BIORISK MANAGEMENT CASE STUDY: NATIONAL INSTITUTE FOR PUBLIC HEALTH AND THE ENVIRONMENT BIOSECURITY OFFICE

Rijksinstituut voor Volksgezondheid en Milieu
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SUMMARY

The National Institute for Public Health and the Environment (RIVM) Biosecurity Office is the expert information and advisory body for high-risk pathogens, knowledge, information, and technologies for the Dutch government. The Biosecurity Office provides support to biosafety officers and researchers in the Netherlands through awareness-raising activities and the development of biosecurity tools. These tools include the Dual-Use Quickscan, which is the focus of this case study. Through its activities, the Biosecurity Office:

- **raises awareness and promotes discussion** between researchers and biosafety officers about dual-use risks.
- **works closely with researchers and biosafety officers** to understand risks "on the ground."
- **leverages existing resources** to create streamlined risk assessment tools.

DISCLAIMER

Biosafety and biosecurity risk management practices can change over time. This case study represents one point in time and is a sample of an evolving set of risk management practices. For additional information on current practices please contact the organization directly.

CONTRIBUTORS

- Rik Bleijs, Head of Biosecurity Office, RIVM
- Kathryn Brink, Stanford University

THE VISIBILITY INITIATIVE FOR RESPONSIBLE SCIENCE (VIRS)

The goal of the Visibility Initiative for Responsible Science (VIRS) is to share information about the value of biorisk management and how life science stakeholder organizations approach the issue. VIRS was conceived by a multi-stakeholder group during an April 2019 working group meeting of the Biosecurity Innovation and Risk Reduction Initiative (BIRRI) program of NTI Global Biological Policy & Programs. With support from NTI, Stanford University Bio Policy & Leadership in Society VIRS produced a set of Case Studies in biorisk management, and The Biorisk Management Casebook that provides cross-cutting insights into contemporary practices.

THE BIORISK MANAGEMENT CASE STUDIES

The Biorisk Management Case Studies describes biorisk management processes for a diverse set of life science research stakeholders. The collection serves to evaluate the feasibility and value of knowledge sharing among both organizations that have similar roles and those that have different roles in managing research. Case studies were developed in consultation with organizations through a combination of research based on public sources, interviews, and providing a template with guiding questions for organizations to complete directly. Additional analysis can be found in The Biorisk Management Casebook: Insights into Contemporary Practices[1] in this collection. Project Directors: Megan Palmer, Stanford University; Sam Weiss Evans, Harvard University.

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ORGANIZATION BACKGROUND

The Biosecurity Office is part of the National Institute for Public Health and the Environment (RIVM) in the Netherlands. It "functions as the expert information and advisory body for both the government and all institutions in the Netherlands that work with high-risk pathogens, knowledge, information and technologies."[1] The Biosecurity Office also acts a liaison between the Dutch government and research organizations, including academic, public health, and industry stakeholders.[2]

The Biosecurity Office evolved from an earlier biosecurity project group formed in 2009 and was formally established in 2013. The Biosecurity Office operates relatively independently from other government agencies, which enables it to pursue projects it feels will be most beneficial to the research community. In the Netherlands, individual research institutions are responsible for safeguarding research project biosafety and biosecurity. Thus, rather than enforcing rules, the Biosecurity Office instead "increases biosecurity awareness in the Netherlands and supports organizations in the voluntary implementation of biosecurity measures."[1] In addition, the Biosecurity Office "supports the government in exploring additional biosecurity laws and regulations."[2] In pursuit of these aims, the Biosecurity Office:

- "Acts as a knowledge and information point and answers biosecurity questions
- Gathers biosecurity knowledge and develops tools and web applications
- Gives (inter)national presentations, lectures and workshops on biosecurity
- Provid[es] knowledge support to the government"[2]

This case study will focus primarily on a tool the Biosecurity Office developed to help researchers and biosafety officers assess research for dual-use risks, the Dual-Use Quickscan.[3,4] The Dual-Use Quickscan is the latest of several tools the Biosecurity Office has developed for researchers and biosafety officers, along with the Self-Scan Toolkit,[5,6] Vulnerability Scan,[7,8] and a biosecurity checklist for laboratory assessment and monitoring.[9] The case study also includes relevant information about the Biosecurity Office's activities that informed the development, implementation, and sharing of this tool.

The Dual-Use Quickscan was developed to fill a gap in practical tools researchers and biosafety officers can use to assess dual-use risks in life science research. While the Royal Dutch Academy of Science had released a report[9] about assessing dual-use research in 2013, its recommendations were too broad to be directly useful to biosecurity officers and researchers. Similarly, in 2019, participants at the North Atlantic Treaty Organization (NATO) Science for Peace and Security (SPS) Programme Advanced Research Workshop (ARW) on Security for Emerging Synthetic Biology Threats[11] noted that there were no hands-on tools for assessing dual-use risks. In response, the Biosecurity Office created the Dual-Use Quickscan, which at the time of this writing is a 15-question online assessment that considers various aspects of dual-use risks. Like other tools from the Biosecurity Office, the Dual-Use Quickscan is designed to be scalable so that it can be used at research institutions in the Netherlands and across the world. Beyond its utility as a risk assessment tool, the Dual-Use Quickscan also serves to raise awareness among the research community about dual-use risks.[3]

PROCESS

Scope of risks considered

The Biosecurity Office offers the following definition of biosecurity within the context of its scope of work:

> *"Biosecurity, including Laboratory Biosecurity, refers to the legislative and institutional framework, the principles, technologies and practices that are implemented to secure pathogens, toxins and sensitive technologies and related equipment from unauthorized access, loss, theft, misuse, diversion or intentional release." —About Biosecurity Office*[2]

The Biosecurity Office considers dual-use research, defined as "well-intended research with potential for malicious use,"[4] to be one part of biosecurity. In the context of the Dual-Use Quickscan, each of the 15 questions on the form addresses a different "theme," or type of dual-use risk. These questions were selected after consulting a wide range of frameworks developed over the past two decades (see Appendix A).[4] The 15 themes addressed in the Dual-Use Quickscan are:

- High-risk biological agent
- Host range and tropism
- Virulence
- Stability
- Transmissibility
- Absorption and toxicokinetics
- Drug resistance
- Population immunity
- Detection methodology and diagnostics
- Reconstruction
- Harmful effects
- Knowledge and technology
- Ecological consequences
- Economic consequences
- Consequences for society

Specific questions for each of these themes are located in Appendix B.

Overall sequence of steps

The Dual-Use Quickscan is an online form designed to assist researchers and biosafety officers in assessing research for dual-use risks. It consists of 15 questions, each answerable with yes, no, or unknown, about a variety of dual-use risks. Though it is designed to be filled out online, answers in the form are only stored locally on the user's computer; no information entered into the form is sent or stored elsewhere. This design helps to ensure that responses are kept confidential, since dual-use issues can be sensitive. Rather than provide a prescriptive answer about whether research contains dual-use risks, the Biosecurity Office encourages researchers to share their results with a biosafety officer, who can provide additional assistance with risk assessment and mitigation steps.

Risk assessment and mitigation

The Biosecurity Office provides the following information to help users understand the outcomes of the questionnaire:

- "The more questions filled in with "yes," the more likely that it is that the research contains dual-use characteristics. However, a single positive answer does not necessarily mean that the research contains dual-use potential.
- One or more questions answered with "unknown" indicates that at the time of completing the questionnaire, it is not clear whether associated dual-use aspects may be present, but this may change during the course of the investigation.
- If all questions are answered with "no," it is unlikely that aspects of dual-use potential are associated with the study, but this cannot be ruled out."[12]

The results of the Dual-Use Quickscan are designed to be shared with biosafety officers at a researcher's institution. The biosafety officer can provide more in-depth information, assist with additional assessment of dual-use risks, or recommend a consultation with the institution's Biorisk Management Committee for further discussions about the dual-use nature of the research.[4] The Biosecurity Office recommends several frameworks that could help guide assessments and decision-making regarding dual-use risks,[4] including Tucker's model[13] and the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern[13] and its companion guide.[15]

Expertise required

The Dual-Use Quickscan is designed to be used by biosafety officers and researchers, who may not have specific expertise related to dual-use risks. However, to develop the tool, the Biosecurity Office drew on its internal expertise and leveraged an "expert committee consisting of renowned researchers, biological safety officers and safety experts from academia, industry and government."[4] The Biosecurity Office itself "consists of a multidisciplinary team of eight RIVM employees with varied expertise, including knowledge of biosecurity, biosafety, biorisk, infectious disease control, environmental microbiology, zoonoses, genetically modified organisms, public health and biological calamities."[2] Biosafety and biosecurity are broad fields that cover both naturally occurring pathogens and genetically modified organisms (GMOs), as well as plant, animal and human pathogens. Given the wide range of risks encompassed by biosafety and biosecurity, the Biosecurity Office finds it valuable to have a team with broad expertise rather than narrowly focusing on a particular topic area, such as human infectious disease or GMOs.

FEEDBACK

The Biosecurity Office regularly interacts with researchers and biosafety officers within the Netherlands and in international fora. Through these interactions, they sometimes hear from individuals who are excited about their tools.

Through the academic review process of the Dual-Use Quickscan publication,[4] the Biosecurity Office received valuable feedback about the tool that has helped inform updates to the tool. The Biosecurity Office is also piloting a questionnaire and follow-up interviews to learn whether and how life scientists use the Dual-Use Quickscan. This is the first time the Biosecurity Office is collecting information from users about their experience with one of their tools, in part because this type of data collection requires significant time and resources. The Biosecurity Office may use information obtained through the questionnaire and interviews to make additional updates to the tool.

SHARING

The Biosecurity Office shares information about its activities, including tools it develops, through a quarterly newsletter sent to biosafety officers and researchers in the Netherlands. In general, the Biosecurity Office reaches researchers via the biosafety officers at their institutions, who are encouraged to share information about tools and activities with the researchers they support.

The Biosecurity Office also shares information about its activities with an international audience at professional meetings (including meetings of the American Biological Safety Association (ABSA) and European Biosafety Officers Association (EBSA) and by publishing academic journal articles. For example, the Biosecurity Office has published articles about each of its biosecurity tools:

- Sijnesael PCC, van den Berg LM, Bleijs DA, Odinot P, de Hoog C, Jansen MWJC, Kampert E, Rutjes SA, Broekhuijsen M and Banus S (2014) Novel Dutch self-assessment Biosecurity Toolkit to identify biorisk gaps and to enhance biorisk awareness. *Front. Public Health* 2:197. doi: 10.3389/fpubh.2014.00197[6]
- Meulenbelt SE, van Passel MWJ, de Bruin A, van den Berg LM, Schaap MM, Rutjes SA, Jacobi AJ, Agterberg MC, de Hoog C, van Willigen G, Kampert E, Heres JHJ, van den Berg R, van den Berg HHJL and Bleijs DA (2019) The Vulnerability Scan, a Web Tool to Increase Institutional Biosecurity Resilience. *Front. Public Health* 7:47. doi: 10.3389/fpubh.2019.00047[8]
- Brizee S, van Passel, MWJ, van den Berg LM, Feakes D, Izar A, Lin KTB, Podin Y, Yunus Z, Bleijs DA (2019). Development of a Biosecurity Checklist for Laboratory Assessment and Monitoring. *Applied Biosafety* 24(2), 83. doi: 10.1177/1535676019838077[9]
- Vennis IM, Schaap MM, Hogervorst PAM, de Bruin A, Schulpen S, Boot MA, van Passel MWJ, Rutjes SA and Bleijs DA (2021) Dual-Use Quickscan: A Web-Based Tool to Assess the Dual-Use Potential of Life Science Research. Front. Bioeng. Biotechnol. 9:797076. doi: 10.3389/fbioe.2021.797076[4]

REFLECTIONS

The Biosecurity Office offers the following reflections about its work:

- Risk assessment is multi-faceted and complex. While specific pathogens are easy to point to, knowledge and technology are more challenging to draw firm boundaries around. Leveraging existing resources can be helpful for developing tools and practices for assessing and managing risks.
- To develop effective risk management tools and practices, it is important to understand the risks "on the ground" by talking to researchers and biosafety officers. Rather than making demands, the best way to reach these individuals is to ask how you can help support their work.
- Fostering a broader culture of trust between biosafety officers and researchers is important for tools like the Dual-Use Quickscan to work well. If researchers do not have good relationships with their biosafety officers, they may be reluctant to share the Dual-Use Quickscan results with these individuals.

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5. Biosecurity Self-scan Toolkit *https://www.biosecurityselfscan.nl/home*
6. Sijnesael PCC, van den Berg LM, Bleijs DA, Odinot P, de Hoog C, Jansen MWJC, Kampert E, Rutjes SA, Broekhuijsen M and Banus S (2014) Novel Dutch self-assessment Biosecurity Toolkit to identify biorisk gaps and to enhance biorisk awareness. *Front. Public Health* 2:197. doi: 10.3389/fpubh.2014.00197
7. Vulnerability Scan *https://biosecurityvulnerabilityscan.nl/*
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APPENDIX A: LITERATURE SOURCES CONSULTED DURING DEVELOPMENT OF DUAL-USE QUICKSCAN

Reproduced from Vennis et al. 2019[2]

Each question can be answered with "yes", "no", or "unknown".

AUTHOR/ORGANIZATION	YEAR	TITLE
Boston University	2014	Identifying and Addressing Dual Use Research of Concern
Canadian Government	2018	Canadian Biosafety Guideline—Dual-Use in Life Science Research
Centre for Biosecurity and Biopreparedness, Denmark	2015	Questionnaire about dual-use research of concern for companies, project managers etc.
German Ethics Council	2014	Biosecurity Freedom and Responsibility of Research
Federation of American Scientist		Case studies Dual-use
iGEM Team Bielefeld-CeBiTec	2015	Dual Use report
Imperiale MJ, Casadevall A	2015	A new synthesis for dual use research of concern
ISO	2019	ISO 35001:2019, Biorisk management for laboratories and other related organisations
Jonathan B. Tucker	2012	Innovation, Dual Use, and Security. Managing the Risks of Emerging Biological and Chemical Technologies
National Academies of Sciences, US	2018	Governance of Dual-use Research in the Life Sciences: Advancing Global Consensus on Research Oversight: Proceedings of a Workshop
National Institutes of Health, US	2014	Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern. A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern
National Institutes of Health, US	2014	Implementation of the USG Policy for Institutional Oversight of Life Sciences DURC: Illustrative case Studies
National Institutes of Health, US		Dual Use Research of Concern
National Research Council, US	2004	Biotechnology Research in an Age of Terrorism
National Research Council, US	2007	Science and Security in a Post 9/11 World: A Report Based on Regional Discussions Between the Science and Security Communities
Robert Koch Institute (RKI), Germany	2013	Handling Dual-use Risks at the RKI - House Order_ Dual-Use Potential in Research
Royal Netherlands Academy of Arts and Sciences (KNAW)	2013	Improving biosecurity: Assessment of dual-use research
Selgelid MJ.	2009	Governance of dual-use research: an ethical dilemma
United States Government	2014	United States Government Policy for Institutional Oversight of Life Sciences Dual use Research of Concern
Whitby S, Novossiolova T, Walther G and Dando M	2015	Preventing Biological Threats: What You Can Do. A Guide to Biological Security Issues and How to Address Them
Working Group Dual-use of the Flemish Interuniversity Council	2017	Guidelines for researchers on dual-use and misuse of research
World Health Organization (WHO)	2020	Laboratory Biosafety Manual 4th Edition; Biosafety programme management

APPENDIX B: DUAL-USE QUICKSCAN QUESTION LIST

Reproduced from Vennis et al. 2019[2]

Each question can be answered with "yes", "no", or "unknown".

THEME	QUESTION
High-risk biological agent	Are you working with a biological agent, or parts of it, that can be considered a high-risk pathogen?
Host range and tropism	Is the host range or tropism of the biological agent likely to be altered?
Virulence	May your research increase the virulence of the biological agent?
Stability	Is it to be expected that the stability of the biological agent outside the host will increase as a result of your research?
Transmissibility	Is it likely that the transmissibility or ability for dispersion or dissemination of the biological agent will increase?
Absorption and toxicokinetics	Is it to be expected that the absorption of the biological agent is facilitated or is an increased toxicokinetic effect to be expected?
Drug resistance	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?
Population immunity	Does the biological agent possibly have a negative effect on the immunity of humans, animals or plants?
Detection methodology and diagnostics	Could your research impact the detection methods, diagnostics, or clinical diagnosis of the biological agent?
Reconstruction	Does your research contribute to the reconstruction of an eradicated or extinct biological agent?
Harmful effects	May changes to the biological agent possibly generate or enhance the harmful consequences, which may involve "improved weaponization"?
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?
Ecological consequences	Could your research contribute to possible harmful ecological consequences due to misuse of the modified biological agent or the knowledge thereof?
Economic consequences	Could your research contribute to possible harmful economic consequences due to misuse of the modified biological agent or the knowledge thereof?
Consequences for society	Could your research contribute to harmful consequences for society from the misuse of the modified biological agent or the knowledge thereof?
Robert Koch Institute (RKI), Germany	Handling Dual-use Risks at the RKI - House Order_ Dual-Use Potential in Research
Royal Netherlands Academy of Arts and Sciences (KNAW)	Improving biosecurity: Assessment of dual-use research
Selgelid MJ.	Governance of dual-use research: an ethical dilemma
United States Government	United States Government Policy for Institutional Oversight of Life Sciences Dual use Research of Concern
Whitby S, Novossiolova T, Walther G and Dando M	Preventing Biological Threats: What You Can Do. A Guide to Biological Security Issues and How to Address Them
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World Health Organization (WHO)	Laboratory Biosafety Manual 4th Edition; Biosafety programme management