

Ex-situ microbial genetic resources within the framework of CBD

WORLD FEDERATION FOR CULTURE COLLECTIONS (WFCC) INFORMATION DOCUMENT

on

ACCESS TO EX-SITU MICROBIAL GENETIC RESOURCES WITHIN THE FRAMEWORK OF THE CONVENTION ON BIOLOGICAL DIVERSITY

EXECUTIVE SUMMARY AND RECOMMENDATIONS

The inclusion of microorganisms in the Convention on Biological Diversity (CBD) recognises the fundamental role played by microbial diversity in the maintenance of the biosphere and as a resource for humankind. The World Federation for Culture Collections (WFCC), sponsored by the International Union of Microbiological Societies and the International Union of Biological Sciences, and representing the majority of ex-situ microbial resource centres, presents an Information Document for governments, policy makers and microbiologists on issues relating to access to ex-situ microbial genetic resources.

A survey of some 500 culture collections in 58 countries is provided and an account given of their role, organisational support, administrative regimes, distribution policies and current access practices.

Information is provided on the special characteristics of microorganisms that distinguish them from plants and animals and the consequences of such characteristics for inventorying, tracking and benefit sharing.

Existing relevant legislation and operating practices are summarised and policy issues addressed.

It is recommended that:

- access to ex-situ microbial genetic resources should remain unimpeded for the purposes of scientific research, industrial application, education and health care;
- multidisciplinary expert groups:
 - develop operational guidelines or a voluntary code of conduct for the introduction of access and benefit sharing procedures, building on existing WFCC guidelines;
 - develop model material acquisition agreements and material transfer agreements;
 - develop management and information systems to track acquisition and transfer of microbial genetic resources;
 - considers the possibility of establishing Registered Culture Collections to meet the access and benefit sharing provisions within the framework of the CBD;
- the legal situation with regard to ownership of microorganisms and working relationships between ratified and non-ratified countries be clarified;

- the Parties to the Convention make full use of the expert advice from the microbiological community in the development of measures and drafting of national legislation relating to access and ownership, to ensure applicability
- partnerships be encouraged between established and new microbial resource centres with the purpose of building technical and administrative capacity through training and technology transfer.

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WFCC INFORMATION DOCUMENT

Prepared by the WFCC Biodiversity Committee and the WFCC Executive Board, in consultation with a number of other expert organisations and persons from environmental law, research, teaching, culture collections and industry (Appendix 1) and with the sponsorship of the International Union of Microbiological Societies and the International Union of Biological Sciences.

In response to Document UNEP/CBD/COP/2/13, 6 October 1995, Access to Genetic Resources and Benefit Sharing: Legislation, Administrative and Policy Information, prepared by the CBD Secretariat.

I. INTRODUCTION AND BACKGROUND

I.1 AIM OF THE DOCUMENT

This document aims to provide Parties to the Convention on Biological Diversity with specialised information relating to access to ex-situ microbial resources and to make recommendations on policy developments that are conceptually sound, scientifically feasible and operationally practicable. Additionally, it will also serve to raise awareness among the Parties and others of issues that must be addressed in developing procedures for implementing these aspects of the Convention.

As well as giving background information on the importance of microbial diversity, the document provides a survey of existing microbial resource centres and current operating practices; it considers existing legislation (including the Budapest Treaty) and the special characteristics of microorganisms that affect implementation of the CBD. It addresses policy issues and makes Recommendations for the establishment of a process that will lead to clear and applicable guidelines and codes of practice for operating the CBD with regard to deposit, access and distribution of ex-situ microbial genetic resources and benefit sharing.

The World Federation for Culture Collections (WFCC) is a multidisciplinary Federation within the International Union of Microbiological Societies and the International Union of Biological Societies of the International Council of Scientific Unions (ICSU) with responsibility for relationships with microbial resource centres. It has as its objectives the overall support of the activities of microbial resource centres (Culture Collections) and the promotion of a world network for information, communication and exchange of MGRs. Additionally, it makes recommendations to national and international organisations, within its terms of reference, as deemed appropriate by the Federation.

The WFCC offers to support the CBD implementation and help its operation at the microbial level, working to ensure that requirements negotiated are practicable and likely to succeed.

I.2 DEFINITIONS [for the purpose of this document]

Microorganism: includes bacteria (including archaea and cyanobacteria), fungi (including micro- and macrofungi), algae and, in the context of this document, protozoa, viruses, plant and animal cell cultures, and includes genetic elements of the above, such as Plasmids.

Microbial genetic resources (MGR): refers to actively growing or conserved resources of the above.

Microbial resource centres: refers to laboratories that conserve MGRs and that may act as a distribution centre.

The term **Culture Collection (CC)** has been used throughout this document to avoid confusion with MGRs. [Note that a CC may range from a major international service organisation to a very small specialised collection managed by an individual].

A culture: refers to a population of microbial cells that are maintained ex-situ. A pure culture may be derived from a single cell (where this is possible); a mixed culture may contain cells that are representative of more than one species or sub-species.

An **isolate:** refers to a culture of a microorganism, named or unnamed.

A **strain:** refers to a pure culture of a named species.

A **deposit:** refers to a culture that has been made available to a CC for conservation.

A **Living Modified Organism (LMO):** refers to an organism which has been modified by means not occurring in nature to contain foreign DNA from another organism.

Ex-situ MGRs: refers to cultures of microorganisms held in a laboratory for future study and use.

In-situ MGRs: refers to microorganisms in the environment.

I.3 HOW IMPORTANT IS MICROBIAL DIVERSITY?

Without microbial activity, life on earth would not be possible. The diversity of microorganisms plays a major role in maintaining the biosphere and provides a vast and largely untapped resource for humankind. Microorganisms are to be found in every ecological niche, performing recycling roles and interacting with other living forms in ways that we are only now beginning to understand (Stackebrandt, 1994). Their total numbers are unknown and their study in-situ is difficult.

As well as their role in the environment, microorganisms play a major role in providing basic material for the development of pharmaceutical drugs, agrochemicals, bioremediation and biocontrol agents, food/drink agents, toiletries and products for

other industries. It has proved difficult to estimate the value of these resources but, as an example, the estimated annual global market for pharmaceuticals from natural resources is \$50 billion (ten Kate, 1995).

Microorganisms that are isolated from the natural (or man-made) environment are typically conserved in CCs (whether public service centres or specialised research collections). The numbers thus maintained form the basis of much of our present knowledge of microbial diversity and are the archival material for future study. They are an invaluable genetic resource, yet form a small part of the vast numbers of undescribed microorganisms.

Scientists isolating microorganisms may have a variety of objectives. They may be involved in environmental, taxonomic, agricultural or biochemical research, or be interested in screening for novel products that may have commercial value.

For the purposes of describing new taxa and to act as essential reference standards for future study and use, the conservation and accessibility of type strains (those on which the taxonomic description is based) and other representative isolates, is fundamental. Furthermore, the ex-situ conservation of all isolated microorganisms, studied and reported in the scientific literature, is also important if science is to progress. The uncertainties associated with re-isolation underline the need for deposit in a CC, providing conservation skills, ready accessibility and the provision of a conserved and unique reference number. Without this, scientists would constantly need to conduct the skilled and expensive processes of characterisation and identification at the start of each new study. Careful documentation of all conserved material is essential and the availability of such data is encouraged and supported by the WFCC.

I.4 SUMMARY OF RELEVANT CBD ARTICLES

Requirements for access to genetic resources are provided in Article 15. Readers are referred to the CBD text for the complete provisions (UNEP Web Site - <http://www.unep/ch>) and to Annex 2 for the text of the most relevant Articles, 15, 16, 17 and 19. See also the IUCN Guide to the Convention on Biological Diversity, Glowka et al, 1994, and Sands, 1994 and Glowka, 1996.

For convenience, a summary of Article 15 is provided below.

Article 15 - Access to Genetic Resources

'Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

Each Contracting Party shall endeavour to create conditions that facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and shall not impose restrictions that run counter to the objectives of the Convention.'

The article continues by specifying that the genetic resources referred to are ONLY those that are provided by Contracting Parties and that have acquired the genetic resources in accordance with the Convention.

It requires that access must be on mutually agreed terms and with prior informed consent (PIC) of the Party providing the resources. It states that research carried out on genetic resources shall be done with the full participation of, and where possible in, the country of origin. It requires that contracting parties shall take legislative, administrative and policy measures with the aim of sharing in a fair and equitable way the results of research and development arising from such research and any benefits. Such sharing shall be on mutually agreed terms.

Other relevant Articles provided in Annex 2 are:

Article 16 - Access to Transfer of Technology,

Article 17 - Exchange of Information and

Article 19 - Handling of Biotechnology and Distribution of Benefits.

II. SURVEY OF MICROBIAL RESOURCE CENTRES, CURRENT DEPOSIT AND ACCESS PRACTICES AND RELEVANT EXISTING LEGISLATION

II.1 Status of ex-situ Microbial Resource Centres (Culture Collections, CCs)

Nearly 500 CCs from 58 countries are registered with the World Data Center for Microorganisms (WDCM) database of the WFCC. This database is available to all on the Internet (Sugawara et al., 1994) (see Table 1).

These CCs may be public, private, academic, governmental or industrial. All operate according to their own institutional or governmental policies and provide a number of professional services (see Table 2). These include:

- preservation and maintenance for long-term access
- distribution
- characterisation and identification
- management and supply of data on maintained strains
- deposit facilities for patent strains
- 'safe deposit' for customers
- quality control testing
- customized microbiological testing and consultancy
- supply of standard strains - relevant research
- training.

Many other CCs exist that are not registered with the WFCC database. These may be private or institutional, transient or permanent. They may exist to provide local services or may offer specialist support.

Not all countries have CCs competent to maintain all kinds of microorganisms. Therefore, MGRs may be isolated in one country and deposited in a CC in another. Further, some CCs specialise in certain taxonomic groups or technical skills and play an international role in these areas.

The WFCC has no legal authority over any of its member collections. The CCs are united on a voluntary basis and through common interests, but are independently administered. They form an informal network. The same is true of the Microbial Resource Centres (MIRCENs), some 20+ laboratories established over the years by UNESCO, to act as regional laboratories providing training and resources. Not all MIRCENs distribute MGRs; those that do are affiliated to the WFCC.

Table 1. Culture collections: the overall situation. Numbers of collections registered with the WDCM in each country.

Country	N. of Collections	N. of Cultures
Asia		
China	13	30,181
India	12	7,763
Indonesia	14	2,182
Iran	1	496
Israel	2	576
Japan	23	50,767
Jordan	1	19
Korea (Republic of)	2	6,695
Malaysia	3	774
Pakistan	1	200
Philippines	8	3,156
Singapore	2	1,572
Sri Lanka	4	220
Thailand	59	11,694
Turkey	2	1,739
Total:	147	118,034
South America		
Argentina	7	6,910
Brazil	44	10,980
Chile	1	174
Colombia	1	3,961
Venezuela	1	150
Total:	54	22,175
North & Central America		
Canada	28	48,249
Guatemala	1	256
Mexico	10	4,681
USA	31	188,248
Total:	70	241,434
Oceania		
Australia	50	64,313
New Zealand	9	13,740
Papua New Guinea	1	270
Total:	60	78,323
Africa		
Egypt	1	880
Kenya	1	205
Nigeria	3	825
Senegal	2	399
South Africa	3	4,800
Uganda	1	550
Zimbabwe	2	702
Total:	13	8,361

Country	N. of Collections	N. of Cultures
Europe		
Austria	1	1,570
Belgium	5	37,000
Bulgaria	3	7,403
Czech	15	17,040
Denmark	2	13,290
Former Fed. Yugoslavia	2	209
Finland	2	2,240
France	15	30,639
Germany	14	23,062
Greece	4	2,065
Hungary	6	6,037
Ireland	2	987
Italy	2	8509
Netherlands	8	46,668
NIS (Former USSR)	10	28,011
Norway	2	2,170
Poland	5	4,266
Portugal	1	1,400
Romania	1	63
Slovenia	1	500
Spain	2	5,294
Sweden	4	44,435
Switzerland	1	2,700
UK	25	61,683
Total:	140	347,241
Grand Total:	484	815,568 *

* This figure includes duplicates held in different collections as a result of multiple deposit for security purposes or, in the case of type or standard strains, for convenience.

[From data supplied by the World Data Center for Microorganisms, Riken, Japan for publication in 'Microbial Diversity and the Role of Microbial Resource Centres'(WFCC, eds. Kirsop, Hawksworth, 1994).]

Note: These data only represent the situation of collections that have registered with the WDCM. The numbers of collections so registered may reflect the enterprise of individuals in stimulating registration, or the existence of regional initiatives in microbial systematics. These figures do not necessarily show the complete situation and many non-registered collections exist. The reason for non-registration may reflect reluctance to promote holdings, the remit of the laboratory being primarily for research or in-house activities rather than the provision of a supply service.

Culture Collections

There are 484 culture collections in 58 countries registered with the WDCM (1994). The Table is compiled from information supplied by the CCs.

- 188 of them state they are supported by government*.
- 28 of them state they are semi-governmental.
- 142 of them state they are supported by universities.
- 6 of them state they are supported by industry.
- 21 of them state they are private. * one such collection (International Mycological Institute) is intergovernmental.
- 96 collections produce catalogues of holdings. 1680 people work in these culture collections.

Cultures Held

There are 815,568 cultures of microorganisms held in the registered collections.

- 343,253 of them are bacteria, including archaea.
- 372,304 of them are filamentous fungi.
- 14,370 of them are viruses.
- 5,156 of them are cell lines.
- 80,485 of them are other kinds of microorganism.

Services provided in addition to regular maintenance. [See Table II for details and proviso]

- 45 provide patent deposit services.
- 128 provide storage services for customers.
- 145 provide distribution services.
- 211 provide identification services.
- 128 provide training services.
- 115 provide consultation services.

Table II. Services provided in addition to regular maintenance.

Numbers of Collections Providing	Pat.	Stor.	Dist.	ID.	Train.	Cons.
Africa						
Egypt	-	1	-	1	1	1
Kenya	-	-	-	-	-	-
Nigeria	-	1	2	1	1	-
Senegal	-	1	1	1	-	1
South Africa	-	-	2	1	2	-
Uganda	-	1	1	-	-	1
Zimbabwe	-	-	1	1	-	2
Asia						
China	2	8	7	6	4	6
India	-	1	7	3	1	2
Indonesia	1	7	7	2	6	6
Iran	-	1	1	1	1	1
Israel	-	-	1	-	-	-
Japan	2	6	4	10	5	3
Jordan	1	1	1	1	-	1
Korea (Republic of)	2	2	2	2	2	2
Malaysia	-	-	2	-	-	-
Pakistan	-	1	1	-	1	1
Philippines	-	1	3	6	3	3
Singapore	-	-	-	-	-	1
Sri Lanka	-	2	4	1	1	3
Thailand	-	1	3	-	-	1
Turkey	-	1	2	-	1	2
Europe						
Austria	-	-	-	-	-	-
Belgium	1	4	4	4	3	4
Bulgaria	1	2	2	1	1	2
Czech	7	5	7	8	6	7
Denmark	-	1	2	1	1	1
Former Fed Yugoslavia	-	-	-	-	-	-
Finland	-	1	1	1	1	1
France	5	7	9	8	6	6
Germany	1	1	9	1	2	1
Greece	-	2	3	1	1	2
Hungary	1	1	2	1	1	1
Ireland	-	-	-	1	-	-
Italy	1	2	5	3	3	3
Netherlands	1	1	4	1	2	1
NIS (Former USSR)	3	5	4	6	5	4
Norway	-	-	1	-	-	-
Poland	-	-	1	2	2	1
Portugal	-	-	1	-	-	1
Romania	1	1	-	-	-	-
Slovenia	-	1	-	1	1	1
Spain	1	1	1	1	1	1
Sweden	-	1	2	2	1	1
Switzerland	-	-	1	-	-	-
UK	8	10	15	12	8	7

Numbers of Collections Providing	Pat.	Stor.	Dist.	ID.	Train.	Cons.
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Oceania

Australia	1	11	22	10	9	12
New Zealand	-	4	7	4	6	3
Papua New Guinea	-	-	1	-	-	-
Numbers of Collections Providing	Pat.	Stor.	Dist.	ID.	Train.	Cons.

North America

Canada	-	9	11	15	3	5
Guatemala	-	-	1	-	-	-
Mexico	2	4	9	3	4	5
USA	2	8	15	9	10	8

South America

Argentina	-	3	4	3	2	3
Brazil	1	7	13	8	6	9
Chile	-	-	1	-	-	-
Colombia	-	-	-	1	-	1
Venezuela	-	-	1	-	1	-

Pat - Patent depository; Stor - Storage service; Dist - Distribution; ID - identification service; Train - Training offered; Cons - Consultation service.

Note: some services may be provided for specific categories of users, for payment only or for in-house purposes only.

II.2 EXISTING OPERATING PRACTICES AND DEPOSIT AND DISTRIBUTION POLICIES

Current operating practices are not legally imposed, but have common features throughout all CCs. They are dictated mainly by the scientific requirements of the microorganisms held, but also depend on the policy of the parent organisation. The WFCC has published Guidelines to the Establishment and Operation of Collections of Cultures of Microorganisms (Hawksworth, 1993) and runs training programmes on collection management.

a) DEPOSIT:

Cultures are deposited in CCs for a number of reasons. The majority of deposits are made by scientists who wish to ensure that their work (recorded in scientific publications) can be perpetuated and their experiments repeated and developed by others in the interests of scientific progress. It is essential that specific source microorganisms are maintained for future study since other isolates of the same species may show different experimental results. CCs have the skills and facilities to provide this service. Such strains are deposited without any restrictions imposed by the depositor with regard to their future distribution.

Important examples of such deposits are type strains (on which descriptions of species are based) and reference strains (for quality control or other testing purposes). Again, these deposits are made for the future benefit of microbiology, particularly taxonomy, and access is unrestricted. The ready availability of essential reference material is fundamental to scientists in all regions of the world.

Other cultures may be deposited for safe-keeping for industrial purposes. Because of the ease with which a population of microorganisms may change during growth in a laboratory, special measures must be taken to eliminate 'strain drift' in important production strains. CCs have long experience in professional culture maintenance leading to stability of properties.

Yet other cultures may be deposited for patent purposes (see II.4, below) and certain collections are registered as International Depositary Authorities for this purpose.

b) DISTRIBUTION:

Subject to national and international safety regulations, and apart from exceptions noted below, most cultures held in public collections are made available to any applicant, regardless of country and usually without knowledge of the ultimate use.

There is a common, implicit and unwritten agreement that CCs maintain the MGRs as a service to the scientific community for future research and application. This attitude has somewhat changed recently as a number of collections are obliged by their States or governing bodies to recover costs and so have adopted a more commercial approach to the distribution of cultures.

The user-community is composed of research scientists in universities and institutes, educational establishments (mainly in higher education) and industrial users. The distribution of supplies to these categories depends greatly on the remit of the CCs, but it is common for service supply CCs to distribute approximately 33% to commercial organisations and 66% to academic research and teaching organisations.

Charges may or may not be made for the supply of cultures. The policy adopted is a matter for each parent organisation. There is no international agreement regarding the imposition of charges or policies made for charges to different categories of user (profit or non-profit, national or non-national, for example). In general, however, the service culture collections adopt similar policies and practices, often coordinated by national or regional bodies or advised by the WFCC through its publications (Hawksworth, 1993).

There are generally no restrictions on end use and knowledge of this is not required before distribution. It is uncommon for material transfer agreements to be made (although some of the major collections are introducing general sales agreements). Restrictions on distribution are generally only imposed as a result of international agreements (eg., shipping regulations, health regulations, Patent Treaty). Categories of MGRs so affected are:

a) strains that are part of a patent procedure (see II.4 below), or that have been deposited for safe-keeping as industrial production strains or for other purposes. Such strains are not generally accessible and special application is required. In the case of patent deposits under the Budapest Treaty, release forms are provided and evidence of legal entitlement is required.

b) pathogens. Such strains are usually made available only to registered users and orders must generally be made on official paper bearing a registered signature. Distribution of such microorganisms by the major service collections is strictly controlled, but the

ultimate responsibility rests with the recipient to meet their national quarantine laws before requesting the culture. The provision of LMO's may be subject to regulatory provisions (Shipping of Infectious, Non-Infectious and Genetically Modified Biological Materials, Rohde and Claus, 1994).

c) strains collected by the CC for its own internal purposes.

There is no formal international agreement existing or being negotiated similar to the International Undertaking on Plant Genetic Resources. Rather, there is a general consensus on operational matters, and broadly similar practices are adopted.

II.3 THE SPECIAL CHARACTERISTICS OF MICROBIAL GENETIC RESOURCES AFFECTING IMPLEMENTATION OF ARTICLE 15

CCs have been established for different periods of time, some for very many years (Sly, Iijima, Kirsop, 1990), as a service to the international scientific community (Sly, 1994; Da Silva, Kalakoutskii & D-K Song, 1993). Their collections exist as a result of deposits made by scientists or of cultures collected by the CCs themselves for future use by the scientific community in research and teaching or for commercial or non-commercial application. Deposits in a single collection may be made by scientists from a wide range of countries and organisations; furthermore, a single isolate may be deposited in collections in more than one country to facilitate ready access or for back-up purposes.

Microorganisms have distinctive features that distinguish them from plant or animal genetic resources. These characteristics suggest the need for policies, agreements and institutional arrangements for access and benefit sharing for microbial resources that may differ from those of other categories of genetic resource. The specific characteristics of relevance are:

- MGRs replicate frequently (sometimes every 30 minutes), leading to changing populations both in the environment and during conservation; if not expertly preserved ex-situ this can lead to genetic and phenotypic instability ('strain drift') and a failure to conserve the original sample (Smith and Onions, 1983, Kirsop and Kurtzman, 1988);
- because of their microscopic size, vast numbers and high speed of replication, microbial genetic resources cannot be accurately enumerated; there can be no microbial 'base line' for inventorying purposes. They may be transferred across borders by wind, water, the movement of animals or human intervention;
- because of their microscopic nature, MGRs cannot be tracked and monitored conventionally; they cannot be readily finger-printed for authentication purposes, although this could become a valuable technical tool in the future. Scope for piracy exists unless universally accepted procedures are developed and adopted (as with the Budapest Treaty, 1977);
- for many bacterial, viral, micro-algal or yeast species, it is unlikely that sampling would lead to species depletion. However, the loss of hosts on which microorganisms depend could lead to the loss of the dependent microbial species. Moreover, the depletion of certain fungal species occurring in unique habitats is known to have taken place and 8% of fungal species are endangered;

- the occurrence of many bacterial and yeast species is recorded in a number of geographical locations, but our knowledge in this area is still very slight (Stackebrandt, 1994). Few such species occur only in one country, although those found in unique or environmentally challenging habitats are dependent on the survival of the habitat;
- within a population of microorganisms in the environment, each isolate of a species may show slight genetic variation from isolates of the same species from similar habitats in other countries - or even from isolates from the same habitat at different times. The isolate is therefore often of considerable significance in terms of genetic expression and many isolates of the same species may be held in a collection for taxonomic or screening purposes; there are species that have only been isolated on one occasion;
- although many new species may be expected to be discovered in gene-rich countries, the same is true of industrial regions (particularly polluted regions) where microorganisms may develop commercially valuable properties in response to environmental stress. Developed and developing countries may therefore have equal interest in collecting and preserving local isolates;
- MGRs require special equipment, technologies and taxonomic skills for their study; their study and conservation are specialised activities (Kirsop & Doyle, 1991).

Typically, microorganisms are isolated, identified, studied, deposited, maintained (conserved in CCs) and distributed to the user community. Many individuals are involved in the transfer of the MGR from habitat to end use.

Records of depositors and information on taxonomic and other properties of isolates are generally well kept, often computerised. However, in the case of early deposits, information on the persons involved in the isolation and identification and even the country of origin of deposits may not have been recorded. It should be noted that microbial research - particularly microbial ecology and microbial systematics - is often carried out by collaborating experts from several countries so that collaborators may be multinational and numerous.

In general, records in national/international service supply collections are more complete than those in-house research collections.

Each microorganism held in major CCs is allocated a unique identifying code (eg, DSM1045, IMI20567). The code consists of the acronym of the CC (which for CCs registered with the WFCC database is also unique), followed by a number. This strain identifier remains constant even if future taxonomic studies require nomenclatural changes. Once a culture is distributed by a CC to a third party there is no control over the continued use of its identity code, which could be changed by the recipient for internal reasons. This may have tracking implications and as the official strain code number may be the sole means of validating eventual benefits, its use should be encouraged. The history and ownership of a strain without an official designation will be less readily accepted in CBD agreements.

II.4 EXISTING LEGISLATION ON ACCESS AND DISTRIBUTION OF EX-SITU MICROBIAL RESOURCES - THE BUDAPEST TREATY FOR THE DEPOSIT OF MICROORGANISMS AND INTERNATIONAL DEPOSITORY AUTHORITIES FOR PATENT PURPOSES

Existing legislation affecting access to and distribution of ex situ microorganisms relates primarily to the control of hazards to people and the environment (for example, EC Directive 90/679/EEC), to transport of microorganisms (Rohde and Claus, 1995) and to quarantine regulations.

Legislation directly affecting access to microorganisms occurs in the Budapest Treaty for the Deposit of Microorganisms for the purposes of Patent Deposit, which came into force in 1980. Under the Treaty, if a patent includes the use of a microorganism, the microorganism forms part of the patent disclosure and must be deposited in an International Depository Authority (IDA).

A number of procedures must be followed both by the depositor and the IDA regarding its deposit and future distribution. These requirements are laid down in the Budapest Treaty and explained in further detail in the Guide to the Deposit of Microorganisms under the Budapest Treaty (WIPO, regular updates). Access to microorganisms deposited for patent purposes is regulated according to the patent system under which the application was filed.

Countries recognize certain national CCs as IDAs for the purpose of the deposit of strains that are the subject of patents. IDAs may accept for deposit the kinds of microorganism for which they have accepted obligations at the time of applying for IDA status, and in which they have expertise. They maintain strains in a viable condition for the life of the patent to the best of their ability. However, should the deposit die, it is the responsibility of the depositor to replace it. IDAs and their clients are kept informed of requirements and changes in procedures by circulars from the World Intellectual Property Organisation in Geneva. A number of publications exist providing information for IDAs on the administration of the Budapest Treaty (Bousfield, 1991; Fritze, 1994; Crespi, 1988).

IDAs are generally appointed by the government of the country in which they reside. They generally obtain IDA status as a result of long experience in culture maintenance, and almost all maintain many non-patent deposits as well.

The system is well established and is successful at the operational level.

II.5 RESEARCH, TRAINING AND CAPACITY BUILDING

CCs carry out essential research in the fields of taxonomy, systematics, culture preservation (freeze-drying, cryopreservation etc) and database software development and may also have specialist activities relevant to the parent institute. Staff need a high level of training and must be skilled in the use of modern equipment.

Collaborations between CCs and other research groups are common and are often based on regional developments or international programmes. Alternatively, a CC may forge a bilateral relationship for a research project with an industrial or university group as the

partner. Such projects may be funded nationally, through international funding agencies or industries.

CCs run training courses at the national or international level, at their own institutes or in other countries under the sponsorship of such organisations as UNESCO, UNEP and other funding organisations or from private sponsorship, and often in collaboration with the WFCC or regional culture collection federations.

Databases and networks are well established and in the major CCs information is organised at a high technical level. Catalogue information of some CCs is available on the World Wide Web, and data on strain properties is increasingly computerised and networked (Edwards, et al., 1995).

Collection staff develop guidelines and generally work to disseminate their knowledge, transfer technology to those requesting training support and contribute to scientific papers and books.

The WFCC has a strong training element in its programmes and has been responsible for many training courses, customised individual training and development of technical information sheets and other publications. A number of regional federations and individual collections have similar programmes.

III. POLICY CONSIDERATIONS ARISING FROM THE CBD ARTICLES WITH RESPECT TO ACCESS TO EX-SITU MICROORGANISMS AND THEIR DISTRIBUTION

III.1 MGRs that are covered by the Articles of the CBD

Microbial genetic resources acquired prior to the Convention's entry into force and those provided by a country of origin that is not a Party to the Convention, are not covered by the Convention's benefit sharing provisions. Nevertheless, there would be some practical difficulties in ascertaining which ex-situ MGRs are covered by the CBD and how.

The uncertainty arises because of the need to know both the status of each country of origin regarding ratification of the CBD and the date on which a microorganism was collected, isolated and/or deposited in a CC for conservation. Because of nomenclatural changes, transfers between scientists and the long history of many of the CCs (100 Years of Culture Collections, Iijima et al., 1990), the necessary information may not always be easy to track and may not be available to the CC whose role it will be to decide whether or not a deposit is covered by the CBD and what distribution policies apply.

Wide and unrestricted access should be guaranteed to all type strains (on which the description of the species is based), reference strains and databases. This is essential for taxonomic studies, to encourage nomenclatural stability and allow tracking of any name changes and, therefore, MGRs. In addition, publicly accessible databases should be built.

III.2 Legal Status: sovereign rights and ownership

The CBD acknowledges sovereign rights of a Party over genetic resources within its jurisdiction. While it is necessary to be able to ascertain the country of origin of isolates that may lead to benefits for that country, the question of ownership of genetic resources is not addressed by the CBD (Glowka et al.). It is not known to what extent national laws cover the ownership of MGRs (both in-situ and ex-situ), but this is thought likely to be complex and differ from country to country. For example, since the isolation of a specific type of microorganism may involve the collaboration of a number of experts - who may separately isolate, characterise, identify, screen, preserve, store, distribute the MGR and who may be located in different States each with a different ratification status - the different rights and obligations of these individuals may need to be clarified if benefit sharing is to be considered.

From the above, the following points arise:

1. It will be necessary to determine whether ownership of microorganisms is covered by national law in the countries of origin, since the terms of access may depend on this knowledge.
2. In many cases, species of microorganisms are not found in a single location, but in several other locations of a similar nature as well. Therefore, one species of microorganism found in the territory of one Party may also be found in the territory of

another Party. It may be technically difficult to prove that an isolate is from a specific country.

3. Microorganisms may easily be transferred across borders, either wittingly or unwittingly. It is almost impossible to track and therefore control such movements.

4. As only MGRs provided by CCs in Contracting States will be affected, the situation that applies when MGRs are provided from a Contracting Party to a non-Contracting Party, or from a non-Contracting Party to a Contracting Party must be clarified. Moreover, it is uncertain if requirements are affected in cases where the MGR has been deposited by a Contracting Party into a CC located within the territory of a non-Contracting Party.

5. The rights of indigenous and local communities over MGRs located within their territories, as well as their knowledge, innovations and practices associated with MGRs, should be recognized.

III.3 Administrative procedures

Information normally supplied to the CC is seldom adequate for the implementation of the CBD. It will be necessary for the CCs to receive fuller information relating to any deposit made in order to meet distributional obligations of the country of origin and the country in which the CC is located. The procedural requirements of the CCs are not clear at present and CC staff are not well informed about such requirements.

The final uses to which a distributed MGR may be put is generally not known to CCs and may not be known to the end user at the time of request, since the importance of a strain may only be recognised following further study on it or related isolates. Further, the user may be unwilling to divulge the envisaged end use. It follows that since the application of the microorganism for environmentally sound use is unknown to CCs, this requirement of the CBD is unlikely to be enforceable by the CCs.

It will be necessary for depositors and CCs within Parties to provide and keep accurate and complete records of dates of deposit and origin of isolates so that the requirements of the CBD are not violated inadvertently.

It will be necessary for procedures to be adopted in the case of the death of a microorganism covered by the CBD, and any need for it to be replaced. As is the case with the Budapest Treaty, such requirements must recognise the fact that it is often difficult to maintain certain microorganisms ex-situ. Account must also be taken of the difficulties arising with contaminated or mixed cultures. Furthermore, CCs must retain the right to cease to maintain a deposit (for a number of legitimate reasons) and provision must be made to allow for the notification of such action and the implementation of appropriate transfer arrangements, if deemed necessary.

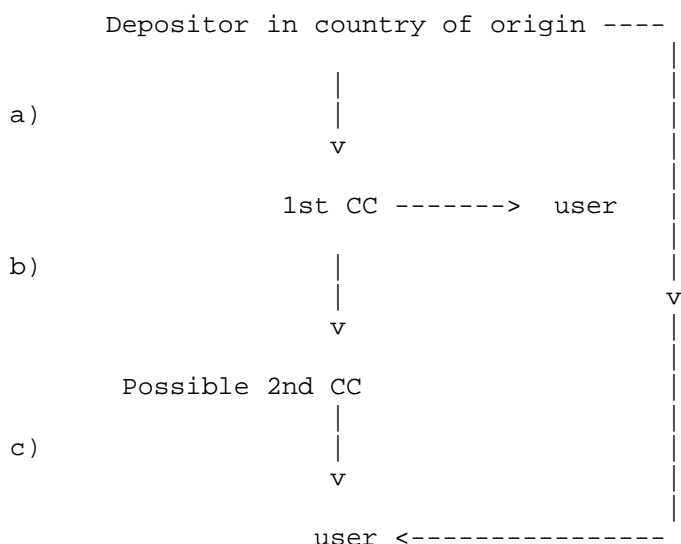
It will be necessary for safety requirements to be met within the CBD operations and for national regulations to be observed. Thus, the distribution of an MGR that is also a pathogen or a LMO, will be regulated both by the CBD and the national/international safety regulations. These will need to be harmonised.

III.4 ELEMENTS FOR INCLUSION IN AGREEMENTS RELATING TO ACCESS TO MICROBIAL GENETIC RESOURCES AND BENEFIT SHARING

A number of parties are likely to be associated with the sustainable exploitation of microorganisms, which involves isolation, purification, identification, preservation, documentation and distribution to users. At each stage, a number of individuals/organisations/states may be involved.

The three basic groups involved in the process are 1) depositors (who may or may not come from the country of origin of the culture, and who may or may not be the collector), 2) culture collections (where more than one may be involved) and 3) users (which may be commercial or non-commercial). It should be noted that in some cases the CCs will also be the depositor. The nature of Agreements between these groups will differ, but all should include clauses relating to possible benefit sharing, access to information and respect for the initial agreement with the country of origin.

Flow diagram to show the movement of a culture from country of origin to end user:



Specific points for arrangements between a, b and c are as follows:

a) Between the depositors and CCs:

1. Agreements will have to be made between depositors and CCs to ensure that possible future benefits deriving from any development of an isolate for commercial purposes take into account the rights of the country of origin and also the efforts of the CCs in maintaining the MGR. Such arrangements should be fair and should not inhibit the essential deposit of material for future scientific study. It is important that continuing deposit be encouraged and that barriers to this are not introduced through the need to comply with the requirements of the CBD.

It is likely that individual CCs will draw up such agreements at the national or institutional level, but there may be advantage in developing internationally acceptable guidelines of elements that should be included in such agreements. Additionally, if a

system of registration is introduced, registered CCs could adopt pre-negotiated global agreements that protect their interests and those of the depositors.

b) Between CCs

In cases where culture collections in the country of origin lack the technical competence for taxonomy and maintenance, partnerships (twinning arrangements) will be required to be made while skills are developed. A network of taxonomic expertise residing in collections in different countries may be needed and agreements between culture collections will be required. Agreements between CCs should respect the agreements made between the depositor and the original CC and appropriate financial arrangements will need to be made between the partner collections involved.

c) Between CCs and users

Elements for inclusion in such agreements depend on knowledge of the origin of the isolate so that all parties derive appropriate benefits, and that arrangements for the repatriation of information and sharing of research results can be addressed.

Elements considered to be important for inclusion in agreements for benefit sharing are:

- Capacity building: research, training, exchange of scientists; collaborative projects; the ability to work directly with scientific groups;
- Technology transfer: in, for example, isolation, characterisation, identification, taxonomy, screening techniques; - Donation of equipment: this should always include an element for training in use and repair. Equipment should be donated for which the manufacturer has a national presence so that maintenance is possible;
- Access to information on MGR's by country of origin: the level of information transfer should be decided during negotiation of agreements. Publicly available databases are important and should be accessible by all parties.
- Up-front payment for equipment, staff costs, materials.
- It should be ensured that remuneration is paid to the appropriate parties within the country of origin (such as the institute which is to carry out the work).
- Contractual arrangements: the meaning of exclusivity, confidentiality, termination and royalty payment arrangements should be made clear to those unused to them. Although such arrangements are likely to be bilateral, there should be guidance for developing countries on, for example, the realistic levels of royalties to expect and the advantages and disadvantages of such agreements. Model contracts could be developed and these and general guidance made available through the CBD Clearing House Mechanism.
- As the economic value of samples is very debatable, a basic guide could be developed to aid those unused to such negotiations, based on experience of agreements that have succeeded.

The key information requirements with all the above agreements are:

* date of collection of the MGR

* country of origin

* date the CBD came into force in the countries involved.

(Footnote: CBD came into force 29 December 1993)

III.5 SPECIFIC POINTS TO CONSIDER REGARDING IN-SITU MICROBIAL RESOURCES

The distinctive features of microbial growth and activity are such that in-situ conservation is difficult and uncertain. Microbial populations are dynamic and continually responding to environmental changes on a far greater scale than with other organisms. It is therefore not necessarily productive to try to conserve such populations, particularly in the case of prokaryotes, even were such a thing possible. However, there are cases where conservation in-situ is important (eg salt lakes, mycorrhizal fungi that have inhabited unique sites for very many years, and so on) and of greater importance than ex-situ conservation.

The major need with regard to microorganisms in the environment is for greater study and an increase in knowledge of the interactions between the micro- and macroflora of the environment. Currently, our knowledge is very limited.

Technology is now developing to make it possible to conserve (by cryopreservation) cores of soil samples. These have the benefit of recording microbial populations at a point in time, for future study.

It seems unlikely that sampling will deplete microbial diversity, except in cases where microorganisms are habitat- specific or host-dependent.

When considering the conservation of microorganisms within the framework of the CBD, ex-situ conservation is the more important operational policy.

IV SPECIFIC RECOMMENDATIONS LEADING TO THE DEVELOPMENT OF A PROCESS FOR THE IMPLEMENTATION OF THE CBD WITH RESPECT TO MICROORGANISMS

The WFCC and other experts contributing to this document make the following Recommendations.

Recommendations 1 - 4 address the overall importance of access to research and educational material, and the need for resources worldwide; recommendations 5 - 8 make suggestions for the development of a voluntary code of practice (or guidelines), the establishment of registered collections and the development of standard documentation, all of which should be considered further by expert groups with a view to establishing a framework for governments to address the issues at the national level.

It is recommended that the Parties make full use of WFCC expertise, specifically with regard to capacity building, training programmes, taxonomic knowledge, conservation skills, access to established databases and advice through the implementation and development of the existing WFCC Guidelines (Annex 2, WFCC Documents).

[1] CCs and the microbial resources they hold are essential for nature conservation, research and industrial applications for the benefit of humankind.

Disease surveillance and control must continue unimpaired and requires access to MGRs and related information.

Access for such purposes is fundamental and should not be impeded, provided that it is in conformity with the CBD and intellectual property rights.

RECOMMEND that access to ex-situ microbial resources remains unimpeded for the purposes of education, research, industrial applications, taxonomy and health care (animal, plant and human) in accordance with Article 15(2). Administrative procedures required to determine rights should not obstruct the exchange of essential material.

[2] There is a need to conserve existing and future isolates of microorganisms ex-situ, to facilitate exchange and build specialist scientific capacity in all countries. However, it is not feasible to establish CCs competent in all microbial groups in all contracting States and the financial implications of establishing culture collections should be recognised (Hawksworth, WFCC Guidelines for the Establishment and Operation of Microbial Resource centres, 1993).

Partnerships with established CCs or expert research groups should be encouraged on the understanding that training and information would be exchanged and agreements forged that will protect any rights that might accrue to the Parties concerned. Such partnerships may lead to permanent sharing of knowledge and resources as capacity is developed in the newly established CCs.

RECOMMEND that appropriate partnership arrangements between established and emerging CCs be encouraged, with emphasis on training in technical and administrative capacity, and with the development of agreements to ensure benefit sharing between the

partners. Collections should be established in countries of origin where appropriate, but should take into account the network of expertise already existing.

[3] The involvement of the microbiological community in negotiation of further measures under the umbrella of the CBD and in drafting of national access legislation should be sought to ensure that decisions made by legal authorities are practicable. [Note: the input of microbiology experts proved critical to the successful negotiation process of the Budapest Treaty]. Legal advice on issues relating to the ownership of microorganisms is required, since this will arise in many access-related decisions.

RECOMMEND that expert advice from the microbiological community is sought in the development of measures and drafting of national legislation relating to access and ownership, to ensure applicability.

[4] Uncertainties regarding the arrangements to be made between States that are Parties to the Convention and those that are not should be clarified. With present uncertainties, the CCs will be unable to devise operating procedures that ensure compliance with the CBD.

RECOMMEND that relationships between contracting and non- contracting states be resolved so that operating procedures may be developed by the CCs.

[5] In order to assist CCs to comply with the provisions of the CBD for benefit sharing, appropriate guidelines or procedures for access to and provision of MGRs should be developed. Parties may wish to consider the need for guidelines or a code of conduct for CCs containing elements on prior informed consent (PIC), mutually agreed terms and benefit sharing. Such guidelines could build upon the existing guidelines for the establishment and operation of collections of cultures of microorganisms (Hawksworth, 1993). The standards contained in these guidelines could be used as a basis for the development of legally binding material transfer agreements (MTAs).

This process could have parallels with the multilateral system for the exchange of plant genetic resources for food and agriculture (MUSE) now under consideration by a number of organizations (IPGRI Feasibility Study on access and benefit sharing, 1996). This study explores different options for access and benefit sharing arrangements, which may provide some useful analogies for microbial resources.

RECOMMEND the establishment of a multidisciplinary expert group to provide assistance and expertise in drawing up operational guidelines (or a voluntary code of conduct) for CCs to incorporate access and benefit sharing procedures, building on the existing Guidelines [see WFCC Documents, Appendix 3].

[6]. Because of the characteristics of microorganisms and the difficulty of tracking their movement, the development of standard minimum terms of agreement between depositors, collections and end-users would greatly assist access arrangements and the distribution of benefits. The development of model agreements such as model prior informed consent (PIC) acquisition agreements and material transfer agreements (MTAs) could be helpful to CCs, reducing unnecessary duplication of effort and minimising costs.

RECOMMEND that the experts' group develop model material acquisition agreements (including PIC) and material transfer agreements (MTAs).

[7]. In order for CCs to be able to fulfil the conditions in material acquisition and transfer agreements, they need to record and track information related to access. Essential minimum information for inclusion in all documents are: date of collection, date of isolation, country of origin, CBD status of country of origin, names and location of all individuals/organizations involved in the process, taxonomic identity of sample (where known) and current and prior CC accession numbers of isolates. Consideration could be given to the need to establish PIC at the time of deposit.

RECOMMEND that CCs should consider how to establish management and information systems to track the acquisition and transfer of MGRs.

[8]. The Parties may wish to consider the possibility of progressively establishing Registered Culture Collections for the purpose of facilitating the access and benefit sharing provisions of the CBD (ten Kate, 1996). Registration would require that certain standards are met and would confer certain obligations on the CCs, but at the same time provide a number of benefits in terms of pre-arranged export/import authorization, pre-negotiated benefit arrangements, national status and so on. Parties could draw upon the experience, standards and quality controls applied by IDAs to establish and operate such a system.

RECOMMEND that an expert group consider the possibility of establishing Registered Culture Collections to meet the access and benefit sharing provisions within the framework of the CBD.

V ANNEXES

ANNEX 1 - CONTRIBUTORS TO THE PREPARATION OF THE INFORMATION DOCUMENT:

a. Preliminary document

WFCC Officers:

- L Sly, President (Australia)
- V Canhos, Vice President (Brazil)
 - * President WFCC as from 28/8/96
- D Fritze, Secretary (Germany)
 - * Vice President as from 28/8/96
- D van der Mei, Treasurer (Netherlands)

WFCC Biodiversity Committee:

- V Canhos, BDT (Brazil)
- R Colwell, University of Maryland (USA)
- B Kirsop, Bioline Publications (UK) [Chair]
- D Hawksworth, IMI (UK)
- M Goodfellow, University of Newcastle (UK)
- U Simizu, Tokyo (Japan)
- E Stackebrandt, DSM (Germany)

Other Experts:

- L Anker, Novo Nordisk (Denmark)
- J Barton, Stanford University (USA)
- D Claus, Past President WFCC (Germany)
- A Doyle, ECACC (UK)
 - * Secretary WFCC as from 28/8/96
- F Fox, Consultant (UK)
- R Gamez, INBio (Costa Rica)
- L Glowka, IUCN (Germany)
- J Hunter-Cevera, Cetus (USA)
- L Kalakoutskii, VKM (Russia)
- K Komagata, Consultant (Japan)
- R Mackenzie, FIELD (UK)
- Y-H Park, KTCC (Korea)
- P Sands, FIELD (UK)
- H Sugawara, WDCM (Japan)
- J Tiedje, University of Michigan (USA)
- K ten Kate, Consultant, Kew (UK)
- G Zavarzin (Russia)
- WHO
- + Members, Forum for Industrial Microbiology (FIM)

- + a number of curators of CCs

b. Additional Workshop participants, Veldhoven, Netherlands, August 30/31st 1996.

- M Ainsworth (Xenova, UK)
- L V Amador (CGEB, Cuba)
- C Babcock (CCFC, Agriculture and Agri-Food Canada)
- R Camacho (ESPO, Ecuador)
- A Cimerman (MZKI, Slovenia)
- T Dando (NCIMB, UK)
- J de Brebandere (BCCM, Belgium)
- P Desmeth (BCCM, Belgium)
- M Engels (Univ. Hamburg, Germany)
- D Fritze (DSMZ, Germany)
- N.Gunde-Cimmerman (MZKI, Slovenia)
- H Gurtler (Novo Nordisk, Denmark)
- B Holmes (NCTC, UK)
- L H Huang (Pfizer Inc. USA)
- I Kurtboke (AMRAD, Australia)
- G P Manfio, (CCT, Brazil)
- N Mateo (INBio, Costa Rica)
- S N Nadkarni (Hoechst-Marcon Roussel, India)
- B Parodi (Interlab, Italy)
- M Sasa (Novo Nordisk, Denmark)
- I Sedlacek (CCM, Czech Republic)
- D Smith (IMI, UK)
- M-L Suihko (VTT, Finland)
- W Untereiner (MUCL, Belgium)
- J van der Toorn (UTD, Netherlands)
- E Wellington (Univ. Warwick, UK)

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- Biodiversity Information Network (BIN21)
<http://www.bdt.org.br/bdt/english/>
- INBio Home Page
<http://www.inbio.ac.cr/>
- IPGRI Documents
<http://www.fqo.org/forms/e/96/06/more/access-e.htm>

See also numerous WWW References in Edwards' publication, above.

ANNEX 3 - SPONSORS OF THE WORKSHOP

- BioMerieux
- European Collection of Animal Cell Cultures
- European Union, DGXII
- International Union of Biological Sciences
- International Union of Microbiological Societies
- Novo Nordisk AS
- Pfizer Incorporated
- Smith Kline Beecham

ANNEX 4 - CBD ARTICLES Articles 15, 16, 17 and 19 of the Convention on Biological Diversity)

Article 15. Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16. Access to and Transfer of Technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Article 17. Exchange of Information

1. The Contracting Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries.

2. Such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1. It shall also, where feasible, include repatriation of information.

Article 19. Handling of Biotechnology and Distribution of its Benefits

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

ANNEX 5 - ABBREVIATIONS

[Individual Culture Collection acronyms not included]

CBD - Convention on Biological Diversity

CC - Culture Collection

COP - Conference of the Party

FIELD - Foundation for International Environmental and Legal Development

FIM - Forum for Industrial Microbiologists

ICSU - International Council of Scientific Unions

IDA - International Depository Authority

INBio - National Biodiversity Institute of Costa Rica

IUCN - The World Conservation Union

LMO - Living Modified Organism

MGR - Microbial genetic resource MIRCEN - Microbial Resource Centre

MTA - Material Transfer Agreement

PIC - Prior Informed Consent

UNEP - United Nations Environment Programme

UNESCO - United Nations Educational, Scientific and Cultural Organisation

WDCM - World Data Center for Microorganisms

WFCC - World Federation for Culture Collections

WHO - World Health Organisation *

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