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 increasing with a current turning on the level of the international community: an awareness of all the countries of the biosafety and biosecurity importance

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. French 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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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

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

Biological Resource Centre (BRC):

What is it?

A center which holds and supplies biological material with **authentification** and **long term sustainability**

↓

Biosecurity

« *BRCs consist of service providers and repositories of the living cells, genomes of organisms, and information relating to heredity and the functions of biological systems. BRCs contain collections of culturable organisms (e.g. Micro-organisms, plant, animal and human cells), replicable parts of these (e.g. Genomes, plasmids, viruses cDNAs), viable but not yet culturable organisms cells and tissues, as well as data bases containing molecular, physiological and structural information relevant to these collections and related bioinformatics.* »

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Biosecurity

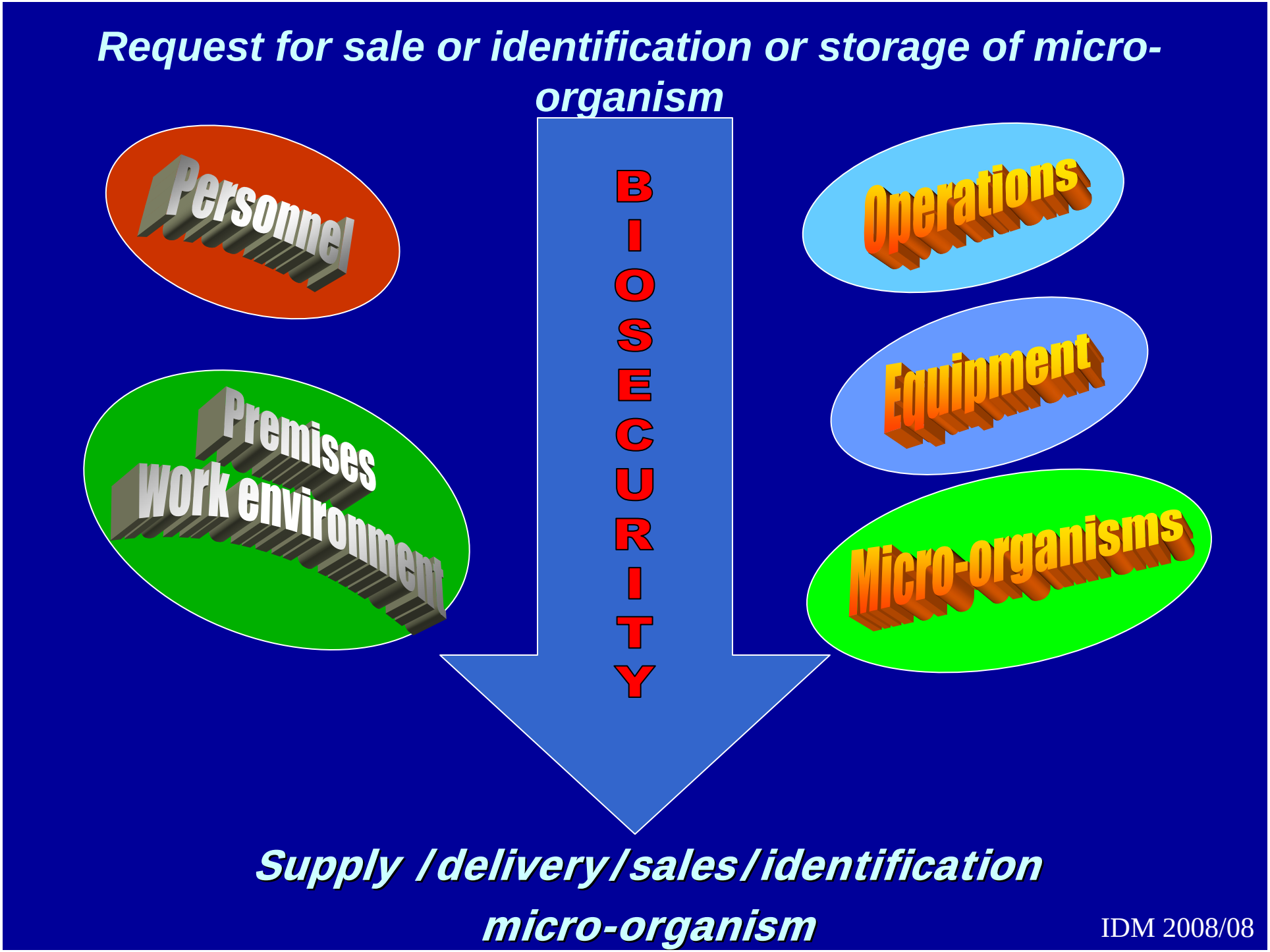
National accreditation + agreement of BRCs

BRC activities under the responsibility of Governments

Transfers under Governmental control

Mutual traceability under international quality criteria

Global BRC Network


Request for sale or identification or storage of micro-organism
Personnel
Premises
Work environment
BIOSECURITY
Operations
Equipment
Micro-organisms
Supply /delivery/sales/identification micro-organism

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Management/ Staff/Personnel

GOALS

WHO ’s doing WHAT? ⟺ Competence

« knowledge & awareness of… »

Organization chart for managerial, technical & key support personnel

BIOSECURITY

responsibilities & traceability of personnel

Premises

GOALS

Appropriate level of containment for the risk hazard group of micro-organism

Construct laboratory to ensure a one-way flow of samples

Hygiene & Cleaning procedures

Control of access

« appropriate arrangements for site security »

Operations

specific of a BRC

BRC check against dangerous pathogen lists before accepting a strain

Receipt & storage the initial sample

Preparation, generation, handling & processing of samples

Preparation & sterilisation of culture media & equipment

Biological material storage area

Supply, delivery/sale

Decontamination cleaning processing of wastes

BIOSAFETY

Biosecurity

traceability

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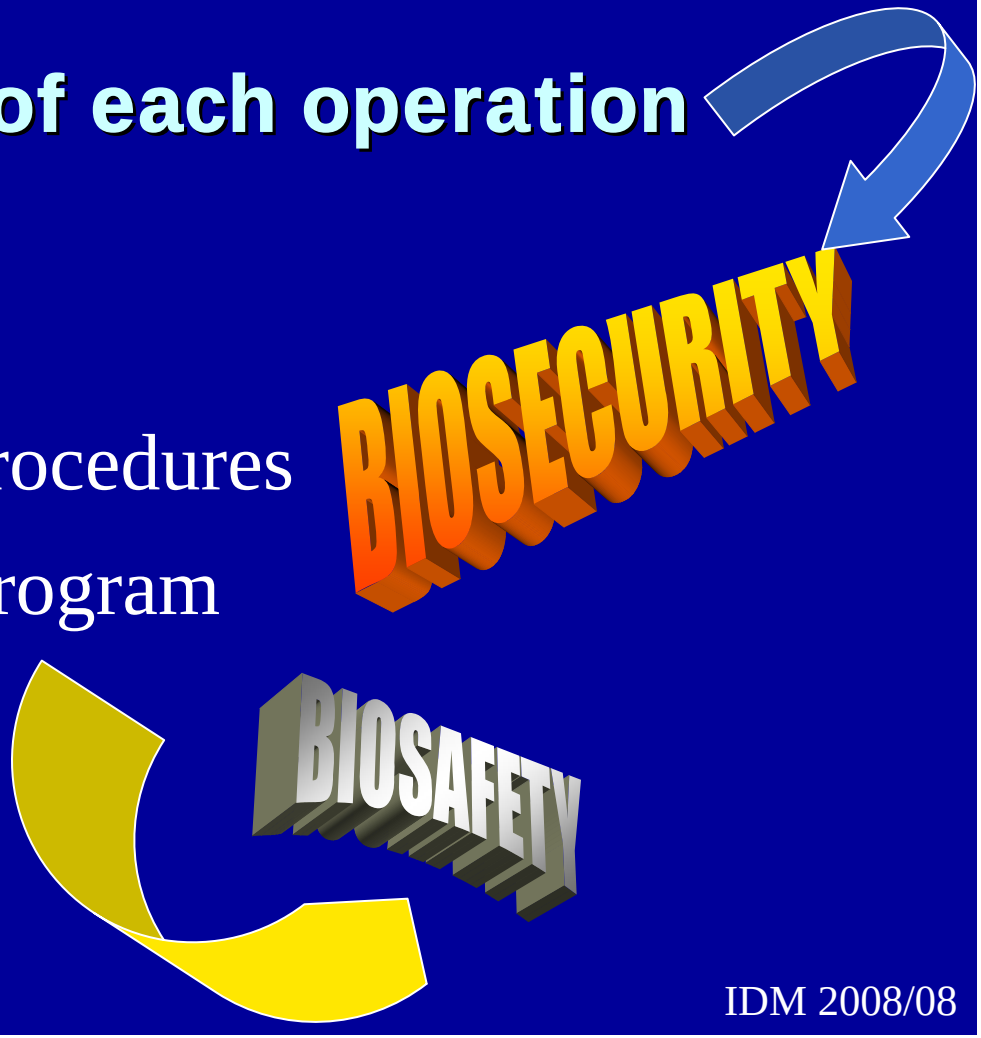
Equipment

GOALS **traceability of each operation**

Maintenance

Cleaning/decontamination procedures

Contamination monitoring program
& if major contamination:
investigation of the source



Micro-organisms

Overall traceability

Acquisition criteria

- name, other identifier or cell culture description
- depositors name & address
- source, substrat or host from which the biological material was isolated or derived
- geographical location of isolation
- depositors strain number or other collection number
- assigned unique collection number
- cell preservation or storage conditions hazard information
- hazard status

Micro-organisms

Overall traceability

- **each operation is registered**
- **quality controls based on the CABRI guidelines**

characterization of the strain with viability, purity, identity, stability

- **preservation methods, distribution forms, set of data describing the products as required in the CABRI guidelines**
- **stock control**
- **storage**
- **recording of all the data**

Micro-organisms

Overall traceability

- **Packaging**

the BRC shall pack and send its biological material according to current postal IATA and quarantine regulations - IATA Dangeraous Good Regulations - biological hazard label -

- **Traceability of biological materials supplied**

the BRC shall keep records of all requests of biological materials - including thoses requests refused for any reason-, showing the biological materials, method and date of shipment, and name and address of person to whom sent.

BIOSAFETY AND BIOSECURITY:

WITHOUT BIORISK ASSESSMENT and QUALITY MANAGEMENT SYSTEMS,

NO SECURITY FOR BIOLOGICAL FIELD

INSTRUMENT FOR STABILITY and JOIN ACTIONS OF EC IN BIOSAFETY AND BIOSECURITY: in order to share with third countries a common culture of biorisk and to raise the level of security

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!

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