# Dual-use risk assessment cycle



#### **Dual-use research**

Dual-use research refers to knowledge, information, methods, products, or technologies intended for peaceful and legitimate research purposes that can also be misused for harmful purposes.

### **Awareness**



It is important for researchers to realize that their research may contain dual-use risks. Awareness can be enhanced through education, training, and interaction with colleagues or the organization's Biorisk Management Advisor (BMA).



## **Evaluation**



The implemented risk management measures are regularly evaluated and, if necessary, adjusted.





## **Escalation**

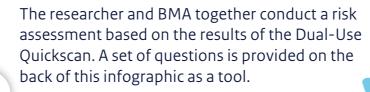


In this phase, an (ad hoc) internal Biorisk Management Committee (BMC) may be consulted, consisting of independent researchers, the BMA, management, and experts in areas such as virology, ethics, regulations, and communication.

The internal committee conducts a risk assessment and has the authority to impose appropriate risk management measures. This phase will only occur in exceptional cases.



## Assessment with the BMA



If there are no dual-use risks or if they are manageable with appropriate risk mitigation measures, evaluation is the next step. Escalation is not required in such cases.

## Monitoring and identification



To recognize potential dual-use risks, it is important to monitor throughout the entire research cycle.

A helpful tool for identifying potential dual-use risks is the Dual-Use Quickscan.



After completing the tool, the researcher shares the results with the Biorisk Management Advisor (BMA). The BMA conducts an initial assessment and can decide, if the research is likely to contain dual-use risks, to have a discussion with the researcher





## Questionlist

## **Mapping**

#### Research objectives and purposes

- 1. What is/are the specific objective(s) of the research project?
- 2. What are the (potential) applications of the research?
- 3. What are the (direct or indirect) benefits that could result from the research?
- 4. Has a biosafety and/or biosecurity (including dual-use) risk assessment been conducted prior to the start of the research by someone with adequate expertise? If so, by whom, and what is their position and expertise?
- 5. Have there been any changes during the research that could affect the outcomes of the risk assessments and potentially lead to reclassification at a different biosafety level?

#### Selection of biological material

- 6. What biological material is being used and why?
- 7. Based on what criteria or arguments was the selection of this specific biological material substantiated and justified?
- 8. What are the potential consequences of the release of this specific biological material into the environment?
- 9. What alternative biological materials or adjustments could reduce the dual-use risks?

#### **Dual-use aspects**

- 10. Which aspects of the Dual-Use Quickscan were answered with 'Yes,' or where is there uncertainty?
- 11. What potential dual-use risks are associated with the research?
- 12. To which specific part(s) of the research are these risks related (materials, methods, techniques, results, etc.)?
- 13. How can these risks be avoided or reduced? If this is not possible, what is the remaining risk, and is it acceptable?

Discuss each 'Yes' or 'Unknown' response in the Dual-Use Quickscan and conduct a risk analysis. Use the eight biosecurity pillars under 'Risk Analysis' to discuss these risks with the researcher. Jointly develop an action plan based on these pillars.

#### Biosecurity awareness

- 1. How does the researcher perceive their role regarding biosecurity and dual-use?
- 2. How does the researcher stay informed about biosecurity risks and measures?
- 3. What arrangements are in place for training and awareness sessions for all involved staff regarding biosecurity measures and dual-use risks?

#### Physical security

- 4. Where and how is the biological material used and stored?
- 5. How are the physical security measures ensured?
- 6. Who are the staff members requiring access to high-risk materials and related equipment?
- 7. What access control measures are implemented for laboratories and storage areas?
- 8. How frequently are audits and monitoring of security measures conducted?

#### Personnel

- 9. Who is working on the research and has access to the research?
- 10. What background checks (e.g., certificate of good conduct) are conducted for personnel working with dual-use materials?
- 11. What systems or monitoring mechanisms are implemented to identify and report suspicious activities?
- 12. How can the researcher identify and report suspicious activities?

#### Transport security and export control

- 13. What risk management measures are in place for the internal/external transportation of biological materials?
- 14. Does the researcher know how carriers are selected, screened, and who is responsible for this process?
- 15. How are transport protocols kept up to date and communicated to staff, including the licensing requirements for the export of dual-use items?

#### **Accountability for materials**

**Risk analysis** 

- 16. How are biological materials (at all stages of the research) identified, labeled, and documented?
- 17. What systems are in place to ensure the traceability of biological materials?
- 18. Who is authorized to order biological materials, and can this be done without the knowledge or approval of the supervisor?

#### Information security

- 19. How are data, including SOPs and technologies, secured?
- 20. Who has access to the data?
- 21. How is the responsible sharing of data ensured, preventing unintended access and misuse?
- 22. How are research results or other sensitive information securely communicated with colleagues or third parties (e.g., email, WhatsApp, etc.)?
- 23. In what way is awareness promoted that knowledge exchange may also be subject to export control regulations?

#### Management

- 24. How do you, as a researcher, contribute to promoting a culture of responsibility and ethical behavior within the organization?
- 25. How do you encourage team members to identify and report areas for improvement regarding dual-use risks?
- 26. What improvements do you personally see in the area of biosecurity and dual-use risks within your research?
- 27. Are you familiar with the policies developed within the organization to manage dual-use risks, and how do you apply them in your work?

#### **Emergency response**

- 28. What procedures have been established for handling emergencies involving biological materials?
- 29. How have direct staff members been trained in these procedures?
- 30. In what way, and how frequently, are the procedures practiced, and what role does biosecurity play in this?
- 31. To whom should incidents related to biosafety and biosecurity be reported?

#### **Dual-Use Quickscan**



#### Dual-use assessment



## How to proceed?

- 1. What agreements do you make with the researcher to manage dual-use risks throughout the entire research project?
- . What agreements do you and the researcher make to detect and report potential incidents related to dual-use risks?
- 3. What measures need to be taken to ensure the long-term security of biological materials and research materials?
- 4. What tools or measures are available to address the identified risks?
- 5. How do you or the researcher ensure proper maintenance and management of stored biological materials and/or data, including long-term archiving and destruction?
- 5. Have you or the researcher consulted biosafety and biosecurity management professionals for guidance and advice?
- 7. Are all stakeholders, oversight committees, institutional review boards, and evaluation committees aware of the research and the associated dual-use risks?
- 8. At what level of detail should information, data, and research methods be disclosed in publications after this research?