MIRRI
MICROBIAL RESOURCE RESEARCH INFRASTRUCTURE

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Your ref.: ENV.E.2 VK/rf ARES(2013)

Utrecht, July 19, 2013

Dear Mr Schally,

Thank you for your invitation to provide information on developments in the work area of microbial culture collections regarding model contractual clauses, best practices etc. in view of the entry into force of the Nagoya Protocol.

Since the entry into force of the CBD, our community of Microbial Resource Centres (MRCs) has worked to reach compliance and harmonise practices. Several initiatives emerged, often leading to EU-funded projects aiming to develop model contractual clauses and best practices. Some projects are now completed, others are currently underway using output of earlier projects that will be updated and supplemented with new elements for best practices. A summary of the work done is presented below. Footnotes and Appendices provide further detailed information.

A first voluntary Code of Conduct
The project **MOSAICC**[1], which was financially supported by European Commission DG Research, aimed to develop a voluntary **Code of Conduct** that provides a set of **model clauses for PIC and MAT** for providers and recipients of microbial genetic resources (MGRs), and for **Material Transfer Agreements** (MTA) for the deposit in public collections (also referred to as Material Accession Agreements) and supply of MGRs by these collections to users. Key elements identified for MTA included (i) description of the MGRs, (ii) specifications of terms of use (commercial or non-commercial) and, (iii) terms of benefit sharing (monetary or non-monetary). MOSAICC was completed in 1999, became listed on the CBD website in the Nagoya Protocol webpage and also appears on the WIPO list of sources of model contractual clauses in the context of the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore. MOSAICC also influenced the drafting process for the CBD Bonn

Guidelines. Appendix 1 provides the MOSAICC document in a version of 2011. The follow-up project **MOSAICS**[2], also funded by the EU, aimed at the development of an Integrated Conveyance System, offering (i) tools to evaluate the economic value of MGR, (ii) standard provisions to enable uncomplicated tracking of MGR, and (iii) a way of balanced benefit sharing for those that are entitled to be rewarded for the services and products they provide to society.

The practice of sharing MGRs and related information by scientists world-wide for research purposes, known as **Microbial Commons**[3, 4, 5] has been key to the development of microbiology over more than a century. Collections have been involved in several recent studies and meetings on the subject of microbial commons, which aimed at analysing current practices of sharing MGRs and information by collections, researchers and their networks, and how this practice could be placed on a more solid scientific, and legally sound, institutional basis. The complicated issues of ownership was also addressed and a "**bundle of rights**" [6] attached to MGRs was proposed, which should be regulated by law and managed through agreements and contracts between stakeholders.

Best practice and the ECCO-Core MTA

Even years after the publication of the Bonn Guidelines in October 2001, many Parties to the CBD still failed to set in place authorities with competence for processing requests for PIC and MAT. Meanwhile, the collections continued their efforts to find ways to enhance compliance under these quite difficult circumstances.

After considerably discussion in various meetings, most public collections adopted a best practice for deposit and supply of MGRs. The main elements for this best practice are:

- Accession forms to be completed by the depositor of the MGR where information on the PIC and MAT should be provided, if applicable
- No acceptance of MGRs without information about the country of origin
- Supply by the collection of MGRs to users under MTA settling the most important conditions for supply and terms of use

Collections recognised that a highly harmonised MTA for supply by all European collections would contribute to improving legal certainty and transparency to both users and suppliers of MGRs. Therefore, the European Culture Collection's Organisation [7, 8] (**ECCO**) developed the **"ECCO-Core MTA"** [9] (full text in Appendix 2), taking recommendations of MOSAICC into account. The Core MTA answered to the need of collections to have a harmonised MTA that settles terms for use of supplied MGRs, and also effectively raises awareness with the users of MGRs about their obligations under the CBD, especially with regard to benefit sharing. The Core MTA was agreed upon by the ECCO members in 2009, and subsequently implemented in many European collections.

Next steps to prepare for the entry into force of the Nagoya Protocol

Member collections of ECCO and other participants in the Global Biological Resource Centre Network (**GBRCN**) Demonstration Project[10], joined in an endeavour to establish a new Research Infrastructure (RI) for microbial collections, the Microbial Resource Research Infrastructure[11] (**MIRRI**). In its EC funded three-year Preparatory Phase (2012-2015), MIRRI is focussing on **the preparation of a legal operational framework** for the RI. In the **MIRRI Response**[12] to the EC proposal for a Regulation for ABS in the Union, partners have expressed their support but also several concerns regarding important articles of the proposed text. MIRRI will take the output of previous projects and initiatives into the next process of formulating minimal requirements for compliance and use these to develop a new common policy for ABS and IPR for MGRs. Alongside, partners of the MOSAICC project have started recently to review its

set of model clauses and recommendations with the help of other experts to make it fully compliant with the Nagoya Protocol.

Beyond the borders of the Union

European MRCs are currently also involved in discussions about the consequences of the NP with collection institutions outside Europe. During international meetings[13] addressing these issues where curators of European as well as non-European collections and representatives of various governments were also present, considerable interest and positive responses were seen to the system of **Union Trusted Collections**, as proposed by the EC in the draft Regulations. On the basis of growing consensus among MRCs world-wide on how to achieve compliance, the "**TRUST**" initiative was coined by the World Federation of Culture Collections (**WFCC**). The acronym stands for "TRransparent User-friendly System of Transfer for Science & Technology". TRUST aims to create an effective global system of trusted sources for microbiology, which could be supported by further development of its pioneering database system which is maintained by the World Data Centre for Micro-organisms[14] (**WDCM**). In the WDCM CCInfo-database, collections can register through a unique acronym and numerical identifier in its official list of MGRs. Today, 644 culture collections are registered in CCInfo, holding over 2 300 000 cultures of microorganisms. The WDCM system will use the recent technology of electronic markers called "Globally Unique Identifiers (GUIDs)" that could be used to set up a robust system to organise transfers of (micro) biological items, tracking the flow of resources and related information.

Conclusions

Our community of microbial collections in Europe has been very active and continues to be so. We are following the negotiations in the European Union regarding the Regulation on ABS with great interest, as the final result will largely determine next steps to be taken towards the development of best practises suited for the new situation. We highly appreciate the interest shown by the EC for what is being done by the collections to reach improved harmonisation and compliance to the expected ABS regime for the Union. Based on our long-standing cooperation in ECCO, WFCC and during several projects that became possible through funding by the EU, we are fully prepared to go forward and contribute to a successful implementation of the NP. It is our hope that it will bring more legal certainty and also justice to the goals of the CBD.

We will be happy to provide more information or answer any questions you might have.

With highest regards,

Gerard Verkleij

Leader MIRRI Workpackage 9 (Legal Operational Framework)

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[1] MOSAICC stands for Microorganism Sustainable use and Access regulation International Code of Conduct (http://bccm.belspo.be/projects/mosaicc/). MOSAICC recommendations facilitate access to MGRs and help partners to make appropriate agreements when transferring MGRs, in the framework of the CBD and other applicable rules of international and national laws. A version that was updated in 2011 is provided as Appendix 1.

[2] MOSAICS stands for "Microorganisms Sustainable use and Access management Integrated Conveyance System". It was funded by Directorate General Research of the European Commission under the Sixth Framework Program. The consortium of the MOSAICS project is made of partners from developed and developing countries, including culture collections, international organisations, branch federations and specialised research institutes. Already in 1999, the MOSAICC project had identified three necessary features for a system to implement coherently the CBD provisions on ABS. MOSAICS central objective is the development of such an integrated conveyance system that:

- has reliable tools to evaluate the economic value of microbiological resources;
- disposes of validated model documents with standard provisions to enable tracking via an uncomplicated procedure, widely applied by microbiologists;
- combines valuation and tracking in one system for trading of microbiological resources, with balanced benefit sharing for those that are entitled to be rewarded for the services and products they provide to society.

[3] Dijkshoorn L, de Vos P, Dedeurwaerdere T (2010). Understanding patterns of use and scientific opportunities in the emerging global microbial commons. Research in Microbiology 161: 407-413.

[4] Dedeurwaerdere, T (2010). Global microbial commons: institutional challenges for the global exchange and distribution of microorganisms in the life sciences. Research in Microbiology 161: 414-421.

[5] Dedeurwaerdere, T (2010). Self-governance and international regulation of the global microbial commons: introduction to the special issue on the microbial commons. International Journal of the Commons 4: 390-403. URN:NBN:NL:UI:10-1-100217.

[6] The innovative concept of "bundle of rights" is a dynamic model of ownership management moving away from the static concept of ownership towards a flexible allotment of rights. Ownership constitutes a "bundle" of use and decision rights that are attributed to a number of stakeholders / economic agents. It is a set of operational and collective choice rights defining respectively who decides upon the use that one can make of a resource, and who decides upon the future exercise of the rights on the resource. Such scheme allows multi-ownership of a gradual level of use and decision rights. These rights can begin with basic access rights, encompassing research delivering outputs to the public domain, distribution on to third parties, exploitation rights to develop intellectual property and its ownership which may include reach through rights. Furthermore, the application of the "bundle of rights" makes possible the enforcement of the "sovereign rights of States over their natural resources" without prejudice to private rights. Unambiguous allotment of rights in advance will facilitate rightful benefit sharing "at the end of the pipe". See also Dedeurwaerdere, T : Understanding ownership in the knowledge economy: the concept of the bundle of rights. BCCM News Edition 18 - Autumn 2005.

[7] The European Culture Collections' Organisation (ECCO, http://www.eccosite.org/) was established in 1981. ECCO comprises 61 members from 22 European countries, holding over 350.000 strains of yeasts, filamentous fungi, bacteria and archaea, phages, plasmids, animal cells including human and hybridoma cell lines, viruses, plant cells, algae and protozoa. The aim of the ECCO is to promote collaboration and exchange of ideas and information about all aspects of culture collection activity. ECCO meetings are held annually and are a valuable forum for discussion and innovation on the future development of member collection activities.

[8] Fritze D (2010) A common basis for facilitated legitimate exchange of biological materials, proposed by the European Culture Collections' Organisation (ECCO). International Journal of the Commons 4: 507-527. URN:NBN:NL:UI:10-1-100222.

[9] Janssens D, Tindal B, Green P, Garay E, Fritze D, Stalpers J, Smith D, Bimet F, Desmeth P (2009). The ECCO core Material Transfer Agreement for the supply of samples of biological material from the public collection. Article 7 of this standard MTA is cited here: "If the RECIPIENT desires to use the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSE(S), it is the responsibility of the RECIPIENT, in advance of such use, to negotiate in good faith the terms of any benefit sharing with the appropriate authority in the country of origin of the MATERIAL, as

indicated by the COLLECTION's documentation." Full text is provided in Appendix 2 (also downloadable from http://www.eccosite.org/)

[10] Global Biological Resource Centre Network Demonstration (GBRCN) Project was supported by the German Federal Ministry of Research and Education (BMBF) following work in the OECD to improve access to high quality biological resources and information to support research and biotechnology as a platform for a knowledge-based bioeconomy. Partners included collections from 15 countries, with representatives of the WFCC, a global network and regional networks, ECCO and the Asian Consortium for Microorganisms (ACM). The final report of the project which was completed in 2012 can be downloaded at http://www.gbrcn.org/.

[11] Microbial Resource Research Infrastructure (MIRRI) is an EU funded project that aims to build one pan-European infrastructure for microbial collections that will more effectively facilitate access to high-quality microorganisms, their derivatives and associated data and services, for research, development and applications. After its acceptance on the European Strategy Forum on Research Infrastructures road-map, MIRRI obtained funding from the European Commission and on Nov 1st, 2012 it entered a three-year Preparatory Phase, in which partners will focus on governance and structure, and technical, legal, and financial issues to build the network. This will establish the links across the distributed RI and between the RI microbiological resource centre (MRC) community, its users, policy makers and potential funders. www.mirri.org

[12] Response of MIRRI to the "Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union" E. Stackebrandt & G. Verkleij, March 14, 2013. [this document was sent to your office by email 12/04/2013]

[13] For example: NITE-NBRC 10th Anniversary Symposium "Impact of Nagoya Protocol on management of Biological Resource Centers", Tokyo, Japan, Dec. 6, 2012.

[14] The World Federation for Culture Collections (WFCC) has developed a pioneering database system by registering its members through a unique acronym and numerical identifier in its official list and urging them to catalogue their microbiological resources. This system is maintained and improved by the World Data Centre for Micro-organisms (WDCM). Combining the WDCM system and the use "Globally Unique Identifiers (GUIDs)" set up a robust system to organise transfers of (micro) biological items, tracking the flow of resources and related information. This system also facilitates the application of ABS since it can potentially retrieve all kinds of information about microbiological resources, including information related to the location and movements of the resource. The WDCM portal acts as an information broker between all online catalogue entries of the culture collections. See http://www.wdcm.org and http://bccm.belspo.be/projects/mosaics/reports/files/ics_report.pdf7.

Appendices

Appendix 1

MOSAICC text (version 2011)

Appendix 2

ECCO Core MTA

MOSAICC

MICRO-ORGANISMS SUSTAINABLE USE AND ACCESS REGULATION INTERNATIONAL CODE OF CONDUCT

Updated June 2011

Louis Pasteur: "The role of the infinitely small is infinitely large"

BCCM

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INTRODUCTION

The World Federation for Culture Collections (WFCC)[1] describes micro-organisms as follows:

"Micro-organisms" comprise viruses, all prokaryotes (archaea and bacteria), some eukaryotic organisms fungi, including yeasts, algae, protists, their replicable parts and other derived materials e.g. genomes, plasmids, cDNA. They are considered ubiquitous and found everywhere not recognising country boundaries although many do have various physiological requirements or are obligate pathogens or symbionts and don't grow everywhere. However, it is becoming more apparent that the environment in which a particular species is found has impact on its chemistry and properties.

Fifty percent of the living biomass on the planet is said to be microbial and micro-organisms have the potential to provide solutions to many problems in agriculture, industry, plant, animal and human health and several other biotechnological applications. The vast majority (95%) of microbial diversity is yet to be discovered. They are involved in nutrient recycling (e.g. breaking down complex plant and animal remains), beneficial mutualistic relationships (e.g. nitrogen fixation, animal digestion, mycorrhiza), and production of atmospheric oxygen; some are pathogens causing disease of man, plants or animals.

Micro-organisms have been used as tools for the production of products for millennia. Their various properties can be harnessed by man for many uses which include the biological control of pests and diseases in agriculture and horticulture; production of natural products (e.g. valuable drugs, enzymes, and metabolites) for pharmaceutical, food and other applications, composting, bioremediation and detoxification of wastes. They play a major role in soil fertility and plant and animal health and are employed in diagnostics, efficacy testing of drugs, biocides, vaccine production and disinfectants or as reference strains. They are multifunctional and consequently have multi-use. The unravelling of the structure of DNA (deoxyribonucleic acid), various species of ribonucleic acid (RNA), and the various processes whereby the manufacture of protein from the nucleic acid templates occurs was pivotal in advancing the use of micro-organisms in biotechnology.

With the passing of time, the realized and potential benefits of micro-organisms and the implementation of strict standards of microbe sustainable use provides increasingly for economic and social benefit at global scale.

On the other hand, many micro-organisms are pathogenic for human, animal, plants or other micro-organisms and must be monitored, studied, controlled and quarantined, to avoid health hazard, depleting food and feed stock or economic loss.

Containment of hazardous micro-organisms or sustainable use of beneficial micro-organisms is possible provided that facilitated, save and sound access as required in CDB article 15 is ensured. That is the purpose of MOSAICC: contributing to facilitate access and transfer of microbiological material.

MOSAICC is a voluntary Code of Conduct. It is developed to facilitate access to microbial genetic resources (MGRs)[2] and to help partners to make appropriate agreements when transferring MGRs, in the framework of the Convention on Biological Diversity (CBD)[3] and other applicable rules of international[4] and national[5] laws. MOSAICC is a tool to support the implementation of the CBD at the microbial level; it can also serve as a model when dealing with genetic resources other than MGRs.

MOSAICC is the result of the European Commission DG Research funded project called "Elaboration and diffusion of a code of conduct for the access to and sustainable use of microbial resources within

the framework of the convention on biological diversity"[6]. MOSAICC was first issued in spring '99, two years before the Bonn Guidelines[7], as result of five successive drafts improved through dialogue between MOSAICC partners and a network of experts of more than 15 different nationalities. The present version is an update that takes over the innovative ideas developed the last decades by life sciences and social sciences researchers to meet the evolving socio-economic environment.

Access to MGRs is a prerequisite for the advancement of microbiology and world-wide sustainable development. Furthermore, monitoring the transfer of MGRs is necessary to identify the individuals or groups that are entitled to be scientifically or financially rewarded for their contribution to the conservation and sustainable use of the MGRs. Therefore, MOSAICC combines the need for easy transfer of MGRs and the need to monitor the transfer of MGRs. It proposes a system that works through two operating principles:

1. The *in situ* origin of the MGRs is identified via initial **Prior Informed Consent** (**PIC**) procedure providing authorisation for sampling. The *in situ* origin of the MGRs is always mentioned when transfer occurs.
2. The transfer of MGRs is monitored and occurs under **Material Transfer Agreement** (**MTA**) which terms are defined by both recipient and provider**.** MTA is a generic term that covers very short shipment document, simple standard delivery notice, standard invoice containing minimal standard requirements, or more detailed specific contract including tailor-made mutually agreed terms. According to the use and intended distribution of the MGRs, mutually agreed terms can be short or very detailed.

MOSAICC aims to assist microbiologists:
- to obtain Prior Informed Consent-PIC (CBD art.15.5) ;
- to establish Material Transfer Agreement (MTA) for access to and transfer of MGRs, access to and transfer of technology, fair and equitable sharing of benefits as well as for technical and scientific co-operation (CBD art.15.4, 15.6, 15.7, 16, 18 & 19).

MOSAICC aims to assist authorities of countries providing MGRs by suggesting procedures:
- to issue PIC for access to MGRs;
- to organise facilitated access to MGRs (CBD art.15.2)
- to monitor the transfer of such MGRs, to enable fair and equitable sharing of the possible benefits arising from their utilisation.

MOSAICC includes recommendations to microbiologists. These recommendations should be considered as guidelines for an optimal implementation of the CBD. National and international legal requirements developed in or outside the framework of the CBD remain compulsory (CBD art.22). As the implementation of the CBD is ruled at national level, some suggestions to authorities are also included as well as some model forms in section II of this document.

As it is not the purpose of MOSAICC to analyse thoroughly the terms and principles of the CBD, readers are advised to check the bibliography and consult other documents for more information about the CBD. In addition, MOSAICC recommends the "OECD Best Practice Guidelines for Biological resource Centre" published in 2007 by the Organization for Economic Co-operation and Development[8] and the "WFCC Guidelines for the Establishment and operation of culture collections"[9]. These documents provide guidance and propose best practices for depositories of biological material. They contain lists of rules and regulation as well as useful references.

[1] Smith, D. & Desmeth, P. (2007). Access and benefit sharing, a main preoccupation of the World Federation of Culture Collections. In: UNEP/CBD/WG-ABS/6/INF/3 13 December 2007

[2] Short definition of microbial genetic resources (MGRs) derived from the CBD definition of genetic resources: *any microbial genetic material of actual or potential value* (article 2).

[3] The Convention on Biological Diversity (CBD, Rio de Janeiro, 5 June 1992) has three objectives " *the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources* "(art.1). To achieve these goals, the CBD lays down new principles governing, among others, access to genetic resources (art.15), access to technology (art. 16, 18 & 19) and fair and equitable sharing of benefits (art. 15 & 19). Since microbiologists must deal with MGRs from all over the world, there is a need for a Code of Conduct dealing with these matters in a practical way. MOSAICC is the result of a consensus obtained between a balanced group of representatives from North and South, including representatives from the public (government, culture collections, academics, NGOs) and the private sector (pharmaceutical, chemical and food industry), from the not-for-profit-sector as from the commercial sector.

[4] Among others the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure (28 April 1977, amended on 26 September 1980 and Regulations) and the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS Agreement, Marrakech, 15 April 1994). See also CBD article 22.

[5] Individual countries may retain their own special interests and goals, even if this involves rules that go beyond those laid down by the CBD. However, a uniform set of guidelines could be more economic and effective to implement the principles of the CBD. The success of countries in co-operating with each other and exploiting in a sustainable way their microbial biological diversity will depend on the feasibility of the national regulations and procedures that these countries impose.

[6] Concerted action n° BIO4-CT97-2206 (DGXII - SSMI). The MOSAICC project involved twelve partners. For more details, see webpage http://bccm.belspo.be/projects/mosaicc/

[7] Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (see Convention on Biological Diversity – Conference of Parties 6 Decision VI/24. http://www.cbd.int/decision/cop/?id=7198)

[8] OECD Best Practice Guidelines for Biological resource Centre, 2007, OECD, Paris. See also document "Biological Resource Centres Underpinning the future of Life Sciences and Biotechnology". OECD Science & Information Technology, May 2001, vol. 2001, no.7, pp.1-68 (69 pages) OECD.

[9] See http://www.wfcc.info/index.php/guidelines/

SECTION I. TERMS OF ACCESS to MGRs

I.1. Prior Informed Consent: definition and contents[9]

In the system proposed by MOSAICC, the "prior *informed consent*" (PIC) is a document / a record that officially identify the *in situ* origin of MGRs and authorise the access to *in situ* MGRs. It is the result of a procedure put in place to monitor the access to and the transfer of MGRs.

The PIC must be: - obtained prior to accessing the MGRs;

- based on legally correct and trustworthy information provided by the applicant;
- granted by a competent authority of the country where the MGRs is provided from and according to the national legislation and procedures. (For the purpose of MOSAICC, the competent authorities that are entitled to provide the authorisation for access to MGRs will be called "PIC-providers[10]").

MOSAICC recommends that, in all cases, the PIC-document or the PIC record should contain[11] (see section II for model PIC):

- the names and addresses of the PIC-applicant and the « PIC-provider »;
- a confirmation of the authority exercised by the « PIC-provider »;
- a confirmation of the precise scope of the PIC (cf. annexed PIC-application, area of sampling, when possible description of MGRs to be accessed);
- a reference to the national legislation concerning the PIC, whether this national legislation is related to regulations or recommendations expressed in an international convention (such as the CBD) or not;
- a reference to a Material Transfer Agreement, if any[12];
- and in annex, if relevant, the permission of right holder (such as landowner and/or usufructuary).

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9 MOSAICC refers to the principles laid down in CBD article 15, in particular:
- the « *sovereign rights of States over their natural resources* " in the sense that " *the authority to determine access to genetic resources rests with the national governments and is subject to national legislation* » (CBD art. 15.1);
- « *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* » (CBD art. 15.2);
- « *Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article* » (CBD art. 15.4)
- « *access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources unless otherwise determined by that Party* » (CBD art. 15.5).

10 There are different kinds of PIC-providers. PIC-providers that have received a mandate from their government to issue PIC within the framework of the CBD and PIC-providers that have received a mandate within national legislation that does not refer to the CBD. Some of these PIC-providers have a limited mandate, for instance the authority to issue PIC for access to certain geographical area(s) like a Department of Forestry or an administration supervising a National Park. Some PIC-providers have a broader competence related to the access to genetic resources (e.g. department of Environmental Affairs). In practice a country may organise itself in different ways. In this regard countries could take two useful steps to facilitate the implementation of the PIC principle: first, designate one or more PIC-providers, secondly, regularly publish updated list of names and addresses of their competent PIC-providers. The lists should include specifications on the scope of the respective mandates of those PIC-providers (kind of genetic resources covered, geographical areas of competence etc.). Countries which have designated PIC-providers, could use standardised PIC-certificates such as the MOSAICC model forms (see section II).

11 Some conditions could be added according to the country's national legislation and/or the specific rules applied by a PIC-provider but too restrictive rules might run counter the attainment of the general objectives of the Convention on Biological Diversity (CBD articles 1 and 15.2).

12 The transfer without MTA of *in-situ* MGRs to *ex-situ* conservation facilities is possible when the present depository has itself isolated the MGRs directly from *in-situ* conditions and stored them at its facilities. In any other cases transfer of MGRs without MTA is inadvisable. Note that when receiving strains of micro-organisms to conserve, culture collections ask the depositor to fill in an "accession form" where basic information is recorded. The accession form is usually one of the first official documents recording the trail of movements of a micro-organism, alongside any scientific paper describing the micro-organisms and its properties.

I.2. Procedure for access to *in situ* MGRs[13]

Prior Informed Consent

MOSAICC recommends that microbiologists, wishing to access *in situ* MGRs, endeavour in all cases to apply for a **Prior Informed Consent** (PIC) both in countries that have or have not yet designated a competent « PIC-provider » within the framework of the CBD[14].

Because "PIC-providers" are not always identifiable where access to *in situ* MGRs is required, MOSAICC recommends that microbiologists:

- always make best efforts to identify the competent « PIC-provider » and to acquire a PIC before accessing MGRs;
- keep proof of their efforts and steps made to acquire PIC;
- when wishing to access *in situ* MGRs[15], always attempt to acquire written permission from identifiable right holders, such as the landowner and/or the usufructuary of the land or water area before accessing this area and its genetic resources;
- use the MOSAICC model PIC-application form as model (see Section II model documents);
- in absence of official forms, ask "PIC-providers" to use the MOSAICC model PIC-document (see Section II model documents).

The PIC gives access to *in situ* MGRs; it authorises sampling of MGRs under certain conditions. Subsequently, for each MGR isolated during the specific field survey / sampling campaign it covers, the PIC proves that the MGR has been isolated in a legitimate way and it identifies officially the *in situ* origin of the MGR. At this point, the issuance of a **Global Unique Identifier** (GUID)[16] attached to the "item" can make the conveyance of MGRs transfer feasible. Another moment when the issuance of a GUID is recommended is the deposit in an *ex situ* long term conservation facility, a culture collection. The World Federation for Culture Collections (WFCC) pioneered the development of an international database on culture resources worldwide: the World Data Centre for Micro-organisms (WDCM)[17]. WDCM has inaugurated a system of tagging strains of micro-organisms in a consistent manner that allows finding back the trail of exchanges of the micro-organisms samples through the culture collections network.

A **fast-track procedure** should be available in cases of emergency such as epidemic or for MGRs needed for biocontrol of non-indigenous pests/flora/fauna originating from the same habitat/ecosystem as the MGRs. In case of such procedure, the use of GUIDs renders the backward procedure possible: instead of getting the PIC before access, here access is granted first and the GUID acts as an electronic tag helping retrieve the item and following the trail of its movements in a backward process. The fast-track procedure is coupled to a regularising procedure (see page 9).

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[13] Given the provisions included in CBD article 15, and the use of terms for the purposes of the CBD (article 2), which state:
- "*country of origin of genetic resources means the country which possesses those genetic resources in in situ conditions* "
- "*in situ conditions means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties* ",
MOSAICC defines *in situ* MGRs as micro-organisms or material of microbial origin containing functional units of heredity, as existing within ecosystems and natural habitats, and, in the case of domesticated or cultivated species in the surroundings where they have developed their distinctive properties. Note: This definition excludes MGRs having acquired their distinctive properties in ***in vitro*** conditions, outside their ecosystems and natural habitats (laboratory conditions).

[14] The last phrase of article 15.5: "*unless otherwise determined by that Party*" means also that imposing the requirement of prior informed consent is an option rather than an obligation and this has the consequence that a user is only required to submit to prior informed consent, if the providing Party has taken steps to establish the necessary procedure in its legal system (Hendrickx/Koester/Prip, The Convention on Biological Diversity – Access to Genetic Resources: A legal Analyses, 23 Environmental Law and Policy 250 (1993)).

[15] The country where the *in situ* MGRs were accessed is the country of origin.

[16] More information related to GUIDs is available at http://bccm.belspo.be/projects/mosaics/reports/files/ics_report.pdf and at https://www.cbd.int/doc/programmes/abs/studies/study-regime-05-en.pdf "Studies on Monitoring and Tracking genetic Resources. Garrity G.M. et al, 2009.

[17] Work of Professor Skerman, University of Queensland, Australia, and his colleagues in the 1960's. See www.wfcc.info

Given the flexibility of the CBD[18] concerning the PIC requirement and the need for appropriate procedure for special cases, countries could put in place such fast-track procedure with shortest possible administrative delay according to the level of urgency, giving access to *in situ* MGRs on basis of minimum information about the purpose of the purchase. This procedure should still enable the monitoring of the distribution and utilisation of the MGRs. In the system proposed in this Code of Conduct, fast-track procedure will match with the contents of Material Transfer Agreement excluding further distribution of MGRs and use-category I (see types and contents of Material Transfer Agreement on page 10 and following).

Having in mind that access to MGRs is the necessary prerequisite to enable basic, upstream research, and the non-monetary benefits it generates[19], a State, exercising its sovereign rights over the natural resources under its jurisdiction (CBD article 15.1), could consider organising a simplified system that will facilitate non-commercial research without jeopardizing potential commercial benefits.[20] Such simplified system can make use of the different tools in development such as GUIDs, bio-molecular markers, fingerprinting, most produced initially by basic life-science non-commercial research.

I.3. Procedure for access to *ex situ* MGRs[21]

Prior Informed Consent

MOSAICC recommends that microbiologists wishing to access *ex situ* MGRs:

- to endeavour in all cases to get, at least, the country of origin or a reference such as a GUIDs that leads to the initial Prior Informed Consent issued when access to *in situ* MGRs was authorised or to an equivalent document delivered when the MGRs were originally deposited in *ex situ* collections[22] (see also recommendation for regularising procedure). When the origin of an *ex situ* MGRs is not known, the source (institution or individual who deposited the MGRs in an *ex situ* conservation facility) must be documented.
- to keep files of correspondence when dealing with *ex situ* resource centres, including possible Material Transfer Agreement (see definition of MTA, page 10).

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18 As already mentioned in footnote 14 , the phrase, "*unless otherwise determined by that Party*" gives the countries some flexibility to deal with the principle of PIC requirement and to provide for possible special procedures. For instance in case of emergency, when a dramatic outbreak of parasitic disease (whether human, animal or plant disease) could cause health or environmental damages, access to the pathogenic MGRs should be possible without delay and restriction for *bona fide* researchers. Indeed, in such case, it is irresponsible for a country to deny or delay access to MGRs and so impeding international aid, and it counters the provisions of CBD article 14 (e) stating « *(Each Contracting Party, ..., shall) Promote national arrangements for emergency responses to activities or events, whether caused naturally or otherwise, which present a grave and imminent danger to biological diversity and encourage international co-operation to supplement such national efforts and, where appropriate and agreed by the States or regional economic integration organizations concerned, to establish joint contingency plans*».

19 As described in appendix II of the Bonn Guidelines and in COP Decision VI/24 Annex II. These benefits include, but are not limited to: human and institutional capacity building, education and training; technology transfer, new research approaches and access to facilities; access to data, information and knowledge that contributes to policy- and decision-making on all levels; and participation in collaborative, multidisciplinary research activities and networks.

20 Schindel et al. Workshop report on access and benefit sharing in non-commercial biodiversity research. Bonn, Germany, 17-19 November 2008. Document accessible at http://barcoding.si.edu/ABSworkshop.html

21 Given the provisions included in CBD article 15, and the use of terms for the purposes of the CBD (CBD art. 2), which state:
-"*country providing genetic resources means the country supplying genetic resources collected from in situ resources, including populations of both wild and domesticated species, or taken from ex situ sources, which may or may not have originated from that country* ",
-"*ex situ conservation means the conservation of components of biological diversity outside their natural habitat* "
MOSAICC defines *ex situ* MGRs as material of microbial origin containing functional units of heredity that is kept outside its natural habitat (such as *in vitro* or laboratory conditions).

22 *Ex situ* MGRs are originally isolated from *in-situ* conditions and subsequently kept *in vitro*. According to the CBD provisions, these MGRs isolated from *in-situ* conditions should have been accessed through a PIC identifying their origin and making reference to the terms of the access.

– to check that the ***necessary minimal information*** regarding the MGRs is attached or retrievable via GUIDs.

– to always mention provider, strain reference number and country of origin in their scientific papers/publication.

MOSAICC recommends that the provider of the MGRs transfer them with the ***necessary minimal information*** about their *in situ* origin**:**

– a reference to the original PIC or to an equivalent document delivered when the MGRs were originally deposited in *ex situ* collections;

– the name of the country where the MGRs were accessed;

– a strain reference number or GUIDs;

– if available, the species name identifying the strain (see comments in footnote 24);

– the place and date of isolation as well as the name of the individual that has isolated the strain from *in situ* conditions or, for lack of individual's name, the name of the institution (legal entity) that employed the individual at the time of the isolation of the strain;

– previous Material Transfer Agreement, if any.

One key procedure at the point of junction between *in situ* and *ex situ* life conditions of micro-organisms is the deposit of a strain in an *ex situ* long term conservation facility. When accepting strains, culture collections require basic information from the depositor which is similar to the necessary minimal information as listed here above. This information is recorded on what is usually called an "**accession form**". The "accession form" is the very first document attached to strains entering a collection. Appropriate use of this form will facilitate management of the micro-organisms throughout its *ex situ* lifespan.

Complementary to the recording of basic information at key point of the micro-organisms life, the use of Global Unique identifiers (GUIDs) will help retrieve the necessary minimal information and more[13].

Many *ex situ* MGRs are not yet covered by a PIC because individuals as well as institutions, including *ex situ* resource centres, have sometimes acquired in the past, and in particular cases are still acquiring MGRs without a PIC.

MOSAICC recommends that a **regularising procedure** will be followed for these *ex situ* MGRs that have been acquired / isolated from *in situ* conditions without a PIC. This regularising procedure consists of the applicant providing the competent authority with an inventory of indexed strains in pure culture, whether identified or not, kept at its facilities. This correcting measure will fulfil the need to identify the *in situ* origin of the strains by recording and transferring the adequate information. This measure must remain exceptional. It is intended to get back into the regular circuit MGRs that have for any reasons bypassed the standard procedure. The regularising procedure applies also in the context of fast-track procedure (see page 7).

Amongst the strains kept *ex situ*, those used in standards for assays and proficiency tests are called reference strains, and the strains that underpin taxonomy and nomenclature are defined as Type strains. The availability of these strains is of central importance in a comparative science, it is essential that access and exchange of these reference strains and Type strains is not impeded to facilitate microbiological systematic research. The emergence of individuals and organisations attempting to restrict use, access or protect intellectual property threatens this access[23], and runs contrary to CBD

[23] Tindall, B.J. & Garrity, G.M. (2008). Proposals to clarify how type strains are deposited and made available to the scientific community for the purpose of systematic research. International Journal of Systematic and Evolutionary Microbiology 58, 1987–1990.

Article 15.2. MOSAICC recommend that the States exercise their sovereign rights upon their natural resources to request *ex situ* MGRs providers such as culture collections in which such strains are deposited to make these available without restriction, a reasonable costs fee, to facilitate future research and enable proper identification.

I.4. Settlement of Material Transfer Agreement

MOSAICC recommends that all transfers of MGRs (*in situ* MGRs to *ex situ* conditions and transfers of *ex situ* MGRs) occur under **Material Transfer Agreement** (**MTA**) the terms of which are mutually agreed[24] upon between the provider and the recipient.

Material Transfer Agreement (**MTA**) is a generic term that includes very short shipment document, simple standard delivery notice, standard invoice containing minimal standard requirements, or more detailed specific contract including tailor-made mutually agreed terms. All these documents can be designated as MTA as long as they contain at least:

- information about the *in situ* origin or the source (see PIC);
- information about provider and recipient ;
- mutually agreed terms for the access to and the transfer of MGRs, the access to and the transfer of technology, the fair and equitable sharing of the benefits as well as for technical and scientific co-operation.

According to the use and intended distribution of the MGRs, mutually agreed terms can be either very short or very detailed.

Model MTA and Standard MTA

For usual transfers, such as delivery of test strains and exchanges between scientists, etc., partners are advised to use widely accepted **model MTA**. The European Culture Collections Organisation (ECCO) is striving towards such a model MTA with a standard core completed with facultative provisions. Such regional model MTA can foster the exchanges of microbial material in a uniform legal system. Designing a model MTA for the members of the World Federation for Culture Collections (WFCC) would be a significant sector based ABS approach for the culture collections community across the world, facilitating exchanges although its members operate in different legal system.

It is also advisable to strive towards the development of sector-based **Standard MTA** (sMTA) such as the one designed for the International Treaty for Plant Genetic resources for Food and Agriculture (ITPGR)[25]. sMTA adapted to the bilateral framework of the CBD can be inspired by the ITPGR sMTA although the latter is used in a multilateral system.

Common rules of access to MGRs and related data can be part of a process to reconstruct "commons" in microbial data, information and material. That is to establish "**microbial commons**" for the exchange of (micro) biological material which would provide basic common use principles for access to both material and information. This development will be complementary to the national regulations on ABS and to existing IPR laws, as it will constitute a demarcated space where material and information are relatively freely accessible provided that the outputs is injected back in this open space, to be shared again[26]. Inside this space access and benefit-sharing are "commonly shared".

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[24] "*Access, where granted, shall be on **mutually agreed terms** and subject to the provisions of this Article*" (CBD art. 15.4).

[25] See www.planttreaty.org

[26] See Reichman, J.H., Dedeurwaerdere, T., Uhlir, P.F. (2008). Designing a Microbial Research Semicommons: Integrated Access to Scientific Materials, Literature and Data in a Highly Protectionist Legal Environment. Paper presented to the conference on the Microbial Commons. Ghent, Belgium, 12-13 June 2008

Outside this demarcated space, access and benefit-sharing will be ruled through ordinary national and international laws, including IPR and specific CBD inspired regulations.

The WFCC supports similar views on such "microbial commons"[27]. Considering that fair and equitable benefit sharing depends upon the usage and activities undertaken with the resource, the benefits for most research and education activities should extend to depositing in collections, publication of associated data including experimental results, and making both material and associated information widely and easily available to stakeholders including the (source) country of origin. If the MGRs are made available with the purpose of commercial exploitation then other ways of sharing could apply such as access, milestone and royalty/license payments, or mechanisms such as IPR related patent and royalties could be activated.

MOSAICC recommends also, as suggested by WFCC, to refer to the concept of "**bundle of rights**"[28] as a dynamic adaptive way to allot rights to stakeholders over microbial material and related information, resulting in effective benefit sharing.

Ownership can constitute a "bundle" of use and decision rights that are attributed to a number of stakeholders / economic agents.

The "bundle of rights" is a scheme allowing multi-ownership structured in gradual levels of use and decision rights. Several rights-owners determine use and access to resources. These rights can begin with basic access rights, up to encompassing research delivering outputs to the public domain, distribution to third parties under the terms agreed and described in a MTA, exploitation rights to develop intellectual property and its ownership which may include reach through rights.

Furthermore, the application of the "bundle of rights" makes possible the enforcement of the "sovereign rights of States over their natural resources" without prejudice to private rights. Unambiguous allotment of rights in advance will facilitate rightful benefit sharing "at the end of the pipe".

Tailored MTA

When sMTA and model MTA do not meet the requirements of the stakeholders and that a more custom-made agreement is needed, partners are advised to use the MTA check list[29] to avoid

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[27] Smith, D. & Desmeth, P. (2007). Access and benefit sharing, a main preoccupation of the World Federation of Culture Collections. In: UNEP/CBD/WG-ABS/6/INF/3 13 December 2007 Compilation of submissions provided by parties, governments, indigenous and local communities and stakeholders on concrete options on substantive items on the agenda of the fifth and sixth meetings of the ad hoc open ended working group on access and benefit sharing. Canada: UNEP/CBD. p 68-70

[28] Dedeurwaerdere, T. (2005) Understanding ownership in the knowledge economy: the concept of the bundle of rights. BCCM News Edition 18.
Dedeurwaerdere, T. (2006). The institutional economics of sharing biological information. Int Soc Sci J 58, 351–368.

[29] **Material Transfer Agreement contents :**

- Accompanying terms
  Mention of the country of origin, reference to the original PIC; previous MTA-terms if any.
- Basic terms
  - Description of MGRs (country of origin, place and date of isolation, strain reference number, identification data, name of the individual that has isolated the strain from *in situ* conditions or, if individual's name is not available, the name of the institution (legal entity) that employed the individual at the time of the isolation of the strain) ;
  - *Bona fide* and sustainable use, following the CBD principles ;
  - Clause governing the payment of the costs of handling ;
  - Type of transfer**:** transfer where distribution to 3rd parties is **either** excluded (by default option) or possible. The choice between these two options is subordinate to the kind of recipients.
  - Information about provider and recipient: names, addresses.
- Use-specific terms
  Category 1: Use for test, reference, bioassay, control, training, and research purposes. No commercial use. No IPR on MGRs, derived technology and information. The recipient has to follow the protocols of standard test and reference procedures.
  Category 2 : Commercial use. Need for more precise MTA provisions on IPR, information feedback, patent application and benefit-sharing (see additional terms).

overlooking important terms when negotiating. Partners are free to draw up these custom-made terms according to their needs, provided that these terms are lawful and in accordance with the principles of the CBD.

The contents of the MTA are defined by two main criteria:

1. the kinds of use of the MGRs.
2. the possibility to distribute the MGRs to third parties, or not ;

1. MOSAICC divides the possible uses of MGRs into two categories:

- Category I: Use for test, reference, bioassay, control, training and research purposes.
- Category II: Commercial use

These categories of use will determine use-related terms to include in each MTA. Potential use and intentions may shift accordingly to results of R&D programmes and subsequent perspectives of new applications (actually, all micro-organisms have the potential to be of commercial interest). In this context all agreements to be signed between the different parties should clearly indicate the need that changes of categories must be negotiated and agreed with the rightful owner or provider. In order to help the partners make the appropriate choice between the categories of use, non-ambiguous definitions and clear descriptions of the uses are needed, especially the definition of "commercial use" with regard to the need for more precise terms for sharing of financial benefits. **"Commercial use"** of MGRs includes but is not limited to the following activities: sale, patenting, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or licence, product development and seeking pre-market approval.

2. MOSAICC recommends distinguishing between two types of material transfer.

- I. By default, transfer where further distribution is excluded (MTA excluding distribution to 3rd parties)
- II. Exceptionally, transfer where further distribution is allowed (MTA allowing distribution to 3rd parties)

The choice between these two types of transfer will be determined by the capacity of the users as well as of the suppliers for keeping records of the individuals or institutions from where or where to they transfer MGRs[30]. MOSAICC recommends that the MTA by default prohibit further down-the-line transfers.

• Additional terms
- IPR related to MGRs and derived technology,
- Terms on training, technical and scientific co-operation, access to and transfer of technology, exchange of information and publication policy. Terms providing possibilities for capacity building in, among others, taxonomy and general microbiology for the provider of microbial genetic resources should be emphasised and prioritised to compensations such as financial arrangements.
- Conservation of MGRs.
- Partnerships involving other stakeholders than provider and recipient of MGRs, including indigenous and local communities
- Monetary terms: Initial, up-front payment; milestones payment and royalties payment.

[30] **I.** MTA **excluding distribution to 3rd parties** is recommended in the following cases :
- Deposition of *in situ* MGRs in a culture collection, when the depositor imposes restriction of distribution (e.g.: patent deposit, some safe deposits). Take care that this does not run counter the principles of CBD art.15.2. *"facilitated access to MGRs"*.
- Deposition of *in situ* MGRs in a laboratory other than a culture collection, in a laboratory that is not used to record information about the transfers it does.
- Transfer of *ex situ* MGRs from an individual or an institution that is not a culture collection to a culture collection, when the depositor imposes restriction of distribution (e.g.: patent deposit, some safe deposits).
- Transfer of *ex situ* MGRs from a culture collection to individuals or institutions that are not used to record information about the transfers they do.
- Transfer of *ex situ* MGRs between individuals or institutions that are not used to record information about the transfers they do.
- Fast-track procedure (see page 7).

II. MTA **allowing distribution to 3rd parties** can be used exceptionally in two cases :
- Deposition of *in situ* MGRs in a culture collection (CBD art.9 (a) « *preferably in the country of origin* »)
- Legitimate exchanges defined as follows:

I. When they choose a MTA **excluding distribution to 3rd parties**, provider and recipient agree that the recipient cannot distribute the MGRs to anybody outside his/her institution. A MTA excluding distribution to 3rd parties stops the further distribution of the MGRs along a chain of contacts. From the provider's side, the monitoring of the distribution of the MGRs is limited to the registration of one recipient. In cases where scientists other than the original recipient would like to acquire a strain of the same MGRs, they can apply to the original provider. Provisioning of strains from the original source also guarantees the quality of the MGRs. This option must be chosen for transfers between individuals or institutions whose primary mission is not the *ex situ* conservation and valorisation of MGRs**19.I**. The MTA excluding distribution to 3rd parties will also be used in case of fast-track procedure (see page 7).

II. MTA **allowing distribution to 3rd parties** should be used exceptionally, in case of a MGRs collected *in situ* and deposited into a culture collection to allow further distribution, and in case of "**legitimate exchanges**".

"**Legitimate exchange**" is defined as "The transfer of the MGRs between named culture collections / Biological Resources Centres (BRC)[31] for accession purposes, provided that further distribution by the receiving culture collections / biological resources centre is under MTA provisions compatible and equivalent as those in place at the supplying collection." In other words, transfer is accepted when MGRs are transferred to a recipient that is a culture collection or when both recipient and provider are culture collections**19.II**. The terms of the transfer will be consistent with the best practices of culture collections and set in the framework of collaborative agreements, when such agreements exist.

Legitimate exchange also includes the transfer of MGRs within a "research group". A "research group" is defined as "Entitled scientists working in a same laboratory, or contractually bound to work on the same research topic."

This system limits the distribution in cascade/in series. It facilitates tracking of the MGRs by shortening the chain of distribution. It also ensures that MGRs keep their original quality and characteristics. Microbiologists wanting to get MGRs should ask for the MGRs preferably to a culture collection and avoid asking fellow microbiologists to provide them with the microbial resources. Note that the kind of MTA covering a particular transfer depends on the terms of a previous MTA when it exists. It also depends on the terms of the PIC because national legislation takes precedence over any specific terms that runs counter the law.

I.5. Monitoring the distribution and utilisation of MGRs

There is a need for a simple administrative system that enables easy circulation of MGRs. Such a system must also monitor the distribution and the utilisation of MGRs, to identify the individuals or groups that are entitled to share «*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* » (CBD art.15.7) because they have contributed to the conservation and sustainable use of the MGRs.

MOSAICC proposes a system that meets both these needs and:

1. allows easy circulation of MGRs at the first level of distribution and

- Transfers of *ex situ* MGRs between culture collection, between microbial genetic resource centre who's primary mission is the *ex situ* conservation and valorisation of MGRs; with terms according to specific collaborative agreements between these institutions
- Transfers between entitled scientists working in a same laboratory, or contractually bound to work on the same research topic. This concept is called a "research group."

[31] For more information related to the concept of BRC see http://www.oecd.org/dataoecd/55/48/2487422.pdf

2. limits the further distribution to third parties, in order to shorten the chain of distribution along which the monitoring of the transfer of MGRs may be lost.

The system works through the adequate choice of MTA terms governing the conditions of transfer (see pages 10 and following), these terms being mutually agreed upon between the provider and the recipient. The expectations of provider and recipient, the available trustworthy information, the legal context (national and international laws) and the contractual context (terms of possible previous agreements) will determinate the contents of the MTA.

More specifically, a balanced use of the options governing -allowing or excluding- the further distribution of the MGRs will help to arrange the flows of MGRs. To make the appropriate choice, to use the adequate option governing the further distribution of the MGRs, provider and recipient will check the following options when they want to transfer MGRs (see figure 1):

A. The MGRs are *in situ* **or** *ex situ*

B. A Prior Informed Consent (PIC) is available **or** not

C. There is a previous Material Transfer Agreement (MTA) **or** not

D. If there is a previous MTA, it may be

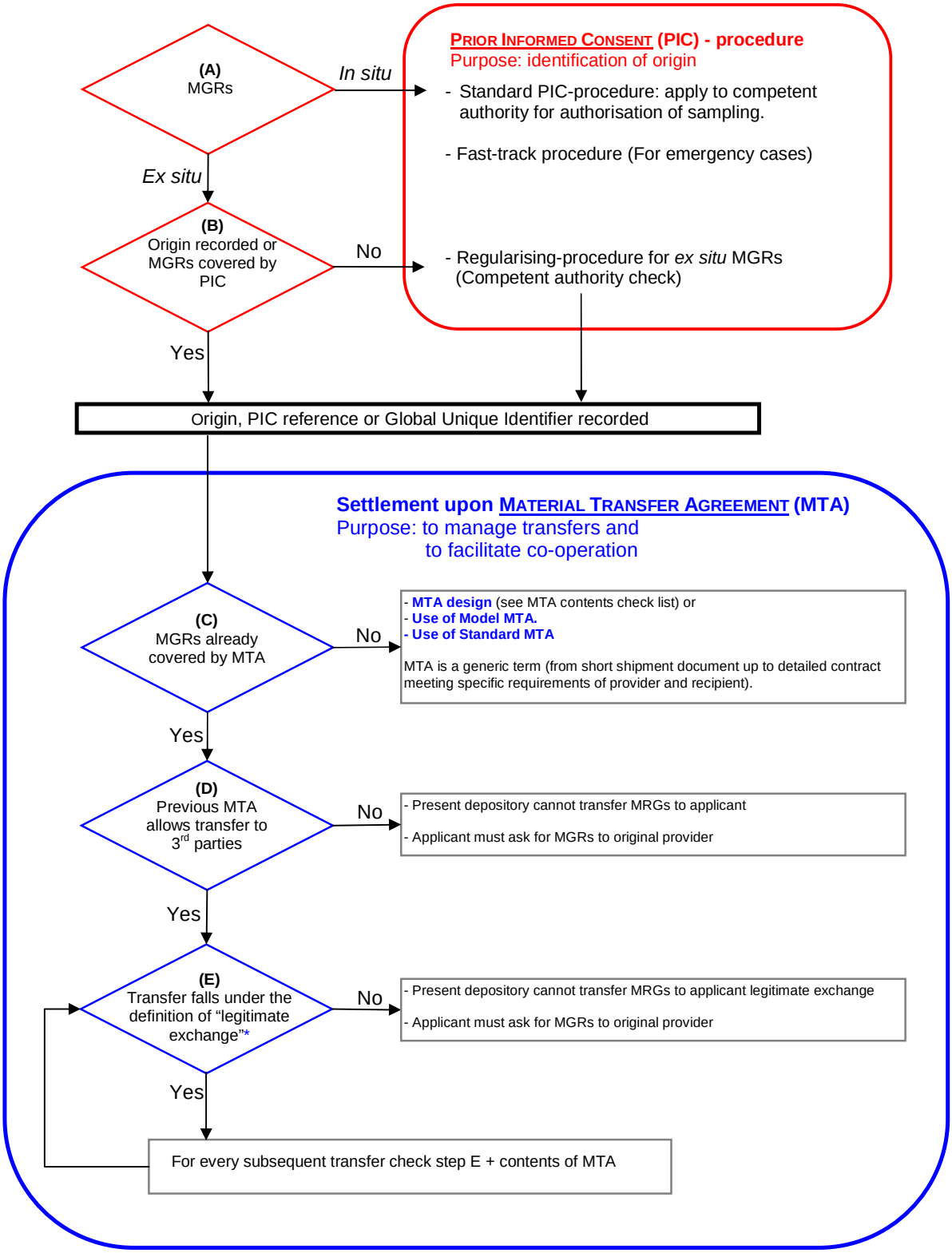
either a MTA excluding distribution to 3rd parties, **-It is the option by default-.**

or a MTA allowing distribution to 3rd parties.

E. A transfer under MTA allowing distribution to 3rd parties is possible in case of "legitimate exchanges", when the MGRs are transferred to a recipient that is a culture collection or when both recipient and provider are culture collection, or when the MGRs is transferred between people working in the same research group. When the MGRs is transferred to a recipient that is not a culture collection, then the transfer of MGRs will be covered by a MTA excluding distribution to 3rd parties.

The use of Global Unique Identifiers as electronic tools to help tracking MGRs and retrieving related information is also recommended.

Figure 1. : Procedure of transfer of Microbial Genetic Resources (MGRs)



*LEGITIMATE EXCHANGE is defined as follows: The transfer of MGRs within the RESEARCH GROUP. LEGITIMATE EXCHANGE also includes the transfer of MGRs between named culture collections/biological resources centres for accession purposes, provided that further distribution by the receiving culture collections/biological resources centre is under MTA provisions compatible and equivalent as those in place at the supplying collection.
RESEARCH GROUP is defined as follows: Entitled scientists working in a same laboratory, or contractually bound to work on the same research topic.

I.6 Definition of terms

Unambiguous definition of terms decreases the level of uncertainty and the risk of dispute between providers and recipients, stakeholders in general. Consistency between definitions existing in various MTA is also necessary to ease dialogue in a uniform textual environment[32], especially for compatibility between several model MTAs and standard MTAs.

Considering the many kinds of MTA, the CBD ABS expert groups' recommendations and culture collections experience, the following key terms should be defined in simple terms:

- **PROVIDER:** whoever provides MATERIAL to RECIPIENT.
- **RECIPIENT**: legal entity or individual who purchases and/or uses the MATERIAL.
- **DEPOSITOR**: legal entity or individual who deposits ORIGINAL MATERIAL in the custody of the PROVIDER.
- **RESEARCH GROUP**: Entitled scientists working in a same laboratory, or contractually bound to work on the same research topic.
- **MATERIAL**: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL shall not include MODIFICATIONS. The description of the MATERIAL being transferred is on delivery note and invoice.
- **ORIGINAL MATERIAL**: that which was supplied to the PROVIDER by the DEPOSITOR.
- **PROGENY**: Unmodified descendant from the ORIGINAL MATERIAL, such as cell from cell, or organism from organism.
- **UNMODIFIED DERIVATIVES**: Substances created by the RECIPIENT which constitute an unmodified functional subunit of the MATERIAL.
- **MODIFICATIONS**: Substances created by the RECIPIENT using the MATERIAL, which are not ORIGINAL MATERIAL, PROGENY or UNMODIFIED DERIVATIVES, and which have new properties.
- **LEGITIMATE EXCHANGE**: The transfer of the MATERIAL within the Research Group. LEGITIMATE EXCHANGE also includes the transfer of MATERIAL between named culture collections/biological resources centres for accession purposes, provided that further distribution by the receiving culture collections/biological resources centre is under MTA provisions compatible and equivalent as those in place at the supplying collection.
- **COMMERCIAL USE**: the use of the MATERIAL for the purpose of profit. COMMERCIAL USE shall include the sale, leasing, exchange, license, or other transfer of MATERIAL for profit purposes. COMMERCIAL USE shall also include uses of MATERIAL to establish service business activities, to manufacture products, to perform contract research, or to conduct research activities for profit purposes.

All nouns used in MTA provisions must be defined. Each additional noun adds to the complexity of the contractual engagement that constitutes the MTA. Short definitions with a minimum of words to define subsequently themselves are to be preferred.

[32] MOSAICC wish to point the specific challenges of nomenclature and classification confronted to the concept of species, especially for the prokaryotes. This is an important factor related to the consistent identification of MGRs, what is important for tracking of MGRs. For more information read Krichevsky, M.I., *Taxonomic Nomenclature: A Useful Tool, Not Truth*. SIM NEWS January / February 2007

I.7. Terms of agreement on benefit sharing, access to and transfer of technology, scientific and technical co-operation as well as technology transfer.

MOSAICC recommends the partners signatory of a MTA to include additional clauses, if applicable, in order to facilitate benefit sharing as foreseen by the CBD[33], especially scientific and technical co-operation as well as access to and transfer of information and technology.

CBD art. 15.7 terms "*... sharing in a fair and equitable way...*" imply that the return for each partner should correspond fairly with the time, money, intellectual input and inventive effort invested by that partner (including for the maintenance of the MGRs), and also reflect the respective specific values that will be added during the execution of the additional terms-package agreement.

When agreeing upon the terms of the MTA, the partners can decide either to wait until benefit arises from some commercial use and other utilisation of MGRs and to specify that complementary terms dealing with these topics will be discussed when the time had come. Or they can decide to agree upon the terms on benefit sharing preliminary to the start of the collaboration, not waiting till the necessity makes law. MOSAICC recommends the partners signatory of a MTA to come to a preliminary agreement about financial benefit sharing.

Partners should prefer terms providing possibilities for capacity building in, among others, taxonomy and general microbiology for the provider of microbial genetic resources.

In accordance with the principles and recommendations of the CBD it is recommended that the partners come to an agreement, as far as wished for, and as far as possible, about the following topics:

- **IPR related to MGRs and derived technology[34]**

  Terms of agreements on IPR related to MGRs and derived technology are recommended use-specific terms when commercial use is involved. MOSAICC recommends partners:

  – to agree on the IPR of the MGRs and/or derived technology before investing in research and development that could lead to the commercial use of the MGRs or derived technology;

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[33] Article 15.7 : " *... 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* "

Apart from the basic terms and the use-specific terms included in the Material Transfer Agreement standard model, MOSAICC foresees the possibility to have complementary mutually agreed terms dealing specifically with benefit sharing, transfer of technology, scientific and technical co-operation and technology transfer (technology including biotechnology). The existence of such additional terms, as well as their precise composition, will depend on each particular case (e.g. countries and organisations involved; nature and value of the MGRs involved; commercial or non-commercial uses, etc.).

In the case where additional terms are used, the success of the negotiation will depend on the goodwill of the respective partners to come to an overall win-win situation and the mutual understanding of each others' interests and the added value of their respective contributions. Such additional terms can, apart from the recipient and the provider of the MGRs, also involve local microbiologists, local competent authorities as well as representatives of local and/or indigenous communities.

[34] MOSAICC refers to CBD articles :

- 1 which mentions as ways to serve the purposes of the CBD "*by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies* ".
- 15.1 "*Recognizing the sovereign rights of States over their natural resources* " in the sense that "*the authority to determine access to genetic resources rests with national governments and is subject to national legislation* ". The latter does not imply, however, that the CBD does grant the state a property right over such genetic resources (Glowka et al. 1994).
- 16.2 stating that "*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* ", as well as CBD-article 16.5 stating that "*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* ".

While IPR laws often differ from country to country, some general principles and rules laid down in international legislation must be shared by those countries that are party to these international arrangements (e.g. Budapest Treaty, TRIPS, Paris Convention). A growing number of countries permit the patenting of micro-organisms, as well as of derived products, technology and processes, and this as far as the criteria of invention, novelty and utility are met. Patent law does not in general consider 'experimental use' for non-commercial purposes as an infringement of the rights of a patent owner.

Partners could make different agreements for different categories of MGRs and derived technology, and this depending on a gliding scale of value added during the acquirement of MGRs (isolation, purification), the characterisation of MGRs (identification of the MGRs; detection of possible uses) and the further development of those MGRs and derived technology. Agreements could range from single to shared IPR-ownership.

- to allocate the IPR to the inventing partner(s); and this while not necessarily excluding that other partners can, in the exceptional case of a successful commercial use of the MGR and/or derived technology, profit from forms of monetary compensation (royalties or other) and/or of a license on concessive or preferential terms (cf. CBD art. 16.2);
- to timely apply for a patent (e.g. before one publishes, if one goes for a patent in a country that does not provide for a so-called grace period).

- **Training, technical and scientific co-operation, technology transfer, exchange of information and publication policy**[35]

  - MOSAICC recommends partners to look for co-operative research programmes since as in most cases, the best training can be provided through technical and scientific co-operation.

  - As also recommended by IUMS, all scientific papers should mention provider, country of origin, date and place of isolation and identification data[36].

- **Place and ways of conservation of MGRs**[37]

  International co-operation can lead to the establishment of conservation facilities in the country of origin or to the development of agreements between on the one hand countries of origin having no conservation facilities yet and on the other hand foreign microbial genetic resource centre.

  In addition, to avoid loss of interesting *ex situ* MGRs in cases where individuals or institutions stop their activities, there should be an arrangement with culture collections that could take over the conservation of those *ex situ* MGRs that have no known duplicates elsewhere.

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[35] **Research and training** : CBD art.12(a) « *establish and maintain programmes for scientific and technical education and training in measures for the identification, conservation and sustainable use of biological diversity and its components and provide support for the specific needs of developing countries* »;
Access to and transfer of technology : CBD art.16 « *Access to and transfer of technology,..., to developing countries shall be provided and/or facilitated under fair and most favourable terms* »;
Exchange of information : CBD art.17: « *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 in combination with the technologies referred to in article 16* »;
Technical and scientific co-operation :
CBD art.15.6: « *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* »;
CBD art.18.1: « *cooperation in the field of conservation and sustainable use of biological diversity,...*»;
CBD art.18.2: « *..., the development and strengthening of national capabilities, by means of human resources development and institution building* »;
CBD art.18.4: « *encourage and develop methods of cooperation for the development and use of technologies* »;
CBD art.18.5: « *the establishment of joint research programmes and joint ventures for the development of technologies...* »;
CBD art.19: « *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* ».

[36] Dr. Cletus P. Kurtzman - US Nat'l Committee for the IUMS and Ms Robin Schoen - US Nat'l Academy of Sciences / National Research Council

[37] CBD art.9: *"Each contracting Parties shall as far as possible and as appropriate,... (a) adopt measures for the ex-situ conservation of components of biological diversity, preferably in the country of origin of such components;..., (e) cooperate in providing financial and other support for ex-situ conservation,..., and in the establishment and maintenance of ex-situ conservation facilities in developing countries"*.

- **Partnerships involving stakeholders other than provider and recipient of MGRs, including indigenous and local communities**[38]

  MOSAICC recommends that partners include indigenous or local communities as parties of an agreement in so far as the community is:

  - owner or usufructuary of the area where the *in situ* MGRs were accessed;
  - well represented by officially recognised representative(s) in their country, and
  - willing to preserve and maintain knowledge, innovations and practices relevant for the conservation and sustainable use of MGRs (CBD art. 8 (j)).

- **Monetary terms**[39]

  MOSAICC recommends that monetary compensations to those that provide or enable access to MGRs should be dedicated to technical and scientific co-operation programmes.

  - Initial, up-front payments[40]

  Initial payments can be made before or after accessing the MGRs, but this does not always take into account the possible, successful commercial use of the MGRs.

  MOSAICC recommends to calculate the importance of the initial payments in terms of the actual involvement of the provider in the delivery of the MGRs (e.g. local community participating or not to field survey; costs of maintenance of *ex situ* MGRs, etc.)

  - **Milestones payments**

  Milestones payments are dependent on the progress of the R&D process leading to a commercialization of a product derived from MGRs. At specific stages of the R&D process, set beforehand by both parties
  The users pays a fixed amount to the provider, as a kind of acknowledgement that the MGRs has some particular feature with possible industrial application.

  - Royalty payments

  Royalty payments are fully dependent on the successful commercial use of the MGRs concerned.

  MOSAICC recommends that public not-for-profit *ex situ* resource centres should not pay any royalties for MGRs they have acquired, and this foreseen that these *ex situ* MGRs, according to their public mission, will be made publicly available for a costs-covering fee.

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38 Apart from suggesting that recipients of MGRs cooperate with , among others, governmental institutions and the private sector of the country providing the MGRs (CBD art. 16.4) and/or the appropriate international and national institutions (CBD art. 18.1), the CBD also makes reference to indigenous and local communities (CBD art. 8 j). However, the CBD does not provide its users with a definition of these communities or guidelines on how to deal with them.

39 Monetary terms can be broadly split into, on the one hand, terms concerning initial payments (e.g. up-front payments) that are made independently of, as well as before, any possible successful commercial use of the MGRs concerned; and on the other hand, royalty payments that are only made in the exceptional cases of successful commercial use of MGRs.

40 In this category, we can consider the normal fees applied by most *ex-situ* resource centres and payable by the recipients of the MGRs after the delivery of the requested MGRs. In case of access to *in-situ* MGRs, up-front payments could be linked to programmes for training, technical and scientific co-operation.

SECTION II. MODEL DOCUMENTS

List of documents that should « cover » the MGRs to guarantee a transfer consistent with the principles of the CBD.

ACCESS TO *IN SITU* MGRS

- **Prior Informed Consent - PIC** obtained from a competent authority
- Optional: permission of the landowner and/or usufructuary
- **Material Transfer Agreement - MTA**

ACCESS TO *EX SITU* MGRS

- **Material Transfer Agreement - MTA**
- **One or more of these options: use of GUIDs, reference to the origin, reference of the PIC, reference of the "accession form"** or equivalent document delivered when the MGRs were originally isolated from *in situ* conditions and deposited in *ex situ* collections (See pages 8 and 9)

MOSAICC recommends that each document (PIC-application, PIC, MTA, accession form):

- fully identifies the parties involved, as well as their representative(s);
- is dated;
- contains a clear indication about duration of its terms;
- in the case of PIC-application and PIC-certificate, is signed by the sender;
- in the case of MTA, is signed by all parties involved, or seen as approved on basis of the purchase order or the notice of receipt of the MGRs. Both options are legally valid. The choice depends on the Provider's policy. Furthermore, considering that electronic ordering via internet is becoming a preferred way to purchase a MGRs from a culture collection/ biological resource centre, the buyer's consent via "click and wrap" or similar procedure like "shrink wrap" at delivery will become the option by default. It has the advantage of facilitating electronic recording and conveyance of the transfers, eventually by using GUIDs.

MOSAICC proposes:

- a model of Material Transfer Agreement;
- a PIC-application model form for access to *in situ* MGRs;
- a model of PIC for access to *in situ* MGRs.

DEFINITIONS

- **PROVIDER:** whoever provides MATERIAL to RECIPIENT.
- **RECIPIENT**: legal entity or individual who purchases and/or uses the MATERIAL.
- **DEPOSITOR**: legal entity or individual who deposits ORIGINAL MATERIAL in the custody of the PROVIDER.
- **RESEARCH GROUP**: Entitled scientists working in a same laboratory, or contractually bound to work on the same research topic.
- **MATERIAL**: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL shall not include MODIFICATIONS. The description of the MATERIAL being transferred is on delivery note and invoice.
- **ORIGINAL MATERIAL**: that which was supplied to the PROVIDER by the DEPOSITOR.
- **PROGENY**: Unmodified descendant from the ORIGINAL MATERIAL, such as cell from cell, or organism from organism.
- **UNMODIFIED DERIVATIVES**: Substances created by the RECIPIENT which constitute an unmodified functional subunit of the MATERIAL.
- **MODIFICATIONS**: Substances created by the RECIPIENT using the MATERIAL, which are not ORIGINAL MATERIAL, PROGENY or UNMODIFIED DERIVATIVES, and which have new properties.
- **LEGITIMATE EXCHANGE**: The transfer of the MATERIAL within the Research Group. LEGITIMATE EXCHANGE also includes the transfer of MATERIAL between named culture collections/biological resources centres for accession purposes, provided that further distribution by the receiving culture collections/biological resources centre is under MTA provisions compatible and equivalent as those in place at the supplying collection.
- **COMMERCIAL USE**: the use of the MATERIAL for the purpose of profit. COMMERCIAL USE shall include the sale, leasing, exchange, license, or other transfer of MATERIAL for profit purposes. COMMERCIAL USE shall also include uses of MATERIAL to establish service business activities, to manufacture products, to perform contract research, or to conduct research activities for profit purposes.

[33]The RECIPIENT will respect, if applicable, the accompanying PIC-terms and the terms laid down in the previous Material Transfer Agreement (see annexes).

[34]The RECIPIENT will use the MGRs described and listed in annex, in a sustainable way, for *bona fide* purposes and in full respect of the principles of the Convention on Biological Diversity and other applicable rules of international and national laws.

[35]The RECIPIENT will not distribute the MGRs delivered.
The RECIPIENT may distribute the MGRs in case of legitimate exchanges, provided that the following conditions are observed:

The RECIPIENT will keep records of the full co-ordinates of all downstream recipients of the MGRs concerned. This information will be available on request (= monitoring the transfers).

The RECIPIENT will transmit to the PROVIDER, as far as applicable, information (e.g. intentions for commercial use,) provided by the downstream recipient(s) of the MGRs concerned (= information feedback);

[36]The RECIPIENT and the PROVIDER distinguish the following categories of use of MGRs:

Category 1: Use for test, reference, bioassay, and control (covering only their use within the framework of the corresponding official (inter)national test-, bioassay and control protocols); use for training and research purposes;

Category 2: Commercial use. Commercial use of MGRs includes but is not limited to the following activities: sale, patenting, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or licence, product development and seeking pre-market approval.

For category 1 uses:

The RECIPIENT will not claim ownership over the MGRs received, nor seek intellectual property rights over them or related information. If the RECIPIENT wishes to utilise or exploit such organisms commercially he will first inform the PROVIDER; when applicable, suitable and adequate recompense to those entitled to be rewarded, and the country of origin will be discussed in the spirit of the Convention on Biological Diversity.

THE RECIPIENT will ensure that any individual or institution, to which the RECIPIENT makes samples of the MGRs available, is bound by the same provision.

For category 2 uses,

In order to ensure adequate benefit sharing with the country of origin and « *names of those entitled to be rewarded* », according to the principles of the Convention on Biological Diversity,

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[33] Accompanying terms: Reference of PIC, mention of the country of origin; previous MTA-terms if any

[34] Basic terms : Description of MGRs (country of origin, place and date of isolation, strain reference number, identification data, name of the individual that has isolated the strain from *in situ* conditions or, if individual's name is not available, the name of the institution (legal entity) that employed the individual at the time of the isolation of the strain.) ;
Bona fide and sustainable use, following the CBD-principles ;
Clause governing the payment of the costs of handling.
Information about provider and recipient: names, addresses
Scientific feedback: publication will mention provider, strain reference number and country of origin. .

[35] Key-terms that differentiate MTA excluding or allowing distribution to 3rd parties

[36] Use-specific terms
Category 1: Use for test, reference, bioassay, control, training and research purposes.
- No commercial use ;
- No IPR on MGRs, derived technology and information ;

Category 2 : Commercial use
- Terms on IPR, information feedback about patent application; need precise terms for benefit-sharing (see additional terms).

the RECIPIENT will immediately inform the PROVIDER and the country where the MGRs were originally accessed, of the intended commercial use(s) of the MGRs and/or derived technology and/or related information. The terms upon which benefit sharing with the stakeholders takes effect are laid down in annex.

For all categories of uses,

The RECIPIENT will mention the PROVIDER, the strain reference number and the country of origin in publication presenting scientific results and related information resulting from the use of the MGRs.

MTA ADDITIONAL TERMS CHECK LIST

- **IPR related to MGRs and derived technology**

  Different regimes[37] of IPR-ownership could be related to different values added by the respective partners during the acquirement (isolation, purification) and/or the characterisation of MGRs (identification of the MGR, detection of possible use(s), etc.).

  Check the following categories: IPR-ownership of the MGRs
  IPR-ownership of the derived technology

- **Terms on training, technical and scientific co-operation, technology transfer, exchange of information and publication policy[38]**

  Terms providing possibilities for capacity building in, among others, taxonomy and general microbiology for the provider of microbial genetic resources should be emphasised and considered as important as financial arrangements. MOSAICC recommends partners to look for co-operative research programmes since as in most cases, the best training can be provided through technical and scientific co-operation.

- **Place and ways of conservation of MGRs**

  International co-operation can lead to the establishment of conservation facilities in the country of origin or to the development of agreements between on the one hand countries of origin having no conservation facilities yet and on the other hand foreign microbial genetic resources centres[39].

- **Partnerships involving other stakeholders than provider and recipient of MGRs, including indigenous and local communities**

  MOSAICC recommends that partners include indigenous or local communities as parties of an agreement in so far the community is:
  - owner or usufructuary of the area where the *in situ* MGRs where accessed;
  - represented by officially recognised representative(s) and
  - willing to preserve and maintain her knowledge, innovations and practices relevant for the conservation and sustainable use of MGRs (cf. CBD-article 8 (j)).

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[37] For instance : - single ownership or co-ownership of the IPR;
- a single or different regimes of IPR-ownership, and the latter depending on the category of MGRs.

[38] As the publication of results of the joint programme might prohibit a successful patent application, no publication should be made without the written agreement of the concerned partner. It is to remember that scientific publications should always mention provider, strain reference number and country of origin.

[39] In this case, a country could transfer *ex-situ* MGRs to (an) *ex-situ* resource centre(s) in (an)other country(ies). This transfer should be covered by an extended MTA including provisions for access and benefit-sharing modalities. Detailed terms may be desired by the respective partners, for example by distinguishing type strains from non-type strains, or by making ad hoc agreements for herbarium material (in case of fungal material) etc.

- **Warranties and liability**

  Stipulate what the warranties offered by the providers of MGRs are. Set who is liable for damage to third parties.

- **Monetary terms**

  MOSAICC recommends that monetary compensations to those that provide or enable access to MGRs should be partly dedicated to technical and scientific co-operation programmes.

  - Initial, up-front payment

    Initial payments can be made before or after accessing the MGRs, but this always independently of the possible, successful commercial use of the MGRs. MOSAICC recommends calculating the importance of the initial payments in terms of the actual involvement of the provider in the delivery of the MGRs[40].

  - Milestones payments

    Payments related to the progress made in the development of a product or process that could be commercialised in fine.

  - Royalty payments

    Royalty payments are fully dependent on the successful commercial use of the MGRs concerned. Agreements should always make reference to net royalties[41].

- **Applicable laws and competent authorities**

  Usually, the applicable laws are these of the country where the culture collection is vested. Unfortunately, there is no agreement on this matter at international level. Specify the applicable laws to avoid uncertainty.

  Competent courts are those of the judicial district of the culture collection establishment.

[40] For example: local community participating or not to field survey, costs of maintenance of *ex-situ* MGRs, etc.

[41] Net royalties mean the gross amount of royalties, license fees, profits or any other payments which result from the use of a MGR and derived technology, less: - the costs incurred by the royalty paying partner to develop a patentable application making use of the MGRs;
- the costs incurred by the royalty paying partner for patenting derived technology;
- the costs of marketing the application.

Examples of Prior Informed Consent (PIC) documents

Considering the minimal information necessary for an authority to assess the purposes and the lawfulness of a demand, a PIC application form must include a minimum of data: information about the applicant, the time frame, the area where the material is accessed, the kind of biological resource, and reference to a Material Transfer Agreement if any. The way it is put in form is secondary; the models hereunder are examples. In cases where the authorisation of a third party (right holders like usufructuary or landowner) is required, a copy should be annexed.

PIC application form for access to *in situ* MGRs

(*Date*)

(*Name and address of the PIC-provider*)

Dear (.....),

According to article 15 of the Convention on Biological Diversity (CBD) stating that «*the authority to determine access to genetic resources rests with the national governments and is subject to national legislation* » and that «*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* », as well that «*access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources* »;

and, as ratified by (*Name of the Country where one wants to access MGRs*),

I would like to get access to (*Name of the field survey area*), as well as to its genetic resources, more specifically samples or isolates from (*name or description of group of plant, animal or microbial resources*), with your prior informed consent (PIC), during the period and under the conditions specified in annex *(copy of MTA if any; copy of authorisation of third party if any)*.

(*Name, address and signature of the PIC-applicant*)

In return, the PIC certificate should confirm the ranges / limits of time, of geographic area and of kind of biological resources it is valid for. Complementary information concerning relevant legislation is recommended.

PIC certificate for access to *in situ* MGRs.

(*Date*)

(*Name and address of the PIC applicant*)

Dear (*Name of the PIC-applicant*),

In reply to your PIC-application of (*date of written demand*) as annexed, we have the pleasure to provide you with the present PIC, in conformity with the CBD provisions, and national regulations referred to in annex.

As competent authority for controlling *in situ* access to the genetic resources of (*Name of the field of competence or geographical area of competence*), we confirm that the present PIC is valid for access to *in situ* MGRs from (*Name of the field survey area*). It grants access to this area from (*date*) to (*date*). This PIC is not transferable from one organisation to another without written agreement of the undersigned authority.

(*Place and date of issue, official administrative seals, name, address, and signature of the CBD PIC-provider*.)

* When applicable

ECCO core Material Transfer Agreement for the supply of samples of biological material from the public collection

Scope of agreement

This Agreement applies to the use, handling, distribution and any disposition of the MATERIAL supplied by the COLLECTION, and addresses the identified key points

- Traceability
- Fair and Equitable Benefit Sharing
- Intellectual Property Rights
- Quality
- Safety and Security

Definitions

a. **The COLLECTION – acronym and address of the Collection/BRC supplying the material.**

b. **AGREEMENT**: This document.

c. **RECIPIENT**: The party to whom the COLLECTION sends the MATERIAL. In case this is not the END-USER but an INTERMEDIARY, this INTERMEDIARY agrees (i) to forward to the END-USER the present MTA and the MATERIAL in unchanged form and quantity as received from the COLLECTION, and (ii) to use for this further shipping the proper packaging, a trained shipper, and an authorized carrier, according to the applicable laws and regulations.

d. **END-USER**: Scientist working with the supplied MATERIAL.

e. **INTERMEDIARY**: Third party, different and independant from the END-USER, that makes an order on behalf of the END-USER, and to which the COLLECTION addresses the MATERIAL. These can be whole-salers, importers, or other type of intermediary agents, unrelated to the END-USER's institution.

f. **DEPOSITOR**: Person(s) or entity that provided the COLLECTION with the ORIGINAL MATERIAL.

g. **MATERIAL**: ORIGINAL MATERIAL, PROGENY and UNMODIFIED DERIVATIVES. The MATERIAL shall not include MODIFICATIONS.

h. **ORIGINAL MATERIAL**: That which was originally supplied to the COLLECTION by the DEPOSITOR.

i. **PROGENY**: Unmodified descendant (e.g. sub-culture or replicate) from the ORIGINAL MATERIAL.

j. **UNMODIFIED DERIVATIVES**: Replicates or substances which constitute an unmodified functional subunit or product expressed by the MATERIAL, such as, but not limited to, purified or fractionated subsets of the MATERIAL, including expressed proteins or extracted or amplified DNA/RNA.

k. **MODIFICATIONS**: Substances produced by the RECIPIENT by using the MATERIAL, which are not the ORIGINAL MATERIAL, PROGENY, or UNMODIFIED DERIVATIVES, and which have new properties. MODIFICATIONS include, but are not limited to, recombinant DNA clones.

l. **COMMERCIAL PURPOSES**: The use of the MATERIAL for the purpose of profit.

m. **LEGITIMATE EXCHANGE**: The transfer of the MATERIAL between scientists working in the same Laboratory, or between partners in different Institutions collaborating on a defined joint project, for non-commercial purposes. This also includes the transfer of MATERIAL between public service culture collections/BRCs for accession purposes, provided the further distribution by the receiving collection/BRC is under MTA conditions equivalent and compatible to those in place at the supplying collection.

THE **COLLECTION** WILL TRANSFER THE MATERIAL UNDER THE TERMS AND CONDITIONS SPECIFIED IN THIS MATERIAL TRANSFER AGREEMENT.
THE **RECIPIENT** – BEING END-USER, INTERMEDIARY OR CULTURE COLLECTION / BRC – ACCEPTS THE TERMS AND CONDITIONS OF THIS MATERIAL TRANSFER AGREEMENT BY PLACING AN ORDER WITH THE COLLECTION.

Following AGREEMENT is between the COLLECTION and the RECIPIENT of the MATERIAL:

1. RECIPIENT agrees that all information provided to the COLLECTION in connection with any order for MATERIAL is accurate and complete, and otherwise complying with applicable laws and regulations.
2. RECIPIENT agrees that MATERIAL designated Risk Group 2 or above (as defined by the national regulations of the country where the Collection is located) may cause human disease, and that MODIFICATIONS, or other MATERIAL, not so designated, may cause human disease under certain conditions.
3. RECIPIENT agrees that any handling or other activity undertaken in their laboratory with the MATERIAL will be conducted under their responsibility and in compliance with all applicable laws and regulations.
4. RECIPIENT therefore assures that within their laboratory (i) access to the MATERIAL will be restricted to personnel capable and qualified to safely handle said MATERIAL and (ii) RECIPIENT shall exercise the necessary care, taking into account the specific characteristics of the MATERIAL, to maintain and use it with appropriate precautions to minimize any risk of harm to persons, property, and the environment, and to safeguard it from theft or misuse.
5. Unless agreed in writing with the COLLECTION, RECIPIENT shall not sell, distribute or propagate for distribution, lend, or otherwise transfer the MATERIAL to any others, except those RECIPIENT that acts as INTERMEDIARY and those RECIPIENT involved in LEGITIMATE EXCHANGES as defined above.
6. Subject to the terms and conditions of this AGREEMENT and any statutory, regulatory or other restriction imposed by law or any third party interest, RECIPIENT may use the MATERIAL in any lawful manner for non-commercial purposes.
7. If the RECIPIENT desires to use the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSE(S), it is the responsibility of the RECIPIENT, in advance of such use, to negotiate in good faith the terms of any benefit sharing with the appropriate authority in the country of origin of the MATERIAL, as indicated by the COLLECTION's documentation.
8. Nothing in this AGREEMENT grants RECIPIENT any rights under any patents, propriety, intellectual property, or other rights with respect to the MATERIAL.
9. RECIPIENT agrees to acknowledge the COLLECTION as the source of the MATERIAL in any and all publications that reference the MATERIAL.
10. Warranty: The COLLECTION hereby assures within the scope of its quality system and as far as can be determined through the COLLECTION's test regimes, that the MATERIAL shall be viable and pure upon shipment from the COLLECTION. Any claim against the warranty will have to be communicated to the COLLECTION within a period of *XX (XX)* days from the COLLECTION's shipment, and will have to be justified to the COLLECTION's satisfaction. The primary remedy for breach of this warranty is replacement by the COLLECTION of the MATERIAL free of charge.
11. Disclaimer of warranties. Except as expressly provided in this AGREEMENT and within the limits of the scope of the COLLECTION's quality system, there are no representations or warranties by the COLLECTION with respect to the MATERIAL, express or implied, including without limitation, any implied warranty of authenticity, typicality, safety, fitness for a particular purpose, or of the accuracy or completedness of the data.
