

Evidence-Based Biosafety

MEACB 2017

8th Meeting of the European Advisory Committees on Biosafety in the field of contained use and deliberate release of GMOs

Liège, 23 November 2017

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EVIDENCE-BASED BIOSAFETY

INTRO

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▶ EVIDENCE-BASED BIOSAFETY

Definition?

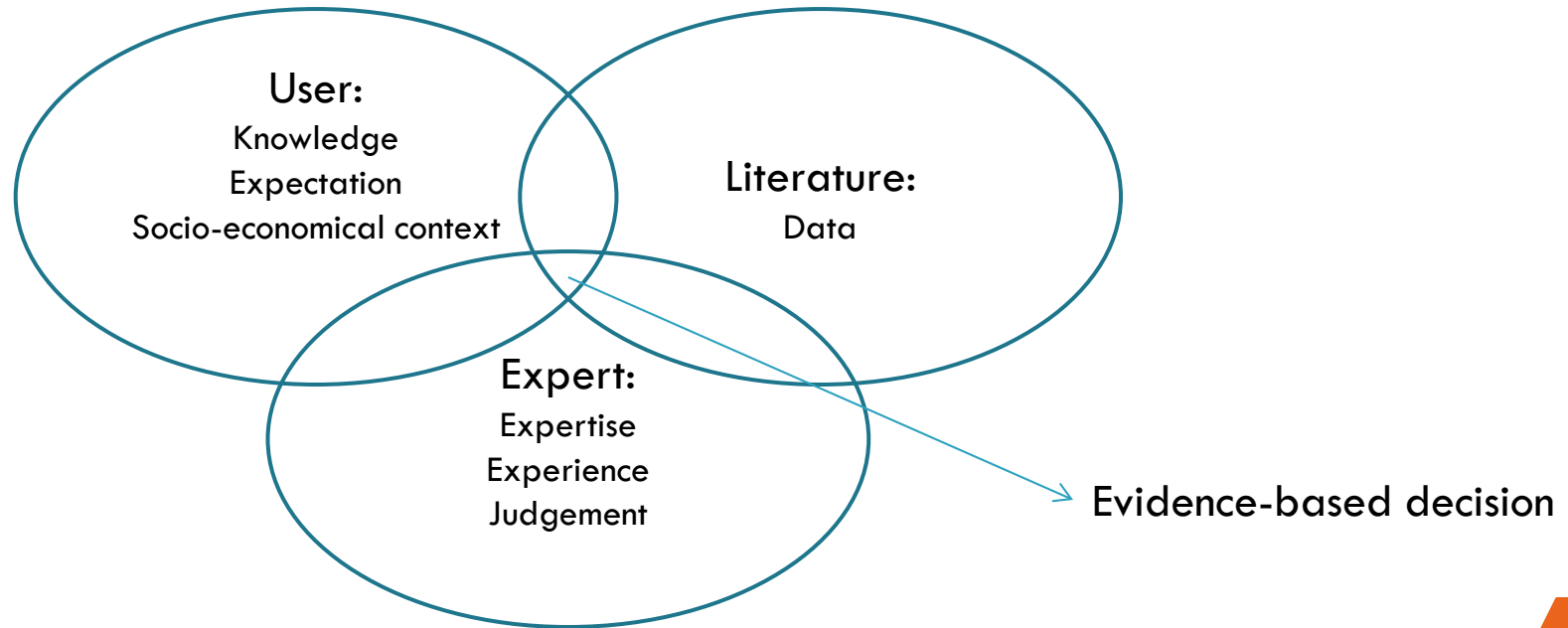
“Biosafety based on substantiation and facts”

Challenges?

EVIDENCE-BASED BIOSAFETY

INTRO

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▶ EVIDENCE-BASED BIOSAFETY:

-Prevent decision based on obsolete knowledge gained during education or expertise without practical experiences

-Guarantees a pragmatic decision based on the most up-to-date and best knowledge

Bottleneck? >>> Data availability

▶ SBB & EVIDENCE-BASED BIOSAFETY:

Creating scientific data on containment measures based on experience, literature studies and sectoral consultation (if possible);

http://www.biosafety.be/CU/EN/Tools_RA_RM.html

Recently with own research data:

- Airtightness
- Classification of organisms
- Education with lab practices on biological agents
- Fumigation
- Bio-incidents, Bio-accidents and laboratory-acquired infections

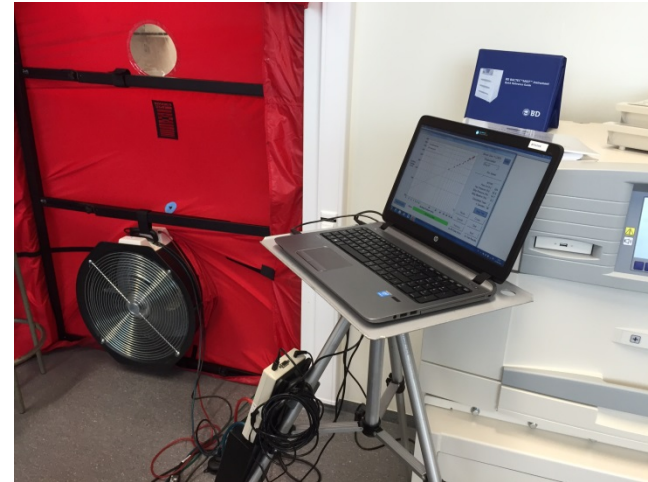
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AIRTIGHTNESS

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► METHODOLOGY:

- blower door test at 50 Pa pressure difference
- Different constructions/renovations of high containment facilities:
 - New construction type BSL3 laboratory
 - Box-in-a-box type BSL3 laboratory
 - Conventional renovation type BSL3 laboratory
 - Superficial renovation type BSL3 animal facility



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AIRTIGHTNESS

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		n_{50} (mean) [h^{-1}]
L3	1. New construction	0,4
	2. Box-in-a-box renovation	0,7
	3. Conventional renovation	4,0
A3	← 4. Superficial renovation	0,4

Norm for passive residential buildings: $n_{50} = 0.6 \text{ h}^{-1}$

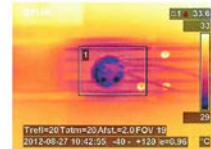
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AIRTIGHTNESS

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OBSERVED AIR LEAKS:

- Double-door autoclave
- Electrical outlets & utilities tubing
- Hatches
- No appropriate outer envelope



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AIRTIGHTNESS

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CONCLUSION & RECOMMENDATION:

- 3 of the 4 high containment facilities showed a good level of airtightness
- Similar sources of air leaks
- Inform building contractors

>>> lab with high airtightness makes decontamination by fumigation more easy!

More info see www.biosafety.be ; http://www.biosafety.be/PDF/2016_Coppens_Willemarck_AirtightnessReport.pdf

Colleague: Dr. Fanny Coppens

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FUMIGATION

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n_{50} (mean) [h^{-1}]

	1. New construction	0,4	
➔	2. Box-in-a-box renovation	0,7	(126m ²)
➔	3. Conventional renovation	4,0	(152m ²)
	4. Superficial renovation	0,4	

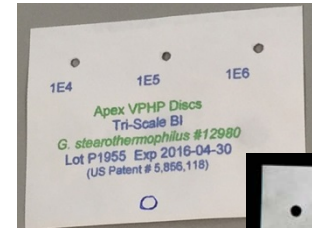
Norm for passive residential buildings: $n_{50} = 0.6 \text{ h}^{-1}$

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FUMIGATION

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	Reduction rate by fumigation type HPV (Tree-fold analysis)	
	Box-in-a-box renovation [126 m ² ; n ₅₀ : 0.7/h]	Conventional renovation [154 m ² , n ₅₀ : 4.0 /h]
on the bench	10 ⁶	10 ⁶
inside open BSC	10 ⁶	10 ⁵
inside closed cupboard	n.a.	<10 ⁴
under / behind	10 ⁶	10 ⁴
highest spot	10 ⁶	10 ⁴
controls	OK	OK



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FUMIGATION

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CONCLUSION & RECOMMENDATION:

- Airtightness is an important parameter for successful fumigation but is not absolute
- Validate the fumigation process before first use

More info available soon (submitted Applied Biosafety) and colleague: Dr. Fanny Coppens

EVIDENCE-BASED BIOSAFETY

EDUCATION WITH LAB PRACTICES ON BIOLOGICAL AGENTS

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METHODOLOGY

- Preliminary study with the help of a checklist with biosafety aspects.
- 15 Flemish institutes (universities, colleges and other scientific institutes).
- 20 teaching activities with contained use of GMOs and/or pathogens.
- Contact with biosafety officer, educator, prevention advisor, occupational health officer and exploitant (CEO, Director, ...).
- Announced visits during the lab practices.



http://www.sbspqi.edu.in/departments_sbspqi.php?pg=microbiology

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EDUCATION WITH LAB PRACTICES ON BIOLOGICAL AGENTS

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FOUR SPECIFIC CATEGORIES EVALUATED (THEMATIC EVALUATION)

- Quality of the risk assessment (RA) performed.
- Use of personal protective measures.
- Inactivation of biologically contaminated material and waste.
- Training

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EDUCATION WITH LAB PRACTICES ON BIOLOGICAL AGENTS

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IDENTIFIED AREAS FOR IMPROVEMENT

- Awareness of the biological risks among the students.
- Separation between personal items and used micro-organisms.
- Storage and release of the lab coats & biological waste.
- Used micro-organisms
- Technical characteristics of the lab.
- Compliance with containment measures (e.g. PPE, BSC,...) imposed in the permit (or authorisation).

More info see www.biosafety.be ; http://www.biosafety.be/ODW/ODW_Rapport_onderwijs_NL.pdf
http://www.biosafety.be/ODW/ODW_Aanvullende_informatie.pdf [DUTCH] ; http://www.biosafety.be/ODW/ODW_Addendum_FR.pdf [FRENCH]

Colleague: Dr. Emilie Descamps

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CLASSIFICATION OF BIOLOGICAL AGENTS

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Classification lists should ideally be dynamic and updated in the light of increased scientific knowledge, by

1. literature
2. contacting experts via
 1. online platform >>> transparent, standardized and reproducible one health approach
 2. face to face >>> to ultimately test the findings from the objective online platform
3. auto-control by the user

More info see www.biosafety.be ; <http://www.biosafety.be/RA/Class/ClassBEL.html> ; publication on influenza will be available soon

Colleague: Dr. Aline Baldo

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BIO-INCIDENTS, BIO-ACCIDENTS & LABORATORY ACQUIRED INFECTIONS

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▶ BIO-INCIDENTS

« All irregularities that occur while handling GMOs or pathogenic organisms in a bio-containment facility »

▶ BIO-ACCIDENT

« means any incident involving a significant and unintended release of GMOs or pathogenic organisms in the course of their handling in a bio-containment facility which could present an immediate or delayed hazard to human health or the environment»

▶ LABORATORY-ACQUIRED INFECTIONS (LAIs)

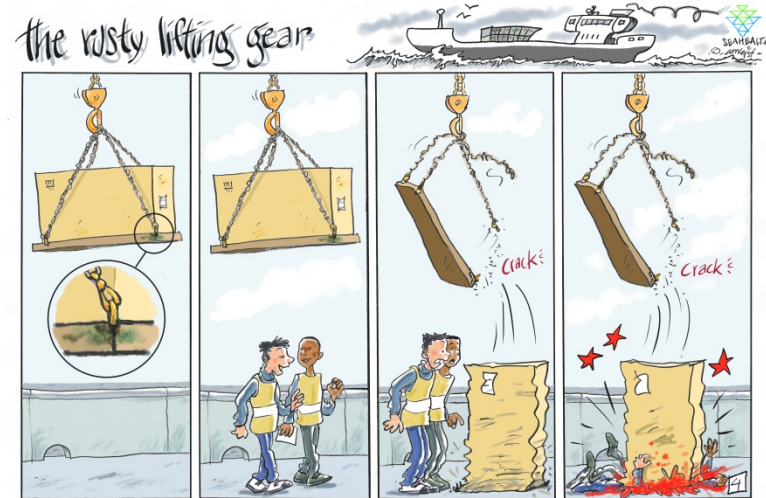
« All direct or indirect human infections with or without the onset of symptoms following exposure to pathogenic organisms in a bio-containment facility»

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BIO-INCIDENTS, BIO-ACCIDENTS & LABORATORY ACQUIRED INFECTIONS

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- ▶ **Every accident** can be seen as lessons learnt
- ▶ **Near-misses** have as much a high value of lessons learnt.



Unsafe condition. • Unsafe act • Near miss • Accident

<http://healthsafetyupdates.blogspot.be/2015/07/toolbox-talk-incident-accident-and.html>

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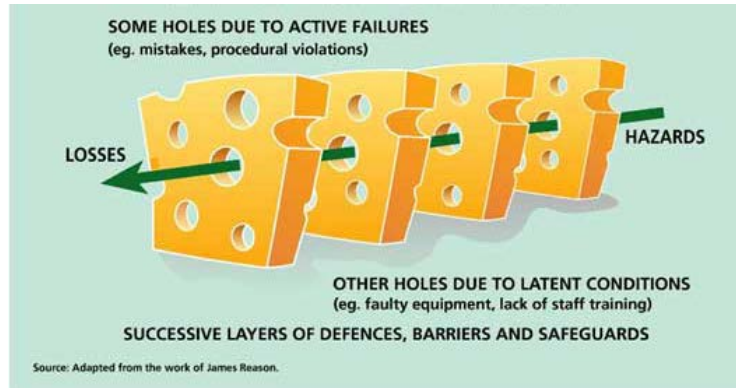
BIO-INCIDENTS, BIO-ACCIDENTS & LABORATORY ACQUIRED INFECTIONS

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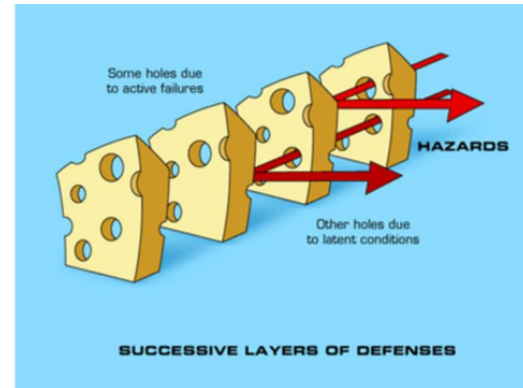
► WHY?

Checking a near thing can prevent the real thing

The Swiss cheese model of accident causation (James Reason)



https://cursos.campusvirtualsp.org/repository/coursefilearea/file.php/19/Content2015/12_Patient_Safety/Patient_safety2015.html



<http://www.firehouse.com/article/12218571/failing-to-report-firefighter-near-misses-leads-to-serious-close-calls-firefighter-safety-richard-kline>

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▶ **ABSOLUTE OR RELATIVE NUMBERS?**

What is the added value to work with relative numbers compared to absolute numbers?

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▶ ABSOLUTE OR RELATIVE NUMBERS?

Relative numbers of accidents and near-misses can be seen as a risk **Incidence** quotation. A quotation of the risk developed within a specified period of time (workload) or for fixed amount of positive diagnostic samples.

>> divided into different manipulation and or containment measures

>>> to identify more risky manipulations

>>> to evaluate effectiveness of containment measures and finally to more pragmatic biosafety.

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LAI Incidence R&D / 1000 hours of manipulation

	Technicians	N-value (workload)
<i>Shigella bacteria</i>	6.295	3
<i>Salmonella bacteria</i>	1.820	6
Herpes virus	0.367	2
<i>Campylobacter</i>	0.212	2
Recombinant viral vector		4

LAI Incidence Diagnostics / 1000 positive samples

		N-value (workload)
<i>Mycobacterium tuberculosis</i>	13.916	4
HIV	8.814	3
<i>Salmonella bacteria</i>	3.503	8
<i>Shigella bacteria</i>	2.988	6
Dermatophyte	1.944	9
<i>Campylobacter spp.</i>	0.045	6

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Outliers can be linked to a 'sub'optimal risk assessment and/or management due to

-lack of knowledge?

-lack of compliance with inadequate personal protective equipments (masks, BSCs,...)?

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BIO-INCIDENTS, BIO-ACCIDENTS & LABORATORY ACQUIRED INFECTIONS

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► QUALITY OF DATA?

Today:

Via surveys, biased in terms of misinterpretations

Via literature, biased by selective outcome reporting

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BIO-INCIDENTS, BIO-ACCIDENTS & LABORATORY ACQUIRED INFECTIONS

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How to create more relative data on bio-incidents & accidents?

ABSOLUTE

RELATIVE

- >> focus on monitoring bio-accidents and its (internal) registration
 - >>> to identify LAIs, releases,...
- >> provide a user-friendly and centralized blame free platform for reporting near-misses & accidents
 - >>> to collect the necessary details for 'lessons learnt'
- >> provide guidance in the legal framework regarding notification requirements
- >> create a system to capture workload
 - >>> to convert your absolute data to relative data at workload level
 - >>>> to identify outliers over time and mutual

Ideally through a legal framework...

More info see www.biosafety.be; http://www.biosafety.be/CU/LAI/Intro_LAI.html

Evidence-Based Biosafety

Conclusion

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Our goal:

Increase awareness of biological risks during contained use activities by more “evidence-based-biosafety”

- >> research on topics of interest
- >> an annual report about (notified) bio-incidents in Belgium + communication to the competent authorities and the community (with respect for any confidentiality)
- >> 5 yearly LAI survey extended with bio-accidents / biosafety in general
- >> development of tools to quantify biological risks

(workload registration, follow up pathogens, bio-incident platform,..)

to gain well substantiated insight into possible biological risk so as to provide the biosafety community with knowledge and tools which can enhance biological safety in pragmatic way.

Questions

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- **Project Airtightness** is financially supported by the Flemish, Walloon and Brussels-capital regions (DO, DGARNE & IBGE- BIM)
- **Project Fumigation** is financially supported by the Flemish, Walloon and Brussels-capital regions (DO, DGARNE & IBGE-BIM)
- **Project Classification of Micro-organisms** is financially supported by the Flemish, Walloon and Brussels-capital regions (DO, DGARNE & IBGE-BIM)
- **Project Education with risk of exposure to biological agents** is financially supported by the Flemish Agency for Care and Health, Department Prevention & the Flemish, Walloon and Brussels-capital regions (DO, DGARNE & IBGE-BIM)
- **Project Bio-incidents, Bio-accidents and LAIs** is financially supported by the Flemish Agency for Care and Health, Department Prevention & the Flemish, Walloon and Brussels-capital regions (DO, DGARNE & IBGE-BIM) & COGEM



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