Question

With regard to the Public Health Agency of Canada, the Department of Foreign Affairs, Trade and Development and the Department of National Defence: (a) what biosecurity threats has Canada identified from 2019 and emerging in the near future; (b) what pathogens were under investigation by the government between 2019 and 2025, and, for each instance, what was the (i) name of the pathogen, (ii) date of the investigation, (iii) department investigating the pathogen, (iv) result of the investigation; (c) what counter-measures are in place or planned to address biosecurity threats or the specific pathogens in (b); (d) how many biosecurity or biosafety laboratories are located in Canada, where are these laboratories located and at what biosafety laboratory levels do they operate; (e) does the government approve or authorize (i) gain-of-function research, (ii) bioweapons or biodefence research; (f) if the answer to (e) is affirmative, which Canadian laboratories conduct (i) gain-of-function research, (ii) bioweapons or biodefence research; (g) if the answer to (e) is negative, does Canada collaborate with other nations to conduct (i) gain-of-function research, (ii) bioweapons or biodefence research; (h) if Canada collaborates with other nations as per (g), which nations are involved, and when were these collaborative relationships established; (i) what international agreements or treaties related to biosecurity, gain-of-function, or biodefence research is Canada party to, and how does the government ensure compliance with these commitments; (j) what oversight mechanisms, standards and audit processes does the government apply to biosecurity and biosafety laboratories; (k) how many laboratory incidents involving human pathogens or toxins have been reported in Canada in the last five years, and what actions were taken in response; (l) what penalties or enforcement mechanisms are in place for conducting unauthorized gain-of-function or bioweapons research in Canada; and (m) did the Public Health Agency of Canada, the Department of Foreign Affairs, Trade and Development or the Department of National Defence assess COVID-19 or SARS-COV-2 as being a bioweapon with respect to international biological weapons conventions, and, if so, what actions were taken and by whom, or, if not, why not?

Response

This response was tabled in the House of Commons on January 26, 2026, as Sessional Paper 8555-451-669.

Tabled on
January 26, 2026

Sessional Paper
8555-451-669

House of Commons

Question number	Asked by	Date asked
Q-669	Cheryl Gallant (Algonquin—Renfrew—Pembroke)	December 8, 2025

Presented by

Kevin Lamoureux

Parliamentary Secretary to the Leader of the Government in the House of Commons

Global Affairs Canada

Reply by: the Minister of Foreign Affairs

Name of Signatory: Parliamentary Secretary Rob Oliphant

Reply

Global Affairs Canada

(a) what biosecurity threats has Canada identified from 2019 and emerging in the near future?

Since 2019, Global Affairs Canada has identified, through various fora, research security, biological weapons proliferation by both state and non-state actors, agroterrorism, emerging biotechnologies/dual-use research of concern and biological threats in Africa (posed by zoonotic infectious disease outbreaks and lack of core capabilities to handle and safeguard high-consequence pathogens) as current and emerging threats.

National Security Guidelines for Research Partnerships

Biological and Chemical Defence Review Committee 2023 Annual Report Building resilience against agro-terrorism and agro-crime Reducing biorisks posed by life sciences research with dual-use potential

(b) what pathogens were under investigation by the government between 2019 and 2025, and, for each instance, what was the (i) name of the pathogen, (ii) date of the investigation, (iii) department investigating the pathogen, (iv) result of the investigation?

It is not within Global Affairs Canada’s mandate to investigate pathogens. Therefore, Global Affairs Canada does not have any information on this subject.

(c) what counter-measures are in place or planned to address biosecurity threats or the specific pathogens in (b)?

It is not within Global Affairs Canada's mandate to investigate pathogens. Therefore, Global Affairs Canada does not have any information on this subject.

(d) how many biosecurity or biosafety laboratories are located in Canada, where are these laboratories located and at what biosafety laboratory levels do they operate?

It is not within Global Affairs Canada's mandate to regulate biosecurity or biosafety laboratories. Therefore, Global Affairs Canada does not have any information on this subject.

(e) does the government approve or authorize (i) gain-of-function research, (ii) bioweapons or biodefence research?

It is not within Global Affairs Canada's mandate to regulate laboratories conducting gain-of-function research or bio-defense research. Therefore, Global Affairs Canada does not have any information on this subject.

Bioweapons research is prohibited under the Biological and Toxin Weapons Convention and in Canada under the *Criminal Code* and the *Human Pathogens and Toxins Act* .

(f) if the answer to (e) is affirmative, which Canadian laboratories conduct (i) gain-of-function research, (ii) bioweapons or biodefence research?

It is not within Global Affairs Canada's mandate to regulate domestic laboratories conducting gain-of-function research or bio-defense research. Therefore, Global Affairs Canada does not have any information on this subject.

Bioweapons research is prohibited under the Biological and Toxin Weapons Convention and in Canada under the *Criminal Code* and the *Human Pathogens and Toxins Act* .

(g) if the answer to (e) is negative, does Canada collaborate with other nations to conduct (i) gain-of-function research, (ii) bioweapons or biodefence research?

It is not within Global Affairs Canada's mandate to regulate collaborations on gain-of-function research or bio-defense research. Therefore, Global Affairs Canada does not have any information on this subject.

Bioweapons research is prohibited under the Biological and Toxin Weapons Convention and in Canada under the *Criminal Code* and the *Human Pathogens and Toxins Act* .

(h) if Canada collaborates with other nations as per (g), which nations are involved, and when were these collaborative relationships established?

It is not within Global Affairs Canada's mandate to regulate collaborations on gain-of-function research or bio-defense research. Therefore, Global Affairs Canada does not have any information on this subject.

Bioweapons research is prohibited under the Biological and Toxin Weapons Convention and in Canada under the *Criminal Code and the Human Pathogens and Toxins Act* .

(i) what international agreements or treaties related to biosecurity, gain-of-function, or biodefence research is Canada party to, and how does the government ensure compliance with these commitments?

With regards to international agreements or treaties related to biosecurity, first and foremost, Canada is a State Party to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, more commonly known as the Biological and Toxin Weapons Convention. The Convention does not currently have a verification mechanism; however Canada submits annual Confidence-Building Measures through the Convention, which are publicly available in both official languages and contains, among other information, declarations on Canada's relevant research centres and laboratories, national biological defence research and development programs, outbreaks of infectious diseases and similar occurrences caused by toxins, legislation, regulations, and other measures, past activities in offensive and/or defensive biological research and development programs and vaccine production facilities. Canada's domestic legislation implementing the Convention's obligations is primarily the *Human Pathogens and Toxins Act* , administered by the Public Health Agency of Canada.

Canada's Confidence Building Measures to the Biological and Toxin Weapons Convention

(j) what oversight mechanisms, standards and audit processes does the government apply to biosecurity and biosafety laboratories?

It is not within Global Affairs Canada's mandate to oversee biosecurity and biosafety in Canadian laboratories. Therefore, Global Affairs Canada does not have any information on this subject.

(k) how many laboratory incidents involving human pathogens or toxins have been reported in Canada in the last five years, and what actions were taken in response?

It is not within Global Affairs Canada's mandate to track laboratory incidents. Therefore, Global Affairs Canada does not have any information on this subject.

(l) what penalties or enforcement mechanisms are in place for conducting unauthorized gain-of-function or bioweapons research in Canada?

It is not within Global Affairs Canada's mandate to enforce domestic legislation on biosafety and biosecurity. Therefore, Global Affairs Canada does not have any information on this subject.

Bioweapons research is prohibited under the Biological and Toxin Weapons Convention and in Canada under the *Criminal Code* and the *Human Pathogens and Toxins Act* .

(m) did the Public Health Agency of Canada, the Department of Foreign Affairs, Trade and Development or the Department of National Defence assess COVID-19 or SARS-COV-2 as being a bioweapon with

respect to international biological weapons conventions, and, if so, what actions were taken and by whom, or, if not, why not?

Global Affairs Canada does not maintain an official position on the origin of SARS-COV-2; the Government of Canada does maintain the position that future studies into the origin of the COVID-19 pandemic should consist of transparent and independent analysis and evaluation, free from interference and undue influence.

Joint statement on the World Health Organization-Convened COVID-19 Origins Study

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Health Canada

Reply by: the Minister of Health

Name of Signatory: Signed by Maggie Chi

Reply

Public Health Agency of Canada

(a) what biosecurity threats has Canada identified from 2019 and emerging in the near future?

For the purposes of this response, a “biosecurity threat” is defined as the loss, theft, misuse, diversion, or intentional release of pathogens, toxins, and related assets.

These types of threats are identified as a result of analysis of publications, including news articles, reports, and threat assessments. Security and intelligence partners have publicly reported on the evolving threats to biotechnology research in Canada through the annual Canadian Security Intelligence Service Public Reports, and the Canadian Centre for Cyber Security’s 2024 threat assessment, “The Cyber Threat to Research Laboratories”.

Threats identified by these partners include the potential targeting of Canadian facilities, the research they conduct, and personal or proprietary information held in them. These threat activities could be carried out by state-sponsored actors or cybercriminals.

The Public Health Agency of Canada continues to monitor the evolving threat landscape, including emerging threats to biosecurity and biosafety. Advances in genetics, synthetic biology and artificial intelligence will continue to pose challenges in this domain.

(b) what pathogens were under investigation by the government between 2019 and 2025, and, for each instance, what was the (i) name of the pathogen, (ii) date of the investigation, (iii) department investigating the pathogen, (iv) result of the investigation?

It is important to note that the investigation of pathogens in general is a broader activity than addressing biosecurity threats, as many pathogens are monitored by the Government of Canada that are not biosecurity threats as defined above.

The Public Health Agency of Canada conducts continuous monitoring on pathogens, including: vaccine preventable diseases, enteric pathogens, zoonotic diseases, sexually transmitted diseases, respiratory diseases, and antimicrobial

resistant pathogens. The Public Health Agency of Canada works closely with provincial and territorial partners to respond to any infectious disease event related to an infectious disease pathogen.

Examples of large-scale investigations from 2019-2025 include COVID-19, monkeypox and avian influenza:

Example 1

i. SARS-CoV-2 (COVID-19)

ii. Date of Investigation: January 27, 2020, onward

iii. Department: Public Health Agency of Canada/National Microbiology Laboratory

iv. Actions: Extensive genomic surveillance, risk assessment and outbreak response; identification of variants of concern; development of national testing and sequencing capacity; established a national wastewater monitoring program for detecting SARS-CoV-2 in wastewater; established federal surge capacity mobilizing 6 testing sites across the country; supported Canada's border testing program February 22, 2021, to September 30, 2022. The Public Health Agency of Canada's National Microbiology Laboratory used genomic analysis to detect mutations that could impact treatment or vaccine performance. Surveillance, testing, genomic analysis and risk assessment informed public health advice and decisions on the COVID-19 pandemic response from public health measures advice, communications, vaccine program priorities, procurement and guidance among federal/provincial/territorial public health authorities in Canada.

Example 2

i. Monkeypox

ii. Date of Investigation: 2022–2023 (Investigation was initiated in May 2022, with subsequent Incident Management System activation until December 2022. In July 2022, following the World Health Organization announcement declaring the global monkeypox outbreak a Public Health Emergency of International Concern, it was determined that a coordinated Federal/Provincial/Territorial response was required, and a Special Advisory Committee on monkeypox was established.) A second monkeypox Public Health Emergency of International Concern declared in August 2024 prompted the activation of an Emergency Response Cell at the Public Health Agency of Canada until November 2024. This Public Health Emergency of International Concern and activation were related to the increase in monkeypox cases in a growing number of countries in Africa, as well as the emergence of clade Ib MPXV.

iii. Department: Public Health Agency of Canada/National Microbiology Laboratory

iv. Actions: Diagnostic support and genomic surveillance; expanded scope of wastewater monitoring to include monkeypox; a Federal/Provincial/Territorial Special Advisory Committee for monkeypox was formed to coordinate the pan-Canadian response; National Microbiology Laboratory leveraged the Canadian Public Health Laboratory Network to enhance provincial testing capacity. National Microbiology Laboratory integration of monkeypox into genomic surveillance systems, improving understanding of the virus. Building on experience from previous emergency management events and informed by the investigation and surveillance of the monkeypox pathogen, the Agency responded promptly to the monkeypox outbreak in a wide-ranging and comprehensive manner. Canada was seen as a global leader in its response to this outbreak.

Based on understanding of the monkeypox pathogen and global epidemiology, Canada was one of the first nations to position and implement vaccine regimes within provinces and territories based on National Advisory Committee on Immunization guidance. Over 119,800 doses of the vaccine were estimated to have been administered during the outbreak. In addition, it took an international lead in wastewater monitoring. The Agency regularly engaged with international partners to support the global response.

An outbreak management report was published on Canada.ca: Management of the 2022 Monkeypox (Monkeypox) Outbreak in Canada. The Public Health Agency of Canada maintains vigilance for monkeypox in Canada (including the emergence of novel clades and subclades) through public health surveillance and monitoring activities.

Example 3

i. Avian influenza A(H5N1)

ii. Date of investigation: December 2021 onwards. The current animal outbreak in Canada was first detected in December 2021 with a new introduction of A(H5N1), clade 2.3.4.4b in farmed poultry. The Government of Canada has continued monitoring this rapidly evolving situation closely, taking proactive measures to protect the health of people and animals in Canada. Health Portfolio Operations Centre activated to Level 1 Enhanced Reporting and Planning Emergency Response Cell in response to detection of A(H5N1) in United States dairy cattle between May 2nd, 2024, and July 2nd, 2024.

iii. Department: Public Health Agency of Canada/National Microbiology Laboratory

iv. Actions: Surveillance of zoonotic signals; outbreak monitoring; collaboration with provincial and territorial partners on all aspects of readiness and response; multi-disciplinary risk assessments; conducted preparedness activities, updated and developed guidance (e.g., Guidance on human health issues related to avian influenza in Canada), One Health coordination and collaboration with internal and external partners including engagement of expert panels to inform public health response in Canada (e.g., Public Health Agency of Canada avian influenza A(H5Nx) expert panel). High-Containment Research: National Microbiology Laboratory developed preclinical studies for H5 vaccine and antiviral candidates. The Public Health Agency of Canada developed recommendations for public health authorities and other stakeholders involved in the prevention and management of actual and potential human health issues related to Avian Influenza outbreaks.

(c) what countermeasures are in place or planned to address biosecurity threats or the specific pathogens in (b)?

As detailed above, countermeasures for pathogens often include surveillance, collaboration with provinces and territories, multi-disciplinary risk assessments, the provision of public health guidance, One Health coordination and collaboration with internal and external partners, and public health research. The exact measures taken will depend on the pathogen being responded to.

The Public Health Agency of Canada also engages in biosafety and biosecurity activities and establishes a safety and security program to protect the health and safety of the public against the risks posed by pathogens and toxins.

The Public Health Agency of Canada's Centre for Biosecurity is the federal authority and regulator of individuals and facilities working with human pathogens and toxins regulated under the *Human Pathogens and Toxins Act* and the *Human Pathogens* and *Toxins Regulations* , which came into force on December 1, 2015.

The *Human Pathogens and Toxins Act* and the *Human Pathogens* and *Toxins Regulations* are one of the key pillars of a national safety and security program for human pathogens and toxins that aims to:

- prevent and reduce the risk of an accidental or deliberate unauthorized release;
- standardize requirements for imported and domestically acquired or produced human pathogens and toxins; and
- strengthen the safe use and secure containment of human pathogens and toxins in Canada.

Acting on behalf of the Minister of Health, the Public Health Agency of Canada provides lifecycle oversight of academia, pharmaceutical, diagnostic and public health-related containment facilities working with pathogens and toxins through a comprehensive licensing regime, security clearance, inspection, and compliance program.

In December 2024, the Public Health Agency of Canada published the Biosecurity Addendum to the Canadian Biosafety Standard, which comes into effect January 5, 2026. The Addendum outlines biosecurity requirements for Containment Level 4 facilities handling Risk Group 4 pathogens.

The Public Health Agency of Canada also manages the National Emergency Strategic Stockpile, a federally owned stockpile of medical assets. The National Emergency Strategic Stockpile, in response to requests for assistance from provinces and territories, facilitates access to a range of medical countermeasures required to safeguard public health by providing the means to protect against and prevent infectious diseases and other health consequences of an intentional, accidental, or naturally occurring public health threat.

(d) how many biosecurity or biosafety laboratories are located in Canada, where are these laboratories located and at what biosafety laboratory levels do they operate?

Province	Risk Group 2	Security Sensitive Biological Agent Toxin	Risk Group 3	Risk Group 4	Total
Alberta	95	1	7	0	103
British Columbia	120	0	8	0	128
Manitoba	34	1	4	2	41
New Brunswick	31	0	1	0	32
Newfoundland	13	0	1	0	14
Northwest Territories	1	0	0	0	1
Nova Scotia	28	0	4	0	32
Nunavut	2	0	0	0	2
Ontario	313	1	17	0	331
Prince Edward Island	10	0	0	0	10
Quebec	298	1	23	0	322
Saskatchewan	29	0	3	0	32
Yukon	2	0	0	0	2
Total	976	4	68	2	1050

(e) does the government approve or authorize (i) gain-of-function research, (ii) bioweapons or biodefence research? (f) if the answer to (e) is affirmative, which Canadian laboratories conduct (i) gain-of-function research, (ii) bioweapons or biodefence research?

Canada does not approve or authorize gain-of-function or bioweapons research. Canada does authorize biodefence research, which focuses on countermeasures, preparedness, and response to biological threats, not weaponization. This includes work on vaccines, diagnostics, and protective measures. Canada's biosecurity program does not involve the systematic review of individual research projects for identification or assessment of dual-use potential (e.g., gain-of-function experiments), nor does it involve authorizing or denying specific experiments. Such reviews and decisions are made at the institutional level and with funding/granting agencies.

Canada is one of over 180 States to have ratified the Biological and Toxin Weapons Convention. The Biological and Toxin Weapons Convention prohibits the development, production, stockpiling, acquisition, and retention of biological weapons.

Each State Party is required to place the provisions of the Convention into its domestic legislation. Canada implements the Biological and Toxin Weapons Convention through a series of laws, including the *Human Pathogens and Toxins Act* .

(g) if the answer to (e) is negative, does Canada collaborate with other nations to conduct (i) gain-of-function research, (ii) bioweapons or biodefence research? (h) if Canada collaborates with other nations as per (g), which nations are involved, and when were these collaborative relationships established?

Not applicable.

(i) what international agreements or treaties related to biosecurity, gain-of-function, or biodefence research is Canada party to, and how does the government ensure compliance with these commitments?

The Public Health Agency of Canada supports Global Affairs Canada in meeting Canada's commitments for the Biological and Toxins Weapons Convention and International Health Regulations.

The Biological and Toxin Weapons Convention prohibits the development, production, stockpiling, acquisition, and retention of biological weapons while facilitating the use of biological agents for peaceful purposes. While the Biological and Toxin Weapons Convention currently has no mechanism for verifying States Parties' compliance, States Parties have agreed to submit voluntary Confidence Building Measures. These measures are meant to prevent or reduce the occurrence of ambiguities, doubts and suspicions, and to improve international cooperation. Canada completes its annual Confidence Building Measures in order to promote transparency and foster confidence that we are meeting our obligations under the Convention. Each State Party is required to place the provisions of the Convention into its domestic legislation. Canada implements the Biological and Toxin Weapons Convention through a series of laws, including the *Human Pathogens and Toxins Act* and the *Criminal Code* .

The International Health Regulations provide an overarching legal framework that defines States Parties' rights and obligations in managing public health risks, events and emergencies that have the potential to cross borders. The International Health Regulations require that States Parties develop a set of core capacities to support this goal which are assessed via Joint External Evaluations and States Parties Self-Assessment Annual Reports. Biosafety and biosecurity capabilities are assessed through the Joint External Evaluations and States Parties Self-Assessment Annual Reports processes. Canada scored a 5/5 on the indicator for "Whole-of-government biosafety and biosecurity system is in place for human, animal and agriculture facilities" in the 2018 Joint External Evaluations and subsequent States Parties Self-Assessment Annual Reports.

(j) What oversight mechanisms, standards and audit processes does the government apply to biosecurity and biosafety laboratories?

The Public Health Agency of Canada administers and enforces the *Human Pathogens and Toxins Act* and its regulations so that activities involving human pathogens and toxins are conducted safely and securely. Oversight mechanisms include:

- Licensing Framework

The Public Health Agency of Canada issues Pathogen and Toxin Licences authorizing controlled activities under the *Human Pathogens and Toxins Act* . Licensing decisions are risk-based and contingent on compliance with the Canadian Biosafety Standard, which sets physical containment, operational practices, and performance verification requirements.

- Inspections and Compliance Monitoring

The Public Health Agency of Canada conducts compliance monitoring and verification through on-site and virtual inspections, document reviews, and audits. These activities verify adherence to licence conditions and the Canadian Biosafety Standard.

Inspections occur at multiple stages: pre-licensing (design and commissioning), post-licensing, and periodically during the licence term.

- Standards and Guidelines

The Canadian Biosafety Standard is the cornerstone for biosafety and biosecurity requirements. It includes:

- Physical containment specifications.
- Operational practice requirements.
- Performance and verification testing matrices for containment zones.

The Canadian Biosafety Standard is complemented by guidance tools, compliance promotion policies, and risk assessments developed by the Public Health Agency of Canada in collaboration with the Canadian Food Inspection Agency and international partners.

- Enforcement Processes

The Public Health Agency of Canada applies a graduated enforcement model that includes corrective action requests, formal notices for non-compliance, and, where necessary, escalating measures such as orders to cease activities, licence suspension or revocation, and prosecution for serious offences

- Plan for Administrative Oversight

Regulated facilities conducting scientific research are required to develop a Plan for Administrative Oversight before a Pathogen and Toxin Licence can be issued. This plan sets out how biosafety and biosecurity will be managed at the institutional level.

The Plan for Administrative Oversight must include an overview of how research is reviewed for its dual use potential. If dual use potential is identified, the organization must indicate how risks are assessed, managed, and controlled throughout the research process.

(k) how many laboratory incidents involving human pathogens or toxins have been reported in Canada in the last five years, and what actions were taken in response?

This information is reported annually through the Government of Canada report titled “Exposure, non-exposure and other reporting data from licensed facilities in Canada”.

In the last five years, there were 694 incidents involving human pathogens and toxins in Canada reported to the Public Health Agency, including 297 exposure incidents.

Report type (mandatory)	2021	2022	2023	2024	2025	Total
Exposure	46	41	65	74	71	297
Non-exposure and other events	62	84	84	74	93	397
Total	108	125	149	148	164	694

Please note:

- Non-exposure reports and other reports were combined for the purpose of this table only; separate reporting forms are used by licence holders to report such incidents.
- The 2025 column presents year-to-date data.

In response to these incidents and to prevent their recurrence, the Public Health Agency of Canada provided licensed facilities with resources outlining incident trends in Canada, recommended risk mitigations strategies, and best practices in biosafety. These resources included:

- Electronic learning courses on topics such as laboratory-acquired infections, introduction to biosafety, personal protective equipment, biological safety cabinets, respiratory protection and operational practices for containment level 1 to 3;
- Webinars providing detailed guidance on how and when to report incidents to the Public Health Agency of Canada as well as what kinds of incidents should be reported;
- Bulletins for licence holders on topics of relevance such as awareness raising about seasonal variation in exposure incidents, risk factors for laboratory-acquired infections, the importance of data completeness and incident risk mitigation;
- Podcast about the main root causes identified in exposure reports and best practices to prevent recurrence;
- Video about safe handling of sharps and needles;
- Signage that can be printed, completed and displayed in facilities to remind personnel who they should report incidents to internally;
- Fillable checklists that outline the incident information that facilities need to gather and report to the Public Health Agency of Canada in the event of an exposure incident; and
- Annual surveillance reports to strengthen awareness of incident patterns.

Additionally, the Public Health Agency of Canada actively engages with the biosafety community by participating in and presenting at conferences to share knowledge and promote dialogue. The Public Health Agency of Canada continues to develop and update guidance material based on emerging data to ensure ongoing improvement in biosafety practices.

(l) what penalties or enforcement mechanisms are in place for conducting unauthorized gain-of-function or bioweapons research in Canada?

The regulatory regime allows for a graduated set of enforcement actions, depending on severity, risk, intent, recurrence and other factors.

Regulatory / Administrative enforcement (non-criminal)

- If a facility or individual is found non-compliant, the Public Health Agency of Canada may use regulatory tools such as: issuing notices of non-compliance, demanding corrective actions, amending licence conditions, refusing to renew a

licence, suspending or revoking an existing licence, or revoking or refusing to issue an HPTA security clearance.

- For materials imported or exported illegally (or without licences), inspectors may seize and detain the materials, refuse entry/exit, and order forfeiture or destruction.
- The regulatory approach is risk-based: interventions scale with the severity, potential harm, and compliance history.
- In the proposed amendments to the *Human Pathogens and Toxins Act* , the Public Health Agency of Canada is expected to gain authority to impose Administrative Monetary Penalties as part of a more nuanced compliance and enforcement framework. This would enable the Public Health Agency of Canada to issue financial penalties for non-criminal lapses such as minor biosafety infractions or reporting delays, without escalating to licence suspension or criminal charges.

Penal (criminal) enforcement

- If the violation is serious, especially if it involves reckless or intentional disregard for public health, safety, or security, criminal charges are possible under the *Human Pathogens and Toxins Act* . Penalties vary depending on the pathogen's risk group, the nature of the offence, and whether it's a first or subsequent offence.
- In the proposed *Human Pathogens and Toxins Act* amendments, the Public Health Agency of Canada has increased the fines and imprisonment terms to align with other federal laws and has removed distinctions between first and subsequent offences.

(m) did the Public Health Agency of Canada, the Department of Foreign Affairs, Trade and Development or the Department of National Defence assess COVID-19 or SARS-COV-2 as being a bioweapon with respect to international biological weapons conventions, and, if so, what actions were taken and by whom, or, if not, why not?

During the time that COVID-19 was classified by the World Health Organization as a Public Health Event of International Concern, no country, including Canada, officially declared the naturally circulating virus as a bioweapon with respect to international biological weapons conventions.

Following the pandemic, Canada (Public Health Agency of Canada and Global Affairs Canada collaboratively) specifically assessed SARS-CoV-2 for potential inclusion on the Australia Group's List of Human and Animal Pathogens and Toxins for Export Control (the List), and decided that, given its inherent properties, vaccine availability, and continuing global prevalence, SARS-CoV-2 did not merit inclusion nor discussion for potential inclusion on the List. The Australia Group is a regime of 43 like-minded countries, including Canada, with a shared goal of minimizing the risk in the proliferation of chemical and biological weapons through the use of common export control lists. No formal discussion of the potential listing of SARS-CoV-2 has taken place at the Australia Group.

National Defence

Reply by: the Minister of National Defence

Name of Signatory: Sherry Romanado

Reply

National Defence

(a) what biosecurity threats has Canada identified from 2019 and emerging in the near future; (b) what pathogens were under investigation by the government between 2019 and 2025, and, for each instance, what was the (i) name of the pathogen, (ii) date of the investigation, (iii) department investigating the pathogen, (iv) result of the investigation; (c) what counter-measures are in place or planned to address biosecurity threats or the specific pathogens in (b); (d) how many biosecurity or biosafety laboratories are located in Canada, where are these laboratories located and at what biosafety laboratory levels do they operate?

National Defence is not the lead government organization responsible for identifying or investigating biosecurity threats in Canada, nor is it the functional authority for tracking information about external biosecurity or biosafety laboratories on behalf of the government.

The Canadian Armed Forces do, however, monitor open-source and classified reporting to identify potential biological events that could have an impact on Canadian Armed Forces operations. This includes global monitoring of various pathogens with outbreak potential such as COVID-19, influenza, viral hemorrhagic fevers, arboviruses and more.

The Canadian Forces Health Services maintain certain countermeasures and track the development of new countermeasures for pathogens that have already been identified as well as those identified and investigated by other government departments and agencies, such as the Public Health Agency of Canada. Pathogens for which the Canadian Forces Health Services maintain countermeasures include anthrax, filoviruses (Ebola, Marburg), botulism, plague, smallpox, ricin, influenzae, and coronaviruses.

(e) does the government approve or authorize (i) gain-of-function research, (ii) bioweapons or biodefence research; (f) if the answer to (e) is affirmative, which Canadian laboratories conduct (i) gain-of-function research, (ii) bioweapons or biodefence research?

National Defence is not the functional authority for approving or authorizing research of this kind on behalf of the government. While National Defence does conduct biodefence research, Canada is party to the *Biological Weapons Convention* (1975) and therefore does not have an offensive bioweapons program.

(g) if the answer to (e) is negative, does Canada collaborate with other nations to conduct (i) gain-of-function research, (ii) bioweapons or biodefence research; (h) if Canada collaborates with other nations as per (g), which nations are involved, and when were these collaborative relationships established; (i) what international agreements or treaties related to biosecurity, gain-of-function, or biodefence research is Canada party to, and how does the government ensure compliance with these commitments?

Canada collaborates on biodefence research with Australia, the United Kingdom and the United States under the *Chemical Biological and Radiological Defence Memorandum Of Understanding* (2006). Canada also collaborates with other North American Treaty Organization Allied countries. Specifically, Canadian Forces Health Services personnel participate in the

Chemical, Biological, Radiological and Nuclear Medical Working Group, the Biomedical Expert Panel, and the Medical Countermeasures Consortium. These groups focus on biodefence interoperability and compliance with North American Treaty Organization standards.

Agreements or treaties related to biosecurity, gain-of-function or biodefence research that Canada is party to also include the *Biological Weapons Convention* (1975) and sections of *The North Atlantic Treaty (1949).* Canada also participates in key international programs and forums such as the International Atomic Energy Agencies Technical Cooperation Programme and The Australia Group. Canada is also a State Party to the World Health Organization's International Health Regulations, which include obligations related to reporting and managing public health risks, events, and emergencies that have the potential to cross borders, including infectious disease events such as outbreaks, epidemics, and pandemics.

(j) what oversight mechanisms, standards and audit processes does the government apply to biosecurity and biosafety laboratories; (k) how many laboratory incidents involving human pathogens or toxins have been reported in Canada in the last five years, and what actions were taken in response; (l) what penalties or enforcement mechanisms are in place for conducting unauthorized gain-of-function or bioweapons research in Canada?

National Defence is not the functional authority for government-wide oversight on compliance with other agreements or treaties related to biosecurity, gain-of-function, or biodefence research, nor is it the functional authority for oversight of biosecurity and biosafety laboratories in Canada.

The Biological and Chemical Defence Review Committee is an independent group of experts in biological and chemical defence the functional authority for conducting an annual review of chemical and biological defence activities within National Defence to ensure they are defensive in nature and compliant with treaty obligations. Their annual reports can be found here.

(m) did the Public Health Agency of Canada, the Department of Foreign Affairs, Trade and Development or the Department of National Defence assess COVID-19 or SARS-COV-2 as being a bioweapon with respect to international biological weapons conventions, and, if so, what actions were taken and by whom, or, if not, why not?

National Defence continuously assessed that Severe Acute Respiratory Syndrome Coronavirus 2, the virus that causes the airborne disease Coronavirus-19, was not a bioweapon with respect to international biological weapons conventions, nor using any method of objective analysis.