

Evaluation of the Biosecurity Program 2019-2020 to 2024-2025

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List of acronyms

BLSS	Biomanufacturing and Life Sciences Strategy
BSP	Biosecurity Plan
CBS	Canadian Biosafety Standard
HPTA	<i>Human Pathogens and Toxins Act</i>
HPTR	<i>Human Pathogens and Toxins Regulations</i>
iSTOP	Integrated Suite of Tools for Operational Processes
NNC	Notice of Non-Compliance
PSDS	Pathogen Safety Data Sheets
PAO	Plan for Administrative Oversight
PIP	Performance Information Profile
PHAC	Public Health Agency of Canada
RG	Risk Group
SSBA	Security Sensitive Biological Agents
SGBA	Sex and Gender-Based Analysis
WHO	World Health Organization

Executive summary

Background and evaluation scope

The Public Health Agency of Canada's (PHAC) Biosecurity Program regulates the use of human and terrestrial animal pathogens and toxins to protect the health and safety of the public through the *Human Pathogens and Toxins Act* (HPTA) and the *Human Pathogens and Toxins Regulations* (HPTR), as well as certain sections of the *Health of Animals Act* and the *Health of Animals Regulations*. The Program is designed to strengthen biosafety by preventing the accidental release of pathogens and toxins from a facility, including via an infected worker, and biosecurity by preventing the deliberate release of these agents or related information by way of an act of terrorism or other criminal activity.

This evaluation, covering fiscal years 2019-2020 to 2024-2025 with a focus on HPTA and HPTR activities, assessed the extent to which the Biosecurity Program has adapted to a changing environment, its progress towards achieving intended outcomes, and how data is leveraged to inform program activities.

Findings

Changing environment

Since the enactment of the HPTA and HPTR, the regulatory framework was primarily focused on biosafety and biocontainment, with limited requirements in biosecurity, which was considered less of an immediate threat at the time. The environment has changed. The Program now operates in an increasingly complex and evolving biosecurity landscape with threats that are growing in frequency, intensity, and variety, including direct threats such as insider activity, dual-use research of concern, and the emergence of novel pathogens. These threats are further amplified by new biosecurity risks such as cybersecurity vulnerabilities, research security considerations, advances in synthetic biology, emerging technologies and international threats.

In response to these emerging threats, the Program undertook several actions, such as establishing new biosecurity requirements for maximum containment facilities (i.e., Biosecurity Addendum) and strengthening the security screening process. [Redacted]



Biosafety encompasses containment principles, technologies, and practices used to **prevent unintentional exposure to, or accidental release of**, pathogens and toxins.

Biosecurity refers to institutional and personnel security measures used to **prevent loss, theft, misuse, diversion, or intentional release** of harmful biological agents and sensitive research information.

The Program was also impacted by the launch of the Biomanufacturing and Life Sciences Strategy (BLSS) and other COVID-19 pandemic-related drivers, including increased private sector investment in research and development and workforce development initiatives, which resulted in an increased number of licence applications from high-risk and large-scale containment facilities that require licensing and ongoing oversight. To handle the increased workload demands, the Program used various funding sources to strengthen core capacity, but these resources were time limited. The ongoing expansion of the biomanufacturing and life sciences sectors, coupled with efforts to enhance biosecurity oversight, have underscored the challenges of relying on temporary funding, particularly in keeping pace with the growth of the sectors as well as attracting and retaining qualified personnel.

Achievement of outcomes

The Program is progressing well towards achieving its expected outcomes. It has produced a substantial number of evidence-based resources to support regulated parties in meeting compliance requirements. Program data shows that 99% of identified compliance issues are classified as minor, and regulated parties implement corrective actions within established timelines. Internationally, Canada is seen as a leader in the fields of biosafety and biosecurity, consistently receiving high marks in international benchmarking assessments. Canada's contributions to various international fora are also well appreciated.

Over the last three years, the Program received temporary additional funding to strengthen core capacity. This funding helped support progress in key areas, such as processing HPTA licensing applications and security clearances, conducting biosafety and biocontainment inspections, conducting pathogen and toxin risk assessments, and enhancing the PHAC e-Learning Portal. However, backlogs and challenges persist in some areas, such as delays with the development of biosafety and biosecurity guidelines and a backlog of pathogen and toxin risk assessments, which have hindered the ability of regulated parties to access timely and relevant information. **[Redacted]**

Although the Program is making progress on achieving its outcomes, its operations have been impacted by the reliance on temporary funding, the need to build a biosecurity oversight function, and the limited availability of biosecurity expertise within PHAC, the Government of Canada, and across the life sciences research sector. **[Redacted]** Nonetheless, improvements were made to address some challenges, as outlined above.

Finally, the modernization of the Program's primary case management system, the Integrated Suite of Tools for Operational Processes (iSTOP), was met with a series of setbacks that led to significant project delays outside of PHAC's control, and the need for additional resources to advance the project.

The system is currently at end-of-life, and its migration to a cloud-based system is a key part of this project, which will be critical for supporting continual updates and maintenance.

Data use

The Program leverages data to inform activities and decision making by using, for example, inspection and incident reporting data to target compliance promotion. Individual program areas identify, track, and analyze systematically recurring biosafety issues, and inform regulated parties of major issues. However, there are opportunities to further strengthen performance indicators to better align with the evolving context in which the Program operates and its intended outcomes.

Recommendations

Recommendation 1: Continue modernizing the biosecurity oversight framework, including:

- **clarifying and aligning biosecurity direction with policy direction;**
- **continuing to enhance stakeholder engagement activities to respond to biosecurity information needs;**
- **continuing to revisit the Advisory Committee on Human Pathogens and Toxins (AC-HPT)'s composition to ensure a relevant and diverse mix of expertise; and**
- **ensuring that, once the modernized iSTOP is deployed, mechanisms are in place to reflect the updated regulatory oversight framework.**

[Redacted]. Once the modernized iSTOP is deployed, the Program should make efforts to ensure that the system can accommodate future updates to the regulatory framework, so that it remains current and adaptable.

Recommendation 2: Identify, stabilize, and maintain critical core activities to comply with current and evolving legislative requirements and roles.

The Program has relied on additional temporary and ad-hoc funding to conduct its core oversight activities. Although the additional funding has allowed the Program to keep pace in most areas, progress in biosecurity oversight has been limited, and the approach may not be sustainable in the long term given the growth of the biomanufacturing and life sciences sectors, and the possibility of an expanding biosecurity mandate. While pursuing regulatory modernization, the Program should clearly identify and articulate the activities that are essential to carry out its regulatory mandate in the medium to long term, based on current and anticipated funding, as well as consider what ongoing ad-hoc mechanisms can help address short-term needs. Activities that need to be carried out on an ongoing basis would benefit from more precise, risk-based approaches, such as establishing a feasible and proportionate number of Biosecurity Plan (BSP) evaluations in relation to the volume and risk group of active licences. [Redacted]

Recommendation 3: Strengthen performance measurement indicators to support decision making.

The Program has a strong evidence-based culture, and it uses data for planning and decision making on an ongoing basis. To continue building on these strong practices, further improvements to a few performance measurement indicators are needed to more effectively measure program outcomes. In addition, the Program should ensure that the Performance Information Profile (PIP) reflects modernization, as appropriate.

Management Response and Action Plan

Recommendation 1: Continue modernizing the Biosecurity oversight framework, including the following measures:

- clarify and align biosecurity guidance with policy direction;
- continuing strengthening communication activities with stakeholders to meet information needs regarding biosecurity;
- continuing reviewing the composition of the Advisory Committee on Human Pathogens and Toxins (AC-HPT) to ensure a relevant and diverse mix of expertise and skills; and
- ensure that once the modernized iSTOP system is deployed, mechanisms are in place to reflect the updated regulatory monitoring framework.

Management response

Management agrees with the recommendation.

Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
1. Continue advancing the modernization of the biosecurity oversight framework by pursuing proposed amendments to the <i>Human Pathogens and Toxins Act</i> (HPTA) and supporting the phased implementation of any resulting authorities or related measures. This includes updating stakeholder guidance, internal policies, and	1.1.1 Submit a comprehensive planning package to support the advancement of proposed amendments through formal planning and approval processes	March 2026	Director General, Centre for Biosecurity	A-Base and B-Base resources
	1.1.2 Modernized oversight implementation tracker	March 2026	Director General, Centre for Biosecurity	A-Base and B-Base resources
	1.1.3 [Redacted]	[Redacted]	[Redacted]	[Redacted]
	1.1.4 [Redacted]	[Redacted]	[Redacted]	[Redacted]

other consequential instruments as applicable. In parallel, implement the <i>Biosecurity Addendum</i> for maximum containment (CL4) facilities by developing stakeholder-facing resources (e.g., guidance materials) and internal protocols that enable risk-based application of biosecurity oversight. Together, these efforts will align biosecurity direction with evolving policy priorities and better address stakeholder information needs.				
2. Build on progress to date to strengthen biosecurity expertise within the AC-HPT by revising the AC-HPT Terms of Reference to more explicitly distinguish biosecurity from biosafety and consider including related domains (e.g., physical security, threat/risk assessment) to the competency; as vacancies arise, run targeted recruitment to increase representation in these areas.	1.2.1 Approved ToR, which includes biosecurity and biosafety expertise distinction and adds related domains into member competency requirements 1.2.2 Targeted recruitment call-out materials, prioritizing biosecurity and related domains	March 2026 June 2026	Director General, Centre for Biosecurity Director General, Centre for Biosecurity	A-Base and B-Base resources A-Base and B-Base resources
3. Maintain operational integrity of the legacy iSTOP system until the modernized cloud platform	1.3.1 ISTOP Legacy on-premise technology upgrade plan	April 2026	Lead: Director General, Centre for Biosecurity	Resource requirements will depend on the duration for which the legacy system must be

is deployed, and manage a rolling multi-year planning and requirements tracking framework that guides system development, release planning, and the prioritization of enhancements in line with evolving authorities, program needs, and available funding.

			Support: Digital Transformation Branch	sustained prior to full cloud deployment, with the potential need for funding beyond the existing budget envelope
1.3.2 2026-27 MOU between CB and DTB for iSTOP	May 2026		Lead: Director General, Centre for Biosecurity Support: Digital Transformation Branch Lead: Director General, Centre for Biosecurity Support: Digital Transformation Branch	A-Base and B-Base resources A-Base and B-Base resources. Incremental resources may be required for plan implementation.

Recommendation 2: Identify, stabilize, and maintain essential activities to comply with legislative requirements and current and evolving roles.

Management response

Management agrees with the recommendation. The completion of the proposed action and deliverable is pending policy and funding decisions.

Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
2.1 Continue to employ a risk-informed approach to prioritize biosafety and biosecurity oversight activities, aligning	2.1.1 Operational plan that confirms risk-informed oversight	May 2026	Director General, Centre for Biosecurity	A-base and B-base resources

implementation with confirmed policy direction, funding, and program demands.	priorities and resource allocations			
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Recommendation 3: Strengthen performance measurement indicators to support decision making.

Management response

Management agrees with the recommendation.

Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
3.1 The Program will strengthen performance measurement by reviewing and updating the Biosecurity Program Performance Indicator Profile (PIP), including revising the logic model, refreshing the indicator inventory, and integrating modernization requirements and new authorities as they come into force. A phased approach will ensure the PIP reflects authorities in force effective FY2026-27, with further updates as additional regulatory elements are implemented.	3.1.1 Updated Performance Indicator Profile (PIP) that addresses identified deficiencies and incorporates in-force authorities	March 2027	Director General, Centre for Biosecurity	A-base and B-base resources

Program description

The Public Health Agency of Canada’s (PHAC) Biosecurity Program regulates the use of human and terrestrial animal pathogens and toxins to protect the health and safety of the public through the *Human Pathogens and Toxins Act* (HPTA) and the *Human Pathogens and Toxins Regulations* (HPTR), as well as certain sections of the *Health of Animals Act* and the *Health of Animals Regulations*. The Program is housed in the Centre for Biosecurity, which is part of the Regulatory, Operations and Emergency Management Branch.

The Program is designed to strengthen biosafety by preventing the accidental release of pathogens and toxins from a facility, including via an infected worker, and biosecurity by preventing the deliberate release of these agents or related information by way of an act of terrorism or other criminal activity.

Any regulated activity, such as the use, production, storage, or importation of human pathogens classified as Risk Group (RG) 2, 3, or 4, or of toxins listed in Schedule 1 to the HPTA, must be conducted under a valid licence issued by PHAC. Table 1 outlines the characteristics of each RG (1 through 4), highlighting the potential risks they pose to individuals and the broader community.

Biosafety encompasses containment principles, technologies, and practices used to **prevent unintentional exposure to, or accidental release of**, pathogens and toxins.

Biosecurity refers to institutional and personnel security measures used to **prevent loss, theft, misuse, diversion, or intentional release** of harmful biological agents and sensitive research information.

Table 1: Description of Risk Group categories

Risk Group	Individual Risk	Community Risk
RG1	No or Low	Low
RG2	Moderate	Low
RG3	High	Low
RG4	High	High

In Canada, all facilities handling or storing RG2 or higher human pathogens or toxins, such as public health, teaching, research and diagnostic laboratories, as well as vaccine production plants, are regulated under the HPTA. Organizations may consolidate several facilities under one licence or hold separate licences for each, so the number of licences does not directly reflect the number of regulated sites. Tables 2 and 3 provide an overview of the number of active licences by RG over the past six years.

Table 2: Number of active licences by RG from 2019-2020 to 2024-2025

Fiscal Year	RG2	RG3/SSBA	RG4/SSBA	Total
2019-2020	930	67	2	999
2020-2021	938	68	2	1,008
2021-2022	943	67	2	1,012
2022-2023	983	69	2	1,054
2023-2024	983	73	2	1,058
2024-2025	969	71	2	1,042

Source: Program administrative data

Notes:

- Reflects year-end totals for each fiscal year shown and does not capture in-year fluctuations.
- RG3/SSBA includes SSBA Toxins

Security Sensitive Biological Agents (SSBAs) are a subset of high-consequence RG3 and RG4 human pathogens and prescribed toxins. Due to their dual-use potential, SSBAs pose a threat to national security if misused. The Program issues licences according to both the risk group and SSBA classification. Licences that cover SSBAs include additional conditions: anyone accessing areas where SSBAs are handled must either hold a valid HPTA Security Clearance or be accompanied and directly supervised by someone who does.

Table 3: Number of active licences with an SSBA designation (August 13, 2025)

Licence Type	Number of Active Licences
RG3 SSBA	19
SSBA Toxin	5
RG4 SSBA	2
Total	26

The Program also supports the domestic implementation of Canada's international biosafety and biosecurity commitments, including the World Health Organization's (WHO) International Health Regulations, the Biological and Toxin Weapons Convention, and the United Nations Security Council Resolution 1540, which collectively support global efforts to prevent the misuse of biological agents and strengthen national oversight systems.

Evaluation scope and approach

This evaluation examined to what extent the Biosecurity Program has adapted to a changing environment, its progress towards achieving intended outcomes, and how data is leveraged to inform program activities. The evaluation focused on activities related to the

implementation of the existing regulatory framework, as well as ongoing work to modernize the biosecurity oversight framework from fiscal years 2019-2020 to 2024-2025. It also followed up on the previous [Evaluation of the Human Pathogens and Toxins Act and Regulations Framework](#) and was guided by the following questions:

- How has the Biosecurity Program adapted to the evolving environment?
- What progress has the Biosecurity Program made towards achieving its intended outcomes in support of reducing the public health risks associated with the use of pathogens and toxins?
- To what extent is data being used to inform program activities and decision making?

To address the evaluation questions, information was collected from documents, performance information, literature, and financial data, as well as interviews with internal staff and external partners and stakeholders. See Appendix A for a more detailed description of the methodology.

Findings

The following sections present the evaluation's findings on the Program's evolving environment, achievement of outcomes, and data use.

Adapting to an evolving environment

Key takeaways: The Program is operating in an increasingly complex and evolving biosecurity landscape and has adapted its activities to address emerging threats and a growing workload.

Over the evaluation period, the Program was heavily involved in the COVID-19 pandemic response and it was subsequently affected by, among other factors, the launch of Canada's [Biomufacturing and Life Sciences Strategy \(BLSS\)](#)¹, which contributed to a growing number of high-risk and large scale containment facilities that require licensing and ongoing oversight.² As of May 2025, approximately 38 projects were being planned or underway, including an application for the first non-Government of Canada maximum containment laboratory. In addition, there has been an increase in licence renewals. Figure 1 provides an overview of the number of licences processed over the past six years, which

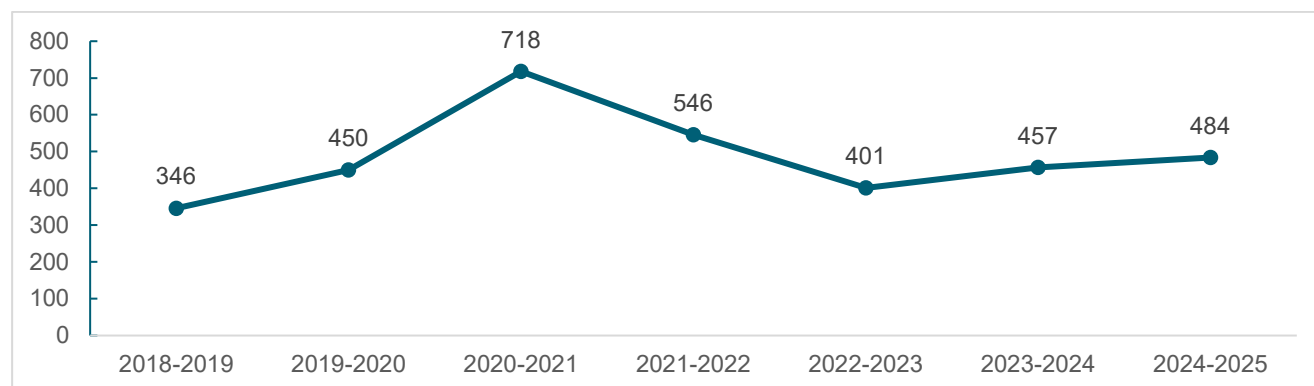


Adapting to COVID-19

During the COVID-19 pandemic, the Program scaled down its non-critical activities and mobilized its resources towards pandemic response efforts. Critical operations, such as HPTA licensing, continued, and adaptations such as virtual inspections were initiated.

includes new applications, renewals, or variations to existing licences.

Figure 1: Number of licence applications processed by fiscal year



Source: Program administrative data

Notes:

- Includes new applications, renewals, variations to a licence, and cancellations.
- The increase in licence applications in fiscal years 2020-2021 and 2021-2022 reflects both a surge in RG2 licence renewals, due to expiring five-year licences, and additional COVID-19 pandemic-related demands such as processing SARS-CoV-2 applications.

The section under “Immediate outcome 2” provides more information about activities supporting the BLSS. Although demand has increased, the Program was not identified as a funded partner under the BLSS and did not receive additional resources to cover the resulting costs.

To date, the regulatory framework primarily focused on biosafety and biocontainment because the main concern has been accidental exposure or release of pathogens. When the HPTA and HPTR came into effect in December 2015, deliberate threats seemed less urgent, so the framework included limited biosecurity-specific requirements. Canada is facing an increasingly complex and dynamic biosecurity risk environment, with threats that are growing in frequency, intensity, and variety. These include direct threats such as insider activity, dual-use research of concern, and the emergence of novel pathogens. Additionally, there are other factors that can increase or introduce new biosecurity risks, including cybersecurity

What is dual-use research of concern?



PHAC defines dual-use potential as the qualities of a pathogen or toxin that allow it to be either used for legitimate scientific applications (e.g., commercial, medical, or research purposes), or intentionally misused as a biological weapon to cause harm (e.g., bioterrorism).

The Program, in collaboration with Canadian Food Inspection Agency, developed the [Canadian biosafety guideline : dual-use in life science research](#) to help identify and mitigate dual-use potential in research involving

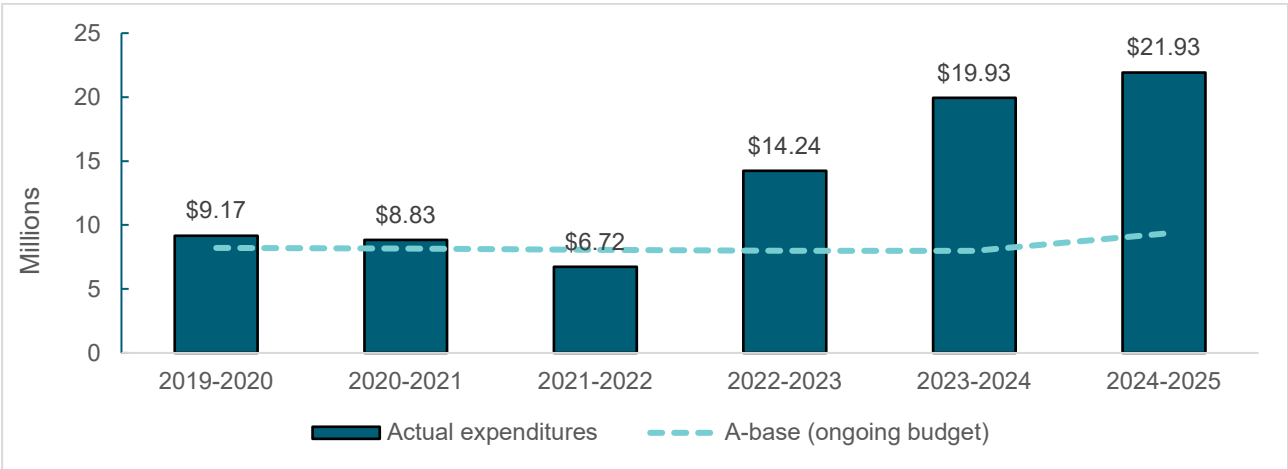
vulnerabilities, research security considerations, advances in synthetic biology, emerging technologies (e.g., AI), and international threats.

In response to emerging threats, the Program undertook several proactive measures. These included sharing cybersecurity advisories and guidance through stakeholder bulletins, implementing ongoing compliance monitoring of Plans for Administrative Oversight (PAOs) to assess institutional oversight of dual-use potential in research, and delivering webinars and e-learning sessions on dual-use research of concern.³ [Redacted]

Although the Program has taken measures to address emerging threats, challenges remain. Efforts to modernize the regulatory framework have been underway since 2022-2023 to address these biosecurity oversight challenges; however, legislative and regulatory changes are complex, require additional processes and approval outside of PHAC, and take time. In the interim, the Program published the Biosecurity Addendum to the Canadian Biosafety Standard, Third Edition (CBS), in December 2024 to establish additional requirements for the maximum containment facilities (i.e., CL4). It comes into effect as a condition of licence for those facilities on January 5, 2026.⁴

In response to increased demands, the Program leveraged multiple funding vehicles to expand its workforce. As a result, the Program’s annual expenditures have doubled in size (see Figure 2), with many of its activities supported by temporary funding sources (see Table 10 in Appendix B for more details). Some of this additional funding extends through the end of 2026-2027.

Figure 2: Actual expenditures by fiscal year



Source: Program financial data

Note: Actual expenditures include core funding (i.e., A-base) and temporary funding (i.e., B-base and internal reallocations) with the exception of temporary COVID-19 funding which is presented in Table 8, Appendix B.

The COVID-19 pandemic significantly disrupted normal operations during fiscal years 2020-2021 and 2021-2022 as many employees were redeployed to support emergency response efforts. Most activities, such as non-critical inspections and compliance promotion, were paused. As such, most of the Program's A-base resources were supporting border travel health related COVID-19 response activities, which led to deviations from planned spending profiles. Even though the Program was scaled down during the COVID-19 pandemic, it still received additional temporary COVID-19 funding for biosafety and biosecurity related functions in support of the pandemic response. Overall, approximately \$5 million in temporary COVID-19 funding supported enhanced monitoring and analysis of rapidly evolving scientific information, timely pathogen risk assessment, the development of guidance documents, updates to containment recommendations, and targeted outreach to regulated parties (see Table 8 in Appendix B). Although temporary funding allowed the Program to manage growing workload and strengthen its core activities, stable long term funding remains uncertain, which has presented challenges for workforce recruitment/retention and operational planning.

Appendix B presents year-end budget and actual expenditures while variance analyses are discussed in the "Financial Analysis" section.

Progress towards achieving outcomes

The Program is effectively achieving its intended outcomes, particularly in the areas of biosafety and biocontainment oversight activities. This is demonstrated by enhanced inspection capacity, consistently high compliance rates, and the increased development and uptake of guidance materials. However, challenges persist in the area of biosecurity oversight. While regulatory modernization is underway, and interim measures for maximum containment facilities are planned for implementation in January 2026, regulated parties continue to face uncertainty in meeting upcoming biosecurity requirements. Additionally, despite improvements to the security clearance review process, many applications remain complex and require significant time and expertise from the Program to review.

Immediate outcome 1: Regulated parties are informed of legal and regulatory requirements

Key takeaways: Following stakeholder consultations, the Program enhanced its outreach to regulated parties by developing and publishing new guidance materials that are widely used and highly regarded. However, delays in developing guidelines and a backlog of pathogen and toxin risk assessments have limited regulated parties' access to timely and relevant information.

The Program provides guidance to regulated parties through the [Canadian Biosafety Standard \(CBS\)](#), [Pathogen Safety Data Sheets \(PSDS\)](#), and the [ePATHogen Risk Group Database](#), and various specific biosafety guidelines and information sheets. Additional guidance is provided through training courses, webinars, podcasts, and the Program's quarterly bulletins.⁵ The Program undertakes ad hoc stakeholder consultations to assess whether the materials meet the needs of regulated parties.⁶ See the "Impact of collaborations" section for more detail.

Canadian Biosafety Standard (CBS)

The third edition of the CBS was released in November 2022 and came into effect on April 1, 2023. The new edition clarified the biosafety and biosecurity intent of its requirements, helping regulated parties better understand the rationale behind each provision, among other changes.⁷ The updates were informed by stakeholder feedback through extensive consultations led by the Program and in collaboration with the Canadian Food Inspection Agency.⁸ The Program hosted a two-part webinar series after the CBS release to update stakeholders on key changes, share public consultation feedback, and answer questions.⁹

The third edition of the CBS is available online and has a mobile application. Since its release, the CBS web page has received over 81,300 views, with a daily average of 83 views. The majority of web page views were from Ontario (35,736) and a considerable number from outside of Canada (9,785). The CBS mobile application provides users with customized requirements and automatically updates when standards change. It has been downloaded over 2,600 times since it was updated in September 2023.

Pathogen Safety Data Sheets

The Pathogen Safety Data Sheets (PSDS) describe the hazardous properties of a human pathogen and recommend mitigation measures when working with these agents in a laboratory setting. Additional temporary capacity since 2022-2023 allowed the Program to address some backlogs and complete a higher number of PSDS annually. In 2024-2025,

the Program completed 35 PSDS, a significant increase over the previous annual average of 7 PSDS completed prior to 2022-2023. However, only 25% of PSDS (56 out of 222) are current, meaning they have been developed or updated in the last five years. The proportion of published PSDS considered current (i.e., less than five years old) rose from just 4% in 2022-2023 to 25% by the end of 2024-2025. Although the Program aims to review and update all PSDS on a five-year cycle, a significant backlog remains.

Of note, the PSDS web page is one of PHAC's most widely accessed pages, with over 1,235,000 page views in 2024-2025. The PSDS application has also been downloaded over 29,500 times since January 2020.

Pathogen and Toxin Risk Assessments

The Program conducts pathogen and toxin risk assessments to evaluate risks associated with pathogens and/or toxins that are uncharacterized or may have been modified. These assessments are essential for determining appropriate risk classifications and are a prerequisite for licensing and containment decisions. The Program also supports other government departments (OGDs), such as Health Canada and Environment and Climate Change Canada, by conducting these risk assessments under existing Memoranda of Understanding (MOUs) to inform their regulatory decisions.

Prior to 2022, the Program completed an average of 77 risk assessments annually, which is well below the volume of approximately 140 requests received each year, resulting in a growing backlog. With the support of temporary capacity, the Program significantly increased its output over the years to complete 284 assessments in 2023-2024 and 231 in 2024-2025, both significantly above the target of 155. According to the Program, they completed 53 fewer risk assessments in 2024-2025 than the previous year, due to reduced capacity and delays in contracting help to support backlog reduction. By the end of 2024-2025, a backlog of 415 active requests remained: 71 requests awaited information, 179 were in progress, and the Program had not yet started work on 165 requests. Notably, according to the Program, some requests in the latter category include, for example, those that fall outside of the scope of the HPTR or are duplicates.

Finally, although the Program has made progress in addressing current demand and reducing backlogs, potential upcoming regulatory changes are expected to increase demand for risk assessments.

ePATHogen Risk Group Database

The ePATHogen Risk Group Database is a searchable online tool that provides regulated parties with authoritative information on biological agents (pathogens and toxins). Drawing from the Program's pathogen and toxin risk assessments and containment level assessments, it provides information on the associated human and animal risk group classifications, their required CLs, SSBA status, regulatory authority and various containment considerations. The database, updated regularly to reflect new assessments and regulatory changes, supports laboratory biosafety and biosecurity professionals, institutions and researchers in maintaining compliance. As of March 31, 2025, there were nearly 6,700 pathogens listed in the database, with over 33,000 page views in the past year from visitors across Canada, the United States, Taiwan, Australia, and Peru.

Training Portal

The Program also disseminates information to regulated parties and other stakeholders through the [PHAC Training Portal](#), which hosts a variety of resources including webinars and podcasts, e-learning courses, printable resources, templates, and quarterly bulletins. The Portal's number of users grew from over 41,000 active users in 2023-2024 to approximately 54,000 active users in 2024-2025, including regulated parties and staff from PHAC, Health Canada, the Canadian Food Inspection Agency, and Statistics Canada. It is also used internationally, with significant uptake of 20% coming from other countries, such as the United States, India, and France. From August 1, 2024 to March 31, 2025, the Portal had close to 160,000 active sessions. Of note, user data does not differentiate between Biosecurity Program users and other portal users, though webinar data shows an increasing trend for biosecurity learning.

With a streamlined publishing process that leverages automation and AI, the Portal has seen efficiency gains. While temporary resources and automation have enabled the Portal team to meet current needs, internal interviewees noted the importance of securing permanent funding to ensure long term sustainability.

Although the Program has developed multiple guidance materials that are made available through a variety of channels, some regulated parties require further communication and support for biosecurity provisions and institutional controls. A few interviewed regulated parties indicated a need for clearer regulations for high containment laboratories, more transparency on HPTA licensing processes, and better guidance for PAOs. The Program acknowledges that more could be done in these areas and is currently developing additional biosecurity educational materials.

Immediate outcome 2: Regulated parties have adequate institutional controls to conduct the activities for which they are licenced

Key takeaways: The Program made significant progress in ensuring regulated parties have adequate institutional controls, largely due to temporary increases in capacity. Expanded activities helped address ongoing challenges and meet rising demands in the biomanufacturing and life sciences sectors. However, there is a persistent backlog of security clearances.

Licensing and Compliance Promotion

The Program launched a new Baseline Containment Assessment process for Risk Group 2 licences¹⁰ and a new online data monitoring compliance verification and promotion process that includes reviewing open data searches, consulting with external informants, and reviewing border monitoring data.

Other key achievements over the last six years included supporting the COVID-19 pandemic response by prioritizing and expediting licence applications to work with SARS-CoV-2 and other emerging public health issues¹¹ as well as managing a licensing renewal surge.

Pre-licensing engagements

The Program has supported the rapid growth of Canada's biomanufacturing and life sciences sectors through early engagement and targeted guidance to upgraded and new high-containment and large-scale production facilities. Since 2020-2021, the Program completed a total of 95 pre-licensing engagements (see Figure 3), including:

- 75 compliance promotion meetings with facility proponents to provide early guidance on biosafety and biosecurity requirements.
- 14 pre-licensing inspections to assess critical infrastructure elements, such as HVAC, piping, and electrical systems, before they are concealed by construction.

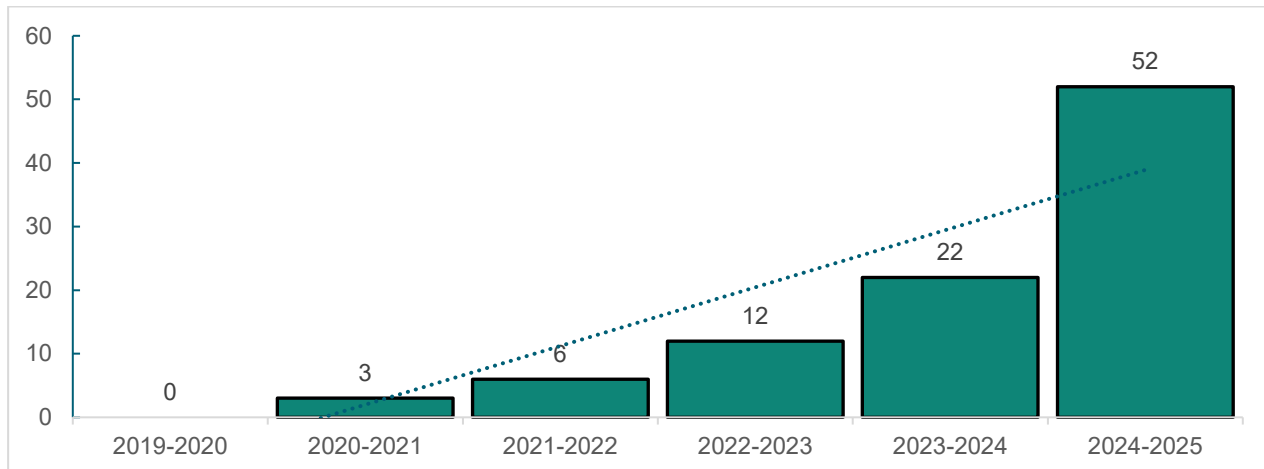
Baseline Containment Assessment



PHAC introduced the Baseline Containment Assessment process, a risk-based process for directly engaging new organizations applying for their first RG2 licences. It helps establish baseline biosafety compliance, identify potential risks, and determine whether additional safeguards are needed before a licence can be issued.

- 6 pre-licensing inspections to verify that facilities meet all regulatory standards before a licence is issued.

Figure 3: Number of pre-licensing engagements with new or upgraded high containment and large-scale production facilities

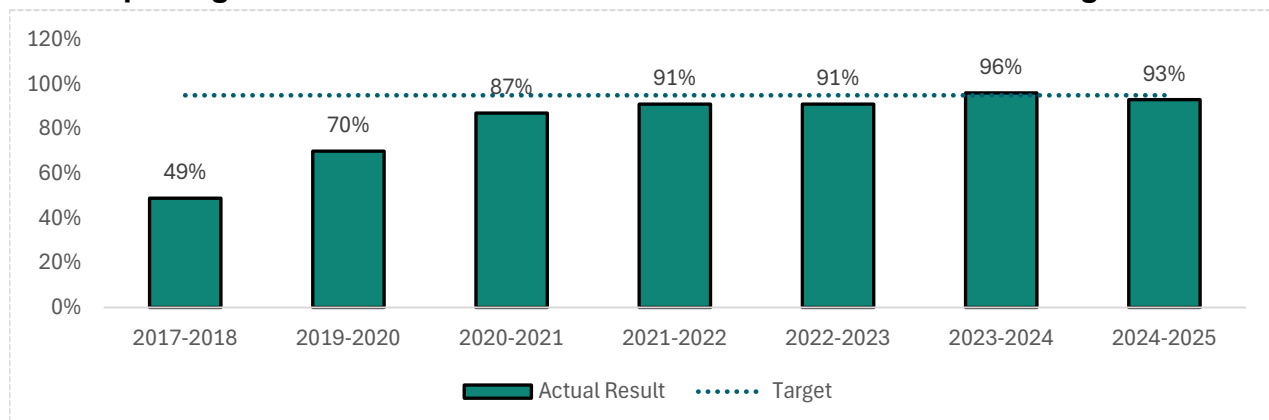


Source: Program administrative data

Plan for Administrative Oversight

Under the HPTA and HPTR, institutions conducting scientific research are required to have a risk management plan that demonstrates how biosafety and biosecurity risks will be effectively managed. The Program has established the Plan for Administrative Oversight (PAO) as the standard approach to meeting this requirement. The Program evaluates PAOs during the licensing process and ongoing compliance and monitoring activities.¹² Following the COVID-19 pandemic, capacity to review PAOs was resumed and enhanced, increasing from completing 3 reviews in 2020-2021, to 75 in 2023-2024, and 69 in 2024-2025.

Figure 4: Percentage of facilities licenced to conduct scientific research with human pathogens and toxins with a PAO assessed as consistent with guidelines



Source: Program administrative data

Note: In fiscal year 2024-2025, the Program implemented a target-based process

As highlighted in Figure 4, the Program's approach to PAO compliance has proven effective, since 96% of all licences requiring a PAO fully adhered to applicable guidelines in 2023-2024, which is up from 70% in 2019-2020. With the original target of 95% surpassed, the Program evolved its approach in 2024-2025. It now assesses PAOs from new applicants and current licence holders that are making biosafety program changes. Additionally, it conducts annual compliance verification sampling of other organizations, prioritizing those whose last review was the longest ago.

Regulated parties would, however, benefit from further guidance on PAOs, as noted by respondents from a 2024 survey of licensed parties. Although 86% of respondents found that the proposed update to PAO expectations to the CBS was clear and understandable, some noted that certain PAO elements needed to be clarified. They commented on the expectations for adherence, such as frequency for ongoing review, scope, risk assessment, communication plans, and duplication with CBS requirements. The Program plans to update the PAO guidance document and training to respond to stakeholder requests.

Security clearance issuance

Security clearance review and issuance is a critical biosecurity measure that safeguards the appropriate access to, and use of, high-consequence human pathogens and toxins, while supporting their responsible use in Canadian research. Over the evaluation period, the Program increased its capacity to process and review security clearances. Additionally, in response to the last internal evaluation, the Program strengthened its security clearance process, including the introduction of more comprehensive scientific security screenings.¹³

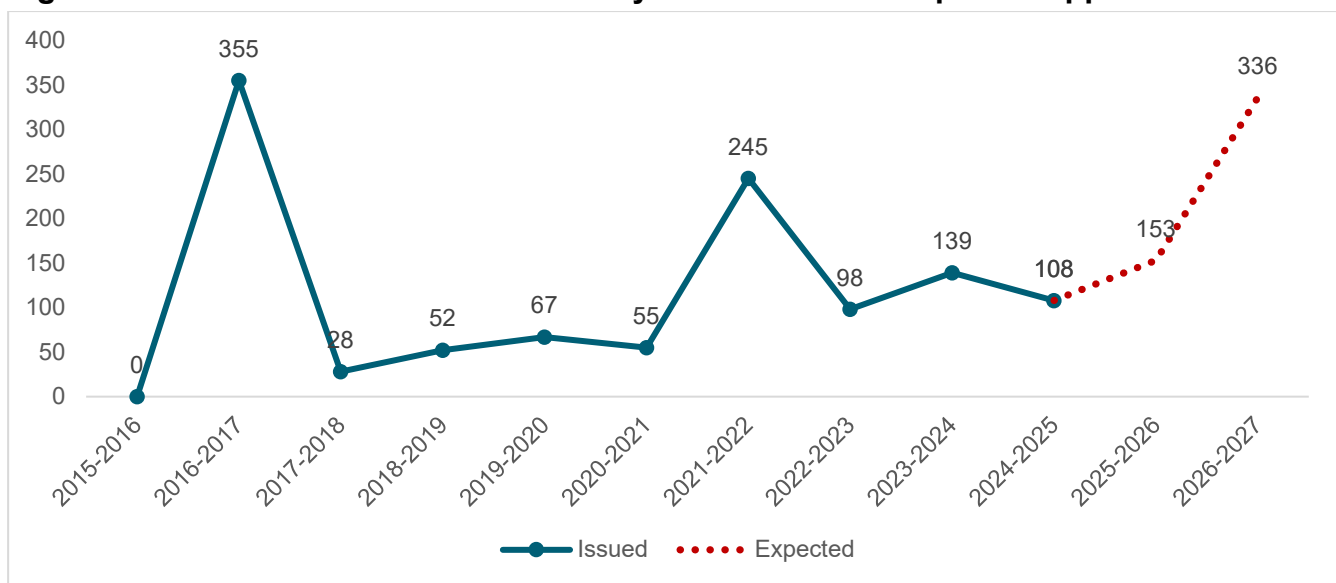
Performance data for security clearance decisions issued within the established service standard shows a five-year average result of 93%, exceeding the 80% target (see Appendix C). However, this only applies to standard cases that do not involve missing or potential adverse information. Taking this into account, as of July 2025, the majority (62%, 49 out of 78) of applications did not meet the conditions for the service delivery standard and were experiencing significant processing delays that have ranged from 200 to more than 400 days to process. These non-standard cases vary in complexity. Most (59%, 29 out of 49) were highly complex files involving sensitive considerations or external factors that require extended processing times.

The backlog of complex security clearances is due to many factors. These include a significant increase in depth and volume of scientific security screenings, which more than doubled from 26 cases in 2023-2024 to 58 in 2024-2025, as well as the inherent

complexity of these reviews. Additionally, staffing and operational challenges, such as reliance on temporary staff and the need for highly specialized personnel, have further contributed to delays in processing.

Moreover, as a result of sector investments, more laboratories will be working with SSABs, leading to a projected increase in HPTA security clearance applications in the coming years (see Figure 5). [Redacted]. Interviews with external stakeholders and supporting documentation highlighted that the timeliness of security clearance issuance is a concern, particularly due to its impact on hiring and onboarding scientists in regulated facilities.

Figure 5: Number of issued HPTA security clearances and expected applications



Source: Program administrative data

Notes:

- Increases in HPTA security clearances in 2016-2017 and in 2021-2022 align with the HPTA and HPTR coming into force in December 2015 and the five-year renewal cycle for HPTA security clearances.
- The projected number of applications is based on current regulatory authorities and does not take into account regulatory modernization, which is expected to result in increased applications.

The Program put in place mitigation measures to address the backlog, such as communication with regulated parties on how to avoid delays, and additional support from internal reallocations. [Redacted].

Immediate outcome 3: Regulated parties proactively address biosafety and biosecurity risk

Key takeaways: Regulated parties do not always submit incident reports in a timely way. These reports are analyzed by the Program's various activity areas to identify recurring issues and develop guidance materials to help prevent future incidents.

Laboratory incident reporting

All licenced facilities in Canada are required to report exposures and non-exposure incidents involving regulated human pathogens and toxins. The HPTA, HPTR and CBS require that regulated parties report such incidents 'without delay'. The Program monitors incidents through the Laboratory Incident Notification Canada surveillance system. In 2024, 60% of exposure incidents were reported in a timely way. The reporting delay ranged from 2 days to 9 days, with 5 days as the median, meaning half of the delays were shorter than 5 days, and half were longer. Timely reporting is defined by the Program as an incident report submitted within 7 days after the incident has occurred, but this target has not been explicitly communicated to regulated parties. As such, the interpretation of 'without delay' could vary between regulated parties. One external interviewee suggested defining the threshold for 'without delay' more clearly.

The Program received additional support over one year to analyze reports given the increased number of incident notification reports submitted. For example, 240 mandatory reports, including reports submitted retrospectively, were reviewed and processed in 2023, as compared to 117 reports reviewed and processed during the 2022 calendar year. The Program also published a new biosafety guideline on incident investigation to identify root causes of incidents, to prevent recurrence.¹⁴

Immediate outcome 4: Regulated parties comply with legal and regulatory requirements

Key Takeaways: Biosafety and biocontainment inspections have increased and regulated parties address corrective actions when they are identified; however, limitations remain in compliance monitoring, verification, and enforcement activities for biosecurity risks.

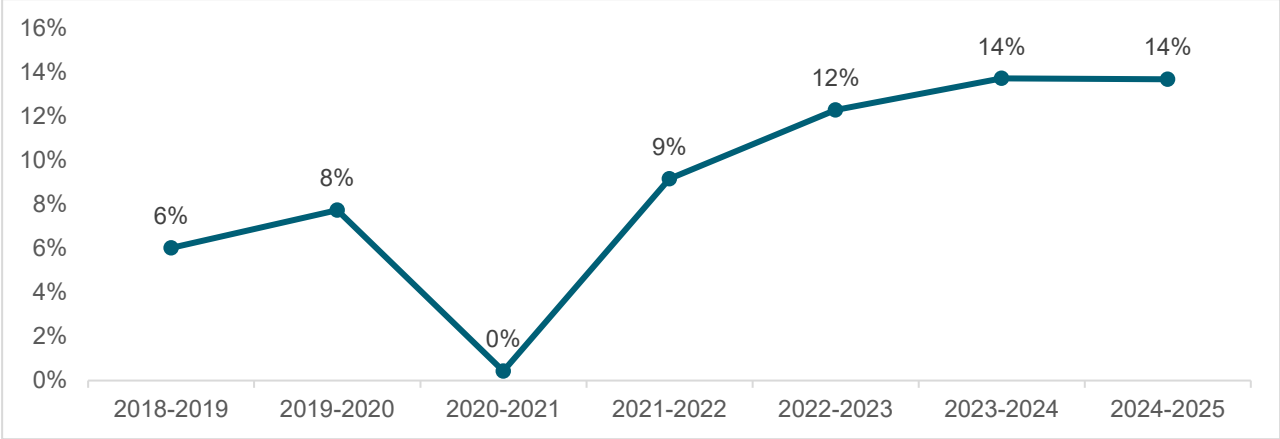
Biosafety and biocontainment inspections

The Program commits to inspecting RG4 licences every year, RG3 licences once every three years, and a risk-based percentage of RG2 licences annually (12%). Overall, the Program conducted 648 inspections, including RG2 to RG4 licences, between 2019-2020

and 2024-2025, which is more than what was initially planned (see Appendix C). Of note, in fiscal year 2020-2021, most inspections were cancelled due to the COVID-19 pandemic.

The Program addressed a recommendation from an internal audit related to articulating the risk tolerance regarding the frequency of RG2 licences. As a result, more inspections of RG2 licences have been carried out over the last four years.¹⁵ As shown in Figure 6, since 2018-2019, inspections of RG2 licences increased by 145%, going from inspecting 6% (55 out of 913) to 14% (135 of 986) in 2024-2025. The enhanced capacity to carry out more RG2 inspections was viewed as a key achievement by many internal interviewees; however, this success was largely dependent on temporary funding. Moving forward, as the biomanufacturing and life sciences sectors continue to expand, the number of high-risk facilities requiring inspections will increase.

Figure 6: Percentage of RG2 licence inspections by fiscal year



Source: Program administrative data

Virtual inspections

Following the COVID-19 pandemic, and in response to a recommendation from the last internal evaluation, the Program piloted virtual inspections to determine how they can complement current on-site inspections. The pilot led to the development of a hybrid oversight model, where virtual inspections are used to evaluate requirements that are suitable for remote auditing.^{16, 17} Given that the pilot found efficiencies and other benefits, such as easier access to remote locations and opportunities to train junior staff, in 2024-2025, the Program formalized the hybrid oversight model, which includes a combination of virtual (30%) and on-site (70%) inspections, adjusting targets as necessary.

Biosecurity plan evaluation

The Program also verifies compliance by evaluating a sample of Biosecurity Plans (BSPs) annually. The BSP outlines the security measures in place to prevent the loss, theft, misuse, diversion, or unauthorized intentional release of biological materials and related assets. To verify this CBS requirement, the Program employs a risk-based approach that prioritizes the evaluation of BSPs for high-risk facilities, particularly those working with SSBAAs, as these facilities are required to submit their BSPs when applying for a licence. [Redacted]

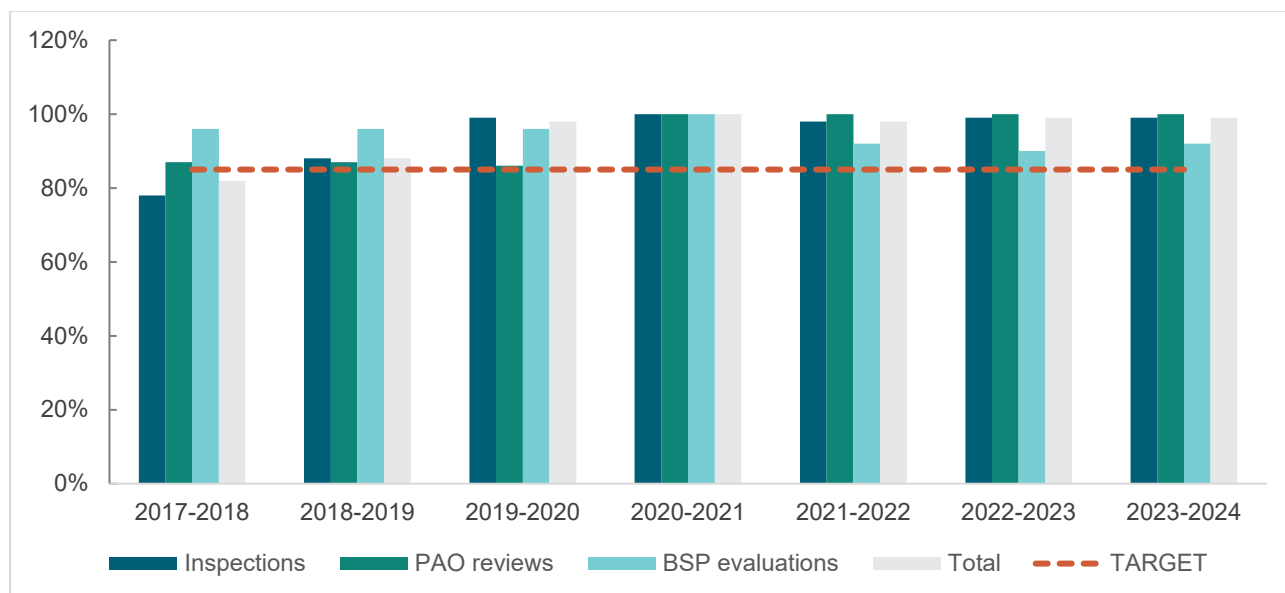
Figure 7: [Redacted]

In parallel, with respect to biosecurity considerations like research security and safeguarding research, and the upcoming implementation of the Biosecurity Addendum in January 2026, a few external interviewees suggested having more prescriptive guidance on how to implement the biosecurity institutional controls in practice. Although clarity is important, some internal interviewees noted that a prescriptive approach does not generally align with regulatory best practices. Instead of taking a prescriptive approach, other opportunities to clarify requirements could be helpful, such as the Program's availability to further discuss guidance and the concerns of regulated parties. A few external interviewees mentioned that they would appreciate having a direct contact within the Program to reach out to, as contact names or staffing changes may not have been communicated widely to stakeholders. As biosecurity is a new and evolving field, internal interviewees and external partners and stakeholders recognize the challenges in developing this oversight function and regulations, including accessing required expertise.

Compliance and enforcement

The Program's [Compliance and Enforcement Policy](#) proposes a risk-based approach, with actions tailored to the severity and circumstances of non-compliance.¹⁸ As outlined in the [Compliance Activities and Enforcement Continuum](#), compliance verification and enforcement activities are progressive.¹⁹ Overall, as shown in Figure 8, compliance rates are high, with regulated parties promptly implementing corrective measures when deficiencies are identified, and enforcement escalation is rarely needed.

Figure 8: Percentage of compliance issues in Canadian laboratories successfully responded to within established timelines by fiscal year



Source: Program administrative data

The vast majority of compliance issues (99%) identified during biosafety and biocontainment inspections were minor in nature, as presented in Table 4, and responded to within established timelines, with very few leading to a Notice of Non-Compliance (NNC), an escalated enforcement action intended to prompt corrective measures and support a return to compliance. Between 2019-2020 and 2024-2025, a total of 11 NNCs were issued to regulated parties that had not resolved identified compliance issues within the established timeframe (see Table 4). Notably, all 11 NNCs were successfully addressed, with each regulated party taking the necessary corrective actions to return to compliance.

Table 4: Number of compliance issues which require corrective actions identified during inspections and number of NNCs issued by fiscal year

	2019-2020	2020-2021	2021-2022	2022-2023	2023-2024	2024-2025	Total
Minor Non-Compliance	457	17	413	556	598	501	2542
Major Non-Compliance	2	0	0	6	4	7	19
NNC	3	0	1	3	1	3	11

Source: Program administrative data

The Program also identified non-compliance through several other mechanisms, beyond inspections, such as online data monitoring and referrals from inspection teams where licensing obligations are implicated. As indicated in Table 5, between 2019-2020 and 2024-2025, a total of 80 licensing-related NNCs were issued, and the failure to designate a new Biological Safety Officer without delay accounted for the majority of NNCs (49 NNCs, or 61%).

Table 5: Licensing related notices of non-compliance by fiscal year

HPTA Section	Reason for NNC	2019-2020	2020-2021	2021-2022	2022-2023	2023-2024	2024-2025	Total
HPTA 36(6)	Failure to designate a new Biological Safety Officer without delay	8	3	8	15	4	11	49
HPTA 18(7)	Failure to comply with a condition of licence	5	1	5	7	3	1	22
HPTA 7(1)	Conducting controlled activities without a licence	1	1	1	3		1	7
HPTA 33(a)	Accessing part of a facility without an HPTA security clearance						1	1
HPTR 4 (1) (c) (ii)	Failure to take reasonable care before the transfer of a human pathogen or toxin		1					1
	Total	14	6	14	25	7	14	80

Source: Program administrative data

Over the last decade, the Program has gained a deeper understanding of its regulated parties with respect to biosafety and biocontainment oversight. The Program regularly analyzes compliance and inspection data like inspection findings, common deficiencies and non-compliances, to inform compliance promotion materials, training, webinars, guidelines, and target inspections, among others. While regulated parties value the collaborative approach to compliance, some internal interviewees expressed that, given the significant efforts made over the years to educate, guide, and support regulated parties on regulatory requirements, there may be an opportunity to adopt a stronger enforcement posture. **[Redacted]**

Additionally, internal staff and documentation noted emerging compliance challenges in the wake of CL2 facility bankruptcies, as some facilities are not fulfilling their regulatory obligations to properly decommission laboratories or dispose of regulated biological materials. Given current economic conditions, internal staff anticipate that further closures are likely to occur, underscoring the need for strengthened mechanisms to manage bankruptcies and mitigate associated risks.

Intermediate outcome 1: Risk of accidental release of a pathogen or toxin is reduced

Key takeaways: Program activities have helped reduce the risk of accidental release, as shown by the number of reported laboratory incidents. While longer-term analyses may help draw additional conclusions, current data is already being used to improve guidance materials. Follow-up reports suggest that risk mitigation strategies are reducing the recurrence of incidents.

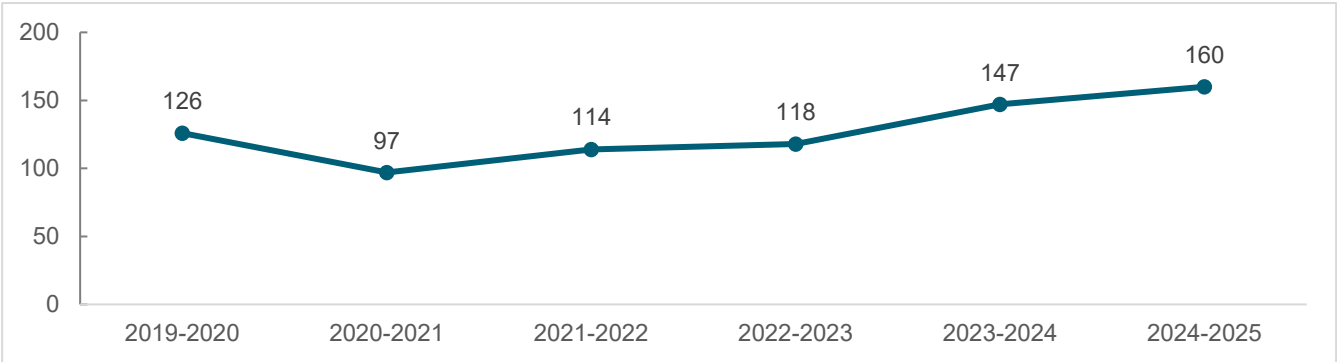
Literature on the topic describes that reporting systems for biological incidents, used to identify trends and improve practices, are part of a strong biosecurity response^{20,21}. A comprehensive review of laboratory accidents worldwide from 2000 to 2021 found that many countries lack mandatory reporting requirements for laboratory incidents.²² Taking this into account, the Laboratory Incident Notification Canada remains one of the only surveillance systems of its kind, enabling the Program to work to better understand the scale of laboratory incidents in Canada and their causes, as well as disseminate related data by publishing surveillance articles in PHAC's peer-reviewed journal, the Canada Communicable Disease Report.^{23,24} Over the last six years, the Program created several new resources to inform regulated parties about common causes of exposure incidents, how to prevent recurrence, and how to promote laboratory biosafety more broadly.²⁵

As shown in documents and mentioned in internal interviews, findings from the surveillance of laboratory exposures are used to inform biosafety practices and procedures in facilities to reduce the incidence of exposure to human pathogens and toxins. For example, Laboratory Incident Notification Canada follow-up reports in 2023 showed that risk mitigation strategies, such as biosafety protocols and ongoing training, reduce incidence recurrence and improve biosafety. Incident reports indicate that exposure to pathogens and toxins can be reduced by implementing support measures like ongoing compliance of regulated parties with legislation and licence conditions, regular inspections, and resources to support regulated parties.²⁶

In parallel, the Laboratory Incident Notification Canada number of mandatory incidents reported has grown slightly over the years (see Figure 9). Laboratory Incident Notification Canada data shows that the rate of exposure incidents resulting in laboratory-acquired infections has increased, rising from 2.4% in 2020-2021 to 8.5% in 2023-2024 (see Appendix C). Interview findings suggest that it is difficult to draw conclusions about trends in the number of incident reports due to multiple factors:

- compliance promotion activities increased regulated parties’ awareness of their requirement to report, creating spikes in incident reports;
- the COVID-19 pandemic led to a decrease of in-person laboratory work, with a resulting decrease in incident reports during that period; and,
- the number may decrease over time with the promotion of training materials.

Figure 9: Number of mandatory incidents reported by fiscal year



Source: Program administrative data

Note: The number of incidents does not include the incidents that were ruled out.

Intermediate outcome 2: Risk of deliberate release of a pathogen or toxin is reduced

Key takeaways: There have been no reports of missing, lost, or stolen pathogens or toxins involving SSBA and few known biosecurity incidents during the evaluation timeframe. Program activities helped reduce the risk of deliberate release of pathogens and toxins as few intentional incidents have been reported in Canada. [Redacted]

In the past five fiscal years, only one incident involving a SSBA has been reported, with another previous incident occurring in 2016-2017. Both incidents were due to an inventory discrepancy. Appropriate corrective actions were taken to prevent recurrence of this type of incident, and no risk of exposure was identified. Few known biosecurity incidents have taken place in Canada.

Moreover, while the Program is recognized as a global leader in the field by many internal and external interviewees, the biosecurity team operates in a rapidly evolving and largely uncharted domain. [Redacted]

To mitigate the risks associated with the potential expansion of high-containment facilities, additional conditions of licence have been developed for CL4 facilities via the Biosecurity Addendum. [Redacted]. Additionally, recognizing that the Program is in the process of developing guidance material for the Biosecurity Addendum, external interviewees raised concerns with its upcoming implementation and the lack of clarity around some of its requirements. As noted under “immediate outcome 1”, there is an opportunity to consider more direct engagement with regulated parties at this time.

Ultimate outcome: Canada reduces public health risks associated with the use of pathogens and toxins

Key takeaways: The Biosecurity Program is well-regarded internationally, and its activities are showing progress in reducing the biosafety and biosecurity risks associated with the use of pathogens and toxins in Canada.

To determine whether Canada is effectively reducing public health risks associated with the use of pathogens and toxins, the Program’s core capacities for biosafety and biosecurity oversight are regularly assessed. Canada has met its target of a score of 5 out of 5, indicating robust oversight capabilities. The score is calculated using the World Health Organization’s (WHO) State Party Self-Assessment Annual Report tool, which is completed annually. Additionally, the score incorporates results from the periodic Joint

Strengthening biosecurity oversight



The [Report of the Special Committee on the Canada–People’s Republic of China Relationship](#), a case study of incidents at one of Canada’s highest containment-level laboratories, highlighted security and biosecurity considerations. In the wake of these incidents and in light of an evolving threat landscape, the federal government initiated several policy and oversight changes to strengthen national biosecurity. PHAC’s Biosecurity Program responded by enhancing its scientific security screening processes for Canadians, permanent residents and foreign nationals, updating policies and practice to better mitigate risks.

External Evaluation, conducted by international experts, which was last completed for Canada in 2018-2019.

External interviewees from OGDs highlighted that Canada is a world leader in biosafety and biosecurity, noting the oversight framework and the CBS and related guidelines are the best in the world. In 2021, the Global Health Security Index ranked Canada first in biosafety and third in biosecurity.²⁷ Canada is also one of the few countries with a regulatory regime that has an element of dual-use research oversight.

Impact of collaborations

Key takeaways: Engagement with partners and stakeholders to date has mostly focused on information-sharing and outreach activities. More could be done to foster more meaningful and direct engagement, particularly in the area of biosecurity. The Program's external advisory committee may not have sufficient biosecurity expertise.

The Program has engaged with regulated parties and other partners and stakeholders via ad hoc consultations, quarterly bulletins, and the Training Portal. It has also reached out to regulated parties by attending conferences and hosting booths at symposiums and conferences. Although there are various channels that provide information about the Program and its resources, external interviewees felt that more could be done to engage them in a more meaningful way, particularly regarding biosecurity. This is especially important for regulated parties who may not be as familiar with security requirements and who would benefit from more opportunities for direct contact, whether on a one-on-one basis or via education or awareness campaigns.

Did you know?



The Program currently serves as Canada's National Authority for Containment of Poliovirus, acts as the secretariat of the International National Authority for Poliovirus Containment, and collaborates with international partners to advance priorities on WHO's Polio Eradication Initiative.

The Program's expertise in biosafety and biosecurity is widely recognized across the Government of Canada. Collaborations with OGDs have increased significantly in the past six years, especially in biosecurity, which highlight the Program's well-recognized expertise. The Program chairs the Canadian Pathogen Security Interdepartmental Group and collaborates on matters like emerging technology, counter-proliferation of biological weapons, and research security. Most of the increased biosecurity activities have not been formalized through an MOU, highlighting the need for formal engagement opportunities with OGDs on shared priorities.

The Program relies on the Advisory Committee on Human Pathogens and Toxins (AC-HPT) to receive scientific and strategic advice. [Redacted]. According to internal interviewees, the Program is actively seeking to improve representation in this expertise area. [Redacted].

Internationally, the Program has enhanced global biosafety and biosecurity capacity by actively engaging in and leading several key initiatives. It has provided leadership as a WHO Collaborating Centre for Biosafety and Biosecurity and it has served as the secretariat and co-chair of the International Expert Group of Biosafety and Biosecurity Regulators, with support from Global Affairs Canada, among numerous other international engagements.^{28,29} Program activities have raised awareness of global threats, and OGDs increasingly recognize the importance of PHAC's role. Their demand for biosecurity expertise and expectations for PHAC's international leadership have grown over the years.

iSTOP Modernization

Key takeaways: The migration of the Integrated Suite of Tools for Operational Processes (iSTOP) to the cloud will help facilitate system updates, improve software security, and streamline operations. However, significant delays outside of PHAC's control have affected the implementation of specific tools and functions. Activities that could be automated are still being completed manually and taking longer to complete. As part of the system lifecycle, ongoing support for continual updates and maintenance will also be needed, especially if legislative changes are made.

iSTOP is the primary case management system used to support the Program's compliance monitoring, verification, and enforcement activities. It includes a public-facing Biosecurity Portal that enables regulated parties to securely exchange information with PHAC and fulfill their obligations under the HPTA and HPTR.



Did you know?

iSTOP supports approximately 100 internal staff, 1,200 regulated parties, and 3,000 external stakeholders. The Canadian Food Inspection Agency, through an MOU, uses iSTOP to regulate animal pathogens and toxins under the *Health of Animals Act* and the *Health of Animals Regulations*.

The Program launched the modernization of iSTOP in December 2021, with the support of Health Canada's Digital Transformation Branch (DTB), which is a shared service between PHAC and Health Canada. Because of limited capacity within DTB during the COVID-19 pandemic, the Biosecurity Program led the iSTOP Cloud Migration Project, which differs from the usual practice of having DTB oversee information technology modernization projects. Moving iSTOP to the cloud is expected to streamline the deployment of new releases and updates, among other efficiency gains. However, the project budget, initially forecasted at \$1.7 million, grew to \$8.1 million, and timelines were affected due to complex and evolving business processes, long lead times in sourcing developers, and limited technical documentation and business processes.

In the interim, the Program has continued operating using the iSTOP legacy system. Since fiscal year 2021-2022, no new features or content have been developed, as enhancements would not yield long term business value. This development freeze of the legacy system will remain in place until the modernized system is deployed. Currently, activities that could be automated continue to require more time to complete manually, reducing efficiencies.

Financial analysis

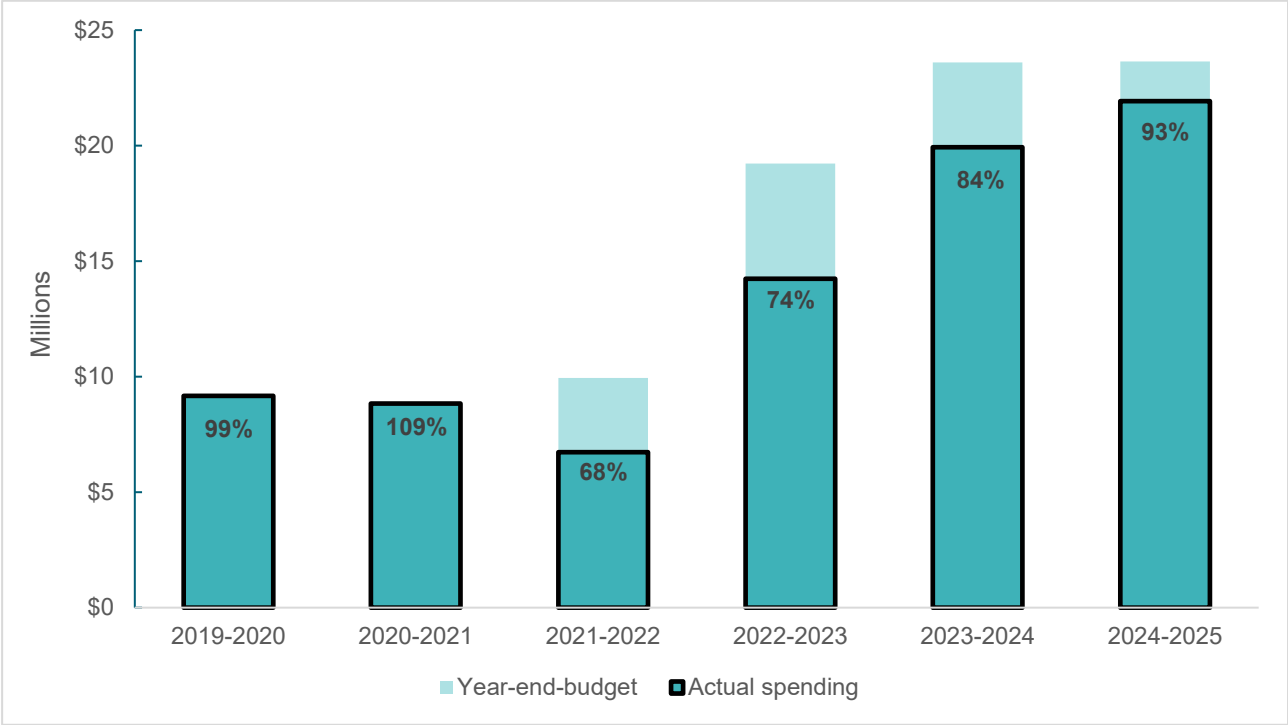
Key takeaways: In the past six years, there have been slight variances between actual expenditures and year-end budgets. While temporary and reallocated funding helped stabilize the Program's growth in response to the COVID-19 pandemic and the expansion of the biomanufacturing and life sciences sectors, the short-term nature of this funding created challenges in hiring and retaining staff. As a result, the Program underspent its staffing and operations and maintenance budgets.

As shown in Figure 10, the Program has slightly underspent its budget, with the exception of fiscal year 2020-2021 where the budget was overspent by 9%. The Program's expenditures have also increased significantly over the last six years in response to the COVID-19 pandemic and the growing needs of the biomanufacturing and life sciences sectors, among other factors. Specifically, the Program was provided one-time reallocation funding in fiscal year 2022-2023 to support approximately 80 FTEs on a one year basis as

well as temporary funding in fiscal years 2023-2024 and 2024-2025 (see Table 10 in Appendix B).

Salary budgets have been consistently under-spent, particularly within the Office of Pathogen Security, due to unfilled positions (see Table 7 in Appendix B). Operations and maintenance budgets have also experienced underspending, as activities such as training and program delivery were reduced. These budget variances are mainly due to ongoing challenges in recruiting specialized regulatory and scientific staff.

Figure 10: Percentage of the year-end-budget spent on program activities



Source: Program financial data

Note: The year-end budget includes additional temporary funding (B-base) received throughout the fiscal year as well as internal reallocations, excluding COVID-19 funding.

Using data and measuring performance

Key takeaways: The Program has leveraged data to inform activities and decision making and focused its Sex- and Gender-Based Analysis (SGBA) Plus considerations where it is appropriate to do so. However, some performance indicators are not effectively measuring program outcomes.

Scientific document and literature reviews conducted as part of the pathogen and toxin risk assessment processes inform Risk Group classification and licence requirements. Incident

reporting and compliance data is used to inform program activities and support the improvement or development of biosafety practices and procedures. For instance, as indicated in previous sections of this report, there are numerous examples of how incident reporting and inspection data is used to target compliance promotion activities, such as recurring issues.

SGBA Plus has been considered in appropriate activity areas, given the Program's scope and its target population, for example:

- The PSDS incorporates information on population-specific health risks, such as increased susceptibility among older adults, or based on sex, where relevant. This information helps protect the safety of those working directly with high-risk materials with the objective to help contribute to a more inclusive approach to biosafety.³⁰
- The Program has considered SGBA Plus in the development of its training material which have been reviewed by PHAC's SGBA Plus Focal Point.³¹

At the time of drafting this report, the Program was preparing to roll out a stakeholder survey to determine the SGBA Plus characteristics of the regulated parties' workforces and better understand how useful and effective the Program's biosafety and biosecurity resources are, and whether different groups of people have different experiences with these resources.

The Program collects and monitors its Performance Information Profile (PIP) performance data on a regular basis. Issues of inconsistency and inaccuracy were noted with some of the performance indicators, namely:

- The indicator on targeted regulated communities who indicate having the information needed to understand and comply with HPTA and HPTR was not consistently measured over the years.
- The indicator on the issuance of security clearance decisions within service standards is not telling a complete story, because it excludes the complex files for which the service standard significantly exceeds the service delivery target.
- The indicator on the timeliness of incident reports submitted has never met its target, and the interpretation of 'submitting without delay' is not explicitly defined for regulated parties.

Conclusions and recommendations

The environment in which the Biosecurity Program operates has changed significantly in the past six years. Canada remains a leader in biosafety and biosecurity; [Redacted]. The Program has prioritized modernizing the oversight framework, and while that work is ongoing as of June 2025, interim measures demonstrate efforts to adapt where possible.

PHAC's Biosecurity Program has made significant efforts to keep regulated parties well-informed of their regulatory obligations through various forms of guidance and outreach via multiple channels, particularly with regards to biosafety and biocontainment practices. However, the lack of a modernized regulatory framework that addresses emerging biosecurity threats has limited the Program's ability to advance a more comprehensive biosecurity agenda. The Program has adapted the existing framework and provided guidance where most needed, such as in the review of security clearances.

During the evaluation period, temporary funding helped the Program address chronic challenges and expand to meet increased demands from the biomanufacturing and life sciences sectors. This funding was key in helping the Program advance support for institutions through improved licence application assistance, strengthening plan reviews, and compliance promotion guidance. However, challenges and backlogs remain in some areas [Redacted] and sustaining this progress will be difficult in the long term without stable long term funding to enable workforce development and retention. Furthermore, the Program has faced challenges in progressing system updates to iSTOP, the primary case management system.

Overall, regulated parties have demonstrated compliance with biosafety and biocontainment requirements following a compliance review or inspections with identified issues being addressed within satisfactory timelines. The findings from these reviews, inspections, and ongoing laboratory incident surveillance help identify common challenges and trends. This information is then used to target the development or enhancement of guidance and training materials, ensuring that regulated parties are better informed and able to improve their practices.

Recommendations

Recommendation 1: Continue modernizing the biosecurity oversight framework, including:

- clarifying and aligning biosecurity direction with policy direction;
- continuing to enhance stakeholder engagement activities to respond to biosecurity information needs;
- continuing to revisit the Advisory Committee on Human Pathogens and Toxins (AC-HPT)'s composition to ensure a relevant and diverse mix of expertise; and
- ensuring that, once the modernized iSTOP is deployed, mechanisms are in place to reflect the updated regulatory oversight framework.

[Redacted]. Once the modernized iSTOP is deployed, the Program should make efforts to ensure that the system can accommodate future updates to the regulatory framework, so that it remains current and adaptable.

Recommendation 2: Identify, stabilize, and maintain critical core activities to comply with current and evolving legislative requirements and roles.

The Program has relied on additional temporary and ad hoc funding to conduct its core oversight activities. Although the additional funding has allowed the Program to keep pace in most areas, progress in biosecurity oversight has been limited, and the approach may not be sustainable in the long term given the growth of the biomanufacturing and life sciences sectors, and the possibility of an expanding biosecurity mandate. While pursuing regulatory modernization, the Program should clearly identify and articulate the activities that are essential to carry out its regulatory mandate in the medium to long term, based on current and anticipated funding, as well as consider what ongoing ad-hoc mechanisms can help address short-term needs. Activities that need to be carried out on an ongoing basis would benefit from more precise, risk-based approaches, **[Redacted]**.

Recommendation 3: Strengthen performance measurement indicators to support decision making.

The Program has a strong evidence-based culture, and it uses data for planning and decision making on an ongoing basis. To continue building on these strong practices, further improvements to a few performance measurement indicators are needed to more effectively measure program outcomes. In addition, the Program should ensure that the PIP reflects modernization, as appropriate.

Appendix A: Methodology

Data collection sources and methods

The evaluation team collected and analyzed multiple lines of evidence which were triangulated to improve the reliability and credibility of evaluation findings and conclusions. The data was collected using various methods outlined below.

Document and file review

The evaluation team received approximately 1,180 files and reviewed 553, including both internal and public documents submitted by the Centre for Biosecurity. Internal documents included strategic planning documents, annual reports, work plans, operational plans, governance documents, surveys, newsletters, consultation reports, meeting summaries, guiding policies, briefing materials, performance reports, and summary reports. Public documents included departmental reports, Canada.ca web pages, and external reviews. Data from documents was collated and analyzed by indicators and themes using evidence matrices.

Interviews

Structured internal and external interviews took place with the following 41 individuals:

- 18 staff members from the Centre for Biosecurity;
- 7 internal staff from other PHAC and Health Canada branches; and
- 16 external stakeholders and partners (6 from OGDs, 8 regulated parties, and 2 other stakeholders).

Performance data review

Performance data from the following sources was reviewed:

- PIP Data for fiscal years 2016-2017 to 2023-2024;
- Other internal tracking and reporting dashboards (i.e., administrative data);
- Laboratory Incident Notification Canada data from two articles in the Canada Communicable Disease Report;
- Data from the World Health Organization's (WHO) International Health Regulations Self-Assessment Annual Reporting (SPAR).

Financial data analysis

Financial data provided by the Chief Financial and Operations Management Branch was reviewed, including budgeted versus actual expenditures.

Literature review

Peer-reviewed articles, grey literature, and scientific resources were scoped in the literature review to answer the following questions:

1. What are the emerging threats to biosafety and biosecurity?
2. What impact has the evolving threat landscape, including the COVID-19 pandemic, had on biosafety and biosecurity regulatory oversight in Canada and internationally?
3. What are the key factors influencing Canada's capacity to respond to the emerging threats to biosafety and biosecurity? What lessons can be learned from other countries?

The evaluation team provided PHAC's Library Services with the literature review's research questions and a systematic search was conducted using keywords on three databases. Library Services provided a list of 85 articles relevant to the topic. Covidence, a systematic review tool, was used to screen articles, reducing the selection to 32 studies. Eight chapters of a biosecurity book were also included. Additional sources were identified from citations of included articles. In total, 47 items were reviewed to identify common findings in alignment with evaluation questions and indicators.

Evaluation lenses and government priorities

The evaluation applied several lenses and frameworks to assess the progress and impacts of PHAC's Biosecurity Program with respect to Government of Canada priorities.

In support of the United Nations' 2030 Agenda for Sustainable Development and the United Nations' Sustainable Development Goals, the Centre for Biosecurity's activities contribute to Goal 3: "Good Health and Well-Being", in particular, indicator 3.D related to strengthening the capacity of all countries for early warning, risk reduction, and management of national and global health risks.

The evaluation applied an SGBA Plus lens to assess program activities, including consideration of health impacts on priority populations and the integration of health equity considerations in biosafety and biosecurity activities. Although Official Languages were not specifically examined, they were not found to be an issue for biosafety and biosecurity

activities. The Quality of Life Framework for Canada and the Truth and Reconciliation Commission Calls to Action were not applicable to this evaluation.

Limitations

Despite triangulation across various lines of evidence, most evaluations still face constraints that may affect the validity and reliability of findings and conclusions. Table 6 outlines the limitations encountered during the current evaluation, as well as mitigation strategies put in place to ensure evaluation findings were sufficiently robust.

Table 6: Limitations, potential impacts, and mitigation strategies

Limitations	Impact on the evaluation	Approach for addressing the limitation
Similar national laboratory incident reporting surveillance systems do not exist outside of Canada, making it difficult to compare results and trends with those from other countries.	It is not possible to compare Canada's trends in laboratory incident rates to other jurisdictions.	The evaluation focused on the longer-term domestic trends and Laboratory Incident Notification Canada data analysis (2016 to 2022), as well as the measures that the Program implemented to address the root causes of laboratory incidents.
There were a limited number of interviews with regulated parties and stakeholder associations.	The findings could not be generalized across regulated parties and stakeholder associations interviewed for the evaluation.	Although limited, interviews were conducted with various regulated parties and stakeholder associations to ensure adequate representation among those who engage with the Program. The evaluation also reviewed consultation input received from partners and stakeholders, as well as survey data, to supplement these findings.

There were challenges with respect to the performance indicators and their effectiveness to accurately assess results and analyze trends over time. For example, for one indicator, the data source changed over the years, making it challenging to conduct a trend analysis.	Performance measurement data may not accurately reflect progress on outcomes.	The evaluation team requested and analyzed additional performance measurement data, beyond the PIP, to address gaps. This included additional program administrative data, a stakeholder survey, and consultation summaries.
The Program's financial data during the COVID-19 pandemic (2020-2021 and 2021-2022) is not completely representative of Biosecurity Program activities, as it included border travel health program activities. As such, the financial data presented in this report does not align with previously reported financial data on the Canada.ca website.	The COVID-19 financial data does not accurately reflect the actual spending on Biosecurity Program activities. COVID-19 funding related to border and travel health activities was carved out through a financial data validation exercise with the Program. For 2020-2021 and 2021-2022, the Program provided an approximate estimate of COVID-19 expenditures related to biosecurity-specific activities, excluding border and travel health related expenditures.	The evaluation examined a component of the COVID-19 funding related to Biosecurity Program activities, representing a very close estimate based on internal financial reporting.

Evaluation governance

To conduct the evaluation, OAE worked closely with the Centre for Biosecurity. OAE shared the evaluation scope secretarially with the PHAC Performance Measurement and Evaluation Committee (PMEC) in January 2025. The preliminary findings were presented to PMEC on June 16, 2025. The final report was presented to PMEC in October 2025, where committee members recommended the evaluation for the President's approval.

Appendix B: Financial information

Table 7: Year-end budget versus actual spending for activities by office from 2019-2020 to 2024-2025

Office	Year-end budget	Actual spending	Variance	Percent of the budget spent
Director General's Office	\$ 10,798,016	\$ 10,393,962.22	\$ 404,053.78	96%
Office of Biosafety and Biocontainment Operations	\$ 29,636,902	\$ 26,839,797.39	\$ 2,797,104.61	91%
Office of Biosafety Programs and Planning	\$ 19,184,853	\$ 17,876,297.55	\$ 1,308,555.45	93%
Office of Pathogen Security	\$ 24,916,549	\$ 17,927,919.68	\$ 6,988,629.32	72%
Office of Stakeholder Engagement and Regulatory Affairs	\$ 9,179,159.00	\$ 7,786,956.87	\$ 1,392,202.13	85%
Grand Total	\$ 93,715,479.00	\$ 80,824,933.71	\$ 12,890,545.29	86%

Table 8: Year-end budget versus actual spending for biosecurity related COVID-19 activities (B-base funding)

Fiscal year	Year-end-budget	Actual spending	Variance	Percent of budget spent
2019-2020	N/A	\$ 269,469.34	-\$ 269,469.34	N/A
2020-2021	\$ 1,947,412.00	\$ 1,163,937.89	\$ 783,474.11	60%
2021-2022	\$ 3,352,734.00	\$ 3,354,407.37	-\$ 1,673.37	100%
2022-2023	\$ 1,095.00	\$ 0.00	\$ 1,095.00	0%
Total	\$ 5,301,241.00	\$ 4,787,814.60	\$ 513,426.40	90%

Note: This table does not include A-base funding/resources that were mobilized for Border and Travel Health activities (i.e., mobilization of Biosecurity Program staff to the Border and Travel Health Program).

Table 9: Year-end budget versus actual spending for program activities by budget lines by fiscal year

	Year-end budget	Actual spending	Variance	Percent of the budget spent
2019-2020	\$9,224,172.00	\$9,167,140.67	\$57,031.33	99%
Capital	N/A	N/A	N/A	N/A
O&M	\$1,912,588.00	\$1,872,431.94	\$40,156.06	98%
Salaries & Wages	\$7,311,584.00	\$7,294,708.73	\$16,875.27	100%
2020-2021	\$8,076,408.00	\$8,833,208.13	-\$756,800.13	109%
Capital	N/A	N/A	N/A	N/A
O&M	\$1,675,648.00	\$1,152,859.65	\$522,788.35	69%
Salaries & Wages	\$6,400,760.00	\$7,680,348.48	-\$1,279,588.48	120%
2021-2022	\$9,941,889.00	\$6,724,511.96	\$3,217,377.04	68%
Capital	N/A	N/A	N/A	N/A
O&M	\$2,903,118.00	\$1,162,084.13	\$1,741,033.87	40%
Salaries & Wages	\$7,038,771.00	\$5,562,427.83	\$1,476,343.17	79%
2022-2023	\$19,227,454.00	\$14,238,882.80	\$4,988,571.20	74%
Capital	N/A	N/A	N/A	N/A
O&M	\$5,551,293.00	\$3,389,584.72	\$2,161,708.28	61%
Salaries & Wages	\$13,676,161.00	\$10,849,298.08	\$2,826,862.92	79%
2023-2024	\$23,606,672.00	\$19,931,618.76	\$3,675,053.24	84%
Capital	\$122,533.00	\$122,494.59	\$38.41	100%
O&M	\$7,253,502.00	\$4,894,276.59	\$2,359,225.41	67%
Salaries & Wages	\$16,230,637.00	\$14,914,847.58	\$1,315,789.42	92%
2024-2025	\$23,638,884.00	\$21,929,571.39	\$1,709,312.61	93%
Capital	N/A	N/A	N/A	N/A
O&M	\$6,246,084.00	\$5,072,748.03	\$1,173,335.97	81%
Salaries & Wages	\$17,392,800.00	\$16,856,823.36	\$535,976.64	97%
Grand Total	\$93,715,479.00	\$80,824,933.71	\$12,890,545.29	86%

Note: O&M refers to Operations and Maintenance.

Table 10: Proportion of the temporary funding received (B-base) shown as a percentage of the total year-end budget by fiscal year and by office

	Total year-end budget	Temporary funding	Proportion of the temporary funding shown as a percentage of the total year-end budget
2022-2023	\$ 19,227,454	\$ 10,969,803	57%
Director General's Office	\$ 1,881,030	\$ 1,031,857	55%
Office of Biosafety and Biocontainment Operations	\$ 5,795,634	\$ 2,725,776	47%
Office of Biosafety Programs and Planning	\$ 3,677,176	\$ 1,447,074	39%
Office of Pathogen Security	\$ 6,080,886	\$ 4,926,480	81%
Office of Stakeholder Engagement and Regulatory Affairs	\$ 1,792,728	\$ 838,616	47%
2023-2024	\$ 23,606,672	\$ 14,211,362	60%
Director General's Office	\$ 2,786,514	\$ 1,747,894	63%
Office of Biosafety and Biocontainment Operations	\$ 7,069,881	\$ 3,588,146	51%
Office of Biosafety Programs and Planning	\$ 4,413,512	\$ 1,961,131	44%
Office of Pathogen Security	\$ 7,030,099	\$ 5,705,534	81%
Office of Stakeholder Engagement and Regulatory Affairs	\$ 2,306,666	\$ 1,208,657	52%
2024-2025	\$ 23,638,884	\$ 14,314,428	61%
Director General's Office	\$ 3,898,962	\$ 2,554,172	66%
Office of Biosafety and Biocontainment Operations	\$ 6,666,417	\$ 3,394,613	51%
Office of Biosafety Programs and Planning	\$ 4,086,184	\$ 1,770,786	43%
Office of Pathogen Security	\$ 6,855,030	\$ 5,598,879	82%
Office of Stakeholder Engagement and Regulatory Affairs	\$ 2,132,291	\$ 995,978	47%
Grand Total	\$ 66,473,010	\$ 39,495,593	59%

Note: This does not include additional funding received for COVID-19 activities.

Appendix C: Program performance measurement data

Note: Targets are indicated in brackets beside indicator results.

	2019-2020	2020-2021	2021-2022	2022-2023	2023-2024	2024-2025
Immediate outcome: Regulated parties are informed of legal and regulatory requirements						
3.2.4. Percentage of targeted regulated communities who indicate they have the information they need to understand and comply with the Act and Regulations	89% (80%)	N/A ¹	100% (80%)	86% (80%)	76% (80%)	87% (80%)
3.2.8. Percentage of planned biosafety and biosecurity resources updated or published	40% (80%)	75% (80%)	83% (80%)	67% (75%)	50% (75%)	60% (75%)
Immediate outcome: Regulated parties have adequate institutional controls to conduct the activities for which they are licenced						
3.2.5. Percentage of facilities licenced to conduct scientific research with human pathogens and toxins with a Plan for Administrative Oversight of Pathogens and Toxins in a Research Setting (PAO) assessed as consistent with guidelines	70% (95%)	87% (95%)	90.8% (95%)	91% (95%)	96% (95%)	93% (95%) ²
3.2.9. Percentage of licensing decisions within the established service standards	96% (90%)	87% (80%)	93% (80%)	97% (90%)	99% (90%)	98% (90%)

¹ Unable to report on this indicator as activities were put on hold due to the Program's role in the COVID-19 pandemic response.

² With the original adherence target of 95% surpassed, the Program has achieved its intended result of 95% of facilities with a PAO fully consistent with guidance by 2023. As such, the Program introduced a target-based approach for this indicator in 2024-2025. As part of the updated approach, the Program continues to assess PAOs submitted by new applicants or by existing licence holders making changes to their biosafety programs, while also reviewing a sample each year to monitor ongoing compliance. In 2024-2025, the Program reviewed 10 PAOs per quarter.

3.2.10. Percentage of security clearance decisions within the established service standard ³	92% (80%)	86% (80%)	85% (80%)	100% (80%)	99% (80%)	75% (80%)
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Immediate outcome: Regulated parties proactively address biosafety and biosecurity risk

3.2.13. Percentage of exposure or laboratory acquired infections reports being reported in a timely manner ⁴	2019: 63% (100%)	2020: 59% (100%)	2021: 54% (100%)	2022: 74% (100%)	2023: 49% (100%)	2024: 60% (100%)
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Immediate outcome: Regulated parties comply with legal and regulatory requirements

3.2.7. Percentage of compliance issues in Canadian laboratories successfully responded to within established timelines	98% (85%)	100% (85%)	98% (85%)	99% (85%)	99% (85%)	98% (85%)
3.2.11. Percentage of planned inspections completed	130% (100%)	7.5% (100%)	111% (100%)	178% (100%)	113% (100%)	108% (100%)

Intermediate outcome: Risk of accidental release of a pathogen or toxin is reduced

3.2.12. Rate of exposure incidents resulting in a suspected or confirmed laboratory acquired infection or toxic effects ⁵	2019: 7.4% (N/A)	2020: 2.3% (5%)	2021: 8.2% (5%)	2022: 7.5% (5%)	2023: 8.5% (5%)	2024: 3.8% (5%)
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Intermediate outcome: Risk of deliberate release of a pathogen or toxin is reduced

3.2.3. Number of missing, lost, or stolen pathogen or toxin incidents involving a security sensitive biological agent ⁶	0 (0)	0 (0)	1 (0)	0 (0)	0 (0)	0 (0)
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Ultimate outcome: Canada reduces public health risks associated with the use of pathogens and toxins

3.2.1. Level of Canada's capacity for oversight of human pathogens and toxins as assessed by WHO criteria ⁷	5 (5)	5 (5)	5 (5)	5 (5)	5 (5)	5 (5)
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³ The indicator does not fully reflect the Program's overall performance as it excludes complex files whose processing times often exceed the standard service delivery target.

⁴ Indicator is measured by calendar year.

⁵ Indicator is measured by calendar year.

⁶ Indicator is measured by calendar year.

⁷ The International Health Regulations' Joint External Evaluation is conducted on a 5-year cycle, and therefore, not applicable for 2019-2020, 2020-2021, 2021-2022, 2022-2023. This indicator is instead measured by the WHO's SPAR score.

Endnotes

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