# AN ANALYTICAL APPROACH FOR THE DEVELOPMENT OF A NATIONAL BIOSAFETY AND BIOSECURITY SYSTEM

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# WHAT IS IT?

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. Recognizing that each country and region has unique needs, processes and capabilities, the Analytical Approach 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).

# WHY USE IT?

The work that takes place in biological facilities across the world is essential to disease prevention, response, and the development of new pharmaceuticals and technologies. In the absence of national oversight frameworks for biosafety and biosecurity, work with pathogens can lead to the accidental or deliberate release of these agents resulting in infection or a spread to the community, potentially causing an outbreak.

Developed with that in mind, the Analytical Approach can benefit a country in:

- > Identifying the most urgent needs within their biosafety and biosecurity systems.
- > Encouraging the development of solutions to address local biosafety and biosecurity issues that are practical and sustainable.
- > Prioritizing opportunities for enhanced preparedness, response and action.
- > Enhancing and strengthening capacity for countries who wishes to increase their World Health Organization (WHO) Joint External Evaluations (JEE) scores for Indicators 6.1 and 6.2, pertaining to national biosafety and biosecurity systems.
- Addressing requirements for countries working to achieve compliance with biosafety and biosecurity requirements under the Biological Weapons Convention (BWC) or the United Nations Security Council Resolution (UNSCR) 1540.





# INTRODUCTION AND CONTEXT

Explains the context for the Analytical Approach and helps with how it might be used.

### STAKEHOLDER ENGAGEMENT

How you consult with those who will be impacted by your framework to increase the chances that what you develop will be realistic, practical, and accepted.

# INTERNATIONAL COMPARISON

How to identify frameworks already in place that may work in your country/region (e.g., for ideas and to assess draft framework).

DENTIFY THE CURRENT SITUATION

How to develop a picture of where, how, and who are using pathogens in a target country or region, and what controls exist.

SSUE 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.

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.

MPLEMENTATION APPROACH
Consider how your framework might be set up in your country/region and the role that senior decision-makers have in this process.

PERFORMANCE MEASUREMENT AND EVALUATION How you can assess the impact of your final framework.

# **BACKGROUND**

The Public Health Agency of Canada developed the Analytical Approach in support of commitments made to strengthen global capacity in biosafety and biosecurity, under the *Global Health Security Agenda* (GHSA) and the *Global Partnership Against the Spread of Weapons and Materials of Mass Destruction* (the Global Partnership). This tool supports the GHSA's commitment to promoting national biosafety and biosecurity by providing tools and training to develop, implement, and maintain national biosafety and biosecurity systems. This project was funded by Global Affairs Canada's Weapons Threat Reduction Porgram.

## **QUESTIONS?**

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