



EBSA Comments on Consultation on OECD Draft Quality Standard for Microbial Biological Resources Centres (BRCs)

The European Biosafety Association (EBSA) is a not-for-profit organization that aims to promote biosafety; provide a forum for discussion and debate on biosafety and biosecurity issues of concern, and represent those working in the field of biosafety and associated activities.

This is a very valuable initiative. Dependable biological resources are key to the research and development in the medical, industrial, food and agriculture areas. The use of these biological resources at BRCs and receiving organizations need to respect human and animal health and safety and preserve the environment and agriculture from their potential deleterious effects. Therefore these organisms need to be used under the guidance of biosafety professionals, in adequate facilities and using biosafety managing systems. There also needs to be mechanisms that ensure the safe and secure transfer and traceability of these organisms to prevent that they fall into the hands of those who may want to use them to cause harm.

Biosafety encompasses the management of potential risks to human health and/or the environment resulting from activities involving natural or recombinant biological agents. Biosafety (working safely) describes containment principles, technologies and work practices to prevent *unintentional exposure* to pathogens and toxins, and to prevent their accidental release into the environment. Biosecurity (keeping the workplace safe) practices should be a logical extension of good laboratory biosafety procedures and good management practices aimed at the prevention of *intentional release* of hazardous micro-organisms.

Biosecurity is considered as an aspect within a biosafety program. A well managed biosafety program covers the following areas which are relevant to biosecurity as well:

- Access to facilities
- Inventory of materials
- Risk assessment and risk management
 - Personnel exposure control
 - Prevention of unintended environmental releases
- Emergency and spills management
- Waste management
- Transportation of materials

This is done through a management systems program that includes

- Training of personnel
- Audits and inspections
- Review of facilities and engineering controls

Specific comments to the documents in the consultation, suggested text in blue:

As a general comment through the document: suggest the use of the term [hazardous organisms](#) instead of dangerous organisms.

▪ **Background Note**

For clarity for those not aware, add the following text (in blue): Under “Nature, Aims and Rules of BRCs (Biological Resource Centres) (page 2):

iii. Conservation of biodiversity [including Access and Benefit Sharing \(ABS\)](#)

Under “INSTRUMENTS FOR THE GBRCN ESTABLISHMENT” point 14. (page 4)
v. [Biosafety, including](#) biosecurity, principles for BRCs. [Note that a good biosafety program covers most of the points required for biosecurity except for the human dimension – who handles the materials, what are his/her intentions ...]

Again under “Biosecurity requirements” it should say “[Biosafety](#)/Biosecurity requirements” (page 4):

[When transferring and exchanging biological materials, the GBRCN must ensure that receiving organizations have biosafety programs and facilities managed by biosafety competent persons commensurate with the biological risk of the organism\(s\) they are requesting and that the material will not be used to cause harm.](#)

▪ **Consultation Document 1**

BRC general criteria (page 4) under point 13. Certified BRCs must comply with: The regulations of relevant countries [as well as international regulations \(UN Model Regulations on the Transport of Dangerous Goods \(latest edition\), Cartagena Protocol on Biosafety, etc.\)](#) when moving biological materials across national boundaries.

▪ **Consultation Document 2**

Point 4.4 (page 5): Replace “Hygiene” by “[Biosafety](#)”

Under 10.2.3 (page 10) the biological materials received must have the following information:

d. “Geographical origin of isolation (the minimum requirement is the country of origin or the furnisher of the source, substrate or host” – “origin” is a difficult and debated concept, note that the organism may come originally (isolated) from country A, but may have been modified, improved in country B – which one should be listed with respect to ABS?

Under 10.3.2 (page 10): Do BRCs require that those that deposit materials provide detection tools, particularly when they are genetically modified?

12.1.1 (page 11): BRCs must only supply biological materials for which they have been given the rights to distribute. They should only supply to users who have the appropriate facilities and meet the specific requirements [including those for biosafety and biosecurity](#) ...

12.4 Packaging (page 12)

12.4.1 to the text add these two aspects: [Although not required by any regulation, plant pathogens should be packaged following good practices to ensure containment of the shipment in a similar manner to animal pathogens. For Living Modified Organisms \(LMOs\), the shipment must also comply with the Cartagena Protocol on Biosafety.](#)

▪ Consultation Document 3

5.1 Construction and operation (page 5)

12. Construction shall respect the containment level appropriate for the risk group of the microorganisms to be used and must meet appropriate national law, regulations and policies, [international guidelines and minimal accepted standards](#). [Note that national laws and regulations may be below accepted international minimal standards.]

5.2 Maintenance and inspection (page 5)

13. Cleaning of laboratory benches and equipment should be performed by authorized and trained staff using appropriate personal protection equipment and following documented [evidence-based validated procedures to ensure effective decontamination of the areas](#).

11. Supply of material

11.1 Order placement (page 7)

29. BRCs must supply micro-organisms only to [organizations that have a biosafety program with containment facilities and individuals that are trained in microbiology and biosafety in accordance to the risk presented by the micro-organisms to be used...](#)

11.2 User validation (page 7)

30. To ensure that only authorized users may access biological material that is pathogenic or toxic to humans, animals or plants, the BRC must:

- Comply with the measures set out in Guidance for the Operations of Biological resource Centres (BRCs), Part 6: [Biosafety/Biosecurity Requirements](#).

11.4 Packing and Transport (page 8)

Note: UN regulations for the transport of dangerous good apply only to infectious substances to human and animals and GMOs. The packing and transport of plant pathogens and quarantine organisms is not regulated by international regulations, but needs to be transported in such a way that the potential release into the environment is prevented.

12. Micro-organism Biological Resource Centres' compliance with national and international law (page 9)

40. The importance of a laboratory's health and safety procedures should extend beyond the laboratory to all those who come in contact with substances and products from that laboratory [and prevent the potential release into the environment](#). ... The BRC must adhere to all legislation that impact upon the distribution of micro-organisms. [In the absence of legislation, it must use best practices to ensure containment and prevent exposure to humans, animals and environment](#).

45. (page 10) A BRC must put in place procedures to manage health and safety of all who may be put at risk by its activities [and containment procedures for organisms that may negatively impact the environment and agriculture](#). This requires a suitable and sufficient assessment of the risks to health and safety to which any person, whether employed by them or not, may be exposed to through their work, [and the](#)

possibility of escape into the environment. These assessments shall be recorded. The distribution of micro-organisms to others outside the workplace extends these duties to protect others, [the environment and agriculture \(animals and plants\)](#).

12.5 Safety information provided to the recipient of micro-organisms (page 11)

55. safety information ...

- The risk group of the organism being dispatched [as classified in the country of the BRC](#) – note that the classification may change from country to country
- [Waste management](#) – include also

12.6 Control of Distribution of Dangerous Micro-organisms (page 11)

57. BRCs must follow the Guidance for the Operation of Biological resources Centres (BRCs), Part 6: [Biosafety/Biosecurity Requirements](#).

58. As written, this point is too narrow considering only human health– there are also animal and plant pathogens that can pose considerable harm to food and agriculture.

Useful Bibliography (page 12)

- [EC Council Directive 2000/29/EC and its amendments](#)
- [EC Council Regulation 1504/2004 amending and updating Regulation 1334/2000](#)
- [EC Council Directive 95/44/EC on establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections](#)
- [EC Council Directives 90/219/EEC and 98/81/EC on contained use of genetically modified organisms](#)
- [EC regulation 1946/2003 on the transboundary movement of genetically modified organisms \[transposition of Cartagena Protocol on Biosafety\]](#)
- [Cartagena Protocol on Biosafety](#)
- [IATA Dangerous Goods Regulations – latest edition](#)

Websites of interest. – add the following:

Transport and shipping. (page 14)

WHO Guidance on Regulations for the Transport on Infectious Substances

http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2005_22/en/

Bio-safety on the internet (page 14)

World Health Organization (WHO) Biosafety Programme

<http://www.who.int/csr/labepidemiology/projects/biosafetymain/en/index.html>

Add links to the biosafety associations:

American Biological Safety Association (ABSA)

<http://www.absa.org>

European Biosafety Association (EBSA)

<http://www.ebsaweb.eu>

Internacional Biosafety Working Group (IBWG)

<http://www.internationalbiosafety.org/english/index.asp>

Organisations (page 15)

Food and Agriculture Organization (FAO)

http://www.fao.org/index_en.htm

World Animal Health Organization (OIE)

http://www.oie.int/eng/en_index.htm

International Plant Protection Convention (IPPC)

<https://www.ippc.int/IPP/En/default.jsp>

International Police Organization (INTERPOL)

<http://www.interpol.int/>

The Australia Group

<http://www.australiagroup.net/>

Biological Weapons Convention (BWC)

<http://disarmament.un.org/wmd/bwc/>