Health Canada and the Public Health Agency of Canada
Santé Canada et l'Agence de la santé publique du Canada
Canada

Evaluation of the *Human Pathogens and Toxins Act* and Regulations Framework 2015-16 to 2020-21

Prepared by the Office of Audit and Evaluation
Health Canada and the Public Health Agency of Canada

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List of Acronyms

BSO	Biological Safety Officer
BTWC	Biological and Toxin Weapons Convention
HAA	Health of Animals Act
HPTA	Human Pathogens and Toxins Act
HPTAR	Human Pathogens and Toxins Act and associated Regulations
HPTR	Human Pathogens and Toxins Regulations
iSTOP	Integrated Suite of Tools for Operational Processes
JEE	World Health Organization's Joint External Evaluation
LAI	Laboratory-Acquired Infections
LH	Licence Holder
PAO	Plans for Administrative Oversight
PSDS	Pathogen Safety Data Sheets
RG	Risk Group
SSBA	Security Sensitive Biological Agents

Executive Summary

This report presents findings from the Evaluation of the *Human Pathogens and Toxins Act* and Regulations (HPTAR). The evaluation is focused primarily on issues of effectiveness and efficiency, and covered activities related to the implementation of the HPTAR for the period from 2015-16 to 2020-21.

Program Context

Human pathogens and toxins pose a significant risk to human health and safety. In the laboratory environment, working with human pathogens and toxins poses a potential risk to safety, including to laboratory personnel who may be exposed to a human pathogen or toxin, through accidental or deliberate release. Accidental release can result from inadequate controls on activities such as possession, use, transfer, or disposal. A deliberate release by way of an act of terrorism or criminal activity could be possible if there are inadequate security measures in place. To address these concerns, the Public Health Agency of Canada (PHAC) established a national safety and security program to protect the health and safety of the public against risks posed by human pathogens and toxins.

The HPTAR came into full force in 2015. The Centre for Biosecurity delivers the national biosafety and biosecurity regulatory program that includes a licensing framework, an inspection program, inventory requirements, incident and exposure reporting, security clearance requirements, standard and guidelines development and implementation, as well as compliance and enforcement.

Key Findings

According to the 2021 Global Health Security Index, Canada ranks very highly in the world, in terms of both biosecurity and biosafety, ranking #1 globally in terms of biosafety and #3 in terms of biosecurity.

The HPTAR Program has shown early signs of success. Regulated organizations covered by the *Act*:

- have the information they need to understand and comply with legislative and regulatory requirements;
- comply with legal and regulatory requirements to improve biosafety and biosecurity in their facilities; and
- identify and proactively address risks to improve institutional biosafety and biosecurity.

There has been a decrease in risk of accidental or deliberate release of pathogens and toxins, leading to a reduced public health risk related to pathogens and toxins. We also found evidence of solid knowledge exchange, effective inspection and enforcement, and good compliance rates.

Issues were raised regarding security clearance requirements, including expanding the criteria for who should have a security clearance, beyond those who work with or have access to RG3 and RG4 pathogens, as well as increasing the level of scrutiny prior to issuing a security clearance to a foreign national. Licensing challenges were also raised, including clearly defining roles and responsibilities between Biological Safety Officers and Licence Holders. Addressing administrative burden for regulated organizations in the areas of licensing, security clearances, and inspections was also identified as a key area of focus (e.g., streamlining application process and the information needed from applicants and harmonizing HPTA requirements with the *Health of Animals Act* (HAA) requirements. Finally, the appropriateness of using virtual inspections and how they could complement existing physical inspections was identified as an area for further consideration. Considering that the Centre for Biosecurity's current complement of inspection staff are only able to inspect 6% of RG2 licences per year, virtual inspections may enhance some of this capacity gap. Where this is not sufficient, the Centre for Biosecurity should work to enhance capacity in this area.
In addition, significant recent investments to advance the biomanufacturing and life sciences sector in Canada has led to new policy and legislative

challenges, such as the need to consider licensing high-containment private sector laboratories, including academic institutions, which introduce new risks and considerations that currently fall outside of the scope of existing regulatory oversight and have national security implications. As a result, the Centre for Biosecurity is undertaking various initiatives to better understand these national security implications to address any issues related to the establishment of these private sector laboratories.

Recommendations

The evaluation evidence discussed in this report led to the development of the following recommendations.

Recommendation 1: Review current security clearance requirements to ensure appropriate levels of scrutiny for individuals who are, or may be, working with or accessing human pathogens and toxins.

Recommendation 2: Consider how virtual inspections can complement current on-site inspections, and under what circumstances they may be appropriate.

Recommendation 3: Clearly define and communicate roles and responsibilities related to Biological Safety Officers and Licence Holders.

Management Response and Action Plan

As part of the Regulatory Impact Analysis Statement for the *Human Pathogens and Toxins Act* and Regulations (HPTAR), the Public Health Agency of Canada (PHAC) committed to adhere to the Government's lifecycle approach to regulatory development through evaluation of the effectiveness of the HPTAR in meeting its objectives. The evaluation identified areas for regulatory review, including enhancements to the security clearance program and opportunities to increase clarity for regulated parties.

In addition, considering the impacts and lessons learned from the COVID-19 pandemic, there has been a rising interest for growth of the biomanufacturing and life sciences industry to prepare Canada for pandemics and other health emergencies in the future.

The Centre for Biosecurity's Management Response and Action Plan (MRAP) to the evaluation presents the opportunity for potential legislative changes to the HPTAR, including considerations in the context of the Government of Canada's Biomanufacturing Life Sciences Strategy. The Centre for Biosecurity's MRAP deliverables where additional full-time employees (FTE) are required, is dependant on securing funding through PHAC's Sustainable Emergency Management Systems for Public Health Events Budget 2022 proposal.

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
Recommendation as stated in the evaluation report	Identify whether program management agrees, agrees with conditions, or disagrees with the recommendation, and why	Identify what action(s) program management will take to address the recommendation	Identify key deliverables	Identify timeline for implementation of each deliverable	Identify Senior Management and Executive (DG and ADM level) accountable for the implementation of each deliverable	Describe the human and/or financial resources required to complete recommendation, including the source of resources (additional vs. existing budget)
Review current security clearance requirements to ensure appropriate level of scrutiny for individuals who are, or may be, working with or accessing human pathogens and toxins.	Agreed	The Centre for Biosecurity will conduct a Threat Risk Assessment on the HPTA that would respond to changes in the threat risk landscape posed by human pathogens and toxins, including amendments to strengthen the HPTA security clearance program and requirements regarding information management for SSBA. The Centre for Biosecurity will review the *Human Pathogens and Toxins Act* and Regulations and seek opportunities to strengthen	Complete a Threat Risk Assessment to determine the appropriate risk mitigations tools and controls Develop policy on: - Expanded Criteria for Security Clearances - Enhanced Security Checks - Continuous Vetting of Existing Security Clearances Complete a legislative review and identify regulatory options to	Fall 2022 Winter 2022-23 Spring 2023	Director General – Centre for Biosecurity	Resource neutral 1 Full time employee (FTE) EC-07 1 FTE EC-06 1 FTE EC-04

		the security clearance process and the biosecurity program.	strengthen the security clearance process and the biosecurity program, if necessary.			1 FTE EC-03 Budget 2022 proposal
Consider how virtual inspections can complement current physical inspections, and under what circumstances they may be appropriate.	Agreed	The Centre for Biosecurity will review its current use of virtual inspections and leverage other departments' experience and lessons learned to determine the mix of delivery models for inspections (virtual, hybrid, or on-site). The use of delivery model should be sustainable, effective, and appropriate to monitor and verify compliance and to prevent or address non-compliance with the relevant legislative requirements with the HPTAR. The Centre for Biosecurity will review the *Human Pathogens and Toxins Act* and Regulations to identify any barriers to virtual inspections.	Develop and optimize criteria and conditions for virtual, hybrid, and on-site inspections (e.g., risk-based inspections, announced vs. unannounced inspections) Complete legislative review and propose amendments to facilitate virtual inspections. This is being done in the context of the review and whether changes might be necessary.	Fall 2022 Spring 2023	Director General – Centre for Biosecurity	0.2 FTE Casual Budget 2022 proposal 1 FTE EC-07 1 FTE EC-06 1 FTE EC-04 1 FTE EC-03 Budget 2022 proposal
Clearly define and communicate roles and responsibilities related to Biological Safety Officers (BSO) and Licence Holders (LH).	Agreed	The Centre for Biosecurity will review the *Human Pathogens and Toxins Act* and Regulations to identify opportunities to clarify the roles of BSOs and LHs, including required qualifications of BSOs.	Optimize process to provide guidance on BSO and LH roles and qualifications on a more systematic basis as opposed to on request.	Fall 2022	Director General – Centre for Biosecurity	0.15 FTE EG-07 Budget 2022 proposal

			Complete legislative review and seek opportunities to clarify the roles of LHs and BSOs, including the need and roles of an Alternate Biosafety Officers and LH Representatives. Develop guidance and tools for BSO development, training, and webinars.	Spring 2023 Spring 2023		1 FTE EC-07 1 FTE EC-06 1 FTE EC-04 1 FTE EC-03 Budget 2022 proposal 0.5 FTE BI-03 Budget 2022 proposal

1.0 Program Description

1.1 Program Context

Biosafety and biosecurity involves the consistent application of safety and security measures to minimize or prevent the accidental exposure or deliberate release of human pathogens and toxins from causing harm to laboratory personnel, building occupants, the public at large, the animal population, and the environment. A biosafety and biosecurity program includes institutional plans and policies that facilitate the safe and secure handling and storing of infectious material and toxins, preventing exposure to, and the release of infectious material or toxins from the containment zone.

1.2 Program Profile

The Public Health Agency of Canada's (PHAC) Centre for Biosecurity aims to protect Canadians from risks associated with the use of pathogens and toxins by administering and enforcing the *Human Pathogens and Toxins Act* (HPTA), *the Human Pathogens and Toxins Regulations* (HPTR) as well as certain provisions of the *Health of Animals Regulations* related to the importation of terrestrial animal pathogens. The primary objective of the HPTAR is to establish a safety and security regime to protect the health and safety of the public against the risks posed by human pathogens and toxins. Controlled activities (e.g., using, storing, importing) with human pathogens that are classified as Risk Group (RG) 2-4, or with toxins listed in Schedule 1 of the HPTA require a licence, issued by PHAC. The following table provides an overview of each RG (1-4) in terms of individual and community risk.

Risk Group	Individual Risk	Community Risk	Example
RG1	No or Low	Low	Commensal bacteria
RG2	Moderate	Low	Pathogenic Escherichia coli
RG3	High	Low	Bacillus anthracis
RG4	High	High	Ebola virus

In Canada, all facilities where human pathogens or toxins are handled or stored, such as public health laboratories, teaching and research laboratories, diagnostic laboratories in hospitals, and vaccine production plants, are regulated under the HPTR. The table below provides an overview of the number of licences issued over the past five years, which could be related to a new application, a renewal, or an amendment to an existing licence due to a new Biological Safety Officer (BSO) or Licence Holder (LH). It should also be noted that these figures include a total of 26 RG3 licences related to the SARS-CoV-2 human pathogen; this includes one new licence and 25 licence amendments.

2017	2018	2019	2020	2021
302	342	407	575	640

This Centre for Biosecurity is responsible for the administration and enforcement of controlled activities with human pathogen and toxins, including the production, possession, handing, use, storage, access to, transfer, disposal, release, abandonment, and import or export of these products. This applies of whether pathogens or toxins are imported or acquired domestically.

The Centre for Biosecurity encourages a strong culture of biosafety and biosecurity in facilities across the country and contributes to

public health and national security by assessing biosafety and biosecurity risks, including risks posed by deliberate or accidental release of a pathogen or toxin, and by addressing emerging risks and mitigation strategies (Appendix 3 presents the HPTAR logic model).

What is biosecurity and biosafety?

Biosafety: containment principles, technologies, and practices that are implemented to prevent unintentional exposure to infectious material and toxins, or their accidental release

Biosecurity: security measures designated to prevent the loss, theft, misuse, diversion, or intentional release of pathogens, toxins, and other related assets (e.g., personnel, equipment, non-infectious material, animals).

The Centre for Biosecurity's main activities focus on compliance promotion and education through the provision of knowledge products, training, and guidance; the publication of the Canadian Biosafety Standard and guidelines; pathogen and toxin risk assessments; laboratory pre-licensing testing and verification; the issuance of import permits; laboratory inspections; and enforcement activities. The Centre for Biosecurity has also established an Advisory Committee on Human Pathogens and Toxins to provide scientific advice on the pathogens and toxins regulated under the HPTA and on its schedules, and to provide recommendations on overall priorities related to regulating human pathogens and toxins in Canada.

The Centre for Biosecurity works in close collaboration with a variety of key stakeholders, most of whom are also regulated parties. The Centre for Biosecurity has aggregated them by the following key sectors:

- Academia, including designated educational institutions across Canada that use human pathogens and toxins for research and teaching in a variety of disciplines (e.g., biology, biopharmaceuticals, medical laboratory technician, biotechnology, biochemistry, immunology, animal health technician, environmental health, nursing).
- Private Industry and Business, including private, small, medium and large businesses that use human pathogens and toxins in products, and for research and development activities, (e.g., animal health, human health, biotechnology, pharmaceutical, food industry, pathogen or toxin distributor), and in the production of vaccines, diagnostic test kits, and proficiency panels. The biotechnology industry may use pathogens in product development for bioremediation, such as waste treatment. The food industry may work with pathogens as a part of quality control on the products they produce.
- Government, including government organizations (federal, provincial, territorial, or municipal governments) having principal areas of focus in scientific research, diagnostics, quality control, waste management, public health, disease and illness surveillance, environmental and radiological testing, emergency response support, laboratory training, and veterinary facilities conducting controlled activities with RG2 human pathogens.
- Provincial and territorial policy and issue experts, including the Canadian Public Health Laboratories Network and the Biosafety Officer Network service providers (engineers, architects, equipment suppliers and repair).
- Other stakeholders, including national associations (e.g., academic, biotech), the do-it-yourself (DIY) Bio community (academia, BioArt), and individual members of the public who are interested or may be affected by this topic.

Appendix 1 details the annual planned budget and expenditures for the Centre for Biosecurity, which include costs associated with the implementation of the HPTAR, as well as other expenses related to the Centre's information technology infrastructure (i.e., the Integrated Suite of Tools for Operational Processes or iSTOP) and security clearance processing, among others.

2.0 Evaluation Approach

2.1 Evaluation Scope

The evaluation focused primarily on issues of effectiveness and efficiency and covered activities related to the implementation of the HPTAR, which regulate all Canadian facilities where human pathogens or toxins are handled or stored, for the period from 2015-16 to 2020-21. This evaluation was conducted to support a commitment to adhere to the Government's life-cycle approach to regulatory development as part of a legislative review process.

The evaluation used multiple lines of evidence, both qualitative and quantitative, to ensure triangulation of findings. The evaluation built on evidence provided by the Centre for Biodiversity, which included consultations with various stakeholders, such as internal staff within the Centre for Biosecurity and federal partners, who were consulted during the COVID-19 pandemic, and other external stakeholders, including regulated parties (e.g., Licence Holders and BSOs), who were consulted prior to the COVID-19 pandemic (see Appendix 2 for detailed methodology, limitations, and mitigation strategies).

2.2. Evaluation Questions

Given that the need to address biosafety and biosecurity is well established, as well as PHAC's role in doing so, the evaluation did not focus on program relevance. Instead, attention was given to impact of program activities, as well as opportunities to consider moving forward.

Evaluation Questions

1. To what extent has the HPTAR Framework improved awareness and knowledge of regulatory requirements, improved collaboration with stakeholders, and decreased the risks of accidental or deliberate release of human pathogens and toxins from regulated entities?
2. Are there opportunities to enhance how the Centre for Biosecurity undertakes activities related to the HPTAR Framework that should be considered moving forward?

3.0 What Difference Did the HPTAR Make?

Overall, awareness related to biosecurity and biosafety has increased, with regulated organizations having the information they need to comply with regulatory requirements. Furthermore, regulated organizations are complying with regulatory

requirements and proactively identifying or addressing risk in order to improve institutional biosafety and biosecurity. As a result, there are early signs of improved safety, including reduced risk of accidental or deliberate release of pathogens and toxins, as well as reduced health risk related to pathogens and toxins.

3.1 Awareness and Understanding of Regulatory Requirements

Information related to biosafety and biosecurity is readily available, including information about inspections and security clearances. Guidance materials come in several forms (e.g., PHAC training modules and webinars, Biosafety and Biosecurity for Pathogens and Toxins quarterly newsletter, published standards and guidelines, biosafety advisories, published directives, direct correspondence with PHAC, the ePATHogen database).

The Centre for Biosafety, specifically the Biosafety Learning and Knowledge Team, hosts e-learning courses in a Learning Portal that is accessible to the public. There are more than 40 courses related to biosafety and biosecurity topics, and more than 78,000 users, with approximately 28,000 individuals having actively used the portal in the past year.

The Centre for Biosecurity has organized 12 webinars since March 2018, on such topics as what to expect when you are inspected, understanding the HPTA and HPTR, biosecurity awareness, and, most recently, on the impacts of Coronavirus / COVID-19 and laboratory biosafety considerations. There have been 4,119 webinar participants in total. The Biosafety and Biosecurity for Pathogens and Toxins quarterly newsletter has had an average readership of 3,400 for both English and French versions since March 2019. A review of web statistics related to the Canadian Biosafety Standards and Guidelines revealed that there were 15,280 unique visits in 2019, 16,607 in 2020, and 15,879 in 2021.

The ePATHogen Risk Group Database was launched in August 2018 to provide a list of pathogens and toxins, and information about how they must be handled in the laboratory. Available web statistics show that there were 5,741 unique visits in 2019 (September 1to December 31, 2019), 16,893 in 2020, and 19,636 in 2021. Furthermore, the Canadian Biosafety Standards App, launched in 2015, allows regulated entities to filter the Canadian Biosafety Standards in order to save containment requirements specific to their facilities. Since 2019, there have been over 3,000 unique visits to the main page of the application, resulted in approximately 1,200 potential downloads of the application.

Finally, Pathogen Safety Data Sheets (PSDSs) are technical documents produced by PHAC as educational and information resources for laboratory personnel working with infectious substances. PSDSs provide organizations across Canada – and around the world – instant access to information on the hazards of various pathogens and how to work with them safely in a laboratory setting. PSDS web content is one of PHAC's most widely accessed pages. While data is limited, nearly 25,000 downloads of the PSDS mobile app have occurred since its release in 2015. In 2019-20, the most recent available data, there were 452,644 unique page visits and 1,001 PSDS downloads.

Regulated organizations also have the information they need to understand and comply with legislative and regulatory requirements. Eighty percent (80%) of external stakeholders indicate that they have the information they need to understand and comply with the *Act* and *Regulations,* **with a rate of 89% satisfaction in the latest year of data collection** (2019-20, meeting the targets in this area). Stakeholders also indicated that they are aware of the regulatory obligations regarding disposal of human pathogens and toxins, and that their roles and responsibilities are clearly defined.

3.2 Compliance with Regulatory Requirements

Regulated organizations are complying with legal and regulatory requirements to improve biosafety and biosecurity in their facilities. The Centre for Biosecurity has regularly surpassed its target of 85% for ensuring that compliance issues are addressed within established timelines. Addressing compliance has improved over the past few years, increasing from 82% in 2017, to 88% the following year, and finally 98% in 2019-20. Furthermore, in 2018-19, improvements were made to support Licence Holders (LH) in meeting established timelines, including the introduction of a 15-day reminder for all corrective actions.

There is also evidence that regulated organizations identify and proactively address risk in order to improve institutional biosafety and biosecurity practices. Specifically, regulated organizations are implementing changes (i.e., corrective actions to address root causes) in response to laboratory-acquired infections (LAI) and intoxication incidents in an effort to improve safety (e.g., training to ensure standard operating procedures are followed correctly, ensuring that laboratory equipment is properly maintained). In 2017-18 and 2018-19, the Centre for Biosecurity reported that at least 90% of LAIs and intoxication reports had led to institutional changes.

3.3 Institutional Controls

While the Centre for Biosecurity has made improvements to ensure that organizations have adequate institutional controls to conduct activities for which they are licensed, performance measurement data notes some challenges, in particular, related to Plans for Administrative Oversight (PAOs).

Under the HPTA, an organization is required to have a PAO before being issued a licence. A PAO is a regulatory tool that allows regulated parties to communicate how they plan to manage and control biosafety and biosecurity risks at the institutional level. The Centre for Biosecurity expects to reach its target of PAOs assessed as fully compliant by 2022. In 2019-20, the reported compliance rate was 70%. However, over the four-year of data collection for this evaluation, laboratory compliance greatly increased, from 40% in 2017-18 to 70% in 2019-20. While the target may not be met in 2022, there is evidence that compliance is moving in the right direction.

3.4 Accidental Exposure and Deliberate Release of Human Pathogens and Toxins

Overall, the HPTAR has demonstrated early signs of success in improving biosafety and biosecurity, with Canada being a top-rated country in terms of having sustainable biosafety and biosecurity.

Under the HPTAR, licence holders are required to report certain laboratory incidents involving a human pathogen or toxin. These can be broadly categorized as either of the following:

- **Exposure incident:** any contact with, or close proximity to, human pathogens or toxins that may result in laboratory-acquired infections or intoxication.
- **Non-exposure incidents:** inadvertent possession, production, or release of a human pathogen or toxin, any missing, lost or stolen biological agents, or an SSBA not received within 24 hours of expected arrival.

These laboratory incident notifications are monitored through the Public Health Agency of Canada's Laboratory Incident Notification Canada (LINC) surveillance system. Launched in 2015, the LINC system is unique in that it is one of the first comprehensive national surveillance systems to provide a systematic framework for reporting human pathogen and toxin exposures and LAIs in various

settings. In contrast, national reporting requirements for LAIs in other countries is often voluntary or conducted via retrospective survey.

International Collaboration

Through active leadership, partnerships, and global knowledge sharing, PHAC supports the advancement of global health priorities and international capacity building in biosafety and biosecurity. For example, the Centre for Biosecurity:

- provides Global Affairs Canada technical assistance and forms part of the Canadian delegation for the Biological and Toxins Weapons Convention;
- serves as the secretariat to the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR); and
- has been designated as a World Health Organization (WHO) Collaborating Centre for Biosafety and Biosecurity.

These types of collaborations extend the Centre's international reach, allowing it to influence safe and secure practices for human pathogens and toxins in laboratories around the world. Stronger, more standardized international approaches to biosafety and biosecurity mean better protection for Canadians at home and abroad.

[1] Please see (https://www.ghsindex.org/) for more information.

[2] The JEE is a voluntary, collaborative, multisectoral process to comprehensively assess country capacity to prevent, detect and rapidly respond to public health risks in the framework of the International Health Regulations. Please see https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/joint-external-evaluations for more information.

LINC allows for an almost real-time identification of causes of incidents and potential areas of improvement that could be addressed nationally, in conjunction with laboratories, to ensure risks are mitigated in a timely manner.

Deliberate Release of Human Pathogens and Toxins

There is evidence that **risk of deliberate release of a pathogen or toxin has become reduced.** Data outlining the number of missing, lost, or stolen pathogen or toxin incidents involving Security Sensitive Biological Agents (SSBAs), which have the highest potential of being used for malicious intent, shows that there have been no incidents reported since 2017-18.

Overall, there is evidence that **Canada has reduced public health risks associated with the use of pathogens and toxins.** The World Health Organization's Joint External Evaluation (JEE) reports and the Global Health Security Index[1] reflect different assessments of health security, and the two can be used together to create a more complete picture of global preparedness. This includes measuring Canada's progress towards establishing a comprehensive national oversight program for biosafety and biosecurity to protect Canadians from the risks associated with the use of pathogens and toxins. In the first ever assessment conducted in 2018, Canada received a perfect score (5/5) on the JEE indicator,[2] which indicates that a sustainable biosafety and biosecurity system is in place in Canada. This next assessment is expected to occur in 2023. Furthermore, on the 2021 Global Health Security Index, which measures the capacities of countries to prepare for epidemics and

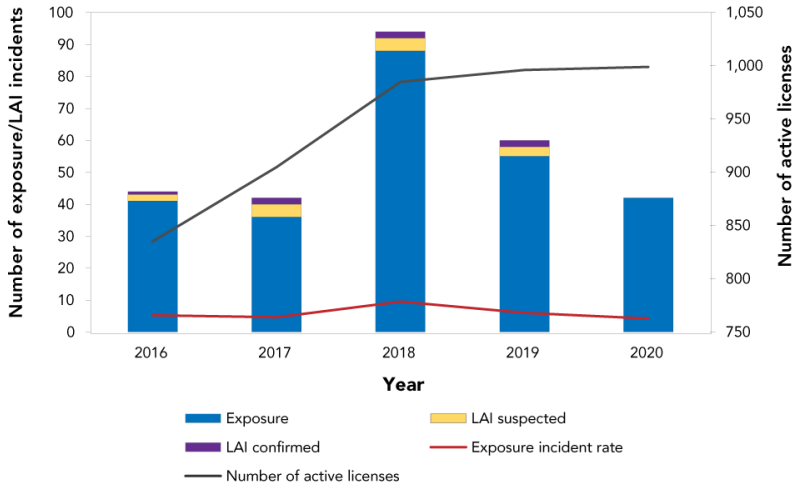
pandemics, Canada was first globally in relation to biosafety and third in relation to biosecurity.

Accidental Exposure to Human Pathogens and Toxins

The HPTA and HPTR set out reporting and notification requirements for licence holders, biological safety officers, and persons conducting controlled activities authorized under a Pathogen and Toxin Licence. The Centre for Biosecurity monitors trends in exposure incidents, including those resulting in suspected or confirmed laboratory-acquired infections or toxic effects. These types of incidents can result in the accidental release of a human pathogen from a laboratory into the community by way of an infected worker. Timely reporting of exposure incidents through LINC helps mitigate the risk of potential outbreaks and permit a rapid response.

Figure 1 presents confirmed exposure incidents, suspected and confirmed LAIs, and active licences. Although it is too early to assess the extent to which the Centre for Biosecurity has been able to reduce the risk of accidental release of a pathogen or toxin, data outlining the rates of exposure incidents resulting in a suspected or confirmed LAI or toxic effect as a percentage of active licences show low rates overall with slight variances in year-to- year performance, with 0.36% (3/835) of active licences in 2016-17, increasing to 0.66% (6/905) in 2017-18, decreasing to 0.61% (6/985) in 2018-19, and increasing again to 0.5% (5/996) in 2019-20. Since 2016, the actual number of exposure incidents reported increased, with a peak (88) reached in 2018. The increase was associated with the rise of the number of licences granted to laboratories over the same period. After 2018, despite the number of licences remaining fairly stable, the number of incidents started to decrease (55 in 2019, 42 in 2020).

Figure 1: Confirmed exposure incidents, suspected, and confirmed laboratory-acquired infections and active licences in Canada, 2016 to 2020



It should be noted:

- Incident notification requirements and the comprehensive reporting process, which came into effect December 1, 2015, are still new to Canadian laboratory workers. As such, the number of reported incidents, including exposures and LAIs, was expected to increase over time due to a continued increase in the number of licences issued in Canada and an increase in the awareness of regulated parties of their responsibility to report. However, it is expected that the rate of exposure and LAI occurrences will eventually stabilize or decrease over time. A stabilization or decrease in this rate may indicate an improvement in the prevention of exposure and LAI incidents, and contribute to a reduction in the risk of accidental release of a pathogen or toxin into the community and the potential for the spread of infectious disease.

- However, at least of five consecutive years of data are needed to establish an accurate baseline (2016-17 to 2020-21). In the interim, a provisional target value of 0.3% was adopted and will be adjusted at the end of 2022.
- The very small proportion (0.36% to 0.66%) of active licences reporting suspected or confirmed laboratory-acquired infections over the period in question suggests that the incident notification requirements and reporting process are still new to Canadian laboratory workers.
- Finally, as with all notification programs, increased reports do not mean lack of success. In fact, they can mean the opposite because outreach activities can stimulate reporting, which is an aim of the program. These reports provide the Centre for Biosecurity with a clearer picture of what is happening in licensed Canadian facilities. This information is then leveraged to strengthen biosafety and biosecurity standards and resources, and inform outreach and engagement efforts across the entire licensed population to help prevent future similar incidents.

4.0 Strengths

In addition to effective information sharing with key stakeholders and good compliance rates discussed above, there is evidence of an effective inspection and incident reporting process, strong service standards, and an improved performance measurement system since the last evaluation.

4.1 Inspections and Incident Reporting

Inspections

In order to encourage compliance with the Act and Regulations, the Centre for Biosecurity completes inspections and audits to assess and address biosafety and biosecurity risks. Licensed facilities handling SSBAs and RG3 and RG4 human pathogens are inspected at least once during the term of their licence, every one to three years. RG2 human pathogens and toxins are chosen for inspection through both risk-informed and randomly-selected approaches, with annual inspection targets based on available human and financial resources. The Centre for Biosecurity has consistently exceeded its annual inspection targets, with a calculated cumulative percentage for all facility types of 113% in 2018-19, and 130% in 2019-20. This was achieved by creating efficiency in the inspection approach and optimizing the use of inspection resources through internal reorganization, investments in cross-training of inspectors, and the inclusion of geographically proximate RG2 inspection sites during planned travel for RG3 licence inspections.

Despite exceeding inspection targets, the Centre for Biosecurity continues to experience challenges meeting the oversight needs of RG2 licensed facilities, an issue that was first identified in PHAC's 2019 Audit of Biosecurity. PHAC currently oversees over 1,000 facilities with RG2 licences, accounting for 94% (941) of the entire licenced population. As previously mentioned, annual targets for RG2 inspections are established based on available resources. The Centre for Biosecurity's current complement of inspection staff are only able to inspect 6% of RG2 licences per year. At this rate, it would take over 16 years to inspect all RG2 licensed facilities at least once, not accounting for further growth in the licensed population. While facilities working with RG2 pathogens are traditionally considered lower-risk, evidence gathered to date through mandatory incident reporting requirements suggests that they account for a disproportionate number of exposure notifications. The disproportionate risk associated with RG2 licensed facilities and the frequency of their inspection was noted in PHAC's 2019 internal audit of Biosecurity. At that time, the Centre for Biosecurity was able to inspect just 4% of the RG2 population, meaning each facility once every 20 years. Since the onset of the pandemic, the Centre

for Biosecurity has already been engaged by over 30 facilities looking to build new containment laboratories that work with the highest-risk pathogens (RG3 and RG4). This represents a sharp increase over the one or two requests every five years that PHAC had previously received, and would result in a 48% increase of the approximately 65 RG3/RG4 licenced facilities that are currently regulated, to 95. The Program has been engaged very early and often throughout the design and construction phases of these new facilities to ensure they have appropriate biosafety, biocontainment, and biosecurity measures in place, leading up to their licensing. This work is resource intensive, requiring specialized regulatory guidance and ongoing oversight. This may negatively affect the Program's ability to provide an appropriate level of oversight to RG2 licenced facilities.

Federal departments and external stakeholders agreed that inspection and enforcement stand out as a key success and viewed them as effective. Among those who had their sites inspected, most attributed their satisfaction to at least one, if not both, of the following:

- **Inspections have been positive experiences with positive effects** (e.g., they are a good learning opportunity, have identified areas for improvement and facilities are safer as a result, they support the work of Biological Safety Officers (BSOs), there are reasonable timelines for corrective actions); and
- **Inspectors have been well received** (e.g., they provided detailed reports and useful instructions for corrective measures and were described in positive terms, such as being thorough, knowledgeable, approachable, and collaborative).

External stakeholders also noted the reasonability, clarity, and effectiveness of requirements; that the requirements lend support to compliance and monitoring activities within organizations; and the helpful support PHAC provides.

A few external stakeholders identified challenges pertaining to time requirements for inspection and enforcement activities, implementing corrective actions, and ensuring consistency in compliance:

- **Considerable time may be required for inspection and enforcement activities, especially to prepare for inspections for the first time** (e.g., preparing copies of documentation, resources may need to be re-directed away from core work and research in support of inspection activities)
- **There can be challenges to implementing corrective actions** based on inspection feedback (e.g., resources are needed such as budget for renovations or hiring additional staff)

Incident Reporting

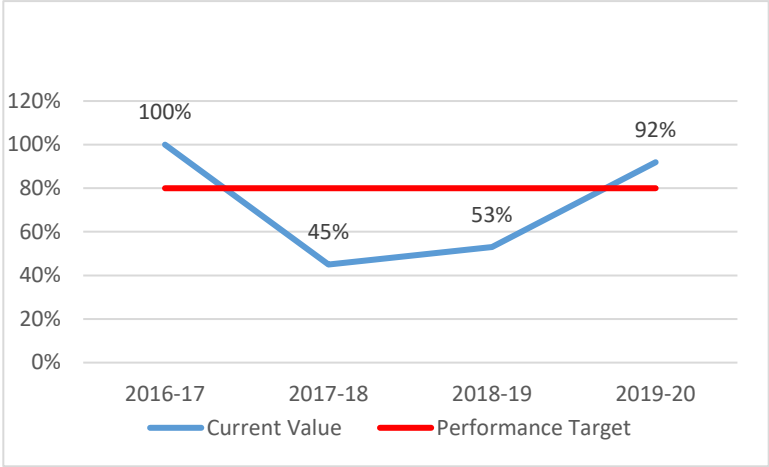
As part of the HPTAR inspection and compliance process, organizations must report incidents to PHAC (i.e., accidental or deliberate release of a human pathogen or toxin, which has or may have caused disease in an individual). The majority of external stakeholders were generally satisfied with incident reporting requirements under the HPTAR. Overall, stakeholders stated that reporting requirements were clear, appropriate, and working well. They also felt that PHAC provided appropriate support, and that the phased and risk-based approach eliminated excessive reporting. Nonetheless, a few challenges related to incident reporting were identified. Specifically, a few BSOs experienced challenges with incident reports, such as determining when to file, as well as having to fill out irrelevant mandatory fields. Added burden was also cited by a few as an area of concern (e.g., facilities already have internal reporting and investigation processes and requirements through Occupational Health and Safety legislation).

4.2 Service Standards

Existing data related to service standards also suggests that the Centre for Biosecurity administrative processes related to HPTAR are efficient. For example, between 2017-18 and 2019-20, the Centre for Biosecurity surpassed published service standards for issuance of RG2 licences, with 100% licences issued within the targeted 80 days. Specifically, the average issuance of RG2 licences was 17 business days in 2017-18, 22 business days in 2018-19 and 41 business days in 2019-20. The majority of licences were issued in 2016, and since then, a significant increase in volume of new licence applications, licence variations, and regulated parties requiring support throughout normal operations has been observed on a yearly basis. In addition, due to the uneven distribution of licences that resulted in a peak of renewals within a few months in 2021, renewal notices were sent out to regulated parties well in advance of their renewal dates, starting in 2019. As a result, renewals that came in months before their expiry date may have been processed intentionally within a longer timeframe in order to calm the next renewal cycle.

As a result of better monitoring and quality control, there was also consistent improvements in the issuance of HPTA security clearances within established service standards from 45% in 2017-18, to 53% in 2018-19, and 92% in 2019-20 (please see Figure 2 below).

Figure 2: Number and percentage of security clearance decisions within service standards



4.3 Performance Measurement

The program has also responded to recommendations from the 2014 *Evaluation of the Biosecurity Program 2009-10 to 2013-14* related to enhancing the performance measurement approach to better inform decision making. The Centre for Biosecurity has enhanced its approach to performance measurement and is currently collecting data on a number of immediate and intermediate outcome indictors to provide information on program performance, including service standards to assess process efficiency. The Centre has developed a strong Performance Information Profile, which includes a robust logic model and key performance indicators, and is supported by regular data collection. It should be noted that performance data was only available up to 2019-20, due to the COVID-19 pandemic.

5.0 Emerging Opportunities and Issues

Collected data identified a few emerging opportunities and issues, including the use of virtual inspections to complement on-site inspections. Significant challenges were noted in relation to licensing and security clearances.

5.1 Virtual Inspections

Due to the COVID-19 pandemic, the Centre for Biosecurity, along with many regulatory agencies across the world, has been conducting virtual inspections of RG2 licensed facilities to monitor compliance under the HPTA and the HAA. Virtual inspections have been organized using a similar format as on-site inspections and allow inspectors to monitor compliance via a means of telecommunication (e.g., Microsoft Teams).

Virtual inspections have been valuable during the COVID-19 pandemic to continue compliance monitoring activities, as travel is not required. Although less costly from a financial perspective, virtual inspections were found to be resource-intensive for both the inspection program and the regulated parties. In particular, preparation and submission of compliance information (e.g., documents, records, videos) can be burdensome to regulated parties. Therefore, there is an opportunity to determine how virtual inspections can complement on-site inspections moving forward. PHAC internal stakeholders noted that virtual inspections have become a valuable and necessary tool used by many regulatory agencies across the world during the COVID pandemic. Therefore, updating the Act to be more relevant and reflective of this reality would better support inspectors. To support virtual inspections and enforcement, internal stakeholders noted that inspectors should be allowed to exercise their powers remotely, via telecommunication.

It should be noted that the HPTA could be updated to explicitly permit inspectors to exercise their powers remotely via telecommunication, similar to several other Acts that have been recently promulgated (*Cannabis Act*) or updated (*Food and Drugs Act*). Federal government stakeholders were a bit less positive about virtual inspections than internal stakeholders. While many positive aspects of virtual inspections were identified (e.g., reduced costs, real-time inspections, opportunity to have record verification, enhanced oversight, reduced exposure of inspectors to pathogens and toxins), the majority concluded that virtual inspections cannot completely replace on-site inspections (e.g., for logistical reasons, they may be difficult to conduct). Some also indicated that on-site interviews are the best way of assessing the proficiency of those handling biohazards and their interactions with facilities and equipment.

Unfortunately, the views of external stakeholders were not captured, as data was collected prior to the COVID-19 pandemic and therefore prior to the Centre for Biosecurity implementing the use of virtual inspections.

5.2 Licensing

Overall, external stakeholders were satisfied with licensing, especially with the risk-based licensing framework for facilities conducting controlled activities with human pathogens and toxins, and reasonable requirements of the HPTAR, as well as support provided by PHAC in understanding requirements. However, there were some challenges reported related to the roles and responsibilities of BSOs.

Most external stakeholders indicated that they were generally satisfied with the licensing requirements of the HPTAR. The following aspects were most frequently cited:

- licensing framework and processes (e.g., using a risk-based approach, being able to include multiple activities under a single licence, user-friendliness of requirements and the Biosecurity Portal, PHAC guidance and flexibility);
- PHAC staff support including clear information regarding regulatory and administrative requirements; and
- Having reasonable requirements that are generally working well.

While most key external stakeholders reported that they did not experience challenges with licensing requirements, a few common challenges were identified:

- **Administrative Burden:** New and additional requirements can be technically challenging, burdensome, and affect business processes (e.g., completing risk assessments, managing oversight activities). Overall, there is more documentation required for Primary Investigators and BSOs, and this represents additional administrative burden.
- **Biological Safety Officers and Licence Holders (LH):** There was some confusion noted about the roles and responsibilities of BSOs and LHs.
    - Currently, each licence allows for one BSO who is responsible for all functions assigned to that role. For larger regulated organizations with several facilities across the country, it is difficult to meet some of their requirements under the HPTA. For example, BSOs are required to conduct periodic inspections and biosafety audits of facilities and report the findings to the LH. In some cases, responsibilities for this requirement have been shared by multiple individuals. Internal staff noted that there would be value in allowing multiple BSOs (or Alternate Biosafety Contacts) per licence to address these issues.
    - There continue to be some challenges in maintaining up-to-date contact information related to LHs and BSOs.
    - It was also noted by internal staff that there should be a mechanism that allows BSOs to notify the Centre for Biosecurity when they take a short-term leave of absence from their role. Furthermore, an Alternate Biosafety Contact should be identified if the BSO is unable to fulfill their functions for a specified period of time.
    - Finally, there is a need to redefine the qualifications of the BSO, as they are too broad to ensure adequate training and successful fulfillment of their role.

5.3 Regulatory Harmonization and Alignment

Several minor challenges were also reported related to regulatory harmonization and alignment between PHAC and GAC, and PHAC and CFIA requirements.

Harmonization between PHAC and Global Affairs Canada (GAC)
It was also noted that the current export controls of human pathogens and toxins require further strengthening and harmonization with GAC. Presently, individuals and organizations must obtain an export permit issued by GAC before exporting any regulated human pathogens and toxins that are present on the *Export Control List*, which is regulated by GAC under the *Export and Import Permits Act*.[3] However, the *Export and Import Permits Act* is not binding on the Crown, and therefore does not provide any authority to GAC to issue such permits to Crown organizations. In

[3] The *Export and Import Permits Act* regulates the export, transfer and brokering of goods and technology and the import of goods into Canada.

addition, prohibitions under the HPTA do not currently apply to the export by Crown organizations of human pathogens or toxins authorized under the *Export and Import Permits Act*. Exports of human pathogens or toxins appearing on the *Export Control List* made by Crown organizations could fall under the governance of the HPTA and associated licensing regime; however, the Centre for Biosecurity does not review or approve each export activity under its licence. It was suggested that PHAC and GAC continue to collaborate to fill potential and existing gaps related to Crown organizations to provide a level of oversight and reduce any related risks by conducting risk assessments of recipients in certain countries, including the potential for misuse of exported material in the development of biological weapons.[4]

Confusion between the Canadian Food Inspection Agency (CFIA) and PHAC

There are areas of uncertainty that can be challenging to navigate (e.g., determining which materials the HPTA applies to due to differential risk classification by regulators, such as PHAC and CFIA). This has resulted in challenges for regulated organizations, such as inspections of laboratories by both PHAC and CFIA. It is important to note that these issues were also raised through a targeted regulatory review and the development of the Agri-food and Aquaculture Roadmap, which lays out a regulatory modernization plan in support of innovation and economic growth in the agri-food and aquaculture industry. Under the Roadmap, PHAC and CFIA committed to exploring alignment of definitions in the HAA and the HPTA; and to consider risk-based exemptions from duplicative regulatory requirements.

5.4 Security Clearances

Overall, a need for improvement in several areas related to security clearances was noted. Internal staff and other federal department stakeholders had concerns, especially related to expanding current security clearance requirements to ensure appropriate level of scrutiny for individuals who are, or may be, working with or accessing human pathogens and toxins, including foreign nationals, those seeking a security clearance; and those who have obtained a security clearance whose situation has changed. Other areas identified were related to such things as confusion about security clearance requirements, process delays, and administrative burden.

A more comprehensive assessment resulting from increased scrutiny (i.e., gathering more information on applicants) helps produce stronger security clearance recommendations. External stakeholders generally believe current security clearance requirements can at least somewhat improve safety and security by mitigating against misuse of human pathogens and toxins, though not all think they are effective or add value to oversight, especially given the added barriers they present. In particular, the amount of time required for the security clearance application process was flagged, with consequences ranging from delaying the work of new hires to preventing student research or grant planning (e.g., in one case, took seven months to receive a security clearance). The

[4] Canada ratified the 1975 Biological and Toxin Weapons Convention (BTWC) that prohibits the development, production, stockpiling, acquisition and retention of biological weapons, while protecting the rights of Parties to exchange equipment, materials, and scientific and technological information for peaceful purposes to avoid hampering their economic and technological development. The Centre for Biosecurity collaborates with GAC and international stakeholders to uphold BTWC obligations.

requirement of personal information in security clearance applications (e.g., credit history, spousal identification without requiring spousal consent) was another source of criticism in this area, as was the inability to use pre-existing federal security clearances acquired for other purposes.
The recent Audit of Biosecurity (2019) found similar issues related to inaccuracies and delays in processing security clearance applications. To mitigate these challenges, the audit recommended that improvements should be made to ensure that the security clearance process is administered accurately and efficiently.

Expanded Criteria for Security Clearances
For the most part, internal and external key informants agreed that security clearance requirements should be expanded to include more individuals working with or having access to human pathogens and toxins. Specifically, internal staff agreed that there should be increased scrutiny related to security clearances, noting that a security clearance should be required for anyone who has access to sensitive information, regardless of the level of risk they pose, or the subset they work for or have access to. While external key informants more frequently stated that there were no additional situations that would require a security clearance that they were aware of, a few, particularly BSOs, suggested that all personnel with access to sensitive data in facilities where SSBAs are handled should be required to hold a security clearance. Among others, this would apply to IT personnel, inspectors, and regulatory officials with access to floor plans or HPT inventory records.

Enhanced Security Checks
An internal discussion paper produced on the subject of security noted that nationality, length of Canadian residency, nor dual citizenship seem to have a clear effect on the safe and secure handling of pathogens and toxins and access to high-risk organisms. Although factors related to nationality do not have a clear connection to the physical mishandling of SSBAs, misappropriation of intellectual property seems to have a more apparent connection to foreign governments, who continue to exploit personal vulnerabilities, such as emotional ties to their foreign country, in order to recruit non-traditional intelligence actors.

The majority of other federal department stakeholders agreed that consideration should be given to nationality, length of residency, or dual citizenship for those handling SSBAs, as someone with no history in Canada is largely unknown to law enforcement or national security. This may trigger a need to undertake an enhanced security assessment.

Other federal department stakeholders also indicated that there should be more consideration to serious and organized crime as part of the security clearance processes, and highlighted the gap in safeguarding against knowledge theft or intangible technology transfer, such as insider threats, cyber threats (including ransomware), as well as theft of intellectual property, assets, technologies, and data. Internal staff disagreed, noting that organized criminals do not present the same level of threat as state-sponsored activities.

Continuous Vetting of Existing Security Clearances
Most federal stakeholders agreed that there is a need for continuous vetting of existing security clearances, typically issued for a five-year period, citing that a person's situation or motivations can change over time (e.g., financial or marital situation, mental health-related issues, such as anger and resentment, sharing knowledge of their work when being approached or harassed by an external threat). They felt that a flexible system could be considered, where risk indicators can trigger renewed vetting or

that there should be open communication between the clients and PHAC, with incidents being reported and reviewed accordingly.

5.5 "Growth of Biomanufacturing and Life Sciences in Canada

In Budget 2021, significant investments of over $3 billion were made to advance the biomanufacturing and life sciences sector in Canada. This has led to new policy and legislative challenges, such as the need to consider licensing private sector containment level 4 (CL4) laboratories, including in academic institutions, which has never previously been done in Canada. Allowing private sector CL4 laboratories introduces new risks and considerations that currently fall outside of the scope of existing regulatory oversight and have national security implications. As a result, the Centre for Biosecurity has undertaken various initiatives to better understand these national security implications of licensing these private sector laboratories. These include assessing existing requirements for government-run CL4 laboratories; determining what authorities may currently exist under the HPTAR to manage identified risks; consulting with a number of national security partners and other government departments; commencing an international scan of management of private sector CL4 labs using multilateral partners from the International Expert Groups of Biosafety and Biosecurity Regulators (IEGBBR); and initiating a threat assessment of the HPTA program to understand the current threat landscape in Canada.

6.0 Conclusions

According to the 2021 Global Health Security Index, Canada ranks very highly in the world in terms of both biosecurity and biosafety, ranking biosecurity #1 globally in terms of biosafety and #3 in terms of biosecurity.

The HPTAR Program has shown early signs of success. Regulated organizations covered by the Act:

- have the information they need to understand and comply with legislative and regulatory requirements;
- comply with legal and regulatory requirements and improve biosafety and biosecurity in their facilities; and
- identify and proactively address risk to improve institutional biosafety and biosecurity.

There has been a decrease in risk of accidental or deliberate release of pathogens and toxins, leading to a reduced public health risk related to pathogens and toxins. We also found evidence of solid knowledge exchange, effective inspection and enforcement, and good compliance rates.

Issues were raised regarding security clearance requirements, including expanding the criteria for who should have a security clearance beyond those who work with or have access to RG3 and RG4 pathogens, as well as increasing the level of scrutiny prior to issuing security clearance for foreign nationals. Licensing challenges were also raised, including clearly defining roles and responsibilities between Biological Safety Officers and Licence Holders. Addressing administrative burden for regulated organizations in the areas of licensing, security clearances, and inspections was also identified as a key area of focus (e.g., streamlining application process and the information needed from applicants, harmonization of PHAC requirements with the Canadian Food Inspection Agency). Finally, the appropriateness of using virtual inspections and how they could complement existing on-site inspections was identified as an area for further consideration. Considering that the Centre for Biosecurity's current complement of inspection staff are only able to inspect 6% of RG2 licences per year, virtual inspections may enhance some of this capacity gap. Where this is not sufficient, the Centre for Biosecurity should work to enhance capacity in this area.

In addition, significant recent investments to advance the biomanufacturing and life sciences sector in Canada has led to new policy and legislative challenges, such as the need to consider licensing high-containment private sector laboratories, including academic institutions, which introduce new risks and considerations that currently fall outside of the scope of existing regulatory oversight and have national security implications. As a result, the Centre for Biosecurity is undertaking various initiatives to better understand these national security implications to address any issues related to the establishment of these private sector laboratories.

7.0 Recommendations

The evaluation evidence discussed in this report led to the identification of the following recommendations.

Recommendation 1: Review current security clearance requirements to ensure appropriate level of scrutiny for individuals who are, or may be, working with or accessing human pathogens and toxins.

There were concerns raised regarding current security clearance requirements, especially in the context of foreign nationals, those renewing or seeking a security clearance for the first time, and those who may have access to human pathogens and toxins but do not require security clearances, such as information technology personnel, inspectors, and regulatory officials who require access to floor plans or inventory records. Reviewing current requirements to ensure an appropriate level of scrutiny is in place would further enhance existing security measures to protect national security interests and the health and safety of the public against risks posed by human pathogens and toxins.

Recommendation 2: Consider how virtual inspections can complement current on-site inspections, and under what circumstances they may be appropriate.

Virtual inspections have become a valuable and necessary tool used by many regulatory agencies across the world since the COVID-19 pandemic began. Although they should not be seen as a viable replacement for on-site inspections, they could be an additional Virtual inspections have become a valuable and necessary tool used by many regulatory agencies across the world since the COVID pandemic began. Although they should not be seen as a viable replacement for physical inspections, they could be an additional cost-effective tool to be used to complement current on-site inspections, as appropriate.

Recommendation 3: Clearly define and communicate roles and responsibilities related to Biological Safety Officers and Licence Holders.

There was some confusion noted from external stakeholders and internal staff about the roles and responsibilities of BSOs and LHs (e.g., designation of roles, a licence allowing for only one BSO for each regulated organization despite its size). There have been challenges to acquire up-to-date information from LHs and BSOs. There were also issues related to the Centre for Biosecurity being informed in a timely fashion when changes to BSOs occur, or when a BSO is no longer able to fulfil their functions for a specific period of time. This is an important consideration, as there are time constraints associated to some BSO responsibilities (e.g., notifications and obligation to inform the Minister). In some circumstances, identifying Alternate Biosafety Contacts could address some of these issues and ensure that an appropriate contact is available should the Centre for Biosecurity need to communicate with the regulated organization and ensure that someone is properly qualified and available to fulfil the functions of the BSO.

Appendix 1: Budget and Actual Expenditures

The expenditures below represent the Centre for Biosecurity's activities to support Canada's national oversight of human pathogens and toxins, which include the implementation of the HPTAR, but also include other expenses related to the Centre's IT infrastructure (i.e., iSTOP) and security clearance processing, amongst others.

Expenditures	2016-17		2017-18		2018-19		2019-20		2020-21	
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual
Salaries & Wages	$6,194,910	$5,942,257	$6,432,322	$6,639,451	$6,499,313	$6,465,189	$7,318,930	$7,768,653	$14,472,131	$11,780,548
O&M (Inc. student)	$1,881,955	$1,772,893	$1,719,881	$1,569,097	$1,873,398	$1,926,255	$1,912,588	$1,901,807	$62,596,938	$30,023,409
Capital	$493,547	$421,908								
Total	8,570,412	$8,137,058	$8,152,203	$8,208,548	$8,372,711	$8,391,444	$9,231,518	$9,670,460	$77,069,069	$41,803,957

2019-2020: Due to the Agency's response to COVID-19, planned expenditures for 2019-20 only accounted for regular funding (A-Base). Actual COVID-19 expenditures represented $273,424.

2020-2021: New planned expenditures for COVID-19 activities were $68,662,283 in 2020-21, while actual COVID-19 expenditures represented $32,129,211.

Appendix 2: Approach and Limitations

Approach

This evaluation was carried out by the Public Health Agency of Canada's Office of Audit and Evaluation. The purpose was to examine whether the HPTAR had improved awareness and knowledge of regulatory requirements, improved collaboration with stakeholders, and decreased the risks of accidental or deliberate release of human pathogens and toxins. It also examined opportunities to enhance how the Centre for Biosecurity undertakes its activities.

The evaluation built on evidence provided by the Centre for Biodiversity, which included consultations with the following stakeholders:

- Internal staff within the Centre for Biosecurity (*n*=9), who were consulted during the COVID-19 pandemic (2020-21);
- Federal partners (*n*=19), who were consulted during the COVID-19 pandemic (2021); and
- External stakeholders (*n*=58), including regulated parties (e.g., biological safety officers, licence holders), as well as members of the Advisory Committee on Human Pathogens and Toxins. These consultation took place in 2019, prior to the COVID-19 pandemic.

The evaluation focused its data collection on a review of documentation, including program reports, research, policies, and guidelines. It also included three discussion papers examining issues related to residency requirements for the purpose of security clearances, HPT waste management, and the exclusion of HPTs occurring in their natural environment from regulation. The evaluation also examined program performance data collected by the Centre for Biosecurity, focusing on the time period between 2016-17 and 2019-20. Due to the COVID-19 pandemic, performance data for 2020-21 was not available during the evaluation period.

Limitations

The following table outlines the limitations encountered during the implementation of the data collection methods selected for this evaluation. Also noted are the mitigation strategies implemented to ensure that evaluation findings could be used with confidence in guiding program planning and decision making.

Limitation	Impact	Mitigation Strategy
The evaluation did not conduct any key informant interviews, but relied on consultations undertaken with internal staff, federal departments, and external stakeholders, including non-federal regulated organizations, undertaken for the Centre for Biosecurity between 2019 and 2021.	The evaluation was unable to follow up with key informants to better understand their perspectives on certain issues.	The evaluation relied on performance data to assess impacts of the HPTAR, while the three consultation papers were primarily used to examine emerging opportunities and issues. Since the previous evaluation, the Centre for Biosecurity has developed a strong performance measurement strategy, including a robust logic model and key performance indicators, supported by regular data

		collection. These findings were also triangulated with other documentation, including international reports.
The impacts of the COVID-19 pandemic resulted in delays in collecting performance data for 2020-21.	Performance data was only available for the period between 2016-17 and 2019-20. Therefore, the results are not current.	Performance data was triangulated with other sources of data where possible, including the consultation reports, which examined impacts and emerging opportunities and issues.
Consultations with internal staff and external stakeholders are retrospective in nature. This may lead to the provision of recent perspectives on past events.	This can affect the validity of assessing activities or results relating to improvements in the program area.	Triangulation of other lines of evidence was used to substantiate or provide further information on data received through the consultations.

Appendix 3: HPTAR Logic Model