

Biorisk management: current state of play

Séminaire: Diagnostic et surveillance des maladies infectieuses

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WIV-ISP, Service Biosécurité et Biotechnologie

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Biorisk management: current state of play

- Definitions
- A little history
- Methodology for biorisk management
- Conclusion

Biorisk

= The probability or chance that a particular adverse event, possibly leading to harm, will occur

Biorisk management

= Relating to **biosafety** and **biosecurity** (and bioethic) where the principal hazard is a **biological agent**

Biosafety

Safety for **human health** and the **environment**, including the protection of biodiversity, during the use of **genetically modified organisms** (or micro-organisms), and during the contained use of **pathogenic organisms** for humans.

- ⇒ Unintentional exposure or release
- ⇒ Containment



Biosecurity

In a laboratory, the protection, control and accountability for **Valuable Biological Material** agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release



Valuable biological materials



Biological materials that require protection, control, accountability (economic, historical, archival value, and/or their potential to cause harm).

May include pathogens, toxins, non-pathogenic organisms, vaccine strains, food products, genetically modified organisms, cell components, genetic elements, and extraterrestrial samples.

“**Biosafety** is to keep bad bugs away from people”

“**Biosecurity** is to keep (malevolent) people away from bugs”

But both aim to keep **VBM safely and securely inside** the area where they are used and stored



Biosafety – biosécurité – bioveiligheid – ...

Biosecurity – biosûreté – biobeveiliging – ...

Pathogenic organisms
19th century

Bioweapons

1st LAI's

Recombinant DNA (70's)

Awareness ↗

90's

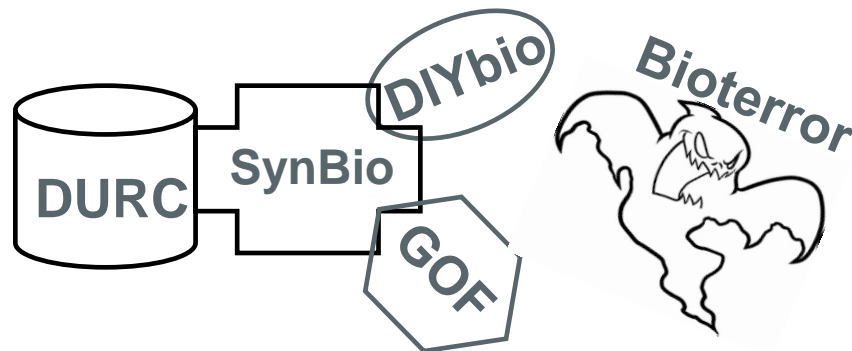
RA - RM

Public Health,
Environment,
Worker protection

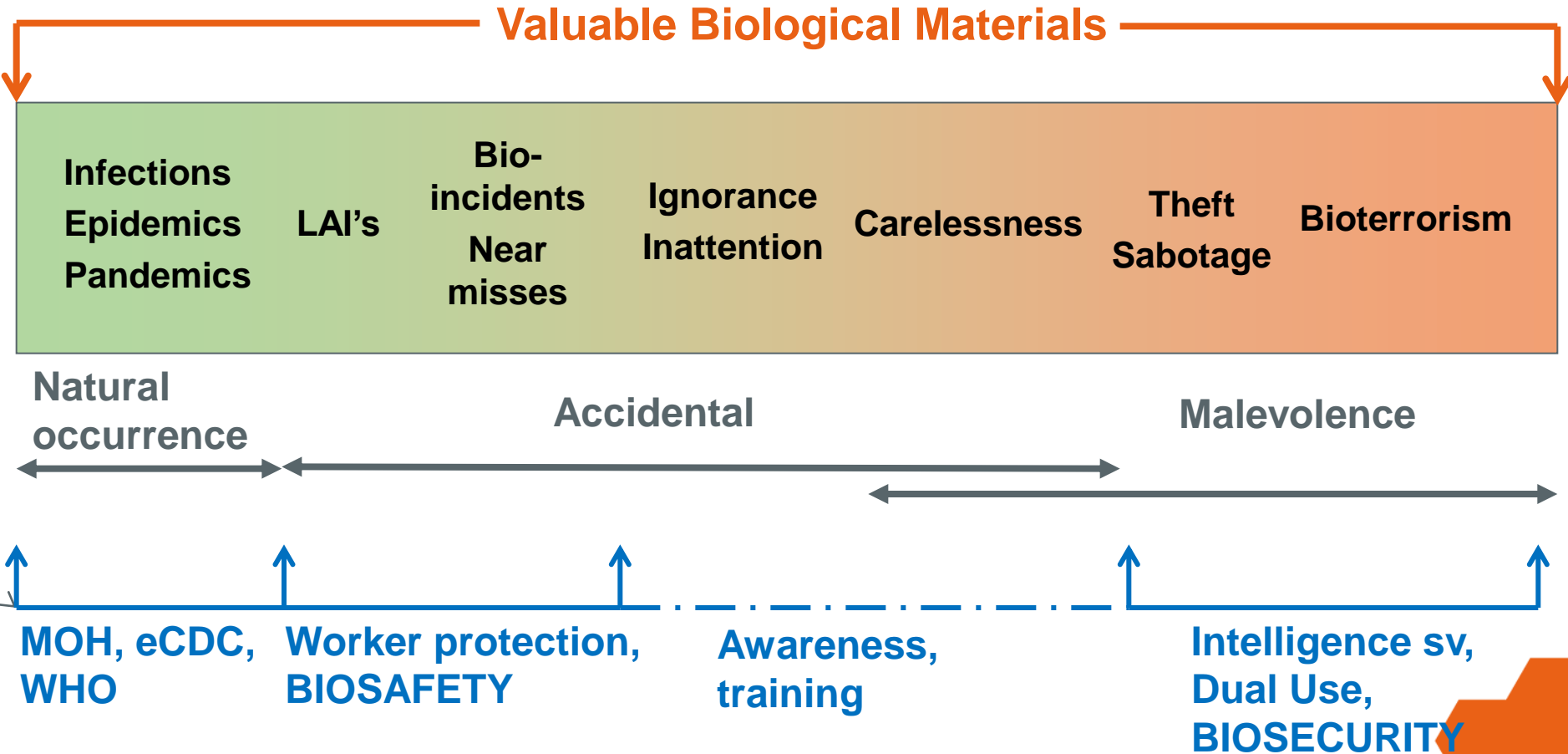
> 2001

EU Green Paper 2007

EU CBRN 2009



Biorisk: sources and legal provisions



Biorisk management

1. Biosafety

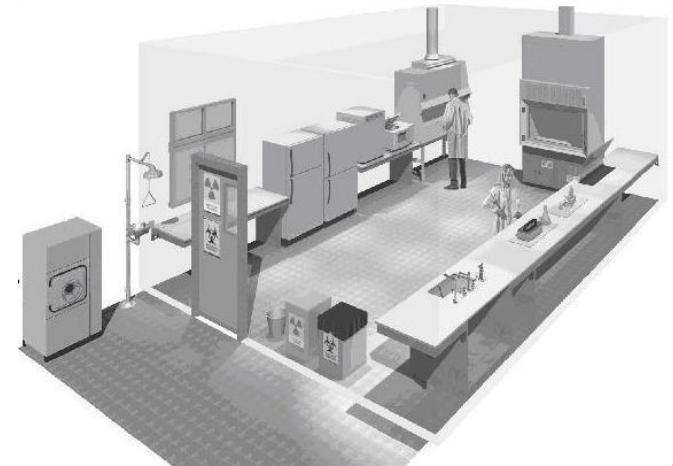
Risk assessment => **Level of risk of the activity**
(class of risk of the organism and type/nature of manipulation)

Risk Level 1 to RL4

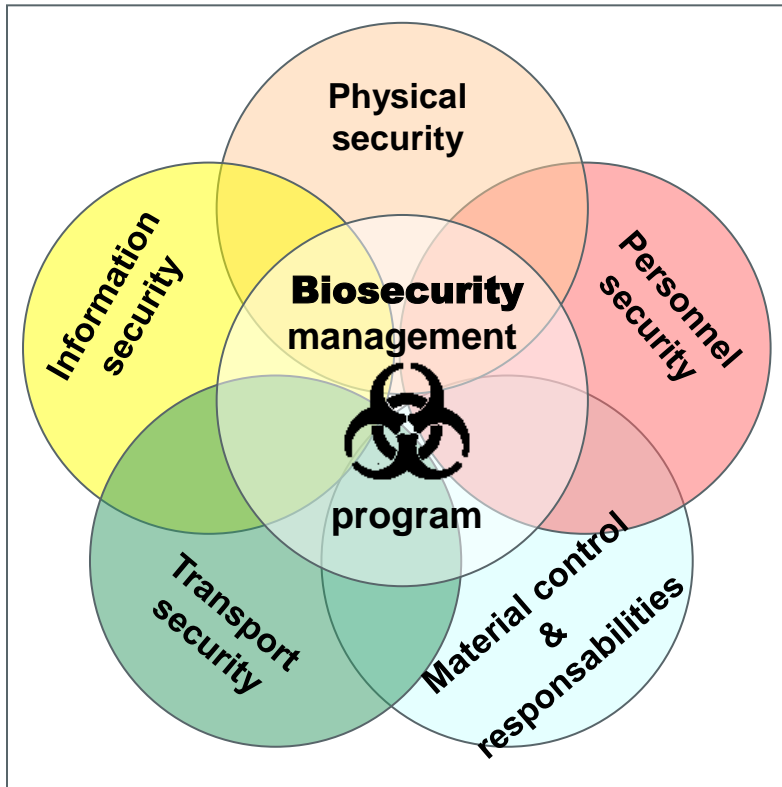
Risk management => **Containment level**

Containment Level 1 to L4

- ⇒ Technical features of the facility,
- ⇒ Equipment,
- ⇒ Personal Protection Equipment,
- ⇒ Work practices,
- ⇒ Waste treatment
- ⇒ Emergency plan



2. Biosecurity



5 domains of action:

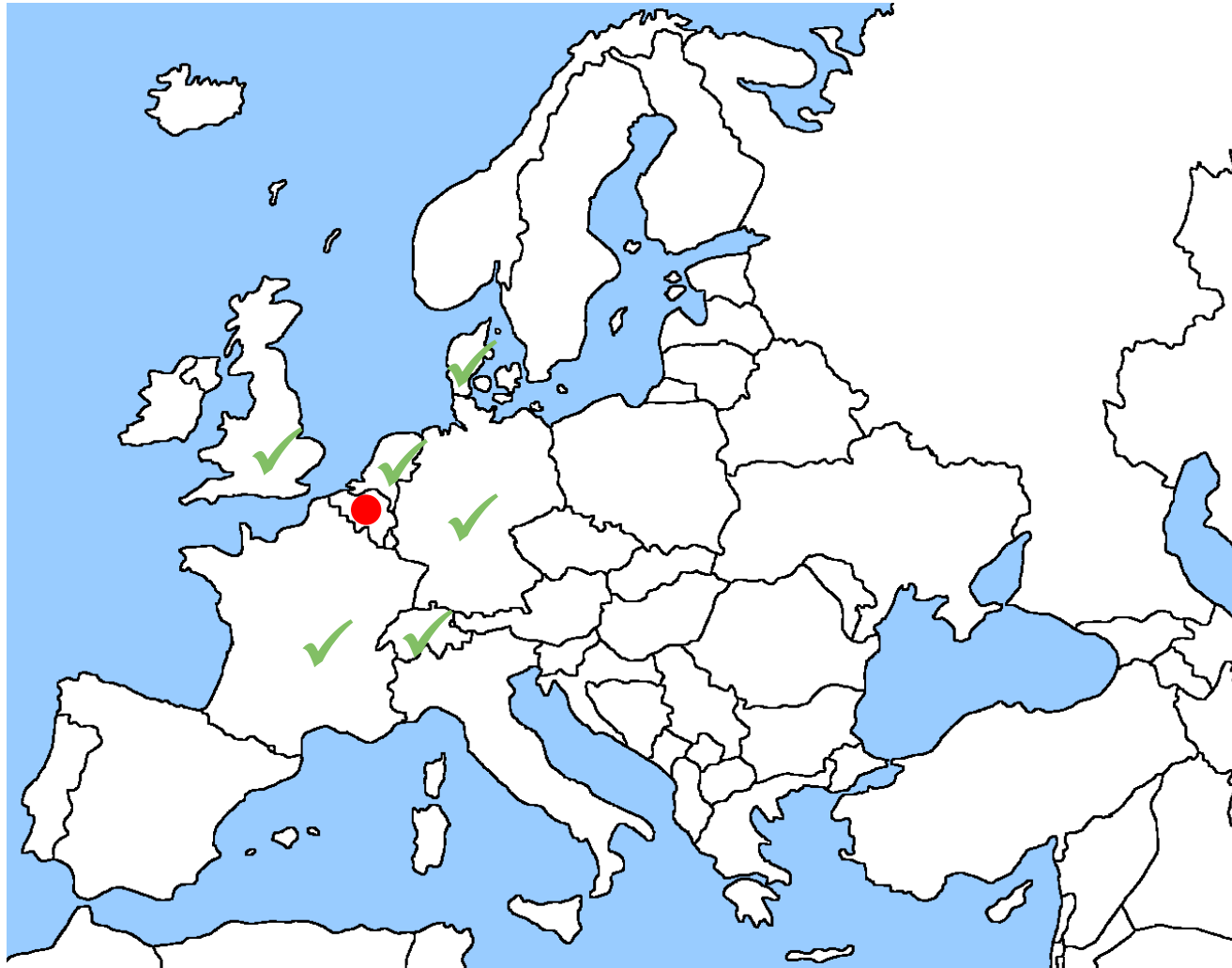
- Physical barriers
- Personnel management
- Biological material protection
- Information and data protection
- Transport security

And biorisk?

- ⇒ Biosecurity is complementary to biosafety
- ⇒ Some provisions are common to biosafety and biosecurity
- ⇒ Some provisions may be in conflict

Biosecurity in Europe

In EU: “each MS is free to determine its biosecurity policy”



All hazard-approach (CBRN) - Counter Terrorism Strategy

In Belgium



Biosafety

Well-established since 1997, implementation of European GMO directives (CU and DR), scope extended to pathogens

Biosecurity

Up to now, **voluntary basis** – no legal binding

Common sense: intellectual property protection coupled with *VBM security*

Tools and Human resources: Biosafety legislation, BSO, prof. network, CEN WA 15793:2011- Biorisk Management, EU CBRN Action plan (proposals), WHO - Biorisk management • Laboratory biosecurity guidance

CWA 15793:2011

Laboratory Biorisk Management



Biorisk management system: The organizational structure, planning activities, responsibilities, practices, procedures, processes and resources for developing, implementing, achieving, reviewing and maintaining an organization's biorisk policy.

→ ISO 35001 ?

Conclusion

Biosafety yes, mandatory!

Biosecurity maybe yes or maybe no.

Anyway, always follow:

**Risk
Identification**



**Risk
Assessment**



**Risk
Management**

