WORLD FEDERATION FOR CULTURE COLLECTIONS GUIDELINES

FOR THE ESTABLISHMENT AND OPERATION OF COLLECTIONS OF CULTURES OF MICROORGANISMS

3rd Edition, February 2010

Revised by the WFCC Executive Board

ISBN 92 9109 043 3

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BACKGROUND

The World Federation for Culture Collections (WFCC) is a COMCOF (Committees, Commissions and Federations) of the International Union of Microbiological Societies (IUMS) and a scientific member of the International Union of Biological Sciences (IUBS). It's key objective is the promotion and development of collections of cultures of microorganisms and cultured cells. Retention and support of existing collections, as well as assistance and advice to help new collections become established remain key activities. The members of WFCC constitute a unique global network for *ex situ* preservation of microbial diversity which underpins life on earth. This is particularly pertinent in 2010, the ***International Year of Biodiversity***. The WFCC has an on-going concern with all aspects of culture collection activity and, in particular, with the encouragement of new initiatives and improvement of the quality standards of scientific services provided to the international user community.

The increasing demands on culture collections for authenticated, reliable biological material and associated information have paralleled the growth of biotechnology. More recently, the Organisation for Economic Co-operation and Development (OECD) have recognised the importance of taking culture collections to a higher level of quality and delivery to underpin biotechnology. One key element of this development is the introduction of best practice (OECD, 2007), for which the WFCC guidelines laid the foundation. These guidelines have been updated to include recent developments and changes to provide basic quality management guidance for culture collections. The OECD Best Practice Guidelines for Biological Resource Centres (OECD, 2007) set the standard for quality management and also covers biosecurity, building capacity, preservation of biological resources and data management. The WFCC guidance provides an excellent first step towards the implementation of the OECD Best Practice. It is anticipated that many member collections will be able to implement this guidance in full immediately but it is expected that each agrees to implement it in a reasonable time frame.

It is hoped that these Guidelines prove valuable and encouraging. The WFCC wishes to emphasise that high standards of scientific service can be achieved in laboratories with modest resources and that sophisticated equipment is not a prerequisite for good microbiological practice; the principles listed in the Guidelines must be applied to any culture collection regardless of size or economic standing.

EXECUTIVE SUMMARY

These Guidelines are prepared by the WFCC to provide a framework for the establishment, operation and long-term support of microbiological and cell resource centres as a fundamental part of the scientific infrastructure.

The Guidelines describe:

- The aims of culture collections
- The services they provide to the international scientific community in terms of resources, information and specialist skills
- The long-term support needed to enable them to provide these professional services, including:
    - Appropriate operational facilities
    - The staffing levels to allow operation at a high standard
    - The training level of staff with research expertise related to the aims of the collection
- The contributions made by collections to the research knowledge base in terms of taxonomic studies, preservation, growth and handling procedures and other linked areas
- The capability of collections to meet all relevant national and international regulations concerning the control, transportation and health and safety aspects of resource handling and distribution
- The need to provide support and training in capacity building on a global basis;
- The need for international collaboration to enhance the value and quality of biological resources
- References and web site links

The guidance demands compliance with national legislation, rules and regulations.

CONTENTS

INTRODUCTION

1.1 The ever decreasing investment in traditional taxonomy, the increasing demand for a molecular approach, the continued depletion of natural resources and concerns over biosecurity and climate change brings a heightened awareness of the value of collections of microorganisms. Conservation of genetic resources and biodiversity provides the essential underpinning for emerging biotechnologically based eco-efficient products and industries in both the developed and the developing world (OECD, 2001); an essential element in the development of a knowledge-based bioeconomy (OECD, 2009).

1.2 Many countries and individual institutions therefore have established or are establishing publicly supported culture collections of microorganisms for the first time, either to provide services to their country or region or in support of their own research programmes.

1.3 The first edition of these guidelines in 1980 was the first attempt to develop guidelines for culture collections. Since then, numerous guidance documents have been developed (see Safety and Standards websites below) these, and international standards are being applied to the operations of collections today.

1.4 The objective of these Guidelines is to provide assistance to those collections of microorganisms offering services outside their own institution (service collections), but it is anticipated that many of the guidelines will be more generally applicable to in-house or research collections. Guidance such as the CABRI guidelines (http://cabri.org) and the OECD Best Practice for Biological Resource Centres are designed for public service collections and are the next level of guidance, which require extensive investment to implement.

1.5 WFCC expects that, wherever possible, service collections will adopt the Guidelines enumerated here. Membership of the WFCC includes the obligation to implement these standards to guarantee consistent and sustainable quality of authentic materials and information.

ORGANISATION

2.1 The parent organisation, or board, under which a culture collection is established should be fully aware of and accept the responsibilities inherent in maintaining a public service to appropriate standards. Commitment to the maintenance of the collection and its services in the long-term should therefore be included in the strategic plans or objectives of the parent organisation as appropriate. In the case of existing collections, where this responsibility is not explicit, this aspect should be clarified with the Director of the parent institute, its Scientific Council, senior university officials, Governing Board, or other such authorities as may be appropriate.

FUNDING

3.1 Administration and funding arrangements for collections require a long-term commitment from the parent organisation. Support solely in the form of short-term contracts or without any allocation of core funding is inappropriate for service collections aiming to provide long-term storage and supply services. Even the establishment of small in-house collections requires an ongoing source of direct, or indirect, financial support from a parent body.

3.2 It is important to consider the level of funding, both now, and likely to be forthcoming on an on-going basis. This must be adequate to provide the range of services being planned and at a standard that users would expect. If secure resources are limited, in general it is preferable to restrict the primary objectives of the collection to those which it has a strong probability of maintaining in the long-term.

OBJECTIVES

4.1 Collections require a clearly summarised general statement of their long-term objectives relating to the scope of their holdings and to the range of outside services that are envisaged.

4.2 In addition, it is often helpful for a collection to have more specific short-term objectives relating to the coming 1, 3 or 5 -year period. These can usefully include the numbers and groups of strains which it is planned to acquire in that time frame and schedules for installing new facilities and services.

4.3 Where possible a mission statement in accordance with 4.1 and 4.2 should be prepared which is sufficiently short to reproduce in promotional and other material disseminated.

HOLDINGS

5.1 The scope of material and numbers of strains to be held requires careful consideration and merits discussion with the parent organisation and any funding bodies concerned when the collection is being established, as this will have long-term financial implications.

5.2 In addition to decisions on the groups of microorganisms to be maintained, and the numbers it is envisaged as being retained in the long-term, it is also necessary to have a clearly defined accessions policy on which new strains are to be taken into the collection. If this is not decided and many unsolicited strains are accepted uncritically without due regard to the collection's objectives, storage capacities, personnel and financial resources can soon become overstretched; at the same time, the range should not be so strictly defined as to limit the effectiveness of the services provided to the users. Collaboration with other collections to provide broader coverage is essential, networking activities to enable co-ordinated accession policy must be considered, whether at a regional, national or global level (see paragraph 16.1)

5.3 If strains are maintained that are potentially pathogenic to man, animals or plants, or produce toxic or hallucinogenic compounds, those holdings should be clearly labelled and kept secure; adherence to any safety regulations in force is mandatory. National legislation impacts on this and many countries require permits or licences to hold, work with and distribute such organisms (see EBRCN legislation document on WFCC website).

5.4 Collections vary substantially in scope with regard to the groups of microorganisms held, geographical emphasis, and user-group orientation. It is beneficial to stress at an early stage areas in which the holdings are planned to become particularly rich as this will be of the utmost value to both potential depositors of strains and those wishing to acquire strains or requiring other services.

5.5 In considering which strains to maintain, it is economically prudent to aim at complementing rather than duplicating those already available through other service collections. While it may be desirable for collections to include some authenticated internationally recognised reference strains, the WFCC wishes to discourage the unnecessary use of scarce resources. Wherever possible, new collections of microorganisms being established should collectively enrich the world's available genetic resources rather than duplicate those already existing.

5.6 In determining which strengths a new collection should have with respect to its holdings, particular attention should be paid to those already present in that particular country or region as well as those providing international services. Information as to which collections already exist can be obtained from the WFCC World Data Centre on Microorganisms (WDCM) – online via the WFCC website. Some other specialist listings are also available (e.g. CABRI, ECCO, JCM etc.).

STAFF

6.1 Culture collections are necessarily labour-intensive. When determining the numbers of full and part-time positions required it is important to consider how time-consuming the routine accessions, preservation, maintenance, and viability checking will become as the collection approaches its target strain numbers. Staff levels need to be sufficient not only for the incorporation and maintenance of cultures, but also to fulfil the anticipated level of culture supply and other services the collection is to offer.

6.2 The effective curation and management of a culture collection is a demanding task. It requires knowledge not only of the organisms themselves, but also their growth and preservation requirements, properties and potential applications and the provision of customer services. The key staff member(s) recruited would be expected to have a higher degree in an appropriate field and some subsequent direct experience or special training in culture collection curation skills. In order to attract and retain sufficient calibre staff, arrangements for ongoing employment should be made. Too frequent staff turnover will jeopardize the maintenance of standards in the collection and hence the quality and effectiveness of the services provided.

6.3 Particular attention should be paid to the qualifications and experience of the persons in charge of the Collection.

6.4 While it is not always practical to have on staff specialists concerned with, for example, the identification and authentication of all systematic groups covered, some basic taxonomic skills are essential for quality control (see para 8.1). Where a need for specialist taxonomic support exists, especially if it relates to services such as identification being advertised, steps need to be taken to provide such expertise through collaborative arrangements within and(or) outside the collection's parent organisation. As such specialist assistance might be required at short-notice, it is preferable for such arrangements to be formal rather than informal.

PRESERVATION

7.1 Different microorganisms often require special preservation methods in order to ensure optimal viability, storage, and purity. For security, and in order to minimise the probability of strains being lost, each strain should, whenever practical, be maintained by at least two different procedures. At least one of these should be by freeze-drying (lyophilisation) or storage at ultra low temperature in liquid nitrogen or mechanical freezers maintaining temperatures of -140°C or lower (cryopreservation); these are the best methods for minimising the risks of genetic change. In some cases, for example cell lines, where only freezing is available, duplicates should be stored in separate refrigerators with different electrical supplies. (See also para 7.3)

7.2 While considerable experience is now available on the optimal preservation methods for many groups of microorganisms, this is not so for all. Particular care is needed with genera and species hitherto not preserved in culture collections when a greater range of procedures should be attempted or research carried out to determine optimal protocols (See para 14.2).

7.3 In order to minimise the risks to important genetic resources from fire, flooding, earthquakes, war or catastrophes, Collections should arrange to have duplicates of at least the most important and irreplaceable strains (and also of their associated documentation) securely housed in a different building or ideally at a separate site.

CULTURE AUTHENTICATION

8.1 Scientists ordering cultures from Collections expect them to be correctly identified. If not, there is a danger of users employing the wrong organism in their investigations which could prove time-wasting, expensive, and lead to invalid published results. The name applied to a strain leads into other information relevant to that species including risk group, potential toxin

production, biosecurity risks and therefore it is of critical and prime importance that the name assigned is correct. Moreover, without proper authentication noxious organisms could be inadvertently supplied. This places a grave responsibility on collections and demands attention from the time the first cultures are received for preservation. WFCC member collections have a responsibility to provide resources with accurate identities as reference materials if they offer a public service and must make every effort to ensure that organisms they supply are authentic.

8.2 When named cultures are received, the person making the original identification should be recorded. The Collection should confirm the identification and check that it agrees with published descriptions of the species. Alternatively, the Collection should confirm that it has been checked by a competent specialist or by comparison with authorised molecular data or other profiles.

8.3 In the case of unidentified cultures received, the Collection should be wary of identifying material in groups for which it has no specialist taxonomist and it should endeavour to have material checked by specialists prior to incorporation. Such materials are to be treated with care and assumed to have a high level of risk until a risk assessment and/or the name of the organism has been established.

8.4 In the case of microorganisms which are recognisable from microscopic preparations or dried cultures (i.e. filamentous fungi, algae, protozoa), it is good practice to make such preparations when they are received for deposit, and/or establish molecular barcodes or other profiles (e.g. MALDI-TOF, fatty acids). This facilitates the checking of whether a strain recovered from the collection conforms to that originally deposited.

8.5 The first time (and at appropriate regular intervals afterward) cultures are recovered from the Collection, during maintenance or routine re-preservation work, or when they are being dispatched, care should be taken to ensure they conform to the original deposit by carrying out appropriate tests, by comparative study (See para 8.4), or checking by a specialist.

8.6 The need to authenticate cultures must be borne in mind when staff are recruited, and arrangements for access to specialists have to be made (See para 6.4).

CULTURE SUPPLY

9.1 Collections should be able to distribute cultures listed as available which are requested. Arrangements for culture supply vary according to the financial basis and policies of the legal owners of the Collection.

9.2 Cultures listed as available in catalogues by Service Collections should normally be provided without prejudice to those requesting them, subject to any import, quarantine or containment regulations that might apply and to normal credit control procedures where charges are required to be made. It is recognised that charging policies and differential rates for users in particular regions or for different purposes (for example teaching vs. industry) may have to be applied in accordance with the policy of the parent organisation or funding body.

9.3 In offering a culture supply service, consideration needs to be given to the provision of sufficient staff to satisfy the numbers of requests it is likely to receive in a timely manner. Cultures that cannot be dispatched for technical reasons within a reasonable time of receipt of an order with any necessary permits, should be indicated in the Catalogue.

9.4 Strains which are pathogenic or toxic to plants, animals or man often are subject to regulations from health and(or) agriculture authorities. Scientists requesting strains may need to obtain permits to import material or to handle certain cultures. There are several elements of legislation that impinge upon distribution of organisms:

- Quarantine – mainly plant (crop) and animal diseases
- Biosafety – restriction on biosafety level (risk group) or hazard level that can be handled by the recipient
- Biosecurity – control legislation on the movement of dangerous pathogens
- Intellectual Property – for example, Patent Strains under the Budapest Treaty often require certificate of release (see para 10.3)

Where cultures are being supplied to a person or institution not known to the Collection, guarantees should be obtained on the credentials of the person concerned and other facilities of the institution before dispatching cultures.

9.5 Collections should maintain detailed records of recipients of cultures showing the material sent (with strain and batch numbers where appropriate), method and date of shipment, and name and address of the person to whom sent. In the case of unsatisfactory results or if it is necessary to supply subsequent information recipients can then be notified. It is recommended that collections utilise Material Transfer Agreements (MTAs) to ensure the recipient is aware of any of the terms and conditions of access. Example minimum text for such MTAs can be found in the ECCO MTA (http://www.eccosite.org). Complementary information is provided by MOSAICC (see Micro-organisms culture collections, Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) at http://www.cbd.int/abs/instruments/).

9.6 In dispatching cultures, attention needs to be given to pertinent postal and shipping regulations regarding packaging and labelling, see Selected Bibliography and para 9.5

9.7 The WFCC require all member collections and recommends to all others that TYPE strains must be made available without restriction to the scientific community.

OTHER SERVICES

10.1 Service Culture Collections may be well placed to provide a variety of support services to the scientific and industrial community worldwide or in the region they serve. If such extension services are contemplated, they need to be carefully planned as they frequently require additional expertise and facilities.

10.2 If identification services are to be offered it should be considered whether appropriately trained personnel are available to undertake this demanding task, either in the collection or in an associated institution. Major problems can arise as a consequence of misidentifications (See paras 6.4, 8.1).

10.3 Where international patent depositary facilities are to be provided, these should be operated according to the procedures laid down in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Regulations, 1977; Guide to the Deposit of Microorganisms under the Budapest Treaty, 1988 [both published by World Intellectual Property Organization (WIPO), Geneva]). In such cases the collection would have to qualify under WIPO rules to satisfy the stringent regulations required to become accepted as an International depository Authority (IDA). A code of conduct for International Depository Authorities is available at http://bccm.belspo.be/tbu/ida/index.php.

10.4 If consultancy, advisory or investigation services are to be offered, attention must be given to the provision of appropriate facilities and properly trained personnel (See para 8. 1).

DOCUMENTATION

11.1 Records need to be kept for each strain held and should, at least, include the following categories of information:

- Place
- Substrate or host
- Date of isolation
- Name of person isolating the strain
- Depositor (or other source of the strain, such as from another Collection)
- Name of the person identifying the strain
- Preservation procedures used
- Optimal growth media and temperatures
- Data on biochemical or other characteristics
- Regulatory conditions applying (relating for example to quarantine, containment levels and patent status)

WDCM provides for an efficient coding of the strains by defining a collection acronym and WFCC number which allows each culture collection to give a Globally Unique Identifiers (GUID) to each strain of its holding, combining their acronym with their own internal numbering. The pioneering work of WDCM enables an appropriate recording and management of the documentation related to the strains. Collections should use this system to be part of the WDCM network and be connected to the international scientific community.

11.2 Whenever resources permit, the records should be computerised. Collections are encouraged to adopt a field structure and field definitions which will enable the data to be integrated into the international and major regional schemes now in operation [e.g. Microbial Information Network Europe (MINE), CABRI Guidelines, OECD Best Practice]. Several compatible programmes exist and the WFCC, WFCC World Data Centre on Microorganisms (WDCM), and CABRI can provide helpful information and suggestions on appropriate levels of management of this information (see Bibliography). Even if data exchange is not being planned in the short-term, it is wasteful of resources to develop independent systems that already exist.

11.3 For security, duplicate computer files or photocopies of records should be kept separately, perhaps deposited with duplicate strains (See para 7.3).

11.4 Where records are computerised, several of the Collection's staff should be familiar with the operation of the system in order to provide cover during periods of absence.

CATALOGUES

12. Printed or on-line catalogues of the strains available for distribution should be produced or updated at regular intervals. While annual printed catalogues are rarely justified, gaps of five or more years would be too great to be useful. On-line catalogues should be updated more frequently. Cultures with restricted distribution should be clearly marked. Cultures which, for any reason, are not available for distribution should not be listed in catalogues or publicly accessible databases.

RESEARCH

13.1 Research programmes should – when possible - be a part of every Collection's activity. It not only helps attract staff of high calibre, but can make important contributions to knowledge of the morphology, taxonomy, physiology, biochemistry and genetics of the groups

of organisms maintained. Research activities also ensure that staff keep abreast of current developments and are aware of the needs of the user community.

13.2 Collections are also well-placed to develop screening procedures for particular organisms, preservation protocols for strains difficult to preserve by routine procedures and optimal cultural media and conditions for growth.

TRAINING

14.1 While Collection staff require appropriate training themselves, once they have become skilled they are well-placed to train others in techniques relating to culture preservation, growth, and identification.

14.2 If training is to be provided, it is important to ensure that adequate provision is made for teaching facilities and supervision.

14.3 WFCC provides training often associated with its International Conference for Culture Collections (ICCC) but it also provides ad hoc training courses and has a work programme on capacity building. Additionally, many culture collections offer individual training on different issues.

SAFETY AND SECURITY

15.1 Safety aspects of all operations carried out in the Collection include biosafety, chemical and physical safety etc and need to be carefully scrutinised with respect not only to national health and safety regulations, but also with regard to good laboratory practice. Risk assessments must be carried out before cultures are brought into the collection and specific procedures are applied. Adequate controls must be implemented to manage risk, not just to collection workers, but to all who may come into contact with cultures, products and services provided including the complete transportation chain.

15.2 Particular attention needs to be given to the containment and biosecurity aspects of strains which are potentially harmful to man, animals or crops. WFCC requires member collections to implement best practice on all safety and security aspects according to the requirements and holdings of individual culture collections. In addition, increased levels of security are an important consideration when a collection accepts secure, safe or patent deposits where a collection has additional client and legal obligations to satisfy.

15.3 Facilities will be required for the safe opening of packages containing new deposits or material for identification which could contain harmful organisms. All steps involved in accessioning new materials shall consider biosafety and biosecurity and clear responsibilities shall be laid down.

15.4 See section 17 on compliance with all aspects of legislation that are most relevant for culture collections

NATIONAL AND INTERNATIONAL COLLABORATION

16.1 Many countries have formal or informal associations or federations of the Collections within them. These provide excellent opportunities for exchange of information and discussions of mutual problems and Collections should be encouraged to support them.

16.2 Similarly, the establishment of formal or informal links with any regional groups active in adjacent countries should be encouraged. Examples of such links are the European Culture Collections' Organisation (ECCO) and the Microbial Resource Centres (MIRCEN) network.

16.3 In order to make their holdings widely known, collections are encouraged to register with the WFCC World Data Centre on Microorganisms (WDCM). It is also recommended that international standards for data exchange and interoperability are adopted to facilitate international communication and data exchange.

16.4 Collections and individual senior staff within collections may join the World Federation for Culture Collections (WFCC). This has work programmes concerned with education, patents, implementation of legislation, endangered collections and standards which all provide information that may be of assistance to new and established collections. The WFCC holds a major international congress every three years which provides a unique forum for the consideration of all aspects of the activity of culture collections. A Newsletter is produced and training schemes and courses are operated. Collection staff should be encouraged to actively participate in the affairs of the WFCC.

COMPLIANCE WITH LEGISLATION

17.1 Operations of culture collections must be carried out safely and compliant with the various legislation and regulations that control these matters. Moreover the legislation is subject to changes, which are not always directly communicated to the interested parties. The WFCC through its Newsletter and website endeavours to keep its membership and users informed. In the process of isolation, handling, storage and distribution of microorganisms and cell cultures there are many stages where compliance with the law, regulations or international conventions is required. A culture collection should comply with:

Health and Safety requirements
Classification of Micoorganisms on the Basis of Hazard
Quarantine regulations
Ownership of Intellectual Property Rights (IPR)
Convention on Biological Diversity
Safety information provided to the recipient of microorganisms
Regulations governing shipping of cultures
Control of Distribution of Dangerous Organisms
Budapest Treaty (for patent deposits)

Health and Safety

17.2 The institutions' director/senior management is responsible for the implementation of all relevant national regulations in the context of occupational health. A structure for verifying this must be set up. The importance of a laboratory's health and safety procedures stretches beyond the laboratory to include all those who may come in contact with substances and products from that laboratory. A risk assessment of handling and supply of organisms is required and should include an assessment of all hazards involved, not just infection, but also all others amongst which are, the production of toxic metabolites and the ability to cause allergic reactions. Organisms that produce volatile toxins or aerosols of spores or cells present a greater risk. It is the responsibility of the scientist or curator to provide such assessment data where known to a recipient of a culture to ensure its safe handling and containment.

Regulatory control of microbiology

Action	Requirement	Law, Regulation, Convention	Further information
Collecting in the field	Prior Informed consent from a recognised authority	Convention on Biological Diversity (CBD)	http://www.cbd.int
	Mutually agreed terms	Convention on Biological Diversity (CBD)	http://www.cbd.int http://www.cbd.int/abs/instruments/
	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://eur-op.eu.int/opnews/395/en/r3633.html
Genetic manipulation	Containment of manipulated organisms	EEC Directives 90/219/EEC. Contained use of genetically modified microorganisms (GMO's), *L117 Volume 33, 8 May 1990. EEC Directives 90/220/EEC. Release of GMO's, *L117 Volume 33, 8 May 1990. Cartagena Protocol on Biosafety	http://www.biodiv.org/biosafety/protocol.asp http://biosafety.ihe.be/Menu/BiosEur1.html http://biosafety.ihe.be/Menu/BiosEur1.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 Procedure	http://www.wipo.int/treaties/en/registration/budapest/
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.php3 http://www.opcw.nl/fact/rel_conv.htm 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 Convention (UPU) United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG)	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.cbd.int
	Access and benefit sharing	Bonn Guidelines	http://www.cbd.int

	Intellectual Property Right ownership Customer licensed to receive organism?	Copyright	http://www.wipo.org
	Dangerous organisms export	EU Council Regulation 3381/94/EEC on the Control of Exports of Dual-Use Goods from the Community	http://eur-op.eu.int/opnews/395/en/r3633.html See national Export Offices

Classification of Microorganisms on the Basis of Hazard

17.3 Various classification systems exist which include the definitions for classification by the World Health Organisation (WHO); Microorganisms are normally classified on their potential to cause disease, their human pathogenicity, into four risk groups:

Risk Group 1 A biological agent that is most unlikely to cause human disease.

Risk Group 2 A biological agent that may cause human disease and which might be a hazard to laboratory workers but is unlikely to spread in the community. Laboratory exposure rarely produces infection and effective prophylaxis or treatment is available.

Risk Group 3 A biological agent that may cause severe human disease and present a serious hazard to laboratory workers. It may present a risk of spread in the community but there is usually effective prophylaxis or treatment.

Risk Group 4 A biological agent that causes severe human disease and is a serious hazard to laboratory workers. It may present a high risk of spread in the community and there is usually no effective prophylaxis or treatment.

Classification of animal and plant pathogens, their handling and distribution are covered by national and regional legislation.

Quarantine Regulations

17.4 Clients who wish to obtain cultures of non-indigenous pathogens may first have to obtain a permit to import, handle and store from the appropriate Government Department. Under the terms of such a licence the shipper is required to see a copy of the Ministry permit before such strains can be supplied.

Rights to further distribute

17.5 On deposit of biological materials culture collections must ascertain terms and conditions of further distribution, for example, Intellectual Property rights or from Prior Informed Consent granted under the Convention on Biological Diversity.

Convention on Biological Diversity

17.6 The WFCC endorses the principles of the Convention on Biological Diversity and requires biological materials to be received and supplied within the spirit of the CBD. First and foremost the WFCC requires its members to follow its national legislation, rules or regulations, which take precedence. The requirements laid down by countries of origin must be honoured. Transfer of materials should be accompanied by material transfer agreements or other forms of conditions of supply informing recipients of any terms and conditions that apply.

Safety Information provided to the Recipient of Microorganisms

17.7 It is recommended that a safety data sheet be despatched with an organism indicating which hazard group it belongs to and what containment and disposal procedures are necessary. A safety data sheet accompanying a microorganism should include:

- The hazard group of the organism being despatched
- A definition of the hazards and assessment of the risks involved in handling the organism
- Requirements for the safe handling and disposal of the organism
    - Containment level
    - Opening procedure for cultures and ampoules

- Transport
- Disposal
- Procedures in case of spillage

Regulations governing Shipping of Cultures

17.8 The IATA Dangerous Goods Regulations (DGR) require that shippers of microorganisms of Risk Groups 2, 3 or 4 must be trained by IATA certified and approved instructors (every two years) if cultures are sent by air transport. Transport of highly pathogenic material classified in Category A, UN 2814 or UN 2900 (see definition of this shipping Category and Table 3.6D, DGR 2010), requires shippers declaration forms, which accompany the package in duplicate.

Cultures of infectious substances meeting the definition of shipping Category B, UN 3373 (majority of the Risk Group 2 organisms), can be transported under deregulated conditions. Different labels and packaging specification markings are used for organisms in transit by air, dependent on the shipping Category. IATA DGR also requires that packaging used for the transport of Risk Groups 2, 3 or 4 must meet defined standards of a UN combination package. See Addendum II to the current DGR 51st Ed., 2010 and IATA homepage http://www.iata.org.

Category A shipments require a Packing Instruction PI 602 packaging whereas for Category B shipments PI 650 packaging are accepted. PI 650 also meets the requirements of UPU for the transport of Risk group 1 organisms. Generally, there is no lesser packaging quality than PI 650. The WFCC homepage offers information on packaging and shipping.

Control of Distribution of Dangerous Organisms

17.9 There is considerable concern over the transfer of selected infectious agents capable of causing substantial harm to human health, animals or crops. There is potential for such organisms to be passed to parties not equipped to handle them or to persons who may make illegitimate use of them. A culture collection must have procedures to check the validity of customers that wish to receive dangerous organisms that present a biosecurity risk and if in doubt must not supply.

The WFCC fully supports the Biological and Toxin Weapons Convention of 1972 (BTWC). But, it is not the policy of the WFCC to influence the range of bioresources maintained or to interfere with research activities of member collections. National governments and authorities are the enforcers of legislation, control lies with the country in which the collection is based. The WFCC urges its members to strictly follow all national and international legislation concerning distribution of sensitive materials to third parties. Such materials shall be clearly labelled and kept secure.

Collections should maintain detailed records of recipients of cultures. The requestors/recipients may need to obtain permits to import or to handle the cultures. In case of trans-border supplies, written and signed guarantees should be obtained on the credentials of the requesting person before despatch if other authorisation is not available. Material transfer agreements before despatch might be an additional security. In the case of new customers, the recipient's institution and the person's name shall be checked against international lists in the context of bio-terrorism.

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USEFUL WEBSITES

Legislation and operation

Convention on Biological Diversity	http://www.cbd.int/ http://www.cbd.int/abs/instruments/ http://bccm.belspo.be/projects/mosaicc/
EBRCN Information Resource	http://www.wfcc.info
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 and www.IATA.org/cargo/dg/links.htm
OECD - Harmonisation Documents	
Chemical programme	http://www.oecd.org/ehs
Classification and labelling	http://www.oecd.org/class
Chemical testing	http://www.oecd.org/test
Currently available test guidelines	http://www.oecd.org/test/testlist
UN Committee of Experts for the Transport of Dangerous Goods (UNSCETDG)	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
World Health Organisation	www.who.org/emc/biosafe/index.htm
World Federation for Culture Collections	http://www.wfcc.info

Organisations

Biodiversity and Biological Collections Web Server	http://muse.bio.cornell.edu/
European Culture Collections' Organisation	http://www.eccosite.org
MIRCEN Scholarships	http://www.unesco.org/science/life/life1/rcenform.htm

World Federation for Culture Collections	http://www.wfcc.info
World Data Centre for Micro-organisms	http://www.wdcm.nig.ac.jp

Patents

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure	http://www.wipo.int/treaties/en/registration/budapest/
Code of Practice for IDAs	http://bccm.belspo.be/tbu/ida/index.php

Safety and Standards

Advisory Committee on Dangerous Pathogens	http://www.doh.gov.uk/bioinfo.htm
Binas Biosafety Site	http://www.un.org/binas
CABRI – Common Access to Biological Resources and Information - Guidelines	http://www.cabri.org
Cartagena Protocol on Biosafety	http://www.biodiv.org/biosafety/protocol.asp
EC Directive 93/88/EEC on Biological Agents	http://eur-op.eu.int/opnews/395/en/r3633.html
International Organisation for Standardisation	http://www.iso.org/iso/en/ISOOnline.frontpage
OECD Best Practice for BRCs	http://www.oecd.org (Search for BRC)
WHO Biosafety Manual	http://www.who.int/csr/resources/publications/biosafety/who_cds_csr_lyo_20034/en/
UK National Culture Collection (UKNCC) Quality Management System	http://www.ukncc.co.uk

Taxonomy and Nomenclature

The creation of a new starting date for prokaryote nomenclature and the mechanism of valid publication of a name is defined in the Bacteriological Code	http://www.ncbi.nlm.nih.gov/books/NBK8817/
Publication of the Approved Lists of Bacterial Names	http://ijs.sgmjournals.org/cgi/reprint/30/1/225
Lists of Bacterial Names is also published in an amended edition	http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=bacname
Valid publication of names of prokaryotes according to the rules of nomenclature: past history and current practice Int J Syst Evol Microbiol 2006 56: 2715-2720	http://ijs.sgmjournals.org/cgi/content/full/56/11/2715
Matters relating to the deposit and availability of type strains in collections have been raised: Proposals to clarify how type strains are deposited and made available to the scientific community for the purpose of systematic research Int J Syst Evol Microbiol 2008 58: 1987-1990.	http://ijs.sgmjournals.org/cgi/content/full/58/8/1987
Confirmation of deposit, but confirmation of what? Int J Syst Evol Microbiol 2008 58: 1785-1787.	http://ijs.sgmjournals.org/cgi/content/full/58/8/1785
A recent review deals with an important aspect in taxonomy, the characterization of strains: Notes on the characterization of prokaryote strains for taxonomic purposes Int J Syst Evol Microbiol 2010 60: 249-266	http://ijs.sgmjournals.org/cgi/content/full/60/1/249 See also the ICSP website http://www.the-icsp.org/
The International Committee on Taxonomy of Viruses	http://www.ictvonline.org/index.asp?bhcp=1

Virus taxonomy and provides a database of names	http://www.ncbi.nlm.nih.gov/ICTVdb/
The taxonomy of fungi and yeast is dealt with by the Botanical Code International Code of Botanical Nomenclature (VIENNA CODE)	http://ibot.sav.sk/icbn/main.htm
Index Fungorum	http://www.indexfungorum.org/
MycoBank	http://www.mycobank.org/
The Botanical Code also covers algae (including cyanobacteria/cyanophytes) and includes protozoa considered to be botanical taxa. This is governed by the IAPT - International Association for Plant Taxonomy	http://www.botanik.univie.ac.at/iapt/index_layer.php
The International Code of Zoological Nomenclature also covers protozoa considered to be zoological taxa	http://www.iczn.org/iczn/index.jsp
International Commission on Zoological Nomenclature	http://www.iczn.org/
ZooBank	http://www.zoobank.org/

USEFUL ADDRESSES

WDCM - World Data Centre for Microorganisms Contacts: Dr. Juncai Ma, Institute of Microbiology, Chinese Academy of Sciences. NO.1 Beichen West Road, Chaoyang District, Beijing 100101, China . Tel: +86-10-64807422. Fax:+86-10-64807426. email:ma@im.ac.cn

WFCC - World Federation for Culture Collections Contacts: Philippe Desmeth, BCCM, Federal Public Planning Service – Science Policy avenue Louise, 231 1050 Brussels,Belgium. Secretary: Ms Anne Depauw. email:depa@belspo.be

GBRCN – Global Biological Resource Centre Network demonstration project Secretariat
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http://www.gbrcn.org

ECCO – European Culture Collections' Organisation
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