



# In Practice In the Netherlands

Dr. Marcel van Bergen

14-05-2025

Marcel van Bergen BioRiskManager @ Radboudumc and Radboud University





### Role

- Bio Safety Officer (BVF)
- Environmental Safety Officer (MVF)
- Occupational Health Hygienst (AH)

**Bio Risk** 

- **Professional** 
  - **Management Advisor**





### Role

Locally: Radboud University and Medical Centre

Radboudumc
Radboud Universiteit

- BioRiskManagement Advisor
- Teamleader Team BioRiskPrevention
- Nationally: Dutch Biosafety Association / BVF-Platform



- Chair
- Member of working groups and projects
- Internationally: European Biosafety Association
  - Chair Scientific Committee / Conference Working Group





## **Content Presentation**

#### Program

14.00 nrs	Opening and welcome by the Netherlands Biosecurity Office
14.10 hrs	Biosecurity, AI and emerging technologies
	Jaime Yassif, Vice President, NTI Global Biological Policy and Programs, NTI   bio, USA
14.35 hrs	Dual-use of emerging technologies & WHO dual use guidance
	Filippa Lentzos, Kings College London, UK
15.10 hrs	Putting the WHO Global Guidance Framework into action:
	Case studies across the world
	Maria J. Espona, Health Security Partners, Argentina
15.30 hrs	Coffee break & networking
16.00 hrs	Biosecurity and dual-use in practice in Denmark
16.25 hrs	Biosecurity and dual-use in practice in the Netherlands
16.50 hrs	Marcel van Bergen, UMC Radboud, the Netherlands
	the Australian Centre for Disease Preparedness
	J.T. Paulley, CSIRO Australian Centre for Disease Preparedness, Australia
17.10 hrs	Short break
17.30 hrs	Bridging policy and practice: Implementing the WHO Laboratory Biosecurity Guidance
	Kathrin Summermatter, University of Berne, Switzerland
17.55 hrs	Kathrin Summermatter, University of Berne, Switzerland Culture of biosafety and biosecurity: What gets measured gets done
17.55 hrs	,, ,
17.55 hrs 18.20 hrs	Culture of biosafety and biosecurity: What gets measured gets done



### **Content Presentation**

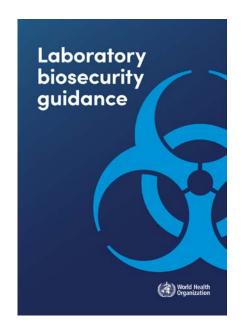
- 1. Biosecurity and Dual-Use (in the Netherlands)
  - Biosecurity and dual-use in practice in the Netherlands
- 2. III Practice (in Nijmegen)
- - Locally

# **Biosecurity and Dual-Use**

In essence, biosecurity is about safeguarding biological resources, while dual-use highlights the potential for misuse of scientific advancements.

To emphasise the importance of addressing biosafety and biosecurity risks of research with biological material that could have severe or even catastrophic consequences to life, the laboratory biosecurity guidance uses the term high-consequence research to describe these experiments. Other terminology is used such as dual-use research of concern, dual-use, or research of concern. High-consequence research is at risk of potential malicious use of biological agents as well as unintentional exposure and/or release of such agents, despite its intended benefits. Hence it is of both biosafety and laboratory biosecurity concern. While some work can be clearly classified as high-consequence research, the aims and effects of other research may not be so obvious.

- My perspective:
  - Dual use is integral part of biosecurity
- Therefore ... :
  - I will not specifically mention "dual use"







# Biosecurity and Dual-Use In the Netherlands

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# Biosecurity in the Netherlands An update...

- External evaluation to identify critical gaps in the Dutch healthcare system (January 2025)
  - WHO
    - Joint External Evaluation (JEE)
    - Voluntarily
  - ECDC
    - Public Health Emergency Preparedness
       Assessment (PHEPA)
    - Obliged

- Biosafety and biosecurity policies in the Netherlands evaluated by WHO and ECDC

  Publication date 25-03-2025 | 10:21

  Dutch JEE-PHETA Musicon Week

  Biosafety en biosecurity beleid in Nederland geëvalueerd door WHO en ECDC | Bureau Biosecurity
- <u>Netherlands</u>: first country to **combine** these two evaluations
- <u>Preparation</u>: National self assessment by experts





Saskia Rutjes

**National Institute for Public Health and the Environment (RIVM)** 

29 January 2025 | Utrecht



Indicator	Capaciteit P7: Biosafety and Biosecurity
P7.1	Whole-of-government biosafety and biosecurity system in place for all sectors (including human, animal and agriculture facilities)
P7.2	Biosafety and biosecurity training and practices in all relevant sectors (including human, animal and agriculture)

# The Netherlands JEE/PHEPA:

P7. Biosafety and biosecurity

Saskia Rutjes

**National Institute for Public Health and the Environment (RIVM)** 

29 January 2025 | Utrecht



**Strengths** 

**Best Practices** 

Areas which need strengthening

Challenges

P7. Biosafety and biosecurity

Saskia Rutjes

National Institute for Public Health and the Environment (RIVM)

29 January 2025 | Utrecht

# **Biosecurity in the Netherlands**

### **BUT....**

the lack of a national legal framework for biosecurity...

does not mean...

that it is not (partly) implemented on local level!

The Nijmegen situation ..... is just an example...
 ... and therefore, not automatically representing other Dutch organisations!







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14-05-2025

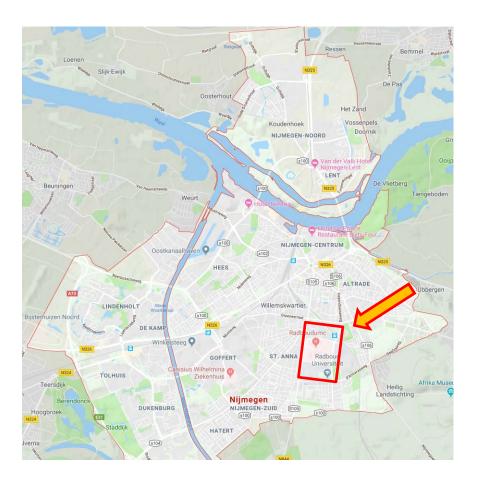
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# Nijmegen, The Netherlands





# **Radboud Campus**



## BioRiskManagement @ Radboud Campus

- One BRM-System
  - University and Medical Centre

- WildType (WT) and Genetically Modified Organisms (GMO)
  - Contained Use
  - Deliberate Release
- Biosafety and Biosecurity





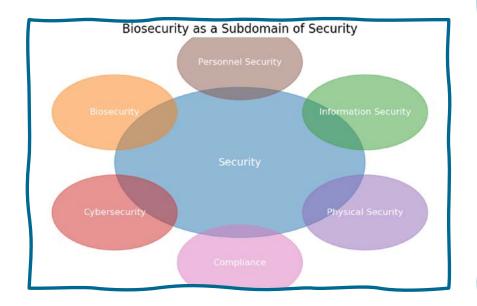


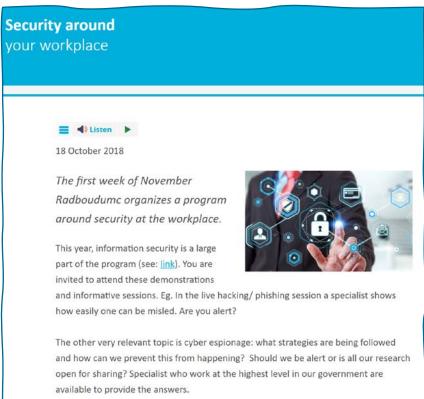






# Biosecurity... ... is just a part of Security





# Biosecurity is covered by

### **Guideline for Working Safely with Biological Agents**

#### Scope

This document has been created for all persons (employees, guest employees, students) working with BA, whether directly or indirectly.

It describes rules for Biosafety ("how to keep bad bugs from people") and for Biosecurity ("how to keep bad people from bugs").

Working with genetically modified organisms (although this also often involves Biological Agents) is not covered in this document. A separate caution system for this is described in the <a href="Modes and Described">GMO manual</a> (UMC) / <a href="webshare">webshare</a> (RU)



**Biosafety**Keep bad bugs
away from people

**Biosecurity** Keep bad people away from bugs



#### **Biosecurity**

#### Introduction

Biosecurity refers to the legislative and institutional framework, principles, technologies and practices implemented to protect pathogens, toxins and sensitive technologies and related equipment from unauthorized access, loss, theft, misuse, abuse or intentional release.

In life sciences research, the term dual-use means that biological agents, including the knowledge about them and the underlying techniques, can be used in two ways.

In most cases, these are risk group 3 and 4 organisms but sometimes they are also risk group 2 organisms or non-human-pathogenic microorganisms. The full list can be found here.

#### **Procurement**

If purchasing a risk group 3 agent is desired then a <u>risk analysis for a category 3 agent</u> (UMC)/ <u>risk analysis for a category 3 agent via webshare</u> (RU) must be completed in advance and reviewed by the BSO. Part of this is a check for the dual-use aspect of the work (dual-use quick scan). If you wish to purchase BA that may fall under the definition of dual-use you should contact the BSO.



Department of Occupational Health and Safety and Environmental Service (AMD)

#### Risk Inventory and Evaluation (RI & E) mapping the risks of activities involving

Click or touch to enter a text.

Date: Click or touch to enter a date. Version: Click or touch to enter a text.

Author:Click or touch to enter a text.

Email address: Click or touch to enter a text.

#### Details of the agent

1.1 Agent

Click or touch to enter a text.

1.2 Pathogenicity class (human)

Choose an item.

1.3 Pathogenicity class (veterinary)
Choose an item.

1.4 Biosafety level

BSL Choose an item.

1.5 Biosecurity

Choose an item. \*

Other: Click or touch to enter text.

- \* Look up the level at: https://www.bureaubiosecurity.nl/biologische-agentia/gecombineerde-lijst-met-biologische-agentia.
- Fill in the Quickscan (https://dualusequickscan.nl/) en stuur deze op naar de BVF.
   Summeray: Click or touch to enter text.

Update Quickscan necessary if research changes.

- b. Follow up questions for when an organism is stated on the EU export list (dual use)
  - Are there any plans for export outside the EU? Click or touch to enter text.
  - Are there plans for publication, presentation at conference, collaboration with researchers outside the EU?
     Click or touch to enter text.

#### Biosecurity information:

- <u>Directly</u>:
  - Dutch Biosecurity Office
- Indirectly:
  - WHO
  - ICS > 03 > 03.100 > 03.100.70

ISO 35001:2019

Biorisk management for laboratories

Export of Strategic Goods

Export of strategic goods

In the case of dual-use, the regulations for the export of strategic goods apply in addition. These are goods to which, for reasons of security and international agreements, so much strategic importance is attributed that their export may not take place or may only take place under certain conditions.

Explanations on the export of dual-use goods can be found on the <u>Bureau Biosecurity</u> website and in a document prepared by customs (<u>UMC</u>, <u>RU</u>). Which dual-use goods require an export licence is listed in Annex I of <u>EU</u> <u>Verordening 2021/821</u>.

Following consultation with customs, the inspecting authority in the field of the transport of strategic goods, laws, and regulations have been translated practically as follows: If a department wishes to dispatch BA that may fall under the strategic goods category, it must make a request to do so via Postbus Biorisk Prevention.

Knowledge and Publication

Knowledge and Publication

Employees who work with risk group 3 or dual-use agents should handle knowledge and information related to the work with care. Publication of data from dual-use research may in rare cases be seen as <a href="export of strategic goods">export of strategic goods</a>; this may require an export license. Please also contact the <a href="knowledge security officer">knowledge security officer</a> and <a href="Postbus Biorisk">Postbus Biorisk</a> Prevention for this.

Security of Facilities and materials

Security of rooms and materials

Risk group 1: No security measures apply to BA in risk group 1.

**Risk group 2:** Departments working with BA risk group 2 and above are not accessible to unauthorized persons. These departments are equipped with an access control system (at the department level) using name badges. The department head is responsible for authorizations.

**Risk group 3:** BA in risk group 3 and dual-use organisms are subject to an increased security level. The space where work is performed is equipped with access security (at the room level) and burglary protection. Access to the rooms is reserved for employees only; students do not have access. A supervisor from the department must be present during <u>maintenance</u> in the room and on vital systems. External personnel must sign a confidentiality statement (included in contract with external party).

Security during activities

Security during activities

Activities with BA from risk group 3 or with dual-use organisms are always conducted by a minimum of two people (or is monitored via a camera). If you notice behavior in colleagues that could possibly indicate involvement in illegal practices with these materials or knowledge of them, you should discuss it with a confidential advisor in the department.

Shipping

Shipping

All shipments of risk group 3 or dual-use agents to third parties should be recorded in the departmental records (including recipient data). For transportation regulations, see the standard regulations at Extern transport.



# **Radboud Campus Self Evaluation**

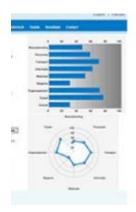
- 2011
- 2015
- 2019
- 2025







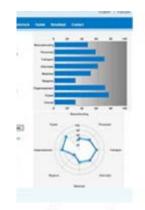
## 







# 2015

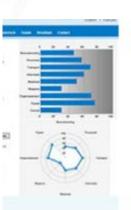






## 2019







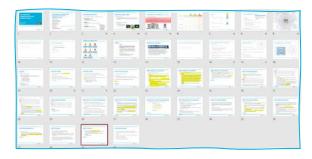
### Results

#### Presented to:

- BioRisk Prevention Committee (permanent)
- Biosecurity Steering Group (temporair)

#### Discussed:

- Outcome varies per topic between 0-100%
- Weighing the deviations
- But....
  - How high do we want to set the bar?
  - What standards do we want to aim for?
  - How ambitious do we want to be?

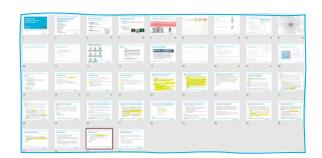




### Results

#### • Presented to:

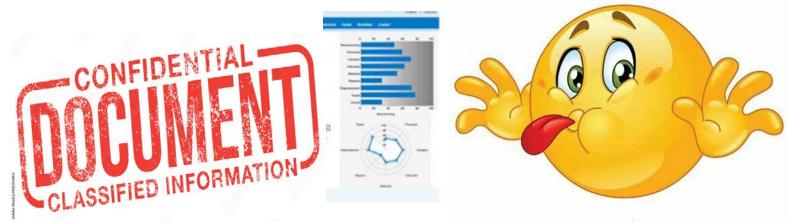
- BioRisk Prevention Committee (permanent)
- Biosecurity Steering Group (temporair)



#### Discussed:

- Many improvements can be covered by team BioRiskPrevention
- Many improvements can be achieved by adding / expanding the existing procedures
- Some improvements are difficult to realise, because the complexity of the Radboud Campus
- Broaden the approach
  - <u>Chemical</u>, <u>Biological</u>, <u>Radiation</u>, <u>Nuclear</u>

### **Status 2025**



- Progress to be discussed...
  - awareness





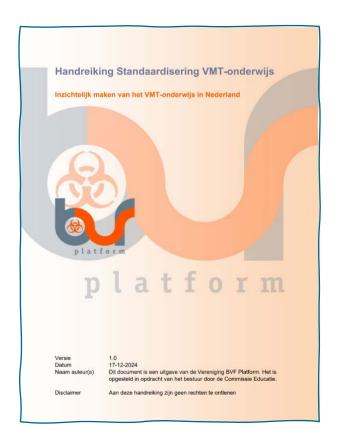
Biosecurity awareness



- Guidance Document on Standardisation of Education in Safe Microbiological Techniques
  - BVF-Platform Commission of Education
  - December 2024

#### Learning objectives:

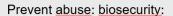
- The student:
  - knows the difference between biosafety and biosecurity
  - is able to mention measures to increase biosecurity
  - is aware of the existence of dual use research





#### 2. Possible risks





- <u>Biological</u> and <u>Toxin Weapons Convention</u> (BTWC, 1975): restrictions
- Nationaal Coördinator Terrorisme Bestrijding en Veiligheid (NCTV)



- Dual use: weigh Risks against Results; maybe we should not publish this?
- · Important:
  - · Awareness and report
  - Safe <u>storage</u> of <u>GMOs</u>
  - Safe <u>storage</u> of data
  - Transport to reliable people and use reliable transporters

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A Code of Conduct for Biosecurity

Report by the Biosecurity Working Group

Royal Netherlands Academy of Arts and Sciences Amsterdam, August 2008



# Acknowledgement

- Team BioRiskPrevention
  - Danielle Odinot
  - Cora Klaver
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  - Marijn van den Hondel
  - Nick van Bakel



- Saskia Rutjes
- Rik Bleijs
- Mijntje Aarts
- My Network

