



MECHANISMS FOR THIRD PARTY ASSESSMENT

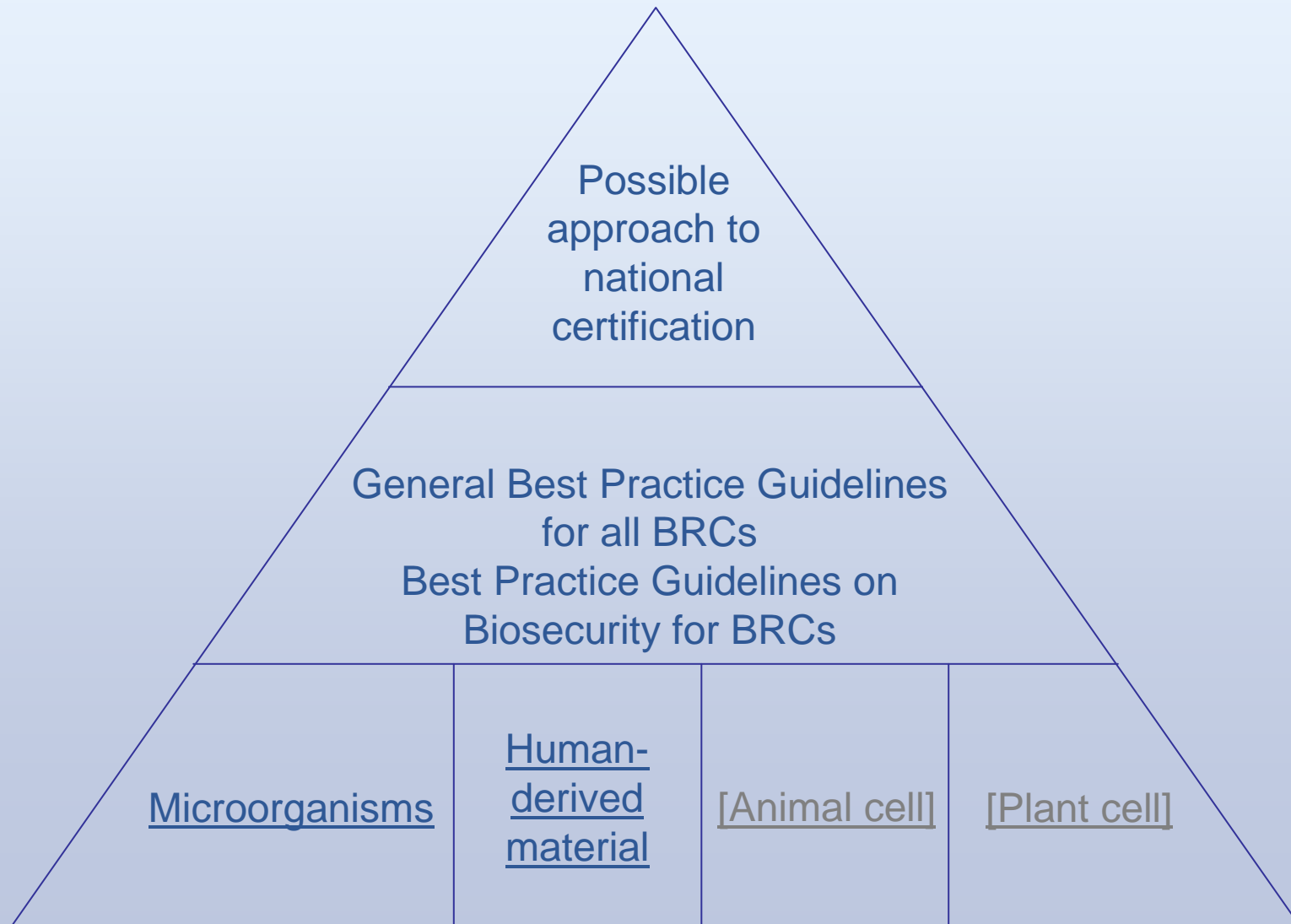
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Belgian Coordinated Collections of Micro-organisms

Joint human & microbial domain GBRCN pilot phase meeting
Vienna, 29-30 November 2010



OECD Best Practice Guidelines for BRCs





Ultimate goals

- **International unified** quality management / quality assurance
- **Authenticity** of biological materials, databases and bioinformatics and accuracy of labelling
- Assurance of **long-term stability** and quality control of cell cultures, cell lines, and genetic constructs, including procedures and standards



Ultimate goals

- Accuracy of the **data** collected and supplied
- Raising of expertise of **human resources**, particularly of a new generation of taxonomists able to use molecular techniques and informatics
- Potential for **sharing of expertise** among centres through co-ordination and networking



Compliance with best practice guidelines



The pinnacle of success:
Achievement of
compliance with all
relevant best practices

Recognition of compliance requires some form
of monitoring and assessment



Assessment of Quality Management Systems

- First-party assessment (self-audit)
- Second-party assessment (e.g. by customer)
- Third-party independent assessment (certification)

The aim of certification is to give **confidence** to all parties that a management system fulfils specified requirements

- ⇒ **Transparent**
- ⇒ **Independent**
- ⇒ **Impartial**
- ⇒ **Internationally recognized**



Mechanisms for third party assessment (1)

- Basis: A new ISO standard to be developed (using OECD Best practice guidelines for BRCs as a foundation)

- Assessment by certification body that is accredited according to ISO 17021

- Advantages:
 - Existing system
 - Transparent procedure
 - Independent and impartial assessment
 - International recognition through IAF/MLA

- Disadvantage:
 - Development of new ISO standard is lengthy procedure



ISO/IEC 17021

- Conformity assessment – Requirements for bodies providing audit and certification of management systems
- Applicable to any certification body of any management system certification scheme
- National accreditation bodies use this norm to accredit certification bodies
- International recognition through International Accreditation Forum (IAF) and Multilateral Recognition Arrangement (MLA)



Mechanisms for third party assessment (2)

- Basis: OECD Best practice guidelines for BRCs
- Assessment by inspection body that is appointed by government (cfr GLP)
- Advantage:
 - “Standard” is existing document
- Disadvantage:
 - System must be put in place for BRCs
 - International recognition by peer review must be organized
 - Independent and impartial assessment is not guaranteed



Mechanisms for third party assessment (3)

- Basis: OECD Best practice guidelines for BRCs
- Assessment by certification body that is accredited according to ISO 17021
- Advantages:
 - Existing system
 - Transparent procedure
 - Independent and impartial assessment
 - International recognition through IAF/MLA



Third party assessment can be

- based on existing document (OECD Best practice guidelines),
- done by recognized, accredited certification bodies,
- in a context of mutual recognition