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Federal Department of Home Affairs FDHA
Federal Food Safety and Veterinary Office FSVO
Institute of Virology and Immunology IVI

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EU FMDV – Biorisk Management Committee

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Biosafety and biosecurity

Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents, or their accidental release. (WHO/CDS/EPR/2006.6)

Laboratory biosecurity describes the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorised access or intentional release. (WHO/CDS/EPR/2006.6)

Biorisk is a combination of probability of occurrence of harm and the severity of that harm where the source of harm is a biological agent or toxin. (CWA 15793)

Definitions of biosafety and biosecurity

Farm – Field - Livestock

Biosecurity is the prevention of disease causing agents entering or leaving any place where they can pose a risk to farm animals, other animals, humans, or the safety and quality of a food product.

The same principles apply within the farm, preventing disease spreading between animals and groups.



EuFMD Constitution

Article V, Paragraph 2.4 sets out special functions:

*The maintenance and promotion of **appropriate biocontainment standards**, and **training in these**, for handling of materials containing foot-and-mouth disease virus by Members.*

BRM Committee Membership

- Laboratories with a national mandate for the diagnosis of FMDV
 - FMDV-research laboratories
 - FMDV vaccine production facilities
- All these institutions face similar issues related to FMDV

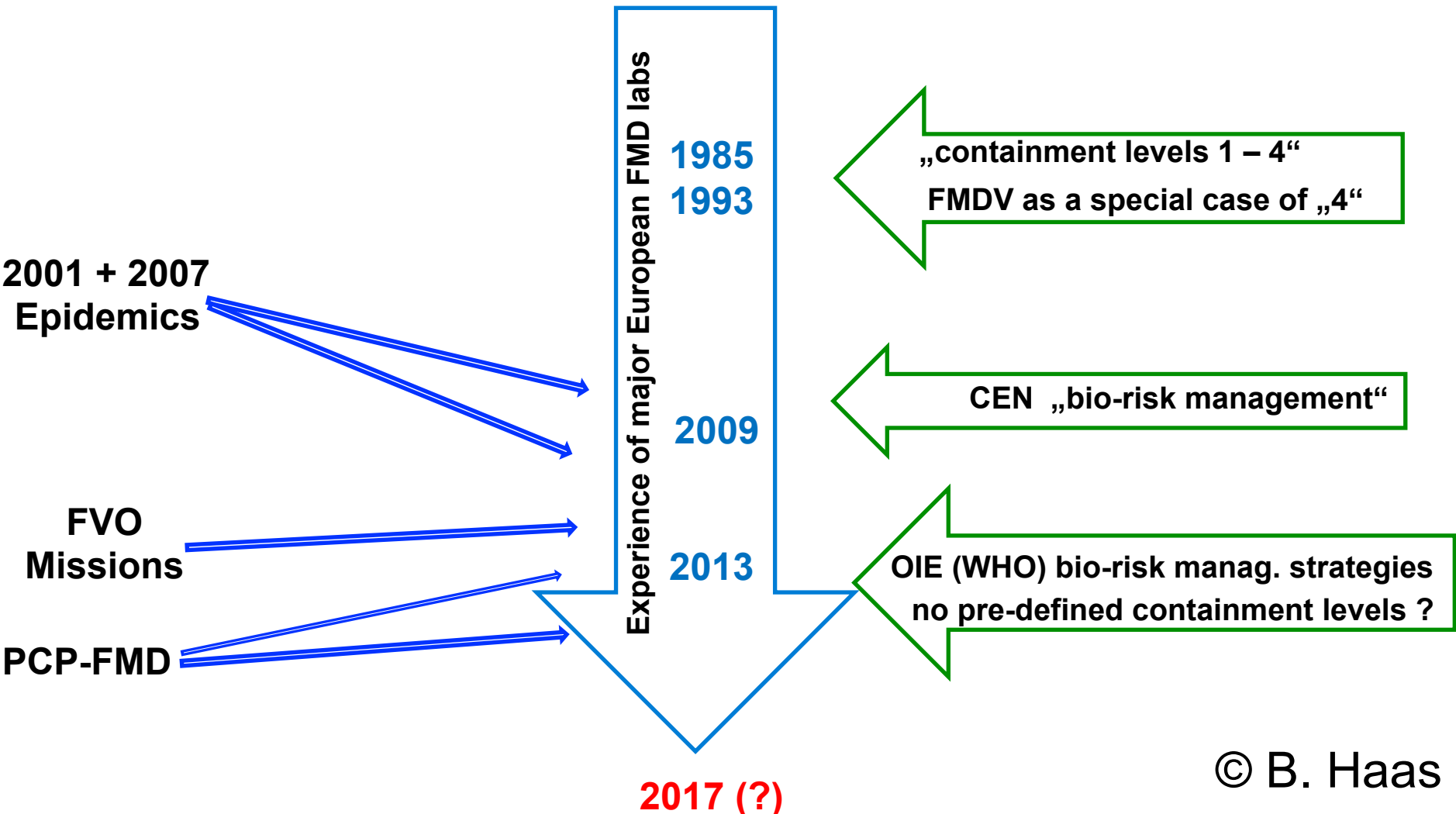
BRM committee remit and ongoing discussions

- FMD biocontainment expert group:
 - Expert opinions related to FMD biocontainment (minimum biorisk management standard)
 - Technical advice related to FMD biosafety / biosecurity issues
 - Biorisk management training activities
 - Support of national enforcement bodies at inspections
 - Alternative fumigation methods (formaldehyde – H_2O_2 ?)
 - Inactivation of samples - transport (field – laboratory)
 - Field / farm biosecurity

EU FMD Minimum Standard - history

- 1985: EUFMD Minimum Standards - *facilities and vaccine failures posed the main disease threat*
- 1990: FMDV Vaccination is stopped in Europe
- 1993: EUFMD Minimum Security Standards updated
- 2003: Minimum Security Standards included in FMDV Directive
- 2009: MS revised to include biorisk management system principles
- 2009 – 2012: European Commission inspects all FMDV labs against Minimum Standard
- 2013: Inclusion of Contingency Laboratories in EUFMD Minimum Biorisk Management Standard

Factors which shaped the EUFMD MINIMUM STANDARDS



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EU FMD Minimum Standard

- Widely used as a reference document for building and construction of new FMDV facilities
- Prescriptive vs. performance based
- Precautionary biosafety principles vs. risk based
- Evidence based



BRM committee interaction with existing initiatives in biorisk

Overview

National Biosafety Associations

- Austrian Biosafety Network
- Belgian Biosafety Professionals
- Biological Safety Officers Platform (Dutch)
- Georgian Biosafety Association
- German Biosafety Officers Community
- Italian Biosafety Platform
- Israeli Biosafety Association
- Nordic Biosafety Network
- Swiss Biosafety Network
- Institute of Safety in Technology and Research UK ISTR
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<http://www.ebsaweb.eu/national-networks>

International biorisk initiatives / associations

European Biosafety Association

- Forum for members to exchange biosafety and biosecurity issues
- Yearly conference with training workshops
- Platform for national and regional biosafety organisations
- President: Gijsbert van Willigen
- <http://www.ebsaweb.eu/>



International biorisk initiatives / associations cont.

International Veterinary Biosafety Workgroup

- Members from all over the world from veterinary facilities with a national mandate (e.g. reference lab), BSL3, BSL3Ag
- Meeting every 18 months, exchange of best practices
- Topics of interest: design, protocols for safe operations, engineering controls, maintenance, costs
- Chair: Kathrin Summermatter
- <http://ivbw.camp9.org/admin/>



International biorisk initiatives / associations cont.

International Federation of Biosafety Associations

- Regional and national biosafety associations worldwide, founded in 2001, Chair: Ben Fontes
- <http://www.internationalbiosafety.org/>



OIE

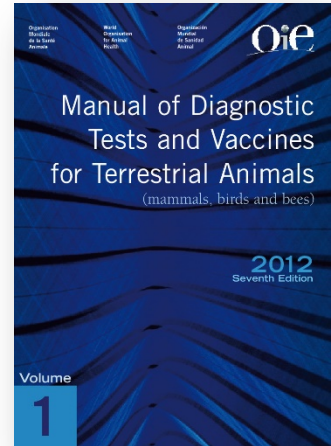
Biosafety and Biosecurity

Chapter 1.1.3 of the Terrestrial Manual:

Biosafety and Biosecurity: Standard for Managing Biological Risk in the Veterinary Laboratory and Animal Facilities:

- Laboratory biosafety and biosecurity background
- Biological risk analysis and management system
- Technical guidance and assessment tools
- applicable in all countries, evidence / performance based, outcomes orientated rather than inputs prescriptive

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.3_BIOSAFETY_BIOSECURITY.pdf



Biorisk standards

- CWA 15793:2011 - Laboratory Biorisk Management standard
Performance oriented and risk based
☞ ISO 35001 Standard in development (draft end 2016)
ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/Workshops/CWA15793_September2011.pdf
- CWA 16393:2012 - Laboratory Biorisk Management - Guidelines for the implementation of CWA 15793:2008
<ftp://ftp.cen.eu/CEN/Sectors/List/ICT/Workshops/CWA%2016393.pdf>
- CWA 16335:2011 - Biosafety Professional (BSP) Competence

Epizone

EPIZONE European Research Group (ERG) is the international network of veterinary research institutes working on **epizootic animal diseases** including those which may have zoonotic potential.

It plays a key role in research on prevention, detection and control of **animal diseases** and zoonoses in order to **reduce the risks and harm to animal health** and the risks to public health in the EU and beyond.

- 23 partner and associate institutions, mainly Europe but also overseas
- <https://www.epizone-eu.net/en/Home.htm>

International eradication programs

Similar biocontainment issues:

Foot and mouth disease

Rinderpest (2011)

Smallpox (1980)

Polio (ongoing)

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Proposed next steps

- BRM committee (BRMC) meeting 2017
- Define / review:
 - remit and mandate of BRMC
 - Composition
 - Work mode
- Up-date / revision of BRM standard – OIE standard
- Interaction of BRMC with other biosafety initiatives
- Actionplan – timetable – responsibilities - ressources

Discussion – questions

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