

# **Biosafety and Biosecurity:**

## **The Instrument for Stability of European Union**

# The Instrument for Stability

A tool for development of cooperation  
measures

What is it ? **Technical and financial assistance**

For whom ? **Towards Third Countries**

**2 components:**

**Short term: flexible tool to prevent conflict,  
support post-conflict political stabilization,  
and recovery after a natural disaster**

# The Instrument for Stability

Financial, economical and technical measures  
with Third Countries

Long term: development of capacities to  
face global threats and to ensure crisis  
preparedness

# ***The Instrument for Stability***

***In the Biological Field, e.g. contribution to:***

- ✓ Risk mitigation and enhance preparedness in order to face the biorisk***
- ✓ Fight against illicit trafficking***
- ✓ Export control***
- ✓ Strengthen civilian disaster preparedness, emergency planning and capabilities in case of pandemic***

# ***The Instrument for Stability***

***How ? By transfer of biosafety and biosecurity***

- ✓ ***technical and financial assistance with transfer of any kind of know-how especially with regard to risk/threat assessment***
- ✓ ***exchange of information***
- ✓ ***research and analysis***
- ✓ ***early warning system and training***

# ***Biosafety and biosecurity: a continuum***

**with two driving forces:**

➤ **Biorisk assessment**



➤ **Biorisk management**



➤ **Quality management systems**

✓ ***Traceability***

✓ ***Competence of the staff***

# *Reminder of key definitions of WHO on biosafety and biosecurity*

**Biosafety** (adapted from: WHO/CDS/EPR/2006.6)

laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release

**Biosecurity** (adapted from: 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 whether or not the biorisk(s) is acceptable

# *Reminder of definitions of biorisks*

**Biorisk** (adapted from OHSAS 18001:2007)

combination of the likelihood of the occurrence of an adverse event involving exposure to biological agents and toxins and the consequence (in terms of accidental infection, toxicity or allergy or unauthorised access, loss, theft, misuse, diversion or release of biological agents or VBMs) of such an exposure

*Biorisk encompasses both biosafety and biosecurity. The term came about as a result of the different uses and schemes that have been established for laboratory biosafety and biosecurity,*

**Biorisk assessment** (adapted from OHSAS 18001:2007)

process of evaluating the biorisk(s) arising from biohazard(s) or VBMs, taking into account the adequacy of any existing controls, and deciding whether or not the biorisk(s) is acceptable.

**Biorisk management system** (adapted from OHSAS 18001:2007)

part of an organisation's management system used to develop and implement its biorisk policy and manage its biorisks.



# ***Biosafety and biosecurity: a continuum***

**Biorisk encompasses both biosafety and biosecurity. The term came about as a result of the different uses and schemes that have been established for laboratory biosafety and biosecurity.**

**Not a single response to the biorisk, but the complementarities of dispositions, and the Instrument for Stability of the European union takes into account any kind of biological risks, both induced (unintentionally -- accidental release -- or intentionally --e.g. bioterrorist act --) and natural (e.g. pandemic)**

# ***Biosafety and biosecurity: a continuum***

**Not a single response to the biorisk, but the complementarities of dispositions which are of different natures and could be measures inside the laboratories and during the exchanges of biological pathogens between the laboratories:**

✓ **Manuals of WHO** (Laboratory Biosafety Manual, Third Edition (WHO/CDS/CSR/LYO/2004.11, 2004) and the WHO Biorisk Management: **Laboratory Biosecurity Guidance** (WHO/CDS/EPR/2006.6, Sept. 2006).

✓ **General standards** (ISO 17025: 1999 General requirements for the competence of testing and calibration laboratories/ **ISO 9000: 2000** Quality management systems - Fundamentals & vocabulary/ **ISO 9001: 2000** Quality management systems – Requirements )

# ***Biosafety and biosecurity: a continuum***

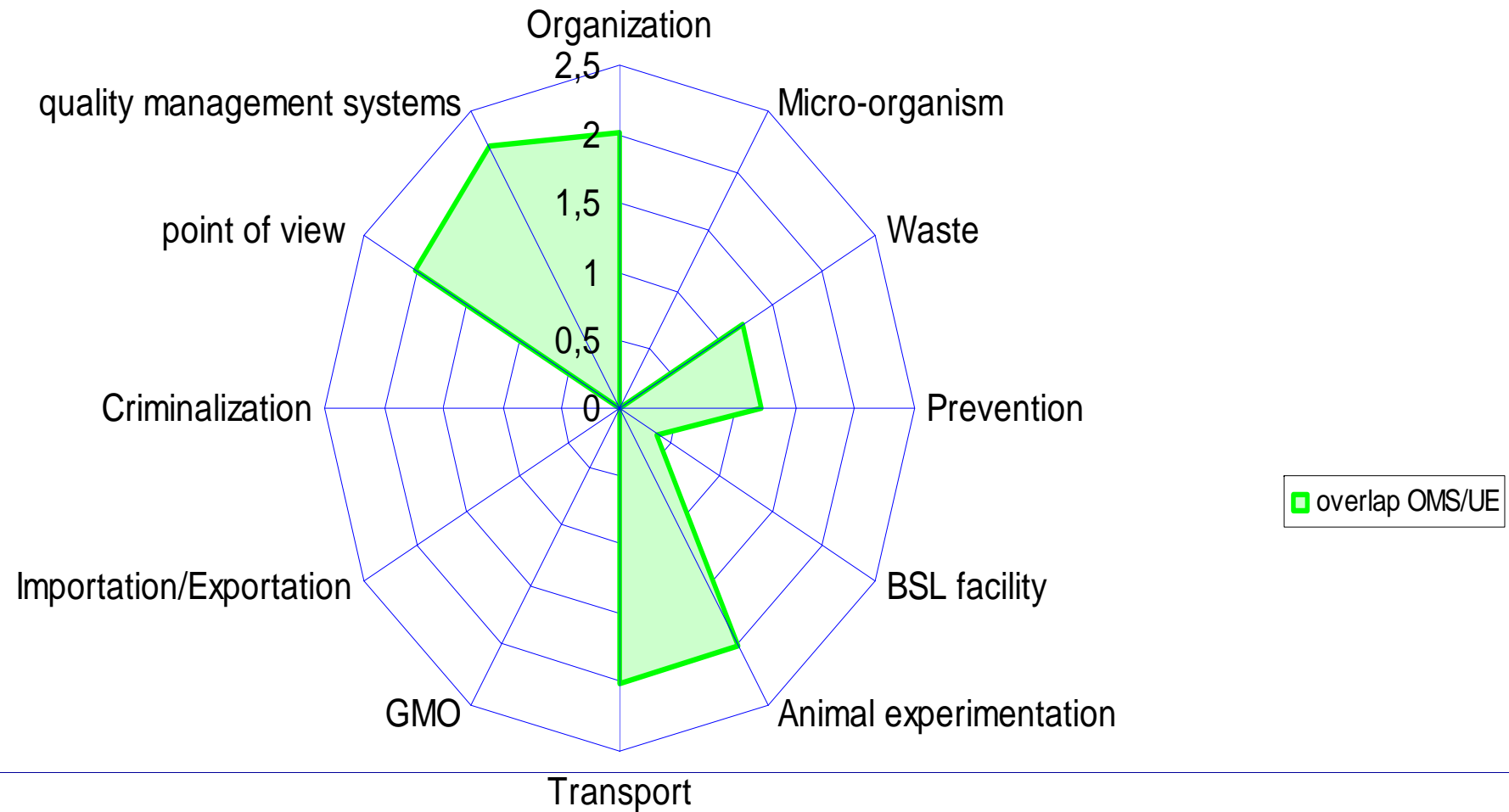
✓ **Specific standards and guidelines** (ISO 14001: 1996 Environmental management systems - Specification with guidance for use/ OHSAS 18001 (Occupational Health and Safety) management systems standards/ The European Committee for Standardization, *Laboratory Biorisk Management Standard*, CWA 15793:2008/ OECD BEST PRACTICE GUIDELINES FOR BIOLOGICAL RESOURCE CENTRES, 2007/ CABRI Guidelines <http://www.cabri.org/guidelines.html>

✓ **Regional and Domestic Laws and regulations.**

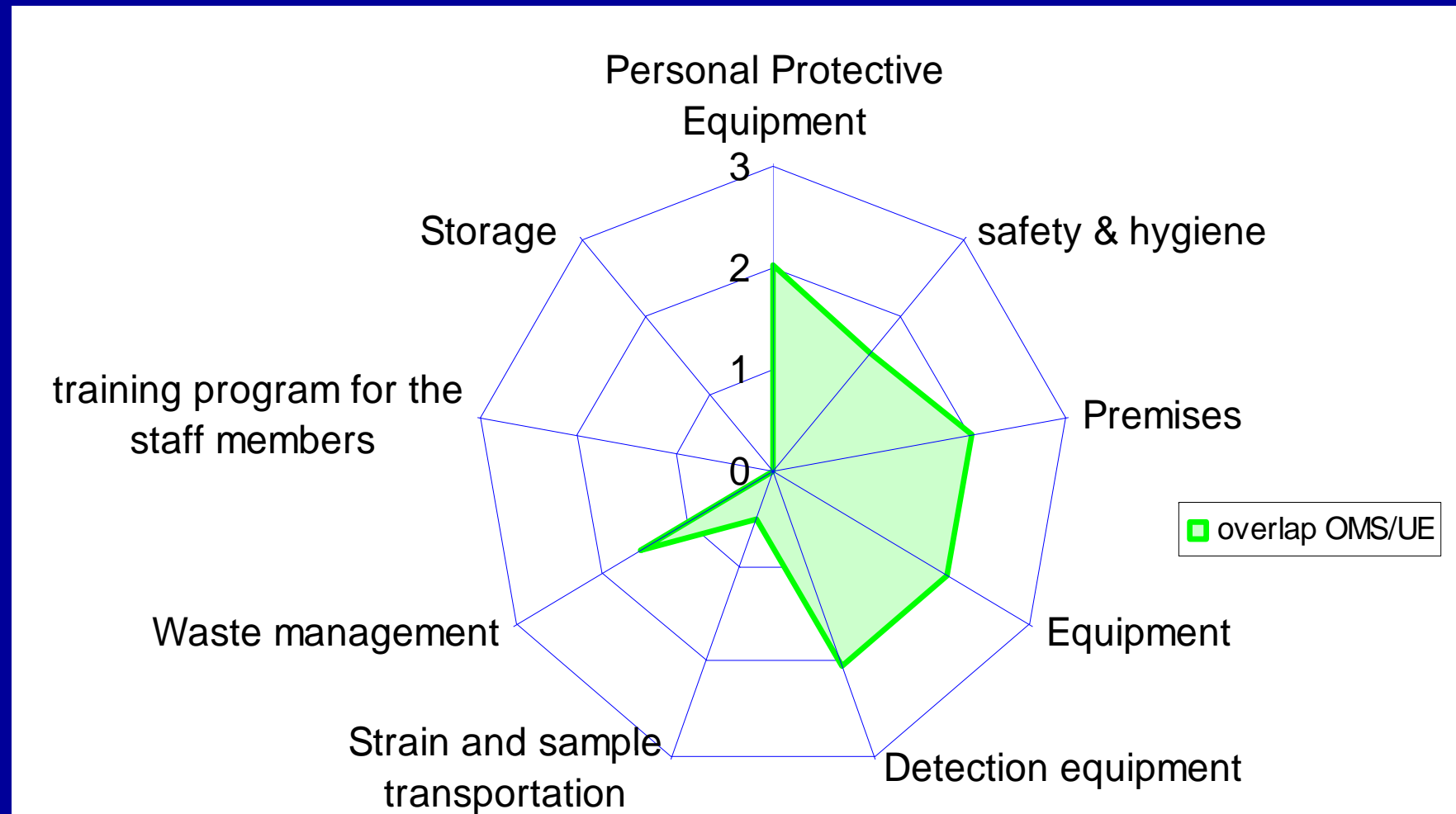
European legislations and decrees takes into account:

- ✓ the continuum between biosafety and biosecurity,
- ✓ Includes biorisk assessment in the lab (type of strains, quantities, infectious doses, type of experimentations, biosafety level,...), but also the lab in its environment. Tools are given to biologists to help them to conduct their own risk assessment.
- ✓ Starting from the biorisk assessment, defines the best recommended operating procedures for an efficient and reliable biorisk management, and is built on quality management systems.

# *Biosafety and biosecurity: a continuum*



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# ***Biosafety and biosecurity: a continuum***

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# QUALITY MANAGEMENT

*coordinates activities to direct and control an organization with regard to quality.*

Quality *management* =

quality {*policy+objectives*}

+

quality {*planning+control+assurance+improvement*}

# **GOOD LABORATORY PRACTICES: the goals**

## **GLP: “OECD Principles of Good Laboratory Practice”**

- **organization and management of studies taking into account test facilities, study director and personnel;**
- **planning, control, recording, diffusion and archiving of the studies.**

***Two keys words: overall traceability and studies  
reproducibility,  
thus reliability***



# ISO 9001: the goals

## “Quality management systems- Requirements”

where an organization:

- needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements;
- aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements

*A key word:* **customer satisfaction**

# ISO/IEC 17025

**“General requirements for the competence of testing and calibration laboratories”**

**= ISO/IEC Guide 25 + EN 45001**

- The main goal: for the laboratories which want to prove that they manage a quality system, are technically qualified, **COMPETENT**, and are able to generate technically valid results, therefore reliable
- A better choice than the ISO 9001 and 9002, because the ISO/ IEC 17025 includes the whole of the requirements of the ISO 9001 and 9002 which are relevant for the field of testing and calibration laboratories
- Testing and calibration laboratories that comply with this international Standard will therefore also operate in accordance with ISO 9001 and ISO 9002
- Certification against ISO 9001 and ISO 9002 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results

**traceability and competence**

# ISO/IEC 17025

**“General requirements for the competence of testing and calibration laboratories”**

**= ISO/IEC Guide 25 + EN 45001**

**An other goal:**

**an open door towards the international cooperation and thus  
the economic development**

- The acceptance of testing and calibration results between countries should be facilitated if laboratory complies with this international Standard and if they obtain accreditation from bodies which are entered into mutual recognition agreements with equivalent bodies in other countries using this international Standard
- The use of this international Standard will facilitate cooperation between laboratories and other bodies, and assist in the exchange of information and experience, and in the harmonization of standards and procedures

# ISO/IEC 17025

“General requirements for the **competence** of testing and calibration laboratories”

= ISO/IEC Guide 25 + EN 45001

An other goal:

an open door towards the international cooperation  
and also a tool which contributes to *biosecurity* and  
*biosafety*

- For all the activities with regard to Research and Development programs (testing laboratories)
- But also for strains conservation: the OECD Initiative on BRCs

# **BIOSAFETY AND BIOSECURITY:**

WITHOUT BIORISK ASSESSMENT and QUALITY  
MANAGEMENT SYSTEMS,

**NO SECURITY FOR BIOLOGICAL FIELD**



INSTRUMENT FOR STABILITY and JOINT  
ACTIONS OF EU IN BIOSAFETY AND

BIOSECURITY: in order to share with third  
countries a common culture of biorisk, to raise  
the level of security and to enhance cooperation

# ***The Instrument for Stability***

***European Experts***

***Dr Isabelle Daoust-Maleval***

***Dr Julien Galabru***

***Dr Antonino Di Caro***

***Dr Daniel Garin***

***Dr Gabriel Gras (P3 mobiles)***

***Dr Mathieu Pampin (risk analysis of  
legislations)***

***Dr Marie-Françoise Saron***

# Bibliography & useful informations sources

- OECD BEST PRACTICE GUIDELINES FOR BIOLOGICAL RESOURCE CENTRES, 2007 & related bibliography
- CABRI Guidelines <http://www.cabri.org/guidelines.html>
- ISO 17025: 1999 General requirements for the competence of testing and calibration laboratories
- ISO 9000: 2000 Quality management systems - Fundamentals & vocabulary
- ISO 9001: 2000 Quality management systems - Requirements
- ISO 14001: 1996 Environmental management systems - Specification with guidance for use
- OHSAS 18001 (Occupational Health and Safety) management systems standards
- Laboratory Biosafety Manual, Third Edition (WHO/CDS/CSR/LYO/2004.11, 2004) and the WHO Biorisk
- Management: Laboratory Biosecurity Guidance (WHO/CDS/EPR/2006.6, Sept. 2006).
- The European Committee for Standardization, *Laboratory Biorisk Management Standard*, CWA 15793:2008

*Thanks' a lot for your attention and ... your patience!*

***Isabelle Daoust-Maleval, DAS + 33 1 42 19 84 30***

***[isabelle.daoust-maleval@defense.gouv.fr](mailto:isabelle.daoust-maleval@defense.gouv.fr)***