Dual-Use Potential of Biological Hazards

A. Introduction

Technological advances in life science research are linked to improvements to human health and standard of living. These advances may result in:

- Vaccines and treatments to combat disease in animals or humans,
- Plant varieties with increased drought or disease resistance to improve crop yields, or
- Clean industrial and environmental products to decrease hazardous materials within our communities.

While most life science research activities are legitimate and well-intentioned, there is a growing concern worldwide regarding the potential negative use of technological advances. The concern is that certain types of research may have the potential to be intentionally used or applied for malicious purposes with detrimental consequences to public health and safety, the environment, or national security. This may not only include the products resulting from the research, but also aspects of the research process:

- Knowledge (i.e., data, models, and information),
- Methodologies (i.e., tools and techniques), and
- Results (i.e., intended or unintended products and by-products).
- Scientists play an important role in advancing the pursuit of knowledge and academic freedom. With this role comes responsibility, including the responsibility to ensure that research meets high scientific and ethical standards (Government of Canada Tri-Council, 2014).

International collaboration is important because it can be difficult to foresee the potential for dual-use and, also for a shared understanding on what is considered “safe” or globally acceptable.

For more information on Dual-Use, please take a look at Public Health Agency of Canada’s Dual-Use Potential training: https://training-formation.phac-aspc.gc.ca

B. Defining Dual-Use Potential

Historically, the term ‘dual-use’ has been linked to civilian and military activities which resulted in potential misuse. Every major technology—metallurgy, explosives, internal combustion, aviation, electronics, nuclear energy—has been intensively exploited, not only for peaceful purposes but also for hostile ones (NRC, 2011). Significant developments in life science research and innovation, such as in the fields of biotechnology and synthetic biology, have brought the issue of dual-use to the forefront of discussions in more recent years. For instance, certain types of life science research, although conducted for legitimate purposes, could generate organisms, products (including by-products), results, methodologies, or technologies that might be exploited by others to purposely cause harm to individuals or the environment, or to threaten public health or national security.

While there have been many ways to describe ‘dual-use’, the definitions often contrast the elements of legitimate intent, misuse, and malicious use. The definitions of dual-use in life sciences are also subject to many deliberations among academia, policymakers, regulatory bodies, and bioethicists.

C. Importance of Biosafety and Biosecurity Practices in Mitigating Risks from Research with Dual-Use Potential

Implementing sound biosafety and biosecurity practices requires an understanding of research with dual-use potential. What is the difference between the two? A memorable distinction between biosafety and biosecurity is made by Salerno & Estes (2005): "Biosafety aims to protect people from dangerous pathogens, while biosecurity aims to protect pathogens from dangerous people."

Biosecurity relies on a sound biosafety program. As with any scientific endeavor, research in life sciences must be performed safely and responsibly through adherence to biosafety and biosecurity practices to ensure the protection of laboratory workers, the public, and the environment. With the increased international focus on dual-use research, there has been a call to action to review the effectiveness of existing biosafety and biosecurity measures in safeguarding against the risks posed by these types of research.

Identifying and Assessing Dual-Use Potential

Identifying dual-use requires many lenses; it does not simply focus on one characterization. There are several considerations that can help guide individuals to determine if their work has a dual-use potential. These considerations are summarized in the Decision tree below:

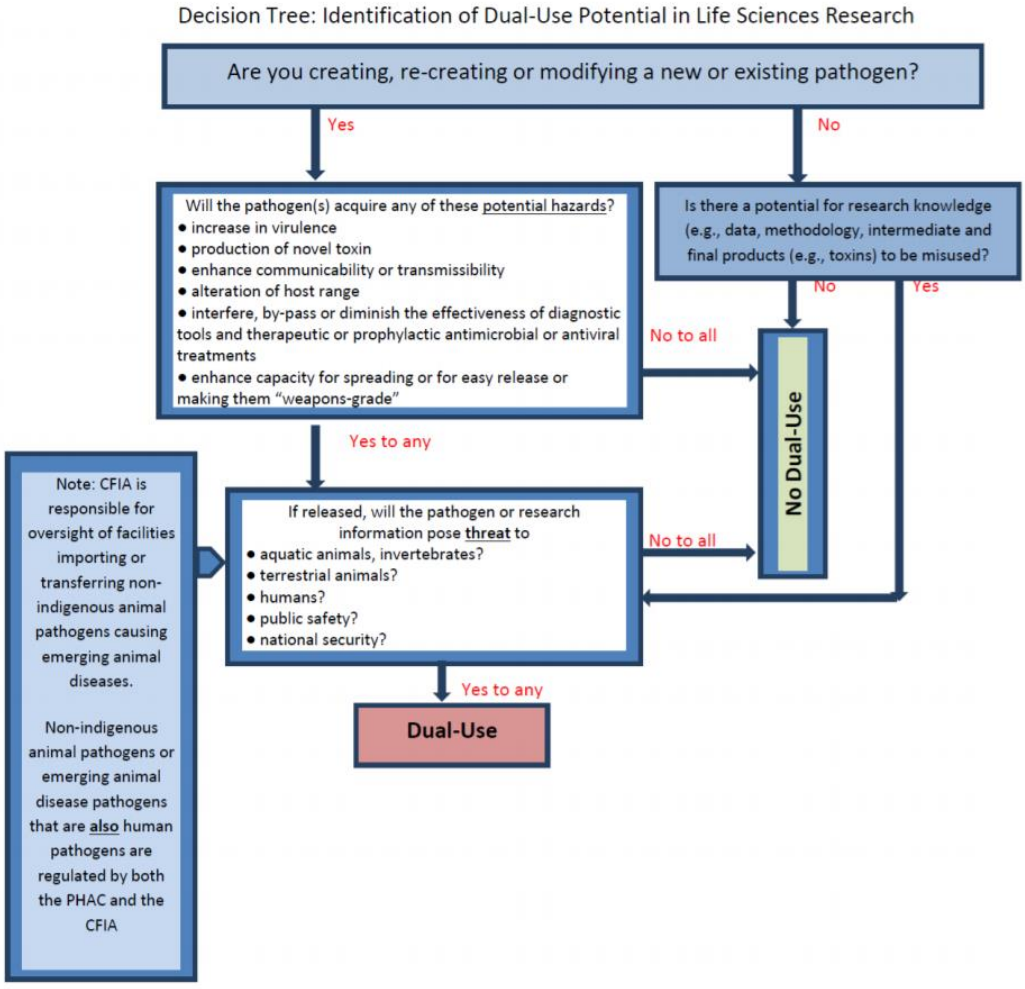

Figure 2. Decision Tree for the Identification of Dual-Use Potential in Life Sciences Research

Once identified, Dual-Use Potentials can be assess through asking these overall questions:

- What is the research being proposed?
- Who/what will benefit and who/what will be harmed?
- What are the implications of the knowledge being gained?
- How will the results of the research be communicated?

D. Mitigation of Dual-Use Potential

Appropriate mitigation measures should be commensurate to the level of risk. A biorisk management plan should include the physical, operational, and security measures that should be implemented by individuals (i.e., principal investigators, scientists, laboratory personnel), and monitored and enforced by organizations (i.e., biological safety officers, institutional administrators, safety and/or review committees, funders, regulators).

It is important to keep in mind that a risk mitigation strategy cannot reduce risks to zero. The goal should be to adequately and appropriately manage the identified risks. A risk management plan should always be available, reviewed on a regular basis, and updated whenever necessary.

Under the *Human Pathogens and Toxins Act* (HPTA), any facility conducting scientific research with human pathogens and toxins must submit a plan outlining how biosafety and biosecurity risks, including those from research with dual-use potential, are administratively managed and controlled at an institutional/organizational level. Basic mitigation strategies for research with dual-use potential should include:

- Adherence to the physical requirements, operational practices, and performance and verification testing requirements under the *Canadian Biosafety Standard* (CBS) in compliance with the HPTA.
- Development of a comprehensive Biosecurity Plan to address potential concerns related to access to pathogens or toxins, knowledge, information, technology, or products.

In facilities that are regulated under the HPTA, principal investigators, research and laboratory staff are encouraged to discuss with their biological safety officers, the research safety committee, and/or licence holders their specific project plans to assess the adequacy of an existing risk management plan.

When creating a plan, the following topics of focus can be considered:

- Education and development - raise awareness of responsible innovation,
- Planning - evaluate the possibility of dual-use potential when applying for new grants. For current grants monitoring the funds on a regular basis to ensure assets are accounted for.
- Research – include periodic review of research and data for potential dual-use. As well as monitor laboratory inventory to ensure they are accounted for.
- Results - certain research information is attractive and is highly sought after by those who wish to do harm. As such, individuals should be aware of the impact and risk of publicly disclosing research information that could be misused.

For more assistance, please contact the Team Leader at Chemical Control Centre: ccc@uwindsor.ca, ext 3524.