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DIRECTORATE FOR SCIENCE, TECHNOLOGY AND INDUSTRY
COMMITTEE FOR SCIENTIFIC AND TECHNOLOGICAL POLICY

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Working Party on Biotechnology

GUIDANCE FOR THE OPERATION OF BIOLOGICAL RESOURCE CENTRES (BRCs)

GUIDELINES FOR THE MICRO-ORGANISM DOMAIN

NOTE BY THE SECRETARIAT

This paper proposes final text for the guidelines in light of the Task Force on Biological Resource Centres (TFBRC) meeting held on 4-5 December 2006. Together with other best practices, this paper will comprise a chapter in the Final Report on Biological Resource Centres (BRCs).

The Final Report on BRCs will be presented to the Committee for Scientific and Technological Policy (CSTP) via the Working Party on Biotechnology (WPB) for declassification..

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ANNEX IV

GUIDANCE FOR THE OPERATION OF BIOLOGICAL RESOURCE CENTRES (BRCs)

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TABLE OF CONTENTS

Foreword

Guidance for the operation of Biological Resource Centres (BRCs) comprises several sets of guidelines that together provide the basis for best practices in the management of BRCs. Two sets of general guidelines address all Biological Resource Centres, no matter what type of biological material they hold and supply. These are: *General Guidelines for all BRCs* and *Guidelines on Biosecurity for BRCs*. Further guidelines provide additional best practices for those BRCs that hold and supply biological material within specific domains. Best practice is achieved when BRCs comply with all sets of general guidelines applicable to the specific domain that the biological materials they hold and supply belong to. Currently two sets of such OECD Guidelines exist: "*Guidelines for the Micro-organism Domain*", and "*Guidelines for Human-Derived Material*". Further domain-specific guidelines for animal and for plant material are envisaged. A final set of guidelines provides best practices for possible national approaches to certification of BRCs.

Where elements addressed in best practices are covered by existing material and/or local laws and regulations, such laws and regulation must take precedence.

1. Introduction

1. These domain specific guidelines provide the basis for best practices in the management of Biological Resource Centres (BRCs) that hold and supply micro-organisms.

2. All BRCs must comply with applicable national and international laws and regulations. These domain specific guidelines provide best practice for managing BRCs and describe the procedures for acquisition, propagation, maintenance and provision of micro-organisms. Best practice requires a BRC to provide a documented description of the nature of the micro-organism domain biological resources being held and in particular to define the level of hazard and containment in place.

3. These domain specific guidelines assist the BRC to put into practice procedures that comply with relevant national law, regulations and policies. Further practical details on the implementation of these procedures may be found in the Common Access to Biological Resources and Information (CABRI) guidelines: (http://www.cabri.org), World Federation for Culture Collections (WFCC) recommendations: http://www.wfcc.info/ or United Kingdom National Culture Collection (UKNCC): www.ukncc.co.uk.

2. Scope

4. The purpose of this document is to help ensure that micro-organisms held and supplied by BRCs are of the highest standard and authentic. The methods used should be such that the key features of micro-organisms maintained are retained and should ensure their consistency amongst BRCs supplying them. This will help to provide a reliable basis for research and development in different laboratories and will contribute towards protection of the health of laboratory personnel, the public and the environment.

5. The potential scientific value of collections that cannot meet these guidelines should be recognised.

3. Definitions

6. The definitions in the document *"General Guidelines for all BRCs"* apply with the following additions:

3.1. Micro-organisms

7. "Micro-organisms" comprise all prokaryotes (archaea and bacteria), some eukaryotic organisms (fungi, yeasts, algae, protozoa), non-cellular entities (*e.g.* viruses), their replicable parts and other derived materials *e.g.* genomes, plasmids, cDNA.

3.2. Biological material

8. The term "biological material" used throughout this text refers to micro-organisms and their derived materials as defined in 3.1 above.

4. Specific BRC Guidelines

4.1. Staff - Qualifications and training

9. Staff should have relevant qualifications, training and competence to carry out their duties.

4.2. Health and safety

10. All staff should follow the procedures laid down under the appropriate level of containment for the micro-organisms being handled, as defined by the World Health Organisation (WHO, 2004) and as interpreted by national law, regulations and policies, to avoid contaminating samples, risk of infection and environmental dispersion.

5. Premises

11. It is the responsibility of the entity which comprises the BRC, or, within which the BRC is located, to provide an environment that is conducive to handling micro-organisms, for example, free from contamination.

5.1. Construction and operation

12. Construction should respect the containment level appropriate for the risk group of the micro-organisms worked with and should meet appropriate national law, regulations and policies. If major building, renovation or repair work, or other work that is likely to compromise containment or clean conditions, is necessary in Biological Resource Centres, normal activities should be suspended until the building renovation or repair work is completed.

5.2. Maintenance and inspection

13. Cleaning of laboratory benching and equipment should be performed by authorised and trained staff using appropriate personal protection equipment and following documented procedures. A contamination monitoring programme should be in place to include environmental monitoring of laboratory air and surfaces. If a major contamination problem arises in the BRC, the BRC manager should be responsible for implementing a cleaning programme and an investigation of the source of contamination. Details of decontamination procedures should be located in a Procedures Manual or relevant Standard Operating Procedures (SOPs). Quality audit and quality review should be carried out.

6. Equipment Use, Calibration, Testing and Maintenance Records

14. As set out in "*General Guidelines for all BRCs"*.

15. Appropriate maintenance and calibration procedures for common items of equipment used in microbial domain BRCs are summarised in Table 1 in the Annex.

7. Informatics

16. BRCs should follow informatics guidelines as set out in *"General Guidelines for all BRCs"*.

17. There should be a minimum amount of information available for each accession in the collection (Minimum Data Set (MDS). Additional data may be included in the Recommended Data Set (RDS) and Full Data Set (FDS). The MDS and RDS are listed in Table 2 of the Annex.[1] The MDS comprises essential information to identify a unique item in the BRC. The RDS includes useful information for an improved description of the material. The FDS provides all remaining information that is available at the BRC for any given biological materials. The MDS should always be recorded and made available whereas the RDS is recommended, and the FDS is additional optional information.

18. Exceptionally, BRCs may accept collections of scientific value that cannot meet the full MDS and should disclose which items of the MDS are missing.

8. Preparation of media and reagents

19. Accurate preparation and storage conditions of culture media, one of the fundamental steps in the growth and maintenance of biological materials, should be given special attention. The BRC should have defined standards for all preparations; media formulae should be documented and procedures put in place to make changes to procedures and for their approval and adoption. Media batches should be clearly labelled and expiry dates (date after which media and reagents are not to be used) defined and clearly indicated.

9. Accession of deposits to the BRC

9.1. Receipt and handling of biological materials

20. The BRC should document and implement safe procedures for receipt and storage appropriate to the type of biological materials handled. All incoming parcels that contain known or unknown micro-organisms should be opened in a suitable containment laboratory or appropriate microbiological safety cabinet with local facilities for the safe handling and disposal of biological materials.

21. The depositor should provide assurance that biological materials were obtained legitimately. Conditions of deposit should be determined and agreed *e.g.* laid down in a material transfer agreement (MTA), for example to protect assigned intellectual property rights (IPRs). Where deposits are outside the expertise of the BRC, alternative suitable BRCs should be recommended.

22. Quality control procedures should be carried out upon receipt of biological material to confirm its purity, identity and viability. The recommended procedures that should be carried out are in Table 3 in the Annex.

23. Before accepting a deposit, the BRC should check against risk group lists and other lists to make sure that the biological material does not exceed the laboratory's biological safety containment level.

1. The MDS, RDS and FDS are drawn from CABRI Guidelines http://www.cabri.org/guidelines.html.

10. Preservation

10.1 Long-term preservation

24. The commonly used approach for sustainable preservation of microbial cultures is long-term preservation employing liquid nitrogen, deep freezing, freeze drying or L-drying methods. These methods allow high quality long-term storage, recovery and use of the micro-organism. For each micro-organism culture, an appropriate preservation method(s) should be chosen by the BRC based on its own experience or on the recommendations of the depositor (see paragraph 24). The methods used should be equivalent to those cited above and should ensure:

- High viability/recovery of the preserved culture.
- No contaminant in the preserved culture (this does not include any recognised co-culture *e.g.* symbiotic micro-organisms), which are not regarded as contaminants so long as the constituents are correctly specified and checked by microbiological and molecular analysis, as applicable).
- Authenticity of the preserved culture and genome integrity (molecular, phenotypic analysis), where applicable.

25. The recommended methods for the storage and preservation of biological materials and the form in which it is distributed are set out in Table 4 of the Annex.

10.2. Validation of methods and procedures

26. Validation of the methods and procedures used for preservation should be carried out to ensure their reproducibility and reliability, and general compliance during the quality control of biological material. Performance of the method(s) should correspond to the criteria listed in Section 10.1.

27. In addition to the requirements laid out in the "*General Guidelines for all BRCs",* the validation of quality check, characterisation and preservation methods should be carried out by using at least one of the following approaches:

- Performing blind tests.
- Comparing the results of the same method performed at different times (reproducibility).
- Comparing results obtained with different methods (reliability).
- Comparing the results obtained for the same method performed by different persons.

28. The results of quality checks and the procedure used should be recorded.

11. Supply of material

29. The means to ensure secure supply of biological material by BRCs are set out in "*Guidelines on Biosecurity for BRCs*". The best practices set out in these guidelines supplement the best practices detailed below.

11.1. Order placement

30. To the extent that it can be determined, BRCs should supply micro-organisms only to laboratories and only to those individuals who are trained in microbiology and have access to properly equipped laboratories, unless otherwise justified and documented. First orders from new clients should be received on an order form with the client's official letterhead and signed by an authorised person. The BRC should accept fax and mail orders with an official user order number unless signature and/or permits are required for release of particular biological materials. E-mail and telephone orders could be accepted from known or registered users where signatures of authority are not required.

11.2. User validation

31. To ensure that only authorised users may access biological material that is pathogenic or toxic to humans, animals and plants, the BRC should implement any national and international requirements and, as applicable, the following measures for the respective hazardous material:

- Comply with the measures set out in "*Guidelines on Biosecurity for BRCs*".
- Check that the name and signature of the head of department/division match against those registered in the BRC's list of authorised institutions.
- Check that the name and signature of the user match against those registered in the BRC's list of authorised users.
- Have written and signed documentation proving that the user has the appropriate containment facilities and the authorisation to import and handle such biological material.

32. An order should only be processed when the required accompanying documentation is completed, signed and returned.

11.3. Availability of the biological material ordered

33. Freeze-dried or cryo-preserved (when supplied frozen) material should be dispatched as soon as possible once necessary licenses and/or documentation are provided. Dispatch for such materials should be according to the laid down procedures and conditions. Where materials cannot be delivered within three working days (*e.g.* actively growing cultures), then the client should be informed of the delay within three working days.

11.4. Packaging and Transport

34. The packaging of biological material and its transport by postal and other transport services is controlled by international and regional agreements and national laws.

35. To ensure safe and secure packaging and transportation of biological material, BRC should follow the WHO Guidelines on International Regulations for the Packaging and Transport of Infectious Substances[2]. These guidelines provide practical guidance to facilitate compliance with current international regulations for the transport of infectious substances by all modes of transport, both nationally and internationally.

2. www.unece.org/trans/danger/publi/unrec/rev13/

36. Those materials exempt from the WHO guidelines (non-infectious micro-organisms allocated to Risk Group 1) may be sent by (air) mail or other means of transport according to the Universal Postal Union (UPU) requirements[3].

37. The International Air Transport Association (IATA) Dangerous Goods Regulations (DGR) are legally binding for shippers and carriers of dangerous goods (including infectious substances) to be transported by air. For transportation via road, rail and waterways, regional and/or national regulations exist. BRCs should follow the IATA DGR and other respective regulations, to ensure that all applicable requirements for packaging and shipping dangerous goods on ground and air are met[4].

38. BRCs should ensure that staff responsible for the distribution of biological material have the necessary knowledge and training.

39. Staff responsible for the distribution of dangerous goods (including infectious substances) via air should have the shipper's training certificate as required by IATA.

11.5. Traceability of hazardous biological materials

40. The BRC should maintain individual records of all requests for hazardous biological materials – including those requests refused for any reason – showing the biological material, method and date of shipment, and name and address of the person to whom sent.

12. Micro-organism Biological Resource Centres' compliance with national and international law

41. Micro-organisms are isolated, grown, characterised, preserved for the long-term, stored and transported between laboratories. They are shipped by various means, by postal mail or by courier service, from one laboratory to another within countries, and often across borders or continents. They are sent for identification, reference, research or for production purposes from colleague to colleague, from and to culture collections. All these actions should be carried out safely and in compliance with the various legislation and regulations that control these matters. The BRC should ensure that any changes to applicable legislation and regulations are implemented in their procedures.

42. The importance of a laboratory's health and safety procedures extend beyond the laboratory to all those who come in contact with substances and products from that laboratory. A micro-organism in transit might put carriers, postal staff, freight operators and recipients at risk, some organisms being relatively hazard free whilst others can be quite dangerous. Safety and shipping regulations should be followed to ensure safe transit. The BRC should adhere to regulations relevant to the distribution of micro-organisms.

43. A Biological Resource Centre (BRC) should, for example**,** comply with:

- Applicable health and safety requirements.
- Classification of micro-organisms on the basis of risk.
- Applicable quarantine regulations

3. http://ibis.ib.upu.org

4. http://www.IATA.org/cargo/dg

- Intellectual property rights (IPR).
- Requirement that safety information is provided to the recipient of micro-organisms.
- Applicable regulations governing shipping of cultures.
- Control of distribution of biological material.
- Provision of appropriate safety information to the recipient of micro-organisms.

44. In the process of isolation, handling, storage and distribution of micro-organisms, there are many stages where compliance with the law, regulations or voluntary international conventions is required. Table 5 of the Annex lists some examples of these.

45. Whether it is compliance with the law, or duties of a caring employer, essential components for a safe workplace are:

- Adequate assessment of risks.
- Provision of adequate control measures.
- Provision of health and safety information.
- Provision of appropriate training.
- Establishment of record systems to allow safety audits to be carried out.
- Implementation of good working procedures.

46. Best practice requires BRCs to have and implement a sound health and safety plan.

12.1. Classification of Micro-organisms according to risk groups

47. Various classification systems exist and are implemented nationally. The key references are the definitions for classification made by the World Health Organisation (WHO). The definition and minimum handling procedures of pathogenic organisms are set by appropriate authorities in each country.

48. The WHO classifies micro-organisms into four groups according to the risk they impose to humans:

Risk group 1: (no or low individual and community risk). A micro-organism that is unlikely to cause human or animal disease.

Risk group 2: (moderate individual risk, low community risk). A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.

Risk group 3: (high individual risk, low community risk). A pathogen that usually causes serious human or animal disease but does not ordinary spread from one infected individual to another. Effective treatment and preventive measures are available.

Risk group 4: (high individual and community risk). A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

49. A BRC should ensure that all biological materials are assigned to appropriate risk groups; this includes a positive assignment to risk group 1 unless otherwise considered hazardous. Risk group information should be recorded and made available to recipients of biological material.

12.2. Quarantine regulations

50. Clients, who wish to obtain cultures of plant pathogens underlying quarantine regulations should first obtain a permit to import, handle and store from the appropriate authority. Under the terms of such a licence the shipper is required to see a copy of a permit before such strains can be supplied.

51. Plant pathogens handled by BRCs that are subject to quarantine regulations should be registered by an appropriate governmental office. Import and transfer of such pathogens within the country should be carried out according to relevant law.

12.3. Intellectual Property Rights (IPRs)

52. On deposit of a micro-organism, BRCs should record terms and conditions for its further distribution.

53. Transparency, retaining the link between the source and all recipients of biological materials, is the preferred practice. Where appropriate, material transfer agreements should be put in place.

12.4. Safety information provided to the recipient of micro-organisms

54. Safety information should be dispatched with a micro-organism indicating which risk group it belongs to and what containment and disposal procedures are necessary. For a micro-organism, a safety data sheet should include:

- The risk group of the organism being dispatched.
- A definition of the risks and assessment of the risks involved in handling the organism.
- Requirements for the safe handling and disposal of the micro-organism.
- Containment level.
- Opening procedure for cultures and ampoules.
- Appropriate transportation of the micro-organism.
- Procedures in case of spillage.

12.5. Control of Distribution of Hazardous Micro-organisms

55. BRCs should follow the *"Guidelines on Biosecurity for BRCs"*.

56. There is considerable concern over the transfer of certain infectious agents capable of causing substantial harm to human health. There is potential for such organisms to be passed to parties not equipped to handle them or to people who may make illegitimate use of them. To reduce the risk a BRC should have procedures in place which meet national requirements to check the validity of customers that wish to receive hazardous organisms.

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EC Council Directive 2000/29/EEC on protective measures against the introduction into the Member States of harmful organisms of plant or plant products. OJ No. L. 169, p.1 of 10.07.2000.

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].

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EC Council Directive 2000/54/EEC On the protection of workers from risks related to exposure to biological agents at work. OJ No. L. 262, pp.21-45 of 18.09.2000.

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IATA - International Air Transport Association (2005) Dangerous Goods Regulations 47th edition Montreal; Geneva: IATA.

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ISO 7218:2000, Microbiology of food and animal feeding stuffs. General rules for microbiological examinations.

ISO 9001:2000, Quality Management Systems – Requirements.

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WHO World Health Organization, Geneva, Nonserial Publication, ISBN: 92 4 154650 6. Laboratory Biosafety Manual, Third Edition, English, 2004.

WEBSITES OF INTEREST FOR INFORMATION

This list will require periodic update; BRCs should review information available to assist them in compliance with legislation and best practice in the operation of the BRCs.

Transport and shipping

International Laboratory Accreditation Cooperation (ILAC)	http://www.ilac.org/
Micro-Organisms Sustainable use and Access regulation International Code of Conduct	www.belspo.be/bccm/mosaicc
CABRI Guidelines	http://www.cabri.org/gidelines.html
Canadian Transport	www.rural-gc.agr.ca/e4.1_canutec.html
European Commission DGVII – Transport	http://europa.en.int/en/comm/dg07/index.htm
Harmonisation of UN documents etc.	www.hazmat.dot.gov/rules
International Air Transport Association	www.IATA.org/cargo/dg www.IATA.org/cargo/dg/links.htm
International Civil Aviation Authority	http://hazmat.dot.gov/icao.htm www.volpe.dot.gov/ohm/icao.htm www.cam.org/~icao/menu3.html
Maritime rules	www.eat.co.uk/ncec/complian/bibliog/bysea.html www.mdnautical.com/imo/cargoes.htm www.imo.org/pubs/pubcats.htm www.info.gov.hk/mardep/notices/mdn98149.htm www.hazmathelp.com/imdg.htm
The European Agreements Concerning the International Carriage of Dangerous Goods by Rail (RID) and by Road (ADR)	http://hazmat.dot.gov/RIDADR.htm www.dsidat.com/products/undisk7.htm www.volpe.dot.gov/ohm/ridadr.htm
Transport – general	www.tci-transport.fr
German magazine	www.hazmathelp.com/dotlink.htm www.cefic.org www.storck-verlag.com/english/gela_e.htm
United Nations meetings agenda and minutes	www.unece.org/unece/trans/danger/meetdoc.htm
UN Model Regulations	www.unece.org/unece/trans/main/dgdemo/intro.htm
UN Committee of Experts	www.tc.gc.ca/tdgoods/consult/unlinks_e.htm
Universal Postal Union	http://ibis.ib.upu.org http://unicc/unece/tra

	www.de/facil/upustr.htm
USA Dept of Transport's Office of Hazardous Materials Management	http://hazmat.dot.gov
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	
Organisation for Economic Co-operation and Development (OECD)	http://www.oecd.org/dataoecd/4/4/34932656.pdf
United Nations Industrial Development Organisation (UNIDO) Bio-safety Information Network and Advisory Service (BINAS)	www.who.org/emc/biosafe/index.htm
International Centre for Genetic Engineering and Biotechnology (ICGEB)	www.aphisweb.aphis.usda.gov.biotech
US Animal and Plant Health Inspection Service (APHIS)	www.nal.usda.gov/bic/
US Food and Drug Administration (FDA)	http://www.fda.gov/
World Health Organization (WHO) Biosafety Programme	http://www.who.int/csr/labepidemiology/projects/biosafetymain/en/index.html
U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) rules implementing USA PATRIOT Act and Public Health Security and Bioterrorism Preparedness and Response Act of 2002	http://www.cdc.gov/od/sap/final_rule.htm
Centre for Food Safety and Applied Nutrition (CFSAN)	http://vm.cfsan.fda.gov/list.html
Belgian Bio-safety Server	www.biosafety.be
The Dutch Genetically Modified Organism Bureau	www.rivm.nl/csr/bggo.html
Biotechnology Information Centre (BIC) of the US Department of Agriculture (USDA)	www.nal.usda.gov/bic/
UK Advisory Committee on Releases into the Environment (ACRE)	www.environment.detr.gov.uk/acre/index.htm
National Chemical Emergency Response UK	www.eat.co.uk/ncec/complian/bibliog/bibliog.htm
American Biological Safety Association (ABSA)	http://www.absa.org
European Biosafety Association (EBSA)	http://www.ebsaweb.eu
International Biosafety Working Group	http://www.internationalbiosafety.org/english/index.asp

(IBWG)	
Advisory Committee on Dangerous Pathogens	http://www.doh.gov.uk/bioinfo.htm

OECD - Harmonisation Documents

OECD Chemicals programme	http://www.oecd.org/ehs
OECD Classification and labelling of chemicals	http://www.oecd.org/class
OECD Chemical testing	http://www.oecd.org/test
Test guidelines	http://www.oecd.org/test/testlist

Biodiversity

Convention on Biological Diversity: http://www.unep.org/biodiv.html

International Organisations

World Federation for Culture Collections: http://www.wfcc.info/

World Data Centre for Micro-organisms: http://wdcm.nig.ac.jp/

Common Access to Biological Resources and Information: http://www.cabri.org

European Biological Resource Centres Network: http://www.ebrcn.org

ASM – Asian Consortium for the Conservation and Sustainable Use of Micro-organisms http://www.abrcn;net

ECCO, European Culture Collection Organisation

http://www.eccosite.orgFood and Agriculture Organization (FAO): http://www.fao.org/

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./

MIRCEN Scholarships: http://portal.unesco.org/sc_nat/

UNESCO People, Biodiversity and Ecology http://www.unesco.org/mab/index.shtml

WIPO - World Intellectual Property Organization : http://www.wipo.int

ISO - International Organization for Standardization: http://www.iso.ch/iso/en

Patents

Budapest Treaty on the International recognition of the Deposit of Micro-organisms: http://www.wipo.int/treaties/en/registration/budapest/

Taxonomy and Nomenclature ICSP

International Committee on Systematics of Prokaryotes (ICSP): http://www.the-icsp.org/

Bacterial Nomenclature up-to-date: http://www.dsmz.de/bactnom/bactname.htm

Species 2000 Indexing Project: http://www.sp2000.org

List of bacterial names with standing in nomenclature: http://www.bacterio.cict.fr/

Viruses' names: http://www.ncbi.nlm.nih.gov/ICTVdb/; http://www-micro.msb.le.ac.uk/3035/virusgroups.html

Fungal names: http://www.ukncc.co.uk

Bacterial Code of Nomenclature: http://www.the-icsp.org/Code history.htm

Index Fungorum: http://www.indexfungorum.org

ANNEX

Table 1. Maintenance and Calibration Requirements for Equipment Commonly Used in BRCs

Item	Maintenance required	Verification of function
Autoclaves	Cleaning, pressure vessel, system of surveillance, maintenance contract as required; run with indicators	As recommended by manufacturer
Incubators	Cleaning, system of surveillance, maintenance contract as required	Manufacturers' standard on service
Liquid nitrogen storage vessels	Cleaning, leakage, pressure	Once yearly Manufacturers' Test
Centrifuges	Cleaning, system of surveillance, maintenance contract as required	Regular cleaning Manufacturers' service
Cryo-storage tanks	Removal of condensation and ice	
LN_2 store oxygen level alarm	System of surveillance, maintenance contract as required	Manufacturers' standard on service
LN_2 level alarms	Look for malfunction	None
Programmed Cooler	System of surveillance, maintenance contract as required	None
Cryomicroscope	Clean after use, Temperature calibration	Calibration equipment provided for test at each time of use
Spin and shelf freeze-drier	System of surveillance, maintenance contract as required	Calibration of the vacuum gauge
Microscopes	Clean after use, System of surveillance, maintenance contract as required	
Laminar Flow Cabinet	Clean after use, airflow	Annual functionality test
Class II Microbiological Safety Cabinet	Clean after use System of surveillance, maintenance contract as required	Manufacturers' standard on service
-20 °C Freezer	Temperature check	None
-80°C Freezer	Temperature check and registration System of surveillance, maintenance contract as required Security advices	
Media Preparation equipment	Clean after use	
Balance	System of surveillance, maintenance contract as required Clean after use	Manufacturers' standard on service
pH Meter	Clean after use	Test against Manufacturers' standard

LN_2 = Liquid Nitrogen

Table 2. Minimum Data Sets (MDS) and Recommended Data Sets (RDS) for Microbial Accessions to BRCs

Filamentous fungi	**Filamentous fungi**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Misapplied names
Other collection numbers	Isolated from
Name	Mutant
Organism type	Literature
Restrictions	Sexual state
Status	Race
History of deposit	
Conditions for growth	
Form of supply	
Geographic origin	
Yeasts	**Yeasts**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Isolated from
Other collection numbers	Mutant
Name	Sexual state
Organism type	Literature
Restrictions on distribution	Misapplied names
Status	Race
History of deposit	
Geographic origin	
Conditions for growth	
Form of supply	
Microalgae	**Microalgae**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Literature
Other collection number	Conditions for storage
Name and taxonomy	Isolate history
History of deposit	
Isolate history	
Form of supply	
Geographic origin	
Conditions for growth	
Bacteria	**Bacteria**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Serovar
Other collection numbers	Other names
Name	Isolated from
Infrasubspecific names	Mutant
Organism type	Genotype
Restrictions on distribution	Literature
Status	
History of deposit	
Geographic origin	
Conditions for growth	
Form of supply	

Table 2. (cont'd) Minimum (MDS) Data Sets and Recommended (RDS) for Microbial Accessions to BRCs

Cyanobacteria	**Cyanobacteria**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Other names
Other collection numbers	Isolated from
Name and taxonomy	Mutant
Infrasubspecific names	Genotype
Organism type	Literature
Restrictions on distribution	
Status	
History of deposit	
Conditions for growth	
Form of supply	
Geographic origin	
Archaea	**Archaea**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Other names
Other collection numbers	Isolated from
Name	Mutant
Infrasubspecific names	Genotype
Organism type	Literature
Restrictions on distribution	
Status	
History of deposit	
Geographic origin	
Conditions for growth	
Form of supply	
Plasmids	**Plasmids**
Minimum Data Set (MDS)	**Full Data Set (FDS); RDS is not applicable**
Collection Accession number	Constructed from
Name	Incompatibility group
Other culture collection numbers	Transfer ability
Type	Helper
Class	Copy number
Literature	Molecular weight
History of deposit	Cloned gene
Restricted distribution	Transposable element
Host for distribution	Promoter
Medium	Ribosome binding site
Selectable phenotype	Start codon
Replicon	Terminator
Host range	Further information (Remarks on propagation and/or on properties and/or on history, other name(s), etc)
	Restriction sites
	Sequence detail
	Price code
	Properties and application

Table 2. (cont'd) Minimum (MDS) Data Sets and Recommended (RDS) for Microbial Accessions to BRCs

Protozoa	**Protozoa**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Biochemical or molecular characteristics
Other collection numbers	Other name
Name	Substrate or host
Organism type	Year of isolation
Stage	Literature
History of deposit	
Status	
Restriction on distribution	
Conditions for growth	
Form of supply	
Geographic origin	
Phages	**Phages**
Minimum Data Set (MDS)	**Recommended Data Set (RDS)**
Accession number	Cell surface receptor
Element name	
Element type	
Other culture collection numbers	
Restricted distribution	
Literature	
History of deposit	
Host for propagation	
Host used for propagation	
Lysogenicity	
Virus used for	
Viruses	**Viruses FDS = MDS**
Minimum Data Set (MDS) = Full Data Set (FDS)	
Accession number	
Virus name	
Virus name abbreviation	
Former name	
Genus	
Pathotype, serotype, strain	
Original host	
Geographic origin	
Isolate history	
Reference isolate	
Quarantine regulations	
Remarks	
cDNA and gDNA Libraries	**cDNA and gDNA Libraries, MDS = RDS**
Minimum Data Set (MDS)	
Library Name	
Organism	
Type (cDNA or gDNA)	
Vector	
Insert Size	
Library Coverage	

Table 3. Quality control procedures recommended for micro-organisms upon receipt

Micro-organism	Viability	Purity	Identity	Stability
Plasmids	Confirm presence by growing the host/plasmid combination on appropriate selective medium.	Check the texture, the size and the opacity of the colonies grown on selective medium. Check also for homogeneity of the colonies and for absence of contaminants.	Check plasmid length by determination of the molecular weight of the covalently closed circle (ccc) DNA or by analysis of the restriction site pattern.	Confirm presence by growing the host/plasmid combination on appropriate selective medium. Confirm presence by PCR for cryptic plasmid.
Yeasts and Filamentous fungi	Check growth on appropriate medium.	Check for absence of contaminants using macro- and microscopic observations on the culture grown on appropriate medium.	Identify to species level using morphological (macroscopic and microscopic) and physiological features, where appropriate use biochemical features and molecular tools dependant on the taxa.	Check viability and purity. Confirm identity.
Bacteria	Check growth on appropriate medium.	Check for absence of contaminants using macro- and microscopic observations on the culture grown on appropriate medium.	Identify to species level using morphological (macroscopic and microscopic), and physiological tools, where appropriate, use molecular tools.	Check viability and purity. Confirm identity.
Cyanobacteria	Check growth on appropriate medium.	Check for absence of contaminants using macro- and microscopic observations on the culture grown on appropriate medium or specific contaminant medium.	Identify to genus level using morphological (macroscopic and microscopic), and physiological tools, where appropriate, use molecular tools.	Check viability and purity. Confirm identity.
Archaea	Check growth on appropriate medium.	Check for absence of contaminants using macro- and microscopic observations on the culture grown on appropriate medium.	Identify to species level using morphological (macroscopic and microscopic), and physiological tools, where appropriate, use molecular tools.	Check viability and purity. Confirm identity.
Viruses	Test infectivity to indicator hosts and propagation hosts.	Use electron microscopic observations.	Combine host reaction, electron microscopic observations and reaction with specific antisera. Where appropriate, use molecular tools.	

Table 3. (cont'd) Quality control procedures recommended for micro-organisms upon receipt

Phages	Test infectivity to indicator propagation host.	Test plaque morphology, use electron microscopic observations, test host spectrum.	Test plaque morphology, use electron microscopic observations, test host spectrum.	Test phage titre (pfu/mL)
Microalgae	Check growth on appropriate medium.	Check for absence of contaminants using macro- and microscopic observations on the culture grown on appropriate medium.	Identify to species level using morphological (macro- and microscopic) features and where appropriate use physiological and molecular tools dependant on the taxa.	Check viability and purity. Confirm identity.
Protozoa	Check growth on appropriate medium.	Check for absence of contaminants using macro- and microscopic observations on the culture grown on appropriate medium or specific contaminant medium.	Identify up to species level using morphological (macroscopic and microscopic), and/or where appropriate use biochemical features and molecular tools dependant on the taxa.	Check viability and purity. Confirm identity.
DNA libraries			For DNA libraries, analysis of the restriction site patterns. For individual clones of ordered DNA libraries, identity done by sequencing	

Table 4. Recommended preservation methods and distribution forms

	Preservation	Distribution forms	Useful information
Plasmids	Two of the following methods : Cryopreservation of the H/P below -70°C. Cryopreservation of the H/P in LN_2. Freeze drying of the H/P. Preservation of the plasmid DNA (preferably precipitated under ethanol) can also be applied as a preservation method.	Actively growing H/P on agar slant Actively growing H/P in liquid medium Cryopreserved H/P in dry ice Freeze-dried H/P Pure DNA	Plasmids containing genes that may tend to destabilise the physical and/or functional integrity (either by insertion, deletion or point mutation) should preferably be deposited, maintained, tested and delivered as pure DNA.
Yeasts and Filamentous fungi	Two of the following methods : Cryopreservation below –140°C is preferred Cryopreservation below –80°C is accepted Freeze drying or L-drying of the strain Sporulating-strains should be maintained by at least two of the four different preservation methods listed, one of which should be cryopreservation or freeze drying Non-sporulating strains will be maintained under oil or water or freeze drying and cryopreservation.	Actively growing strain on agar slant Freeze-dried or L-dried material in vials sealed under vacuum or inert gas Cryopreserved material in dry ice. Suspensions in liquid Liquid suspension deposited on filter paper	-
Bacteria	Two of the following methods : <u>Cryopreservation</u> below -140°C is preferred in a freezer below -80°C is accepted <u>Drying:</u> L-drying Shelf-freeze-drying Vacuum drying Spin-freeze drying	Actively growing strain on agar slant Freeze-dried or L-dried material in sealed vials Cryopreserved material in dry ice	-
Cyanobacteria	Two of the following methods : L-drying Cryopreservation in or above liquid nitrogen, in ultra low temperature (below -140°C) or on agar slant Freeze drying Serial transfer (if long term preservation is not possible)	Actively growing strain on agar slant Actively growing strain on liquid medium Cryo-preserved material in dried ice Freeze-dried material in sealed vials	-

Table 4. (cont'd) Recommended preservation methods and distribution forms

Archaea	Two of the following methods : Cryopreservation below -140°C is preferred below -80°C is accepted L-drying Freeze drying	Actively growing strain Freeze-dried or L-dried material in sealed vials Cryopreserved material in dry ice	-
Viruses	Two of the following methods : Virus maintenance in situ LN2 Freeze drying	Freeze-dried material in sealed vials Cryopreserved material in dry ice	-
Phages	Two of the following methods: LN2 L-drying on filter paper in glass ampoule Storage of aliquots at -4°C	LN2-aliquots at ambient temperature or in dry ice Freeze-dried material is sealed ampoule Liquid aliquot (refrigerator)	-
Microalgae	Two of the following methods : Sterile liquid medium Sterile semi-solid medium (agar, alginate beads) Cryopreservation below – 140°C	Actively growing in liquid/semi-solid medium Cryopreserved material in dry ice	-
Protozoa	Cryopreservation in or above liquid nitrogen below –140°C	Actively growing strain on liquid medium, or in animal biological liquid. Cryopreserved material in dry ice	-
DNA libraries	Two of the following methods: Cryopreservation of the H/P below -70°C Cryopreservation of the H/P in LN2 Freeze drying or L-drying Preservation of the DNA precipitated under ethanol	Pure DNA Actively growing H/P Cryopreserved H/P in dry ice Freeze-dried H/P	-

H/P = host/plasmid combination; LN_2 = liquid nitrogen

Table 5. Summary of key elements of national and international regulatory controls related to micro-organism domain BRCs

Action	Requirement	Law, Regulation, Convention	Further information
Collecting in the field	Prior Informed consent from a recognised authority	Convention on Biological Diversity	http://www.biodiv.org
	Mutually agreed terms on use	Convention on Biological Diversity	http://www.biodiv.org
	Consent from the land owner	Property law	
Import	Non-indigenous plant pathogens require licenses from country authority	Quarantine regulations	
	Human, animal and plant pathogens can often only be imported to specified laboratories	Health and Safety	
Handling: Manipulation; Growth	Containment dependent on hazard	Control of Biological Agents - Health and Safety EC Directive 2000/54/EEC on Biological Agents	http://www.brad.ac.uk/acad/sbtwc/btwc/nat_imp/leg_reg/uk/ec_com_2000_54.pdf#search='EC%20Directive%202000/54/EEC%20on%20Biological%20Agents
Genetic manipulation	Containment of manipulated organisms	Council Directive 98/81/EC from October 26th amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC Cartagena Protocol on Biosafety	http://www.biodiv.org/biosafety/protocol.asp http://www.biosafety.be/GB/Dir.Eur.GB/Cont.Use/90.219/TC.html http://www.biosafety.be/GB/Dir.Eur.GB/Cont.Use/98_81/98_81_TC.html
Deposit as part of a patent process	Long-term storage and compliance with the Budapest Treaty	Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedures	http://www.wipo.int/treaties/en/registration/budapest/

Table 5. (cont'd) Summary of key elements of national and international regulatory controls posting to micro-organism domain BRCs

Storage	Appropriate containment	Health and Safety Licence to hold pathogens Security	
Export to another country	Some plant and animal pathogens require export licences	Quarantine regulations	
	Dangerous organisms with potential for dual use	Export Licences for dangerous organisms, Biological and Toxin Weapons Convention (BTWC)	http://binas.unido.org/binas/regs.php http://www.opbw.org/convention/documents/btwctext.pdf http://www.dfat.gov.au/isecurity/pd/pd_4_96/pd9.html
Distribution	Packaging and transport considerations	IATA Dangerous Goods Regulations (DGR), Universal Postal Union (UPU) United Nations Committee of Experts on the Transport of dangerous goods	http://www.iata.org/cargo/dg/dgr.htm http://www.upu.int/ http://www.unece.org/trans/danger/danger.htm
	Sovereign rights over the strains	Convention on Biological Diversity	http://www.biodiv.org
	Access and benefit sharing	Bonn Guidelines	http://www.biodiv.org
	Intellectual Property Right	Patent Cooperation Treaty (PCT) The Budapest Treaty (BT)	http://www.wipo.int/treaties/en/registration/pct http://www.wipo.int/treaties/en/registration/budapest
	Customer licensed to receive organism	National regulations	
	Dangerous organisms	EU Council Regulation No 1334/2000 of the 22 June 2000 setting up a Community regime for the control of exports of dual-use items and technology	http://europa.eu.int/eur-lex/en/consleg/pdf/2000/en_2000R1334_do_001.pdf#search='EU%20Council%20Regulation%20No%201334%2F2000'