Building Capacity for Dual-Use Oversight in the Life Sciences through the IEGBBR

Leanne DeWinter (she/her)
IEGBBR Secretariat
Logistics

• Please mute your microphone to ensure that all participants can hear the speakers

• During the Question & Answer session following each presentation, please ask all questions by entering them into the chat function

• Simultaneous interpretation available by selecting the appropriate language from the Interpretation bar at the bottom of the screen
Principles of Conduct

• The IEGBRR strives to maximize participation by diverse groups of people

• We encourage self-identification of personal pronouns to promote an inclusive environment

• We aim to reduce potential barriers experienced by some individuals and groups by:
  ✓ Providing for virtual attendance
  ✓ Adhering to schedules

• All participants shall conduct themselves professionally and respectfully
Outline of Virtual Event

Presentation 1
Leanne DeWinter - Introduction to Dual-Use Oversight

Presentation 2
Rik Bleijs - Identifying Potential Dual-Use Risks in Research

Presentation 3
Linda Rheaume - Oversight of Scientific Research Involving Human Pathogens and Toxins
Outline: Introduction to Dual-Use Oversight

• About the IEGBBR
• IEGBBR Mobile Application
• What is Dual-Use?
• International Context and Commitments
• Oversight of Dual-Use
• Stakeholders and Raising Awareness
• Key Concepts of Dual-Use Oversight
About the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR)

• A group of national government authorities with established regulatory oversight systems in place for biosafety and biosecurity

• World Health Organization (WHO) and the World Organisation for Animal Health (OIE) participate as non-member observers

• Created in 2007 under the leadership of the Public Health Agency of Canada with support from Global Affairs Canada
Objectives of the IEGBBR

To strengthen and advance global biosafety and biosecurity by:

• Sharing of knowledge and experience of human and zoonotic animal pathogen biosafety and biosecurity oversight issues

• Promoting international co-operation and convergence among regulatory authorities

• Developing reference tools and materials that are universal in nature and can benefit the international community, regardless of the national level of development or resources
IEGBBR Mobile Application of Biosafety, Biosecurity and Dual-Use Oversight

• Reference tool for countries that aim to develop or strengthen:
  ✓ Compliance with international biosafety and biosecurity commitments
  ✓ National biosafety, biosecurity, and DU oversight capacities

• Two modules:
  ✓ The Compendium of International Biosafety and Biosecurity Oversight Systems for Human and Animal Pathogens and Toxins
  ✓ The Review of Oversight of Dual-Use in Life Sciences
What is Dual-Use?

“Knowledge, information, methods, products or technologies generated by peaceful and legitimate research that may be appropriated for non-peaceful or harmful purposes.”

https://www.who.int/publications/i/item/9789240056107
### Potential Consequences of Dual-Use Risks

<table>
<thead>
<tr>
<th>Category</th>
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<tbody>
<tr>
<td>Public health</td>
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<tr>
<td>Animal or plant health</td>
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<td>Biodiversity</td>
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<tr>
<td>Environment</td>
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<td>Safety and security</td>
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<tr>
<td>Human rights</td>
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<tr>
<td>Economy</td>
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</tbody>
</table>
International Context and Commitments

• Biological and Toxins Weapons Convention
• United Nations Security Council Resolution 1540
• Wassenaar Arrangement
• Australia Group
• International Health Regulations (2005)
  ✓ Mandatory annual reporting of public health capacities
  ✓ Joint External Evaluation of International Health Regulations Core Capacities
Oversight for Dual-Use in the Life Sciences

Centralized Approaches

• National Oversight
• International Collaboration

Decentralized Approaches

• Self-governance and Institutional
• Funders and publishers

• Multi-pronged governance approaches will be the most effective
Options for Oversight Measures

**Regulatory Measures**
- Statutes and regulations (in national framework)
- Licensing requirements
- Review boards

**Non-Regulatory Measures**
- Codes of Conduct
- Allocation of funding
- Review at publication
- Review boards
Oversight for Dual-Use Among the IEGBRR Member Countries

• Oversight measures are highly interwoven into a number of relevant objectives:
  ✓ Biosafety
  ✓ Biosecurity
  ✓ Ethics
  ✓ International commitments that also touch on foreign policy, national defence, and national security interests

• There are many possible intervention points to identify, assess, and mitigate dual-use risks
Stakeholders and Raising Awareness

• Raising awareness necessitates involving a wide range of stakeholders
• Mitigating biorisks is a shared responsibility

- Laboratory workers
- Research scientists
- Citizen scientists
- Ethics committees
- Healthcare institutions
- Diagnostic laboratories
- Life science academia
- Institutional review boards
- Biomedical companies
- Funding organizations
- Scientific editors and publishers
- Governmental policy makers
- Biorisk professionals
- Public
Key Concepts of Dual-Use Oversight

• Raise awareness and engage relevant stakeholders
• Determine regulatory and non-regulatory intervention points
Identifying Potential Dual-Use Risks in Research

Rik Bleijs, PhD (he/him)

Netherlands Biosecurity Office
National Institute for Public Health and the Environment (RIVM)
Can the results of your *Well-intended* research be used for harmful intent?
Key Elements in Dual-Use assessment
Stakeholders

- Researcher
- Principal Investigator
- Laboratory supervisor
- Management
- Biorisk Management Advisor (BMA)
- Oversight Committee
- Inspection / auditing committee
- Policy makers
- Publishers
- Funders
- Public

- Views
- Risk perception
- Interest
- Knowledge
- ...
Key Elements in Dual-Use assessment
Dual-Use considerations in the research lifecycle: from grant application to publication

- The research lifecycle eventually ends with the publication of your results in a scientific research journal
Dual-Use considerations in the research lifecycle: from grant application to publication

- A research project always starts with a brilliant idea
- This idea is discussed with your colleagues
- And eventually be transformed in a research proposal
Grant application processes

- The research proposal is often used to apply for grants

- Examples of funders of research programs:
  - National Institutes of Health (NIH)
  - European Union
  - United Nation
  - Cancer research project funders

Idea → Funding

The Netherlands Biosecurity Office | 30 May 2023
www.bureaubiosecurity.nl
Permits, regulations, protocols

- Before you start your experimental work, all the permits, regulations and protocols should be in place:
  - Biosafety regulations and permits
  - EU Regulatory Framework on biosafety
  - Genetically Modified Organisms (GMO) regulations
  - ....
Research phase in laboratory

- After previous phases have been finalized, the actual experimental work in your laboratory can take place.
Presentation of preliminary results

- During your research you often attend different scientific meetings
- At the meetings you are eager to communicate and present your results and new ideas
- Presentations could be oral or as a poster presentation
Manuscript and publication

- Eventually, the results of your research experiments are ready to be drafted in a manuscript
- Your manuscript will be reviewed by colleagues and after submission by the editors of the journal
- At the end, your manuscript is published
Dual-use considerations in the research lifecycle: from grant application to publication

Be aware of potential dual-use issues throughout the whole research lifecycle

Idea → Funding → Research → Manuscript → Publication

0 time Many years
Research process

The ideal world

The reality
Treating (unexpected) findings carefully

Unanticipated findings with biosecurity implications...

What to do?

→ Alert Biorisk Management Advisor, collaborators and the scientific community in a secure way
WHO Global Health Foresight:

- Proactively identifying dual use research of concern
Be aware!

- Different stakeholders, different views
- Risks could arise throughout whole research lifecycle
- Code of conducts
- How to deal with unexpected results?

➢ Training and education
Key Elements in Dual-Use assessment

- **Aware**
- **Identify**
- **Assess**
- **Mitigate**
- **Review**
- **Stakeholders**
Dual-Use Research of Concern (DURC)

7 Experiments

1. Enhance the harmful consequences of the agent or toxin?
2. Disrupt immunity or the effectiveness of an immunization against the agent or toxin?
3. Confer to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies?
4. Increase the stability, transmissibility, or ability to disseminate the agent or toxin?
5. Alter the host range or tropism of the agent or toxin?
6. Enhance the susceptibility of a host population to the agent or toxin?
7. Generate or reconstitute an eradicated or extinct agent or toxin or will synthetic biology techniques be used to construct a pathogen, toxin, or potentially harmful product?

15 Agents and Toxins

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin (For purposes of this Policy, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.)
4. *Burkholderia mallei*
5. *Burkholderia pseudomallei*
6. Ebola virus
7. Foot-and-mouth disease virus
8. *Francisella tularensis*
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of Clostridium botulinum
13. Variola major virus
14. Variola minor virus
15. *Yersinia pestis*
Knowledge and Technology

Is it likely that the knowledge you obtain and technologies you develop in your research allow others to use them for malicious purposes?

- Virus reconstruction method can also be misused to synthesize a pandemic virus

Dual use of artificial-intelligence-powered drug discovery

An international security conference explored how artificial intelligence (AI) technologies for drug discovery could be misused for de novo design of biochemical weapons. A thought experiment evolved into a computational proof.

Fabio Urbina, Filippa Lentzos, Cédric Invernizzi and Sean Ekins

Published online: 07 March 2022
https://doi.org/10.1038/s42256-022-00465-9
NATURE MACHINE INTELLIGENCE | www.nature.com/natmachintell
Knowledge and Technology - Case study

Researchers from a pharmaceutical company built an artificial intelligence systems for virtual drug discovery

This Machine Learning model, MegaSyn:
● Looks for compounds for increased target activity
● Searches for new molecules with low toxicity
● Generates de novo libraries of compounds
● Generates molecules based on their synthetic feasibility
Knowledge and Technology - Case study

- Changing the AI models to search for molecules with more toxicity
  - < 6 hours
  - 40,000 molecules were generated that were likely lethal, including nerve agent VX and potentially even more lethal molecules

“The thought had never previously struck us”
Consequences of misuse

Could your research contribute to possible harmful consequences due to misuse of the modified biological agent or the knowledge thereof?

- Ecological
- Economical
- Society

Evidence of microalgal isotopic fractionation through enrichment of depleted uranium

Beatriz Baselga-Cervera, Camino García-Balboa, Victoria López-Rodas, Marta Fernández Díaz & Eduardo Costas


Plant pathogens as agroterrorist weapons: assessment of the threat for European agriculture and forestry

Frédéric Suffert, Émilie Latxague & Ivan Sache

Food Sec. (2009) 1:221–232
Tool: Dual-Use Quickscan

- Stimulating awareness among researchers
- Screening research for potential dual-use aspects

"More work for researcher"
"We have something else to do"
"That is not necessary for my research"
"Can't I do anything anymore?"

1. Easy
2. Fast
3. To the point
What is already international available?

- WHO LBM4; Biosafety programme management - 2020
- KNAW advice Improving Biosecurity - 2013
- Fink report - Biotechnology Research in an Age of Terrorism - 2004
- US Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern – 2014
- CBB Denmark - Questionnaire about dual-use research of concern - 2015
- VIB Belgium - Guidelines for researchers on dual-use and misuse of research – 2017
- RKI Germany - Hausverfügung: Dual-Use-Potenzial in der Forschung – 2013
- ...
Dual-Use Quickscan

15 questions - themes

1. Biological agent
2. Knowledge about the biological agent
3. Consequences of misuse
Dual-Use Quickscan

• 15 questions - themes
• Online web application
• Anonymous
• Yes / no / unknown answers
• Explanation of questions
• More info through literature examples
• Results overview (pdf file)
Welcome to the Dual-Use Quickscan of the Biosecurity Office. The purpose of this online Dual-Use Quickscan is to identify potential dual-use aspects in research. In addition, this tool contributes to stimulate dual-use awareness among researchers. The Dual-Use Quickscan and the results can be used for consultation about research that contain or may contain dual-use characteristics and how to deal with it carefully. The researcher may consult a person in the organization responsible for biological safety and security.

Questionnaire
The Dual-Use Quickscan consists of 15 questions about different aspects of research that may contribute to a dual-use character of your research. These questions have been extracted from scientific literature and reports. For each question, an explanation is given on the basis of some characteristic examples from the literature. The question can be answered with: yes, no or unknown.

Final overview
The results of the questionnaire are shown in the final overview. Here you will find the answer you have given for each question.

Disclaimer
The Dual-Use Quickscan is anonymous, no data is stored. This web application has been developed by the Biosecurity Office. For questions, remarks, or more information please contact the Biosecurity Office at: biosecurity@rivm.nl.
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High-risk biological agent

1. Are you working with a biological agent, or parts of it, that can be considered a high-risk pathogen?
   - Yes
   - No
   - Unknown

Explanation
Are you working with a biological agent, or parts of it, that can be considered a high-risk pathogen?

- Yes
- No
- Unknown

**Explanation**

The Biosecurity Office has developed a [combined list](https://www.dualusequickscan.com) on which you can easily see whether your pathogen is on one of the lists of high-risk pathogens. In this case, high-risk pathogens refer in particular to pathogens of risk class 3 and 4. The combined Biosecurity Office list is based on the EU Export Control List (EU 428/2009 Dual-use Regulation), the [Australia Group list](https://www.australia-group.org), and the [US Select Agents List](https://selectagents.dhhs.gov). Plant pathogens are listed on the [Quarantine list of plant pathogens](https://www.dualusequickscan.com). Besides these international lists also national lists may exist. It is also possible that the pathogen you are working on is not (yet) classified or is not included in one of these lists, but may still be assumed as a high-risk pathogen.

**Literature examples**

- [Ranking of biological agents that pose the greatest threat to be used as a biological weapon](https://www.dualusequickscan.com)
- [The reconstruction and assembly of infectious human endogenous retrovirus particles from existing provirus sequences in human DNA](https://www.dualusequickscan.com)

**Host range and tropism**

Is the host range or tropism of the biological agent likely to be altered?

- Yes
- No
- Unknown

**Explanation**

**Virulence**
The reconstruction and assembly of infectious human endogenous retrovirus particles from existing provirus sequences in human DNA

Dual-use aspect
This article demonstrates the ability to reconstruct a human endogenous retrovirus from existing mutated virus sequences (proviruses) within the human genome. Expression of this reconstructed human endogenous retrovirus genome resulted in infectious virus particles. While this development may provide insight into how these particles can be expressed in tumors or in autoimmune diseases, it may also lead to the reconstruction and construction of other human endogenous retroviruses.

The study
A provirus is the sequence of a (retro) virus that has been incorporated into the human genome after viral infection. Nearly 8% of the human genome consists of these proviruses, which during evolution have often mutated to such an extent that they are no longer functional. In this study, a provirus is used that is relatively less mutated and contains many intact, but inactive, parts of the original retrovirus (the HERV-K family). In this study, a human endogenous retrovirus (from the HERV-K family) has been reconstructed from existing and mutated sequences from the human genome (proviruses). Afterwards, this reconstructed retrovirus was generated, resulting in infectious virus particles.

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<thead>
<tr>
<th>Number of questions answered with Yes: 2, No: 9 and Unknown: 4</th>
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<tbody>
<tr>
<td>1. High-risk biological agent</td>
</tr>
<tr>
<td>Are you working with a biological agent, or parts of it, that can be considered a high-risk pathogen?</td>
</tr>
<tr>
<td>2. Host range and tropism</td>
</tr>
<tr>
<td>Is the host range or tropism of the biological agent likely to be altered?</td>
</tr>
<tr>
<td>3. Virolence</td>
</tr>
<tr>
<td>May your research increase the virulence of the biological agent?</td>
</tr>
<tr>
<td>4. Stability</td>
</tr>
<tr>
<td>Is it to be expected that the stability of the biological agent outside the host will increase as a result of your research?</td>
</tr>
<tr>
<td>5. Transmissibility</td>
</tr>
<tr>
<td>Is it likely that the transmissibility or dispersion of the biological agent will increase?</td>
</tr>
<tr>
<td>6. Absorption and toxicokinetics</td>
</tr>
<tr>
<td>Is it to be expected that the absorption of the biological agent is facilitated or is an increased toxicokinetic effect to be expected?</td>
</tr>
<tr>
<td>7. Drug resistance</td>
</tr>
<tr>
<td>Is it likely that your research will increase the resistance of the biological agent to clinical and / or agricultural prophylactic or therapeutic interventions, including antimicrobial resistance?</td>
</tr>
<tr>
<td>8. Population immunity</td>
</tr>
<tr>
<td>Does the biological agent possibly have a negative effect on the immunity of humans, animals or plants?</td>
</tr>
<tr>
<td>9. Detection, methodology and diagnostics</td>
</tr>
<tr>
<td>Could your research impact the detection methods or diagnostics of the biological agent?</td>
</tr>
<tr>
<td>10. Reconstruction</td>
</tr>
<tr>
<td>Does your research contribute to the reconstruction of an eradicated or extinct biological agent?</td>
</tr>
<tr>
<td>11. Harmful effects</td>
</tr>
<tr>
<td>May changes to the biological agent possibly generate or enhance the harmful consequences, which may involve impaired well-being?</td>
</tr>
<tr>
<td>12. Knowledge and Technology</td>
</tr>
<tr>
<td>Is it likely that the knowledge you obtain and technologies you develop in your research allow others to use them for malicious purposes?</td>
</tr>
<tr>
<td>13. Ecological consequences</td>
</tr>
<tr>
<td>May possible harmful ecological consequences occur due to misuse of the biological agent or the knowledge thereof?</td>
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<tr>
<td>14. Economic consequences</td>
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<tr>
<td>May possible harmful economic consequences occur due to misuse of the biological agent or the knowledge thereof?</td>
</tr>
<tr>
<td>15. Consequences for society</td>
</tr>
<tr>
<td>May possible harmful consequences for society occur from the misuse of biological agents or the knowledge thereof?</td>
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Dual-Use Quickscan: A Web-Based Tool to Assess the Dual-Use Potential of Life Science Research

Iris M. Vennis, Mirjam M. Schaap, Petra A. M. Hogervorst, Arnout de Bruin, Sjors Schulpen, Marijke A. Boot, Mark W. J. van Passef, Saskia A. Rutjes and Diederik A. Bleijs*

https://doi.org/10.3389/fbioe.2021.797076
Who should fill in the Dual-Use Quickscan?

- You’re employed in the field of life sciences and
- You work with (parts or products of, or knowledge about) microorganisms, and
- You perform (laboratory) activities for research, development or production processes.
When and how often using the tool?

- Regularly, in coordination with the Biorisk Management Advisor
- Depending on various factors such as the nature of the research or based on previous dual-use assessments
What are the next steps?

**Quickscan**

**Dual-Use Quickscan**

- Researcher
- Biorisk Management Advisor (BMA)

*Frequency Quickscan: regularly*

**Indication of dual-use risk**

**Meeting**

- BMA & Researcher

*Frequency: Sometimes*

- Risk assessment & Risk management
Take home messages

✓ Be aware that research could pose biosecurity or Dual-Use risks.

✓ Addressing biosecurity and Dual-Use is crucial but need not prevent important research.

✓ Awareness among scientists is key.

✓ Researchers, laboratory staff and Biorisk Management Advisors (BMA) play a key role in addressing, signaling and preventing biosecurity and Dual-Use risks.

✓ Assessing Dual-Use aspects already starts with the initial idea to the actual publication of the results.

✓ The risk assessment framework for Dual-Use includes biological factors, including knowledge and techniques about the biological agent, but also includes social- ecological and political factors.
Key Elements in Dual-Use assessment

- Stakeholders
- Aware
- Identify
- Review
- Communicate
- Mitigate
- Assess
Take home messages

√ The Dual-Use Quickscan can be used to monitor potential dual-use risks of your research and can be found via www.biosecuritytoolkit.com.

√ Dual-Use Quickscan provides a practical implementation of dual-use governance documents and guidelines

√ Information and risk mitigation practices can be found at the website of the Biosecurity Office: www.bureaubiosecurity.nl.
Contact Us

www.bureaubiosecurity.nl
www.biosecuritytoolkit.com

biosecurity@rivm.nl

@B_Biosecurity
Oversight of scientific research involving human pathogens and toxins

Plan for Administrative Oversight

Linda Rheaume (she|her)
Acting Manager, Centre for Biosecurity
Public Health Agency of Canada
May 2023
Purpose

To provide an overview of the PAO program and its role in risk management of dual-use potential in research

- Dual-Use Research – Canadian context
- Oversight in Canada
- Plan for Administrative Oversight
- Compliance and Enforcement
- Case study
- Resources
Canada’s Biosecurity Program

• The Biosecurity Program regulates the use of human pathogens and toxins in Canada across all sectors and purposes through the *Human Pathogens and Toxins Act* (HPTA) and the *Health of Animals Act* (HAA)

• Comprehensive, national approach includes:
  – Licensing
  – Security clearances for individuals accessing high-risk pathogens
  – Incident and exposure reporting
  – Pathogen risk assessments
  – Standard and guidance development
  – Stakeholder outreach and engagement
  – Compliance monitoring, verification, and enforcement through inspections, audits, and document reviews
Dual-Use Research – Canadian Context

In Canada, the following documents and terms provide context about dual-use potential in respect of research involving human pathogens and toxins:

- **Canadian Biosafety Standard, 3rd edition: Dual-use potential**
- **Security sensitive biological agents (SSBAs)**
- **PHAC Guidance and Guidelines**
Dual-Use Potential

Products
- Pathogens, toxins, all SSBAs*

Knowledge
- DNA sequences, synthesis methodology

Technology
- Tools that allow ease of analyzing, modifying, synthesizing biological material, 3D printing, kits, gene editing
Scientific Research Policy for Human Pathogens and Toxins

Provides guidance on the definition of scientific research as it pertains to controlled activities under the HPTA to clarify when a PAO is required. Scientific research includes:

- Basic research
- Applied research
- Experimental development

Core elements of scientific research contribute to new discoveries that advance science but also bring certain unpredictability and risks:

- Novelty
- Creativity
- Uncertainty of Outcome
Dual-use and the Research Continuum

Opportunities for oversight throughout the research continuum
Mitigating biorisks from dual-use research is a shared responsibility

In Canada, many different groups and individuals play a role in dual-use research accountability and research security.

At the federal level, accountability is a collaborative effort:
• Public Health Agency of Canada
• Canadian Food Inspection Agency
• Global Affairs Canada
• Transport Canada
• Health Canada
• Canadian Border Services Agency
• Innovation, Science and Economic Development Canada
• Public Safety Canada
Spotlight: Plan for Administrative Oversight

The research sector faces additional risk factors that other sectors (e.g., diagnostic) normally do not.

- autonomous research and researchers
- perceived diffuse accountabilities
- complex reporting and governance structures

Section 3 of the *Human Pathogens and Toxins Regulations (HPTR)* states:

If the applicant for a licence is a person who intends to carry out scientific research, the Minister must, before issuing the licence, determine that the person has developed a plan that sets out administrative measures for managing and controlling biosafety and biosecurity risks during the period in which the licence is in effect.

The plan is a high-level document that provides an overview of the mechanisms in place in an organization conducting scientific research to administratively manage and control **biosafety and biosecurity risks**, including those from research with dual-use potential.
Plan Elements

1. Commitment from Senior Management of the organization
2. Delineation of the roles and responsibilities for committees, individuals, departments etc.,
3. Single point of contact to provide guidance on the Plan and represent biosafety issues at a senior level
4. How biosafety and biosecurity risks, including those from research with dual-use potential, are identified
5. How biosafety and biosecurity risks, including those from research with dual-use potential, are assessed once they have been identified
6. How biosafety and biosecurity risks, including those from research with dual-use potential, are managed and controlled
7. Description of all work areas covered by the Plan
8. Description of all individuals covered by the Plan
9. Summary of how the Plan is communicated.
10. Procedures to review and monitor the Plan.
Plan Element 1 – Commitment from Senior Management

Demonstrates presence of internal accountability system with respect to pathogens, toxins, and other regulated infectious materials.

Reference documents (policy, code of practice, strategy) specific to the organization that highlight the commitment of senior management to the implementation and ongoing performance of the system in place.
Plan Elements 2&3 – Roles and Responsibilities

Outlines governance within the organization, including a point of contact, and strategies in place to address integrity issues.

- Reporting structures of personnel and committees and areas of expertise
- Appointment process of committee members
- Focus on the BSO roles and responsibilities
- Real, potential, perceived conflicts of interest
- Access to financial budgetary resources for biosafety enhancements
- Communications plan
Plan Elements 4, 5, & 6 - Risk Identification/Assessment/Management and Control (1)

- **Overarching Risk Assessment**: broad assessment of the program intent and activities at the organization level.
- **Local Risk Assessment**: site-specific risk assessment used to identify hazards based on the regulated materials in use and the activities being performed.
- **Biosecurity Risk Assessment**: assessment of risks associated with the loss, theft, diversion, or intentional unauthorized release of pathogens, toxins, and related assets.
- **Dual Use Risk Assessment**: overview of how research is reviewed for dual-use potential throughout the entire research life cycle.
Plan Element 4 – Identifying and Assessing Risks: Dual-Use Potential

Are you creating, re-creating, or modifying a new or existing pathogen?

- **YES**
  - Will the pathogen(s) acquire potential hazards?
    - **YES**
      - If released, will the pathogen or research information pose a threat to humans, animals, public safety, or national security?
        - **YES**
          - Dual-Use
        - **NO**
          - **NO**
    - **NO**

- **NO**
  - Is there a potential for research knowledge (data, methodology, results), technologies, and intermediate or final products to be misused?
    - **YES**
      - **NO**
    - **NO**
      - **NO**

**PHAC Decision Tree: Identification of Dual-Use Potential in Life Sciences Research**
Plan Element 5 – Assessing Risk associated with Dual-Use

• Dual-use is just another way of thinking about biosecurity

• Everything has dual-use potential. Organizations already implement significant risk mitigation through their biosafety and biosecurity controls.
Plan Element 6 - Risk Management and Control

Dual-use potential can appear at any time; therefore, every research project should be reviewed for dual-use potential during the planning stages, throughout the course of the project and prior to the use or dissemination of the results (publication).

When dual-use is identified, it is necessary to assess the risk associated with the research; a proper risk assessment will guide the selection of appropriate mitigation strategies.

The potential risks posed by dual-use research can be mitigated through biosafety and biosecurity programs. Appropriate mitigation measures are commensurate to the level of risk and include physical, operational, and security measures that should be implemented, monitored, and enforced by organizations.
Plan Elements 7,8,9&10 - Communication, Monitoring, Review

- Capturing all work areas included in the HPTA licence where controlled activities take place.
- Capturing any individual with access to the lab (including students, contractors, visitors).
- Communicating the Plan to impacted individuals as part of the biosafety training program.
- Updating the plan (and at what frequency) when organizational changes are made (new areas added, new scopes of work, etc.).
- Monitoring the effectiveness of the plan through regular audits/inspections, reporting and investigation of incidents/accidents.
Compliance Rating

Each element of the plan is assessed during the review

**Incomplete**: Significantly below minimum expectations. Essential documents missing or not explained.

**Needs improvement**: Below minimum expectations. Documents missing/incomplete.

**Meets expectations**: Policies/procedures have been documented.

Overall compliance of the plan with the requirements of HPTR is determined based on the individual rating of the 10 elements of the plan.

**Major non-compliance**: the risk management strategy cannot be evaluated.

**Minor non-compliance**: risks are being managed, but clarification is required to evaluate if proper controls are in place.

**Compliant**: adequate internal controls, governance and risk management processes are in place.
Compliance and Enforcement

• The Centre for Biosecurity Compliance and Enforcement Policy applies to all regulated parties under the HPTA/R and HAA/R

• Risk-based approach to compliance monitoring, verification, and enforcement.

• Conditions of Licence
  ➢ Compliance with Canadian Biosafety Standard
  ➢ Addressing corrective actions
  ➢ Keeping the plan up to date
  ➢ Implementing the plan
  ➢ Submission of documents when requested by the Minister of Health (or delegate)

• Enforcement actions are considered to stop or prevent non-compliance and may include
  ➢ Regulatory enforcement
  ➢ Penal action
Case Study – Dual-use research involving pandemic potential pathogen

- **Who:** Research organization conducting experiments involving SARS-CoV-2
- **What:** Manipulating strain to alter its virulence
- **Why:** Understand determinants of disease severity and assess effectiveness of vaccine candidates
- **Considerations:**
  - Uncertainty of outcome
  - Gain-of-function
  - The PAO outlines processes that are to be followed to identify dual-use potential and determine appropriate strategies
- **Result:** Institutional awareness of dual-use potential via internal accountability structures and obligations for compliance
Resources

Legislation
- Human Pathogens and Toxins Act
- Human Pathogens and Toxins Regulations

Standards and Guidelines
- Canadian Biosafety Standard, third edition
- Canadian Biosafety Guideline - Dual-Use in Life Science Research
- Conducting a biosecurity risk assessment

Policy and Guidance
- Plan for Administrative Oversight for Pathogens and Toxins in a Research Setting - Required Elements and Guidance
- Scientific Research Policy for Human Pathogens and Toxins
- Centre for Biosecurity Compliance and Enforcement Policy

Research Security
- Safeguarding your Research
- Safeguarding Science

International
- Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research
Contact us

Pathogen and Toxin Licences and Biosecurity Portal: licence.permis@phac-aspc.gc.ca

Biosafety Standards and Guidelines, Risk Assessments, Pathogen Safety Data Sheets (PSDS), Consultations, Training and Learning (PHAC e-learning portal), Biosafety and Biosecurity Newsletter: pathogens.pathogenes@phac-aspc.gc.ca

Biosafety Containment, Inspections, Document Reviews, Plans for Administrative Oversight (PAO), Biosecurity Plans, Incident Notification: biosafety.biosecurite@phac-aspc.gc.ca

Website: http://www.phac-aspc.gc.ca/
Thank you! Are there any questions?
Survey and Contact Us

• Please complete the 3 question survey about this event. It will help us to provide the information that is the most useful to you

• You can reach the IEGBBR by emailing contact@iegbbbr.org