Ninth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

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English only

Item 11 of the provisional agenda
Consideration of issues identified in the review of the operation of the Convention as provided for in its Article XII and any possible consensus follow-up action

An Analytical Approach: Biosafety and Biosecurity Oversight Framework

Submitted by Canada

1. In support of the G7-led Global Partnership Against the Spread of Weapons and Materials of Mass Destruction[1] (GP) and as a former co-lead of the Global Health Security Agenda (GHSA) Action Package Prevent 3 (Biosafety and Biosecurity), Canada made a commitment to help build global capacity in biosafety and biosecurity program development and regulatory oversight. Following up on these commitments, the Public Health Agency of Canada (PHAC) developed and piloted the Analytical Approach for the Development of a National Biosafety and Biosecurity System, with financial support from Global Affairs Canada's Weapons Threat Reduction Program. The tool aims to strengthen global biosafety and biosecurity and is available for free on the Government of Canada's website[2].

I. Introduction to the Analytical Approach

2. The Analytical Approach for the Development of a National Biosafety and Biosecurity System (the Analytical Approach), is a methodology that can be used by regional, national or local authorities in the development or modernization, and implementation of national policies and oversight frameworks for biosafety and biosecurity. The approach was developed based on the successful outcomes of Canada's Human Pathogens and Toxins Act (HPTA).[3] The HPTA came into full force on December 1, 2015 and is one of the key pillars of a safety and security program for human pathogens and toxins along with the Human Pathogens and Toxins Regulations (HPTR)[4], the Canadian Biosafety Standard3, as well as supporting activities.

3. The major components of the Analytical Approach are:

- Identification of the current situation: how to develop a picture of where pathogens are located, how and for what purpose they are being used, who is using them in a country or region, and what controls exist;
- Issue identification, risk assessment and prioritization: analysis of the situation and regulations in place—what works well, what does not work, who contributes to the issues, and where action needs to be taken;

[1] https://www.gpwmd.com/
[2] https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/analytical-approach.html
[3] https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/human-pathogens-toxins-act.html
[4] https://laws.justice.gc.ca/eng/regulations/SOR-2015-44/page-1.html

- Scope and objectives for new oversight instruments: how to make choices on what risks to address, how much impact the national biosafety and biosecurity system will have, and by when;
- Policy instruments: an exploration of policy instruments, their pros, and cons;
- Combine policy instruments into national system options: how to combine policy instruments into coherent national oversight system options;
- Implementation approach: considerations on how the framework might be set up in a country/region and the role that senior decision-makers have in this process; and
- Performance measurement and evaluation: considerations on how to assess the impact of the final framework.

II. Benefits to Biosafety and Biosecurity Oversight Systems

4. The establishment of a comprehensive regional or national oversight system is key to mitigating the public health risks posed by the use of pathogens and toxins in facilities, the absence of which can lead to the accidental release or deliberate misuse of pathogens and toxins. The Analytical Approach supports Articles IV and V of the Biological and Toxin Weapons Convention (BTWC) by creating measures to safeguard pathogens and toxins, as well as by offering shared learning to safeguard global security.

5. The Analytical Approach can benefit a country's biosafety and biosecurity systems by helping it identify the most urgent needs, encouraging development of relevant solutions, prioritising opportunities for preparedness, response and action, improving their WHO-Joint External Evaluation (JEE) scores (i.e., JEE indicators 7.1 and 7.2),[5] and achieving compliance with biosafety and biosecurity standards under the BTWC and United Nations Security Council Resolution 1540. The tool can further help countries meet their biosafety and biosecurity standards for international benchmarking exercises including States Parties Self-Assessment Annual Reporting (SPAR), and more recently, the Universal Health and Preparedness Review (UHPR).

6. Recognizing that each country and region has unique needs, the tool has a modular and flexible format that enables countries and regions to work through the methodology independently and at their own pace. Countries and regions can also enter the methodology at different points depending on their current state (e.g., those who already have a framework and wish to validate it versus those who have no oversight in place).

III. Canada's continued efforts in upholding national and global biosafety and biosecurity oversight

7. Canada continues to uphold, maintain and strengthen its biosafety and biosecurity standards. PHAC recently completed a mandated 5-year evaluation of the HPTA and HPTR, which focused on issues of effectiveness and efficiency from 2015 to 2021. Results from the evaluation will inform Canada's future approach to biosafety and biosecurity, particularly as its supports implementation of the government's Biomanufacturing and Life Sciences Strategy. This review also holds potential to further inform the Analytical Approach.

8. In upholding its commitment to strengthen global biosafety and biosecurity, Canada continues to promote the development, improvement, implementation or maintenance of biosafety and biosecurity oversight systems internationally, including through the Analytical Approach. We encourage interested jurisdictions to reach out should they wish to engage with Canada or other members of the Global Partnership on these issues.

[5] https://www.who.int/publications/i/item/9789240051980