record as holding the market authorization when the invoice is issued is responsible for payment. The invoice and any subsequent monthly statements list the market authorization holder, and they are sent to the regulatory affairs section of the company or address identified as the billing address for the market authorization holder on the returned Biocide Annual Confirmation of Marketing Status. Payment is due 30 days from date of issuance.

Instructions on the payment of fees are further outlined in the document How to Pay Health Canada Fees. All payments must be in Canadian funds. Cheques must be made payable to the “Receiver General for Canada”.

Mitigation measures

Biocide right to sell fees can be requested to be waived or reduced for submissions or applications filed by:

- a small business
- a publicly funded health care institution
- any branch or agency of the Government of Canada or of a province or territory

To be considered for mitigation, market authorization holders must apply by indicating the type of mitigation requested on the Biocide Annual Confirmation of Marketing Status. In the case of small businesses, market authorization holders will be required to register as a small business and ensure that their registration information is kept up to date.

Small business

Market authorization holders who meet the criteria of a small business will be invoiced at the reduced fees described below. However, should Health Canada subsequently determine that the market authorization holder does not qualify as a small business, the full fee is then due. Therefore, an additional invoice will be issued for the difference between the full fee payable and the original invoice.

A small business is defined as any business, including its affiliates that:

- has fewer than 100 employees OR
- has between $30,000 and $5 million (CAD) in annual gross revenues

Note that the definition is an OR statement so you must meet one of the 2 qualifications. The annual gross revenues must also include all revenues and are not limited to the biocides being authorized for sale.

Market authorization holders that meet the above definition are eligible for a 25% reduction of the applicable right to sell a biocide fee.

Every year, market authorization holders must indicate that they are requesting small business mitigation on the Biocide Annual Confirmation of Marketing Status. Market authorization holders who have not registered as a small business will be charged the full fee. Market authorization holders must provide the following information when registering as a small business prior to submitting a Biocide Annual Confirmation of Marketing Status:

- Annual gross revenue for their last completed fiscal year
- Number of full-time or equivalent employees for their last completed fiscal year
- Fiscal year end date
- Breakdown of the above information for each affiliated company
- Contact information for all companies listed

Affiliated companies are those that:

- Are controlled by the market authorization holder's company whereby the market authorization holder's company holds 50% or more of the affiliate's votes or shares

- Control the market authorization holder's company whereby the affiliate holds 50% or more of the market authorization holder's company's votes or shares
- Share a parent company with the market authorization holder's whereby they are controlled by the same company that controls the market authorization holder's company

A company that has not yet completed a full fiscal year may estimate or project their annual gross revenue and number of employees. In these cases, Health Canada will follow up once the market authorization holder's fiscal year-end date has passed to verify their small business status.

At any time, Health Canada may ask the market authorization holder for additional information in order to verify their small business status. Information may include:

- Records that identify the number of persons employed for the previous fiscal year
- Financial statements
- Tax returns
- Corporate and/or management organization charts
- Other official documents issued or certified by a business registration authority

More information on small business mitigation can be found here.

Publicly funded health care institutions

Biocides right to sell fees will be waived for all publicly funded health care institutions.

A publicly funding institution is defined as an institution that is funded by the Government of Canada or a provincial government, and is:

a) licensed, approved or designated by a province in accordance with the laws of the province to provide care or treatment to persons or animals suffering from any form of disease or illness; or

b) owned or operated by the Government of Canada or a province and/or territory and provides health services.

Government organizations

Right to sell fees will be waived for branches or agencies of the Government of Canada or of a province or territory. For example, the Department of National Defence or the Public Health Agency of Canada will not have to pay a right to sell fee.

Missed performance standards

Performance for processing the Biocide Annual Confirmation of Marketing Status is tracked individually. In the event that Health Canada's Biocides Tracking System is not updated within 20 calendar days following receipt of a complete Biocide Annual Confirmation of Marketing Status, a 25% credit will be reflected on the invoice issued to the market authorization holder.

Applicable Fees

The biocide right to sell fee is an annual fee for the right to maintain a biocide product on the Canadian market. The applicable fee is given in section 58.1 (1) of the Fees in Respect of Drugs and Medical Devices Order. The fee is payable by the market authorization holder if they have sold the biocide in the 12 months preceding October 1. Beginning on April 1, 2026, fees will increase annually to keep up with inflation by an amount equivalent to the Consumer Price Index from the previous year. Health Canada will publish a Notice of Intent in Canada Gazette every fall specifying the fee amounts that will take effect the following April 1. Health Canada's web site will be updated accordingly.

Transition to *Biocides Regulations*

Products that are currently regulated under the *Food and Drug Regulations* (FDR) or *Pest Control Products Act* (PCPA) may transition to the *Biocides Regulations* at any time up to four years following the coming-into-force date (by May 31, 2029).

Food and Drug Regulations

All applicable fees will continue to be charged during the transition period. A disinfectant with a Drug Identification Number (DIN) assigned under the FDR will continue to be charged a Drug Right to Sell – Disinfectant fee until it is transitioned to the *Biocides Regulations*, at which point it will be charged the Biocides Right to Sell fee.

On June 1, 2029, the day following the transition period, all DINs for disinfectants that have not transitioned to the *Biocides Regulations* will be canceled.

Pest Control Products Act

A pest control product with both surface sanitizer and pesticide-related claims will continue to be subject to the annual charge during the transition period until it is transitioned to the *Biocides Regulations*. Following transition to the *Biocides Regulations*, it will be charged the Biocides Right to Sell fee.

Once transferred to the *Biocides Regulations*, or otherwise at the end of the transition period (on June 1, 2029), registered surface sanitizers with no remaining pesticide-related claims will be discontinued under the *Pest Control Products Act*, and will no longer be subject to the *Pest Control Products Act*.

General contact information

Service hours are Monday to Friday from 8 a.m. to 4 p.m. (EST) and closed statutory holidays. Emails will be responded to within 10 business days.

Invoice Inquiries

Office of Submissions and Intellectual Property By email:

annual-biocides-annuelle@hc-sc.gc.ca

Payment Inquiries

Accounts Receivable

Chief Financial Officer Branch Address Locator: 1918B

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