TRUST
TRANSPARENT USERS-FRIENDLY SYSTEM OF TRANSFER

Version March 2016

Based on MOSAICC
Micro-Organisms Sustainable use and Access regulation
International Code of Conduct

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

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The best way to achieve Access and Benefit Sharing (ABS) with effective socio-economic profits is to optimize existing procedures, to make the appropriate linkages between the various actors, and provide for the necessary incentives to the users so that ABS is effectively more beneficial to all and does not require coercive measures or penalties.

Several institutions specialized in microbiology, including culture collections (CC)[1], have decided to join forces and adjust their procedures. The objective is to provide a cost-efficient, simple, fast, multiple users and multiple purposes global system. Because trust is a prerequisite for lasting scientific cooperation and because trust can be attained partly through a transparent system of transfer of microbial material, they have decided to coordinate their efforts, to build TRUST, literally and practically.

TRUST stands for TRansparent User-friendly System of Transfer, for Science & Technology. It aims at managing the incidence of the Convention on Biological Diversity (CBD) and the Nagoya Protocol (NP) on the scientific, technical and administrative activities of culture collections and, more generally, at incorporating the legal obligations and the ethical standards into the daily life of microbiologists.

TRUST is a modular system having as backbone the Global Catalogue of Microorganisms and using the expertise gained by MOSAICC, MOSAICS and other initiatives. The TRUST system comprises four elements:

i. Updated MOSAICC features with administrative **workflows** adapted to the structure of the Nagoya Protocol and improved in light of past experience. **The flow of information will be connected to the ABS Clearing House - ABSCH**[2] via a machine-processed link from a defined ABSCH-IRCC[3] field to a defined GCM-IRCC field[4].

ii. Contractual documents **Material Accession Agreement (MAA) and Material Transfer Agreement (MTA) models** with standardized definitions. Considering the concept of "registered collections" as defined by EU Regulation 511/2014 implementing the Nagoya Protocol[5], the culture collections community has responded by developing an efficient information and material handling strategy to deal with administrative processing of transfers of material, especially the Prior Informed Consent and the necessary information to exercise due diligence. The concept of registered collections as future trusted sources for ABS-compliant genetic resources is imbedded into the culture collections community at the outset. It is of primary importance that:
   a. Every microbial genetic resource "entering" a collection is covered by a PIC obtained at the time of its sampling from *in situ* conditions, or after corrective administrative action.
   b. Every microbial genetic resource having entered a collection with the appropriate PIC may be distributed, accompanied by the original PIC, without any additional PIC procedure set by the country of origin or the country of use.

iii. **An integrated data management and processing system** able to provide for any information related to microbial material: the **Global Catalogue of Microorganisms (GCM)**. The CGM provides users with the ability to trace the possession, location, transmission and use of accurately identified microbial strains. GCM, via its application Analyser of Bio-resources Citations (ABC), compiles information about the country of origin, PIC and MAT, derived patents and all associated scientific publications and information published online. This system already includes more than 80 collections from 35 countries, and information on nearly 350.000 strains from 45.000 species.

iv. **Community of professionals** wherein culture collections cooperatively:
   a. use the latest ICT technology to develop the necessary identification and tracking system, primarily for scientific purposes but also for any other bona fide ends.
   b. conduct and facilitate research in genomics and functional genomics, thus develop capacities of storage and processing of genomic, transcriptomic, proteomic and metabolomic information.
   c. conduct their efforts in networks, in conformity with NP provisions on Technology Transfer, collaboration and cooperation.

INTRODUCTION

Matters at stake

"Microorganisms" comprise entities of microscopic size such as viruses, all prokaryotes: archaea and bacteria, several eukaryotic organisms: fungi including yeasts, algae, protists, their replicable parts, inclusions and other derived materials, e.g. genomes, plasmids, cDNA. Most microorganisms are considered ubiquitous and can be found everywhere, but some have specific physiological requirements, are obligate pathogens or symbionts and don't grow anywhere. Also, the environment in which particular species live affects their metabolism and their characteristics.

Fifty per cent of the living biomass on the planet is said to be microbial. Microorganisms 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 (estimated 90 to 95%) of microbial diversity is yet to be discovered. They are involved in nutrient recycling, beneficial mutualistic relationships and production of atmospheric oxygen; some are pathogens causing disease of man, plants or animals. An adult human of average weight carries about 1.5 to 2 kg of microorganisms; what is called the human microbiota.

Although their scientific discovery only dates back to the 19th century, the microorganisms have been used for millennia. Their various properties can be harnessed by man for many uses which include the control of pests and diseases in agriculture and horticulture; making of natural products such as 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, animal and human health and are employed in diagnostics, testing, vaccine production and disinfectants or as reference strains, etc. They are multifunctional and multi-use. The unravelling of the structure of the deoxyribonucleic acid, the ribonucleic acids and the various processes whereby the manufacture of protein from the nucleic acid templates occurs was pivotal in advancing the use of microorganisms in biotechnology. Socio-economic benefits directly and indirectly produced by the sustainable use of microorganisms are increasing in all fields of biotechnology.

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

Protection against hazardous microorganisms and sustainable use of beneficial microorganisms are possible provided that facilitated, save and sound access is ensured.

Objectives and principles of TRUST

The purpose of TRUST is to facilitate access, transfer and sustainable use of microbiological material, contributing to the appropriate sharing of benefits to support human development as covered by the Nagoya Protocol.

TRUST is an initiative launched on 6 December 2012, at the occasion of the 10th Anniversary of NITE BRC Symposium focusing on "Addressing Public function of BRC and the Nagoya Protocol on ABS". Following the suggestion of the President of the World Federation of Culture Collections (WFCC), representatives of BCCM, BIOTEC, CBS, JBA, KCTC, NBRC, UNU, WDCM, NHML and WFCC[6] decided to revisit MOSAICC in light of the latest legal and scientific developments to answer efficiently the Nagoya Protocol technical challenges.

TRUST stands for TRansparent User friendly System of Transfer. It intends to set the best to implement the Nagoya Protocol (NP)[7]. TRUST is rooted in MOSAICC and takes over the innovative ideas developed by life sciences and social sciences scientists to meet the evolving socio-economic environment during the last decades.

MOSAICC[8] is a voluntary Code of Conduct. It was developed to facilitate access to microbial genetic resources (MGRs)[9] and to help partners to make appropriate agreements when transferring MGRs, in the framework of the Convention on Biological Diversity (CBD)[10], and other applicable rules of international[11] and national[12] 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 CBD"[13]. MOSAICC was first issued in spring '99, two years before the Bonn Guidelines[14]. It has been updated in 2011.

Access to MGRs is a prerequisite for the advancement of microbiology and global sustainable development. 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 study, conservation and sustainable use of MGRs. **TRUST** offers a system that meets these requirements through a process in three points;

1. The *in situ* origin of a sample with MGRs is identified and recorded via initial **Prior Informed Consent** (**PIC**) procedure of notification and/or authorisation for sampling. An **Internationally Recognised Certificate of Compliance** (IRCC) is issued as proof.

2. When the MGR is deposited in an *ex situ* conservation facility usually called "culture collection", it receives a **Globally Unique Identifier (GUID)[15].** This code is kept throughout transfers and is connected to the GUID of the sample[16]. The Deposit of MGRs into a collection is made under a **Material Accession Agreement** (MAA) which on the one hand records basic data such as place and date of sampling, etc. in a standardized form and on the other hand specifies the role, rights and duties of depositor and collection. These data are compiled in catalogues and usually publicly accessible.

3. The transfers of MGRs are recorded by the CC and occur under **Material Transfer Agreement** (**MTA**) which terms are defined and accepted by both recipient and provider**.** MTA is a generic term that covers short shipment documents, simple standard delivery notices, standard invoices containing minimal standard requirements, or more detailed, specific, tailor-made contracts. According to the use and intended distribution of the MGRs, the **mutually agreed terms**[17] of the contracts can be short or very detailed (see Section II, Chapter 2).

TRUST aims to assist microbiologists:
- to obtain Prior Informed Consent-PIC (CBD art.15.5; NP art.6 and 7) ;
- to define the Minimum Data Set that unambiguously characterise the MGR, and provides for persistent identification and administrative record;
- to deposit MGRs adequately, under Material Accession Agreement (MAA)
- to establish Material Transfer Agreement (MTA) setting mutually agreed terms for transfer of MGRs, 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; NP art. 5, 9, 18, 22, 23).

TRUST also may help competent authorities of countries of origin of MGRs by suggesting procedures:
- to issue PIC for access to MGRs;
- to organise facilitated access to MGRs (CBD art.15.2, NP art.6.3d);
- to monitor the transfer of such MGRs, to enable fair and equitable sharing of the possible benefits arising from their utilisation (NP art. 17).

TRUST is for all microbiologists. The TRUST recommendations are intended as guidelines for optimal implementation of the CBD and the NP. Other national and international legal requirements developed in or outside the framework of the CBD remain compulsory (CBD art.22; NP art. 4).

The TRUST system is possible because it relies on the **Global Catalogue of Microorganisms (GCM)**. GCM automates the management of information and makes TRUST more powerful and effective.

The Global Catalogue of Microorganisms is the initiative of WDCM to link all possible data to the CCs' catalogues and make it accessible at once. Once an organism is deposited in a WFCC member collection and is assigned a number it can be traced through all publications it is mentioned in, including patent files.

Combining the WDCM registration system of culture collections and the use of electronic markers called "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 origin and movements of the resource.

GCM makes use of the pioneering WFCC database system developed by the **World Data Centre for Microorganisms (WDCM)[18]:**

- The WFCC database system registers the CCs in its official directory CCINFO[19]. CCINFO assigns a unique acronym and numerical identifier to each CC.
- WFCC members are requested to have an online catalogue of their MGRs. The catalogue of MGRs displays the Minimum Data Set (MDS) of every MGRs. The Minimum Data Set is the data set necessary for accurate identification of MGRs. MDS differs depending on the kind of MGRs.
- The combination of the CC's acronym with the numbering of every strain in the catalogue creates a code; giving a GUID to this code creates a global label system specific for MGRs. This can potentially connect a MGR to all relevant data stored in various databases in different institutions: scientific, technical, administrative, legal, etc., for any kind of use: research, conveyance, resources conservation, resources exploitation, etc.

Microbiologists and the Nagoya Protocol

The Nagoya Protocol, like the CBD and most international conventions, is implemented via national laws imposing obligations on their nationals. TRUST invites the reader to check the laws of his/her country and consult the ABS Clearing house (https://absch.cbd.int/) of the CBD to find out which regulations his/her activities is subject to.

As cited in regulation EU 511/2014 on ABS[5], general principle that should prevail in all situations is the obligation for all users to "*exercise due diligence to ascertain whether genetic resources and traditional knowledge associated with genetic resources have been accessed in accordance with applicable legal or regulatory requirements and to ensure that, where relevant, benefits are fairly and equitably shared*."

To that end, all users will seek, keep and transmit information relevant for access and benefit-sharing. TRUST proposes minimum due diligence measures. A system based on trustworthy accurate information increases transparency.

As it is not the purpose of the TRUST guidelines to analyse thoroughly the terms and principles of the CBD and the NP, readers are advised to check the bibliography and consult other documents for more information about the CBD and NP.

TRUST recommends the "OECD Best Practice Guidelines for Biological resource Centre" published in 2007 by the Organization for Economic Co-operation and Development[20] and the "WFCC Guidelines for the Establishment and operation of culture collections" edited in 2010[21]. These documents provide guidance and propose best practices for depositories of biological material. They contain lists of rules and regulations as well as useful references.

According to practices of microbiology and following the quality management principle, the cycle of implementing the Nagoya protocol can be divided in four works: Analyse, Action, Coordination, Correction:

I. FRAMEWORK - Read the script - First, one must define what should we aim for and how. Translate the general objective of the Protocol into operational objectives for the sector; transcribe the terms of the CBD and NP in a relevant glossary for microbiology; identify the most profitable benefits for microbiology.

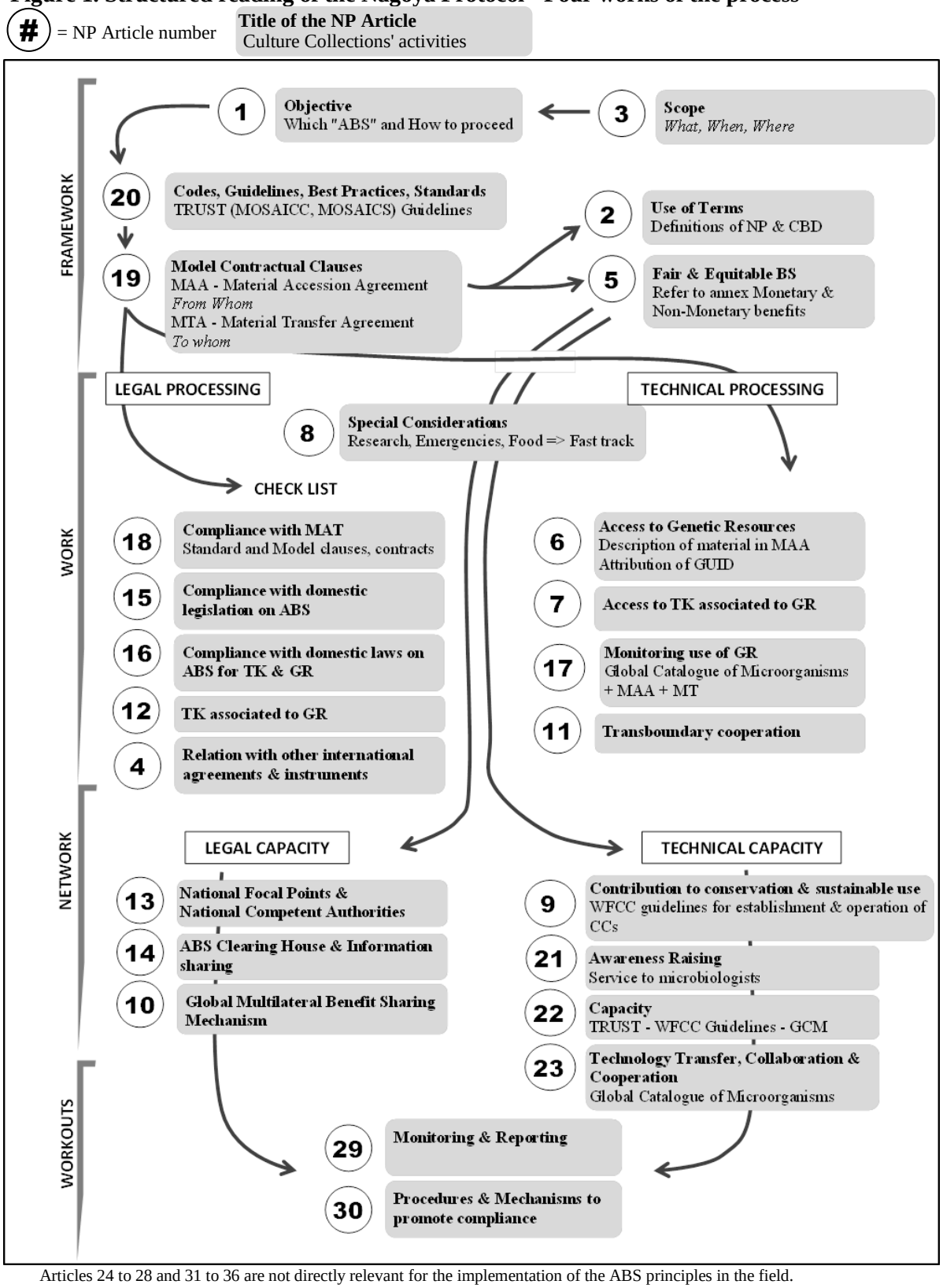
II. WORK - Act in consequence - Then, one must define what it takes to succeed. The parts to develop and assemble are grouped in two major blocks:

a) Technical measures. Technical tools developed initially for scientific purposes can be exploited to manage access and use of microbial material;
b) Legal measures. Administrative and juridical procedures set to manage contractual arrangements rooted in private laws also organise the rights and duties of stakeholders in ABS matters.

III. NETWORK - Join forces and coordinate - The objective is to foster the capacity building process. Life sciences technology and bioinformatics increase at a speed exceeding the pace of legislation design and update. Cooperation in both technical and legal fields, between lawyers and life scientists is crucial because complementary as stated by NP article 22 concerning capacity building in technical and legal field.

IV. WORKOUTS - Imagine solutions and improvements- Fourth, the system should include a cyclic improvement system, assessing the system efficiency, especially the cost/benefit ratio, and encourage innovation and creativity.

Figure 1. Structured reading of the Nagoya Protocol - Four works of the process



Articles 24 to 28 and 31 to 36 are not directly relevant for the implementation of the ABS principles in the field.

1. Procedure for access to *in situ* MGRs[22]- Nagoya Protocol articles 6 & 17

1.1 Prior Informed Consent: definition and contents[23]

In the TRUST system, the "prior *informed consent*" (PIC) is handled as a record of the authorization of access to *in situ* MGRs. It officially identifies the *in situ* origin of MGRs. It is the starting point of a procedure of facilitated access and transfer of MGRs. As stated in article 6.3(d) of the Nagoya Protocol, issuance of a PIC should be done "*in a cost effective manner and within a reasonable period of time".*

The PIC must be:
- obtained preferably prior to accessing the MGRs;
- based on legally correct and trustworthy information provided by the applicant;
- granted by a Competent National Authority (CNA) of the country where the MGRs is accessed and according to the national legislation and procedures. Nagoya Protocol article 13 paragraphs 2 and following define the role of the NCA.

For the purpose of TRUST, the "Competent National Authorities" that are entitled to provide the authorisation for access to MGRs will be called "PIC-providers"[24].

TRUST recommends that the PIC document or the PIC record contains[25]

- 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 information related to the MGRs to be accessed);
- a reference to the national legislation concerning the PIC, whether this national legislation is related to an international convention (such as the CBD and the Nagoya Protocol) or not; TRUST recommends all relevant legislation to be made accessible and explained via the ABS Clearing House (NP article 6)
- according to Nagoya Protocol Article 9, information about disposition, if any, taken for the *ex situ* preservation of the samples and reference to the terms of deposit, as indicated in a Material Acquisition Agreement (see MAA section I, chapter 2 Procedure for deposit in *ex situ* conservation facilities)[26] ;
- when relevant, the permission of right holder(s) (such as landowner/bare owner and-or usufructuary/ beneficiary).

1.2 Requesting access to *in situ* MGRs

Microbiologists, wishing to access *in situ* MGRs, should apply for a Prior Informed Consent in countries where PIC is required by national legislation[27] .

In accordance with NP articles 14 and 13 the official website of the ABS Clearing House of the Secretariat of the CBD at https://absch.cbd.int/ publishes updated information related to the status of a country towards the Nagoya Protocol, the National laws, the National Focal Point where local information may be requested and the Competent National Authorities who may issue authorizations related to the Nagoya Protocol.
Although provided by official national representatives the data published on the ABSCH website are informative. A crosscheck of the information is recommended. Also because PIC-providers are not always identifiable when and where access to *in situ* MGRs is sought, it is recommended that microbiologists:

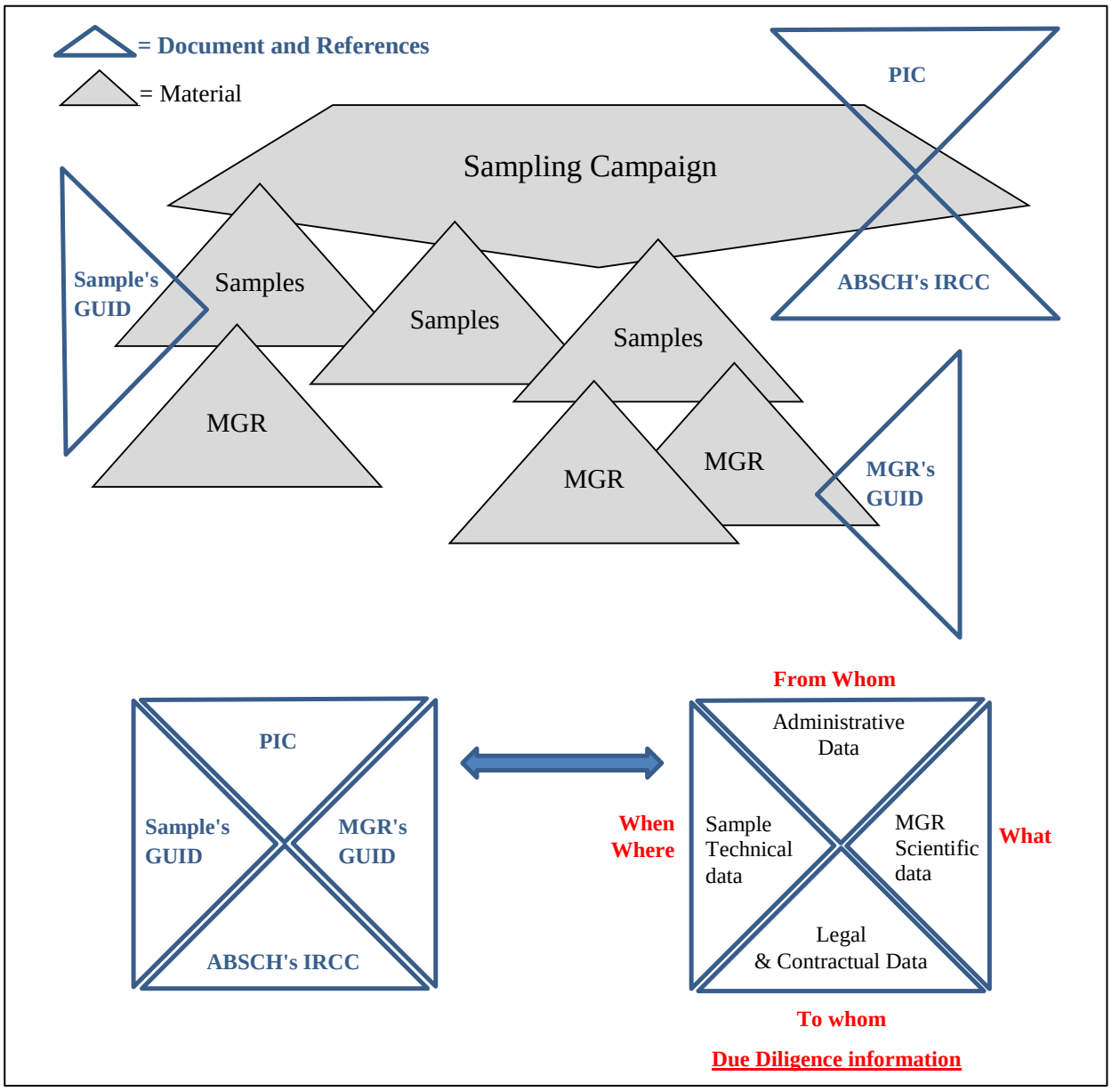
- always make best efforts to identify the competent PIC-provider and to get a PIC before accessing MGRs;
- keep proof of their efforts and steps made to acquire PIC[28];

- when wishing to access *in situ* MGRs[29], 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 ("water area" comprise freshwaters and sea waters within national jurisdiction);
- in absence of official forms, ask PIC-providers to use the PIC document checklist (see Section II model documents, PIC check list).

The PIC gives access to *in situ* MGRs; it authorises sampling of MGRs under certain conditions called "mutually agreed terms" in the Nagoya Protocol terminology.

Practically, "sampling MGRs" means that during a survey, a study or a testing, several samples are taken (e.g.: blood or tissue samples, plant, animal parts or fluids, soil or water samples, etc.). Thus one PIC may cover several samples. Moreover, from each of these samples one or more MGRs may be isolated. That means that a PIC may concern one or more ecological sample(s) from each of which one or more specific microbial strain(s) may be extracted and isolated (Figure 2). In other words, a PIC authorise a sampling where several samples are taken from each of which several MGRs may be isolated.

Figure 2. Combining official documents and GUIDs[15] to retrieve all necessary information



Technically, to link the strains to the original PIC and all other data, in other words to allow data concatenation, 3 interconnected references are required:

- A code, the GUID for the biological or ecological sample.
- A code, the GUID for each strain "extracted" from the sample[30].
- A code, a GUID for the PIC or for the Internationally Recognized Certificate of Compliance IRCC related to the PIC.

When issuing codes/identifiers, one must make the difference between an ecological sample such as soil sample which can contain many MGRs and a pure culture of one microbial strain. The Global Catalogue of Microorganisms makes this distinction.
The GUID related to a sample is issued at the time of collecting *in situ*.
The GUID related to a pure culture of a microorganisms (a strain) is issued at the time of deposit in a culture collection (see next section concerning procedure for deposit in *ex-situ* conservation facilities).
A GUID for the PIC as well as an Internationally Recognized Certificate of Compliance (IRCC) are issued when the PIC is recorded in the ABSCH.

Here, it is important to note that to capture the full extent of the interactions of microorganisms in particular ecological niches and their impact on the expression of genomes into particular phenotypes, studies take a holistic approach of the microbiota[30] of these niches of ecosystem. Such holistic approach requires handling the MGRs not only in axenic culture but also in consortia, in mixed culture containing different microbial specimens. Proper coding of these consortia may need adapted identifiers.

Fast-track procedure

As foreseen in the special considerations specified in NP article 8b, a fast-track procedure should be available in cases of emergency such as epidemic. In such cases, the use of GUID makes the backward procedure possible. Instead of getting the Prior Informed Consent (PIC) before access, access is granted first and the GUID acts as an electronic tag keeping track of the item and following the trail of its transfers in a process where the Consent is given afterwards. The fast-track procedure is coupled to a regularising procedure (see page 14).

Given the flexibility embedded in the CBD[31] as well as in Nagoya Protocol article 6 concerning the PIC requirements and the need for appropriate procedure for special cases (NP art. 8 a, b, c), countries could implement such fast-track procedure with short administrative delays according to the level of urgency. This fast-track procedure would give access to *in situ* MGRs on basis of minimum information about the purpose. It should still enable the monitoring of the distribution and utilisation of the MGRs.

In the same way, having in mind that access to MGRs is the prerequisite for basic, upstream research, and the non-monetary benefits it generates[32], a State, exercising its sovereign rights over the natural resources under its jurisdiction (CBD article 15.1), could consider organising a simplified system (NP Article 8.a)[33] that will facilitate non-commercial research, without jeopardizing potential commercial benefits (see Procedure for Type strains and Reference strains in page 13).

Such simple system can use different tools such as GUIDs, bio-molecular markers, fingerprinting, most of them produced initially by and for basic, upstream, life-science non-commercial research. When proven reliable and cost effective such coding system could be extended to all uses, including for-profit utilization because a viable and sustainable ABS system requires cost-effectiveness.

This procedure is of major importance in microbiology because at the very first stage of access to *in situ* MGR, the samples are often not yet identified. "Tagging" a microorganism is not possible at very early stage of "access". It is possible only after identification which can be a relatively simple process or may require extensive analysis. Thus, in microbiology an authorization like a PIC almost never refers to a specific microorganism.

2. Procedure for deposit in *ex situ* conservation facilities (cultures collections)

2.1 Principles and common practices

The process that formalizes the switch from *in situ* and *ex situ* life conditions of microorganisms is the deposit of a microbiological item (e.g. a strain[34] of a particular microbial species) in an *ex situ* long term conservation facility. For microbiological items these facilities are called cultures collections. When accepting strains for deposit, culture collections require a minimum of basic information from the depositor.

In collection's jargon, the deposit of a strain in a collection is called "accession" because it reflects the fact that the collection "accesses" the material. *Ex situ* conservation of a microbial strain in a collection facilitates its use. When microorganisms are listed in a public catalogue, they are made "accessible"; they can be purchased for research, education, innovation and invention. The concept of "Access" was used by CCs well before the existence of the CBD.

The **Minimum Data Set - MDS** developed for scientific and technical purposes by microbiologists managing microbial culture collections is similar to the minimal legal and administrative information required by the Nagoya Protocol, according to the due diligence principle.

The **issuance of a GUID** attached to the MGR **at the time of deposit** is most effective and make the conveyance of MGR transfers feasible. The GUID will help retrieve the necessary minimal information and more. It is not necessary to have all data grouped in one database; but it is necessary to link all databases and to connect all relevant data to the referred item, in a cost effective manner as iterated in articles 6.3d and 17.1c of the Nagoya Protocol. That is the system developed by the World Data Centre for Microorganisms (WDCM) in the Global Catalogue of Microorganisms **(**http://gcm.wfcc.info/).

These data are recorded on an "Accession form". The Accession form is the very first document attached to strains entering a collection. The Accession form makes part of the Material Accession Agreement - MAA. Appropriate use of this form will facilitate management of the microorganisms throughout its *ex situ* lifespan.

Proof of deposit in a registered collection could be considered as an Internationally Recognized Certificate of Compliance (IRCC) as defined by Nagoya Protocol article 17. 3 provided it contains or links to the minimum information as listed in NP article 17. 4.

Note also that not all collected samples are ultimately deposited in collections or preserved. Many are discarded because they are already stored in collections or because they are very common.

2.2 Structure and contents of MAA as proposed by TRUST (see also model in Section II)

Material Accession Agreement - Acquisition policy of microbiological collections

Scientific, financial and legal considerations determine the policy of culture collections.

- The scientific expertise of a research team determines the group of microorganisms that will be preferably preserved in the collection.

- Next to the scientific research strategy, the financial means of a collection impacts on its capacity to store, to handle and to study the microbiological material it preserves. The manager of the collection sets priorities based partly on available budgets. For instance the collection will have either a vertical (many specimens of a limited number of species and genera) or a horizontal (large range of species and genera but with limited number of specimen per kind) diversity of microbial groups.
  Collections need to secure funding to ensure their sustainability while having to accept and distribute a huge number of microorganisms so as to provide for high quality reliable raw material for research and innovation, fostering cumulative research.

- The laws frame the rights and duties of all stakeholders in knowledge based bio-economy. Collections promote and respect the intellectual property rights (IPR) of all stakeholders, including their own. Those that are International Depository Authorities (IDA) contribute to the system of patenting inventions where microbiological material is utilized.
  They also operate according to safety and security rules in force in their industry, especially when shipping microbiological material to customers.

Collections operate in function of these objectives and adjust their accession and distribution policies in consequence. The accession policy of a collection is transcribed in its Material Accession Agreement (MAA). The MAA set the rules of deposition in a collection. It includes a mechanism allowing cost-effective conveyance of the PIC requirements (NP Art 6) connected to the National Focal Point and ABS Clearing House (NP Art 13) system.

The material deposited in collections is very diverse, as well as the technical and scientific information (including taxonomic) needed to identify this material, to describe his *in situ* ecological niche and to determine the best *ex situ* preservation methods. Consequently, the MAA is made of two parts:

A. the Accession Form

B. the Material Accession Agreement sensu stricto

2.2.1 Part A. the Accession Form

It is the administrative and technical part of the document. It is adapted to the need of each collection and it is specific to the kind of material, because the necessary information for one kind of microorganisms may be not relevant for another and *vice versa*. This part is specific for each collection or sub-collection.

The form can be freely adapted to the needs of the collection and to the kind of material, as long as it record essential data, the Minimum Data Set.

Minimum Data Set and ***Due Diligence Principle*** **-** ***What, When, Where, From Whom***

The Minimum Data Set (MDS is the set of data necessary to identify unambiguously a particular microbial strain from a particular provenance. In bioinformatics these technical and scientific data are digitalized in specific fields of database. There is a minimum of data necessary to identify and characterize a MGR.

The Minimum Data Set includes information relevant for NP purposes:

- The scientific name. In terms of due diligence requirements this information answers the question "**What?**" = What is it?
- The provenance. This information answers the question "**Where?**" = Where was it sampled?
- The time of sampling. This information answers the question "**When?**" = When was it sampled?
- The depositor. This information answers the question "**From whom?**" = Who deposited the strain in the microbial collection?
  Several people can take part in a sampling process that leads to the cultivation of microbial strains in a collection, the one who collects the sample, one that isolates the strain, one that identifies the microbe and one that deposit the specimen in a collection. In other words, the answer to the question "From whom?" is not always simple and obvious.

Minimum Data Set recorded in the ***Material Accession Agreement***

- **General data - When, Where, From Whom**
  - Administrative data
    - *Authorization of sampling* or assimilated (PIC)
    - *Collection reference* - Globally Unique Identifier of the strain
  - Technical information - collecting data
    - *Place, Date of sampling, Name of collector, Substrate*

- **Data specific to the type of material - What**
  - Scientific data necessary to identify the material:
    - *Taxonomical data*
    - *Result of analysis, study of the strain*
  - Technical data, necessary to ensure the long term preservation of the MGRs
    - *Growth temperature, Media composition, Specific growth conditions (Anaerobic or Aerobic, Pressure, Light, Nutritive requirements such as carbon source, etc.)*

2.2.2 Part B. the Material Accession Agreement contract sensu stricto (see model MAA in Section II)

It is the legal part of the document. It is a contract between the depositor and the collection. It is subdivided in two sections: Definitions and Contractual clauses.

Contrary to the Accession form that is the technical part specific for each type of material, the legal part of the MAAs of the various collections should have as much as possible the same structure and contents, as far as the different relevant national laws are themselves compatible. Model of structure and contents of MAA are presented in section II of this document.

This procedure of deposit in a culture collection (or when necessary the regularising procedure) ensures that further Prior Informed Consent is not needed any more when a user obtains a strain from a culture collection.

2.3 Catalogues of Culture Collections and Global Catalogue of Microorganisms (http://gcm.wfcc.info/)[35]

Recording minimum data in the Accession form is the first step to build a database on the biological material of a collection. Compiling all accession forms, every individual data sheet of every MGRs stored in a collection into one database produce a catalogue. The catalogues of collections formerly in hard copy are now generally accessible online.

The objectives of the **Global Catalogue of Microorganisms** programme developed by WDCM are
- to help all culture collections to get their data digitalized and accessible online,
- to connect these strain catalogue information with corresponding nucleotide and protein sequences, as well as genome sequences and bibliographic reference or patent citations,
- to create a comprehensive database and information retrieval, analysis and visualization system for microbial resources.

The GCM is the backbone of the conveyance system; it can be linked to the international ABS Clearing House (ABSCH). Appropriate arrangements need to be organised with the international ABSCH, the national and other international clearing houses (NP article 14 The ABS Clearing-House and Information-Sharing). TRUST recommends an active dialogue with the managers and the developers of the ABS Clearing House to ensure maximum flexibility, reliability and minimum burden.

Culture Collections store metadata and data related to the material they preserve. The existing facilities and networks provide for the conservation and distribution of microbiological material and related data. However these collections are neither designed nor capable of checking or policing compliance with legislation or regulatory requirements on ABS (NP articles 15 and 16 as well as article 17 on monitoring the utilization of

genetic resources). Collections can provide for essential data and metadata and be sources where necessary information related to compliance to legislation can be retrieved but they are nor equipped, nor manned appropriately and do not have the relevant authority to substitute themselves or act in the place of the national authorities.

If and when other roles and duties are placed upon long term conservation facilities such as culture collections or any other botanical or zoological repositories, adequate funding, training and equipment are required. Where checkpoints (NP article 17) are organised, these should be supported financially to cover the additional costs of storage and management of data.

3. Procedure for access to *ex situ* MGRs[36] (Nagoya Protocol article 17)

3.1 Facilitated, documented and legal access

- TRUST recommends to **microbiologists** wishing to access *ex situ* MGRs:
  - **to work with "registered collections"** as defined by the EU Regulation 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on ABS in the European Union and similar institutions in non-EU countries. The EU Regulation is supplemented by its Implementing Act, the Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015. EU 2015/1866 lays down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices.
  - **when the microbiological material they are looking for is not available in any "registered collections" to ask the provider information about, at least, the country of origin or a reference, such as a GUID or IRCC**. These GUID or IRCC lead 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[37] (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 any kind of Material Transfer Agreement for purchasing material from and Material Accession Agreement for depositing material into a collection.
  - **to always mention the provider, the strain reference number (GUID), and the country of origin in their scientific papers/publication**
  - **to check that the *necessary minimal information* regarding the MGRs is attached or retrievable via GUID** (see Minimum Data Set).
- TRUST recommends that **the provider of MGRs** transfer them with the ***necessary minimal information*** (Minimum Data Set) 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;
  - if available, the species name identifying the strain[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;
  - possible previous mutually agreed terms, if any, included in Material Accession or Material Transfer agreements.

All these metadata can eventually be retrieved via the **strain reference number;** that is the GUID of the strain. When used in a system such as the Global Catalogue of Microorganisms the strain reference number can collect all information connected to the strain.

Procedure for Type strains and Reference strains (NP Article 8 (a))

Comprehensive exploration and structured study of microbial diversity implies access to huge numbers of specimens. These assets of fundamental scientific importance must be conserved and provided with the highest level of reliability to ensure consistent cumulative research.

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 comparative science, it is essential that access and exchange of these Reference strains and Type strains is facilitated and support research in systematics. Article 8 paragraph (a) of the Nagoya Protocol was designed to deal with this need and encourage appropriate, facilitated, yet well controlled access to these strains.

Type strains and Reference strains require a system that on the one hand highly facilitates access and circulation but on the other hand provides for effective conveyance of their use outside pure taxonomic purposes. Indeed countries of origin have expressed their concerns about the apparent contradiction between easy access and efficient control.

A possible solution may be the NIEMA[38] initiative (Network of International Exchange of Microbes in Asia) led by NITE BRC in the Asian Consortium for the Conservation and sustainable Use of Microbial Resources (ACM). NIEMA is a model of free circulation of specific strains within a closed network.
This initiative implements partly the microbial commons concept, to create an open access system, a zone of free circulation of key raw material, for users adhering to a strict code of conduct.

The coding system of strains performs well and can be expanded for administrative purposes. Yet the cost of maintaining such an expanded system can be born neither by culture collections only nor by the scientific community as a whole, especially when this system is to be used for other purposes than pure scientific or technical aims.

At the opposite of these solutions, the emergence of individuals and organisations attempting to restrict use and access or to overprotect intellectual property threatens this facilitated access[39] and runs contrary to CBD Article 15.2.

TRUST recommends that the States exercise their sovereign rights upon their natural resources to request *ex situ* MGRs providers such as culture collections based in territories under their jurisdiction to make such Type and Reference strains available without restriction, at reasonable fee, to facilitate cumulative research.

Regularising procedure

TRUST recommends implementing a regularising procedure for the *ex situ* MGRs that have been acquired / isolated from *in situ* conditions without a PIC. This regularising procedure consists of the applicant providing the relevant competent authorities with an inventory of indexed strains in 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 put 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 10).

At reception of the MGR, the collection will inform its national ABS Competent National Authority(ies). The depositor will do the same with its national authorities. This information will be centralized at the International ABSCH node.

Material Accession Agreement provisions include this obligation of reporting to the ABSCH (see article 4 of the model MAA at page 27).

4. Managing the distribution and utilisation of MGRs

That requires a simple administrative system complementary to the computerized conveyance based on the use of GUID. TRUST proposes a system that at the same time:

1. Allows easy circulation of MGRs and facilitates their uses.
2. Limits indefinite distribution to third parties, in order to shorten the chain of distribution along which the monitoring of the transfer of MGRs may be jeopardized.

Basically:

- Redistribution is prohibited, except in clearly defined cases - legitimate exchanges-;
- Initially all uses are permitted, except commercial use. Commercial use is permitted with prior notification by the user to the provider who stores the information and who generally approves without delay. The purpose of this process is to keep track of important steps towards producing benefits.

Next to conveying the transfers and uses of microbiological material, it is necessary 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; NP article 1 Objective).

The management of the entire process is based on four referral points:

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

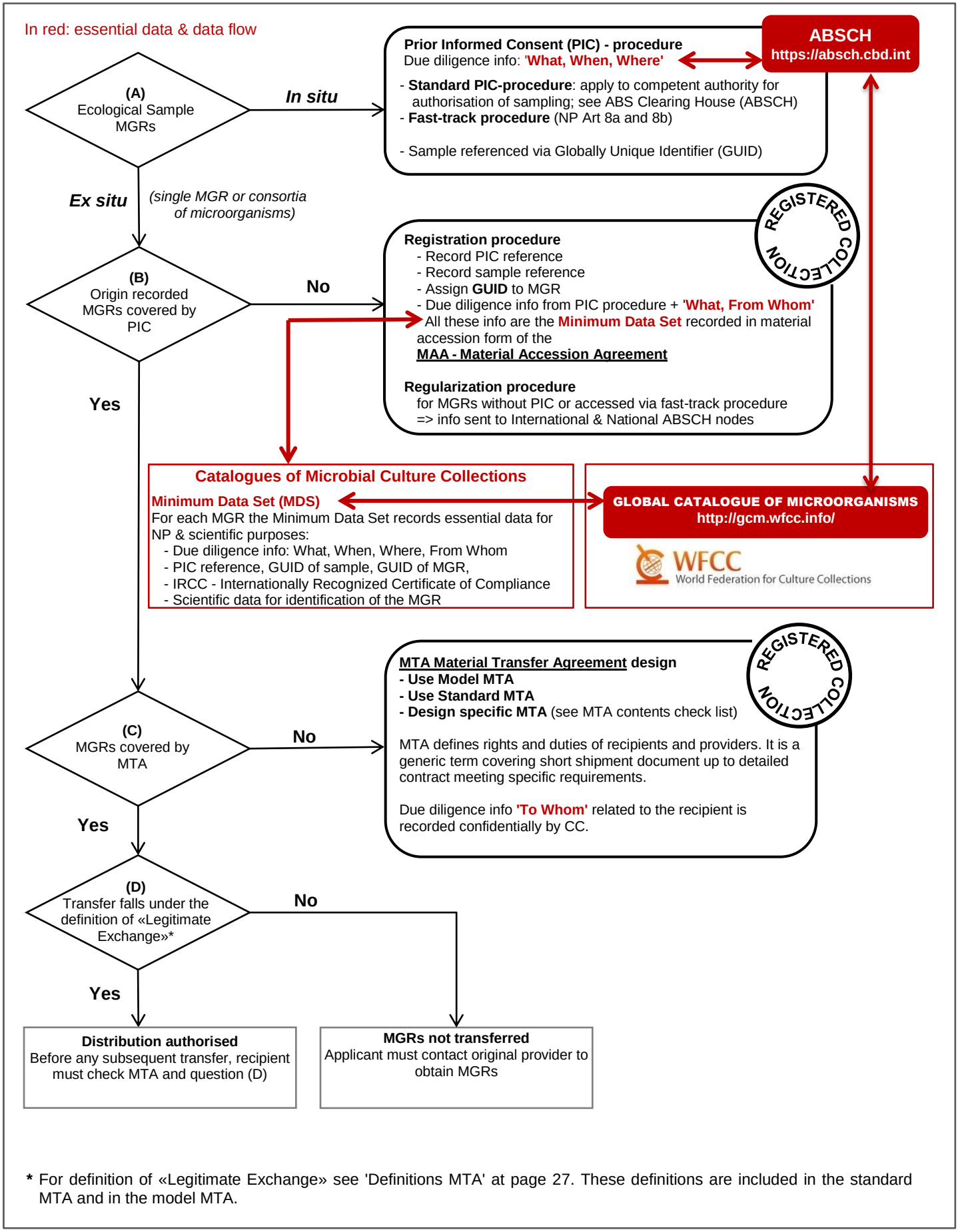
D. Transfer falls under the definition of "Legitimate Exchange"

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.

These definitions are included in the standard & model MTA (see section II)

Figure 3: Procedure of access and transfer of MGRs



* For definition of «Legitimate Exchange» see 'Definitions MTA' at page 27. These definitions are included in the standard MTA and in the model MTA.

5. Settlement of Material Transfer Agreement

All transfers of MGRs must take place under **Material Transfer Agreement** (**MTA**) the terms of which are mutually agreed[40] upon between provider and 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.

5.1 Model MTA and Standard MTA

A "**model MTA**" designates a template of contractual conditions. It serves as a reference to facilitate the settlement of an agreement by suggesting contractual terms that are generally in use in particular sectors. The parties of such contract may select and adapt the terms most appropriate to their mutual needs.

The European Culture Collections Organisation (ECCO) proposes such a model MTA with an invariable core completed with optional provisions[41]. Such regional model MTA can foster the exchanges of microbial material in a uniform legal system. The model proposed to the members of the WFCC is included in TRUST. Broad acceptance of this kind of model MTA will significantly reduce the transaction costs and facilitate ABS management in the microbiologists' community across the world, facilitating exchanges, uses and eventually benefit sharing.

A "**standard MTA**" is a fixed contractual document accepted as the standard for a particular sector. It will be implemented as such, without changes, by the sector's players in a well-defined framework. It is generally not editable.

The best example of such standard MTA is the one designed for the International Treaty for Plant Genetic resources for Food and Agriculture (ITPGR)[42]. Although the ITPGR standard MTA is designed for a multilateral benefit-sharing mechanism, it may serve as model for standard MTA adapted to bilateral agreements in framework of the CBD. The reverse is also possible: a standard MTA for bilateral use may become the standard of a multilateral scheme.

In microbiology, the use of widely accepted standard MTA may be appropriate for usual transfers, such as, but not limited to, delivery of test strains, reference strains and exchanges between scientists.

Model MTA, standard MTA, as well as model MAA or standard MAA reduce transaction costs and save time.

Microbial Commons - legal concept facilitating exchange of biological material and data

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 can 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[43]. Inside this space access and benefit-sharing are "commonly shared". 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"[44]. 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.

Bundle of rights - legal concept facilitating allotment of rights between stakeholders

TRUST recommends also, as suggested by WFCC, to refer to the concept of "**bundle of rights**"[45] as a dynamic adaptive way to allot rights to stakeholders over microbial material and related information, resulting in effective benefit sharing.

The concept of bundle or rights derives from notarial rules and has emerged as a possible effective way to answer the difficult question of "ownership of biological diversity."

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".

5.2 Tailored MTA

When standard or model MTA do not meet the requirements of the stakeholders and that a more custom-made agreement is needed, partners are advised to use a MTA check list to avoid overlooking important terms when negotiating. Partners are free to draw up custom-made terms according to their needs, provided that these terms are lawful, thus also in accordance with the principles of the CBD, the Nagoya Protocol and other relevant national and international laws.

Contents of the MTA are defined by two main criteria, the kind of use of the MGRs and the possibility to distribute or not the MGRs to third parties.

Concerning the kind of use, "*commercial use*" is usually handled differently from all other cases. Accurate definition of commercial use is thus essential. TRUST defines generally "commercial use" as: "The use of MGRs for the purpose of profit. Commercial use includes but is not limited to the placing on the market, the sale, exchange, leasing, licensing, or other transfer of MGRs as well as service activities for profit purposes."

Words like "research", "research and development", "innovation" "experimentation", "commercial" must have stable and generally accepted definitions. It is important because these terms and definitions differentiate activities with or without commercial intents or commercial outcomes.

It is recommended to define in advance these terms, and also delineate a range of benefit sharing scenario so that the users know, in advance, the cost of the MGRs in the service or product he/she will commercialize. A recommended reference is the Frascati Manual OECD (2015)[46] which proposes accurate, clear definitions and explanation for life science scientists as well as lawyers. The Frascati Manual is an objective reference to support accurate, appropriate use of terms related to Research, R&D, R&I, etc at the time of contract redaction and for disambiguation of terms when discussion arise about the effective meaning of a contractual terms.

Another approach is to consider the contribution to the public domain versus the proprietary purposes. The latter supposes that profit is directed to private interests, while the previous means that all benefit flows back to the community. In the case of the public domain, benefits are mainly non-monetary outputs, while proprietary purposes include often monetary benefits or privatization of rights, intangible rights such as intellectual property rights, and tangible rights.

The potential use and intentions can change depending on R & D results and subsequent perspectives of new applications. Actually, all microorganisms have the potential to be of commercial interest. Therefore all agreements should indicate what a change of intended use implies. In other words what are the contractual consequences of a shift to commercial use.

Activities where biological material is used as pure commodity are not subject to the Nagoya Protocol in the contrary of material that is studied in R&D / R&I processes falling under the Nagoya Protocol subject of matter.

Concerning the distribution of biological items, TRUST distinguishes the case by default where further distribution is excluded and exceptions where further distribution is allowed.

The MTA by default prohibits further down-the-line transfers. Provider and recipient agree that the recipient cannot distribute the MGRs to anybody, except in case of legitimate exchange 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. Prohibiting distribution to 3rd parties is also the rule in case of fast-track procedure (see page 8).

Distribution to 3rd parties is only allowed in case of "legitimate exchanges". That means within a research team or when the supplier and the recipient are able to keep track and to record the individuals or institutions from whom or to whom they transfer MGRs, in short when supplier and recipient are CC.

"Legitimate exchange" is defined as "The transfer of the MGRs between named culture collections / Biological Resources Centres (BRC)[47] 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 between culture collections. 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.”

Excluding distribution to third parties 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 some terms in a MTA depend on the terms of possible 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. In the case of transfer under "legitimate exchange", the obligations of the initial MTA are viral clauses[48]; they are transferred integrally to the next recipient who is bound that the same rules as the original recipient.

5.3 Specific terms related to monetary and non-monetary benefits

Standard Material Transfer Agreements usually do not detail benefit sharing arrangement concerning scientific and technical co-operation as well as technology transfer because it is too specific and can be different in each case. MOSAICC foresees the possibility to have complementary mutually agreed terms dealing specifically with scientific and technical co-operation and technology transfer. 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

These additional terms concern:
- 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.

TRUST recommends to the partners signatory of a MTA to include additional clauses, if applicable, in order to facilitate benefit sharing as foreseen by the Nagoya Protocol[49], especially scientific and technical co-operation as well as access to and transfer of information and technology.

NP objective “... *fair and equitable sharing…*” imply that the return for each partner should correspond fairly with the time, money, intellectual input and inventive efforts 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 common activities.

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. TRUST recommends the partners signatory of a MTA to come to a preliminary agreement about financial benefit sharing. A useful provision may to agree on a triggering event to determine when a detailed benefit sharing

agreement is needed. This might be at a milestone point such as applying for patent protection, a decision to start clinical trials or the need to seek investment capital.

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 and the Nagoya Protocol[34] 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[50]**

  Terms of agreements on IPR related to MGRs and derived technology are recommended use-specific terms, whether commercial use is already foreseen or not. 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;
    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[51]**

  - 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[52]. Much of this information can be disclosed by including the GUID of the International Certificate of Compliance.

- **Place and ways of conservation of MGRs[53]**

  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.

- **Partnerships involving stakeholders other 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 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**[54]

  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[55]

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. The quantum involved is partly a function of the sector involved and of the relative contribution the material makes to the final product.

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.

5.4 Special cases of benefit sharing allocation[56]

When several sources of biological raw material are implicated, the allocation of benefits to those who are entitled to be scientifically or financially rewarded for their contribution to the conservation and sustainable use of the MGRs may be complex. The contribution of each MGRs to the end product or services may be difficult if not impossible to evaluate. Prof. Gerd Winter proposes to consider a pragmatic approach of "disappearance" of the ABS right of provider states.

Nagoya Protocol article 5 requires that “benefits, ... , shall be shared in a fair and equitable way with the Party providing such resources”. One may ask how to deal with the cases where the contribution of the MGRs, including any gene of it, does disappear in the flow of R&D so that benefits cannot anymore be considered to “arise from” it? One may consider that there is disappearance in 5 cases:

- “*Comparator*“: a MGR is used as a comparator to identify functions of another MGR; only the other gene is used as basis for further R&D
- “*De minimis*”: the presence of the MGR in the final product is not characteristic
- “*Recurrence*”: genes of the MGR code for basic functions reappear in many other GRs
- “*Ubiquity*”: a GR is spread globally (e.g. E-coli)
- “*Time*”: provider states should, in analogy to patent and copy rights, let expire their rights after some time post-market, say after 25 years (~ one human generation)

Acknowledging such disappearance helps to create a “realistic” understanding of the right to benefit sharing, avoid futile negotiation, lengthy litigation and reduces transaction costs. More work, further developments are needed to get a satisfactory way to implement this pragmatic solution.

SECTION II. MODEL DOCUMENTS

To ensure accesses and transfers consistent with the principles of the CBD and the Nagoya Protocol, the following documents should be attached to the MGRs:

ACCESS to *in situ* MGRs

- **Prior Informed Consent - PIC** obtained from a competent authority.
- **Globally Unique Identifier** of the ecological sample **- GUID**
- Optional: Internationally Recognised Certificate of Compliance - IRCC[57]
- Optional: Permission of landowner(s) or usufructuary(ies)[58] (CBD art 8(j) and NP art. 12)

DEPOSIT in *ex situ* conditions

- **Material Acquisition Agreement -MAA**
  Accession form with technical data
  Material Acquisition Agreement *sensu stricto*, legal provisions
- **Globally Unique Identifier** of the microbiological material **- GUID**

ACCESS to *ex situ* MGRs

- **Material Transfer Agreement - MTA**
- **GUID of the microbiological material**
- One or more of the following information:
  - GUID of the ecological sample
  - Reference of the origin, source of the microbiological material
  - 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)

Like MOSAICC, TRUST recommends that each document (PIC, MAA, MTA, IRCC):

- 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 the MAA, is signed by all parties or shown as approved;
- 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 MGRs from culture collections / biological resource centres, the buyer's consent via "click and wrap" or similar procedure like "shrink wrap" at delivery will become the option by default.
- refers to the GUID attached to the MGRs. That has the advantage of facilitating electronic recording and conveyance of the transfers.

TRUST proposes:

1. a model of Material Acquisition Agreement (MAA);
2. a model of Material Transfer Agreement (MTA);
3. a PIC check list for access to *in situ* MGRs.

1. Material Acquisition Agreement - MAA

The MAA has two sections: a list of definition and the terms and conditions.

1.1 Structure of definitions

Definitions used in MAA and MTA are identical for the sake of compatibility and coherence. Some definitions are used in both documents, others are only necessary either in MAA or MTA.

DEFINITIONS MAA	
a. **COLLECTION** b. **DEPOSITOR**	Parties to the contract
c. **MATERIAL**: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. d. ORIGINAL MATERIAL e. PROGENY f. UNMODIFIED DERIVATIVES g. MODIFICATIONS	Material that is or isn't subject to the contract
h. RECIPIENT	Other subsequent stakeholder in the chain of transfer
i. ACCESSION FORM: Official form of the COLLECTION Makes integral part of the Material Accession Agreement	Disambiguation. Define the other part of the MAA

1.2 Examples of definitions

a. COLLECTION: Name of the culture collection.

b. DEPOSITOR: natural or legal person who deposits ORIGINAL MATERIAL in the custody of the COLLECTION.

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

d. ORIGINAL MATERIAL: what was supplied to the COLLECTION by the DEPOSITOR. The ORIGINAL MATERIAL is described on the ACCESSION FORM.

e. PROGENY: Unmodified descendant from the ORIGINAL MATERIAL, such as cell from cell, or organism from organism.

f. UNMODIFIED DERIVATIVES: Substances created by the RECIPIENT which constitute an unmodified subunit of the MATERIAL.

g. MODIFICATIONS: Substances created by the RECIPIENT using the MATERIAL, which are not ORIGINAL MATERIAL, PROGENY or UNMODIFIED DERIVATIVES, and which have new properties.

h. RECIPIENT: Purchaser of material provided by the COLLECTION. The purchaser is submitted to the terms and conditions of the COLLECTION's MATERIAL TRANSFER AGREEMENT defining the terms and conditions applicable to the use, handling, supply, distribution, sale, and any disposition of the material.

i. ACCESSION FORM: Form of the COLLECTION recording the minimum data set of administrative, technical and scientific information enabling the unambiguous identification of the ORIGINAL MATERIAL. The ACCESSION FORM is an integral part of the MATERIAL ACCESSION AGREEMENT.

1.3 Structure of provisions of Material Acquisition Agreement

CONTRACTUAL CLAUSES – GENERAL CONDITIONS applicable to the deposit of biological material in a public collection	
1.The DEPOSITOR deposits 2. 3. 4. 5.	Duties and rights of the Depositor Corrective action in case of absence of Prior Informed Consent (PIC)
6. The COLLECTION's role 7. 8. 9.	Role of the Collection = preservation and distribution Duties and rights including those related to the CBD & the Nagoya Protocol
10. Disclaimer 11. MAA not assignable 12. MAA version in effect 13. Choice of laws and dispute settlement	Legal frame of the agreement.

1.4 Example of clauses

1. The DEPOSITOR is willing to deposit the ORIGINAL MATERIAL in the custody of the COLLECTION and to grant the COLLECTION a non-exclusive license to preserve, to study and to supply the MATERIAL under the terms and conditions specified in this MAA.
2. The DEPOSITOR confirms that he has acquired, obtained, or discovered lawfully the ORIGINAL MATERIAL. More specifically and if applicable the DEPOSITOR will observe the regulations of the Nagoya Protocol to the Convention on Biological Diversity.
3. In the framework of the Nagoya Protocol, when the DEPOSITOR has a valid document equated to Prior Informed Consent he/she may claim non-monetary or monetary benefit sharing arising from the rightful utilization of the MATERIAL.
4. In case the DEPOSITOR has no proof of Prior Informed Consent or equivalent at the time of deposit in the COLLECTION, the COLLECTION will inform the competent Belgian authority that biological material has been accepted in the COLLECTION because of its scientific or socio-economic importance but without appropriate documentation. It is the responsibility of the DEPOSITOR to inform its competent national authority in the same way and reserve copy of this information to the COLLECTION.
5. By effectively transferring the ORIGINAL MATERIAL in the custody of the COLLECTION and completing the ACCESSION FORM the DEPOSITOR accepts the terms and conditions of the MAA.
6. The COLLECTION receives and is willing to keep the ORIGINAL MATERIAL in custody. The COLLECTION will assign a unique identifier to the MATERIAL and record it in its public catalogue. In agreement with the DEPOSITOR, the COLLECTION will make data and information concerning the ORIGINAL MATERIAL publicly accessible.

7. The COLLECTION makes every effort to ensure optimal preservation of the MATERIAL. It is understood that biological material is subject to contingencies, therefore no express or implied warranties are given as to the preservation of the MATERIAL in time.
8. The COLLECTION is allowed to sell, lease, license, lend, supply, distribute or otherwise transfer the MATERIAL to third party under the terms and conditions specified in the COLLECTION's Material Transfer Agreement (MTA).
9. The MATERIAL will be distributed under the responsibility of the COLLECTION in compliance with all applicable laws and regulations.
10. Any MATERIAL handled pursuant to this MAA is understood to be experimental in nature and may have unknown hazardous or beneficial properties. The DEPOSITOR and the COLLECTION will follow the recommendation of the MOSAICC code of conduct and the TRUST system (*hyperlink or reference*) for microbiological genetic resources to minimize legal, technical and environmental risks and maximize socio-economic benefit.
11. Neither this Agreement nor any rights or obligations contained herein are assignable, whether by operation of law or otherwise, without the prior mutual consent of DEPOSITOR and COLLECTION.
12. The version of the MAA applicable to any MATERIAL shall be the version in effect at the time of deposit, on signature of the ACCESSION FORM by the DEPOSITOR
13. This Agreement shall be governed by and construed in accordance with the Laws of "*Country Name*" In the event of dispute arising out of this Agreement the Parties shall seek to resolve such dispute amicably. In case the Parties fail to settle the dispute amicably, the dispute shall be brought in the courts of defendants' principal place of business, and the Parties expressly agree to the exclusive venue and jurisdiction of such courts.

2. Material Transfer Agreement - MTA

2.1 Structure of definitions

Definitions used in MTA are identical to these of MAA. Some definitions are used in both documents, others are only necessary either in MAA or MTA.

DEFINITIONS MTA	
a. COLLECTION **b. RECIPIENT**	Parties to the contract
c. DEPOSITOR d. RESEARCH GROUP	Others involved in the material handling but not parties to the agreement
e. **MATERIAL**: f. ORIGINAL MATERIAL g. PROGENY h. UNMODIFIED DERIVATIVES i. MODIFICATIONS	Material that is subject to the contract
j. LEGITIMATE EXCHANGE k. COMMERCIAL USE	Clarification of the terminology

2.2 Example of definitions

a. COLLECTION: Name of culture collection

b. RECIPIENT: See purchaser on invoice and user on delivery note if different of purchaser.

c. DEPOSITOR: natural or legal person who deposits ORIGINAL MATERIAL in the custody of the COLLECTION.

d. RESEARCH GROUP: Entitled scientists working in a same laboratory, or contractually bound to work on the same research topic.

e. 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.

f. ORIGINAL MATERIAL: what was supplied to the COLLECTION by the DEPOSITOR.

g. PROGENY: Unmodified descendant from the ORIGINAL MATERIAL, such as cell from cell, or organism from organism.

h. UNMODIFIED DERIVATIVES: Substances created by the RECIPIENT which constitute an unmodified subunit of the MATERIAL.

i. MODIFICATIONS: Substances created by the RECIPIENT using the MATERIAL, which are not ORIGINAL MATERIAL, PROGENY or UNMODIFIED DERIVATIVES, and which have new properties.

j. 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.

k. COMMERCIAL USE: the use of the MATERIAL for the purpose of profit. COMMERCIAL USE includes but is not limited to the placing on the market, the sale, exchange, leasing, licensing, or other transfer of MATERIAL as well as service activities for profit purposes.

2.3 Structure of provisions of Material Transfer Agreement

MTA TERMS AND CONDITIONS	
1. Define the conditions of transfer and non-exclusive license to RECIPIENT	Purpose of the Agreement
2. No transfer of material	RECIPIENT's duties
3. Lawful and proper use of the material	
4. Permitted uses.	Approval required before commercial use
5. Principle of precaution and prohibited uses.	Compulsory indications in publication
6. Citations, Nagoya protocol, TRIPS	
7. IPR	Tangible and intangible property rights
8. Licenses and other authorization from right holders	
9. Specific modalities	Restrictions imposed by DEPOSITOR
10. Quality of product and related services	COLLECTION's duties
11.	
12.	Disclaimer
13.	
14. MTA not assignable	
15. Applicable version of MTA	Legal technicalities
16. Choice of laws and dispute settlement	

2.4 Example of clauses

1. The COLLECTION transfers the MATERIAL to RECIPIENT and grants RECIPIENT a limited non-exclusive license to use the MATERIAL under the terms and conditions specified in this Material Transfer Agreement.
2. The RECIPIENT shall not sell, lease, license, lend, supply, distribute or otherwise transfer the MATERIAL to any others, save those involved in LEGITIMATE EXCHANGES.
3. The RECIPIENT agrees that the MATERIAL is to be used under the responsibility of the RECIPIENT, in compliance with all applicable laws and regulations.
4. Subject to the terms and conditions of this Agreement and any statutory, regulatory or other restriction imposed by law, RECIPIENT may use the MATERIAL in any lawful manner for research, teaching or quality control purposes. Any COMMERCIAL USE of the MATERIAL requires the prior written authorization of the COLLECTION. Such approval will not be unreasonably withheld.

5. The MATERIAL is to be used with caution and prudence and is not to be used for testing in or treatment of humans or non-laboratory animals. Furthermore, no animal used in testing, or their offspring, shall be used for any food or feed purposes.

6. The RECIPIENT agrees to mention the COLLECTION, the COLLECTION's catalogue number referring to the MATERIAL and the provenance of the MATERIAL in all publications, as recommended by the code of conduct MOSAICC and the TRUST system (*hyperlink or reference*), taking into account national laws implementing the Nagoya Protocol to the Convention on Biological Diversity as well as the TRIPS article 29 as to the conditions on patent applicants concerning invention disclosure.

7. Use of the MATERIAL may be subject to intellectual property rights. No express or implied licenses or other rights are provided herein to the RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights.

8. It is the RECIPIENT's sole responsibility to obtain any intellectual property licenses necessary for the use of the MATERIAL. The RECIPIENT agrees, in advance of such use, to negotiate in good faith with the intellectual property rights owner(s) to establish the terms of a commercial license; taking also into account specific national laws implementing the Nagoya Protocol.

9. The use of the MATERIAL may be subject to specific restrictions which are mentioned in the catalogue description for the particular MATERIAL and are hereby acknowledged by RECIPIENT.

10. The COLLECTION will process, package and ship the MATERIAL in accordance with applicable laws and regulations. RECIPIENT is responsible for ensuring that all permits required for RECIPIENT to receive its order are obtained.

11. Any MATERIAL delivered pursuant to this MTA is understood to be experimental in nature and may have hazardous properties. The COLLECTION makes no representations and extends no express or implied warranties, including any warranty of merchantability or fitness for a particular purpose, or that the use of the MATERIAL does not or will not infringe any patent, copyright, trademark, or other proprietary rights.

12. Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages, which may arise from its use, storage or disposal of the MATERIAL.

13. The COLLECTION will not be liable to the RECIPIENT for any loss, claim or demand made by the RECIPIENT, arising from the use of the MATERIAL by the RECIPIENT, except to the extent caused by the wilful misconduct of the COLLECTION.

14. Neither this Agreement nor any rights or obligations contained herein are assignable, whether by operation of law or otherwise, without the prior written consent of the COLLECTION.

15. The version of the MTA applicable to any MATERIAL ordered by the RECIPIENT shall be the version in effect at the time of order placement (*Hyperlink or reference to version*).

16. This Agreement shall be governed by and construed in accordance with the Laws of "*Country Name*". In the event of dispute arising out of this Agreement, the Parties shall seek to resolve such dispute amicably. In case the Parties fail to settle the dispute amicably, the dispute shall be brought in the courts of defendants' principal place of business, and the Parties expressly agree to the exclusive venue and jurisdiction of such courts.

2.5 MTA terms check list

Whether using a model or standard MTA, a check list helps verify the relevance of the contract.

IPR related to MGRs and derived technology

Different regimes of IPR-ownership and licenses may 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 and other rights related to MGRs
IPR and other rights related to derived technology

Terms on training, technical and scientific co-operation, technology transfer, exchange of information and publication policy[59]

Terms providing possibilities for capacity building in, among others, taxonomy and general microbiology for the provider of microbial genetic resources should be promoted and considered as important as financial arrangements. TRUST recommends partners to look for co-operative research programmes because 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 agreements between countries of origin having no conservation facilities yet on the one hand and on the other hand foreign microbial genetic resources centres[60].

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

TRUST 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
- have effectively contributed and will further contribute to the development and perpetuation of the knowledge, innovations and practices relevant for the conservation and sustainable use of MGRs (cf. CBD art.8 (j) and Nagoya Protocol art.12)[61].

Warranties and liability

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

Monetary terms

TRUST 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, independently of the possible, successful commercial use of the MGRs. TRUST recommends calculating the importance of the initial payments in terms of the actual involvement of the provider in the delivery of the MGRs.

- *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 preferably make reference to net royalties[62].

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.

An alternative solution for international dispute resolution is arbitration where mediation is organized within a professional arbitration institution providing arbitration services or with the intervention of international bodies such as the WIPO Arbitration and Mediation Center as neutral, international and non-profit dispute resolution provider.
Designation of such arbitral tribunal is possible for transaction outside national jurisdiction, at international level.

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

3. Prior Informed Consent (PIC) check-list

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 => Who
- The time frame => When
- The area where the material is accessed => Where
- The kind of samples and MGRs sought => What
- Reference to mutually agreed terms if any
- Type of Globally Unique Identifier to be applied on the samples and on the MGRs
- Specify when the authorisation of a third party (right holders like usufructuary or landowner) is required.

Basically the data mentioned on the PIC match the Minimum Data Set, as defined by the Global Catalogue of Microorganisms; it is also the information recorded on the material accession form of a culture collection.

The layout of such document is of little importance, but an electronic version is essential to make the system work automatically.

In return, the PIC certificate should confirm the ranges: the limits of time, the geographic area and the kind of biological resources it is valid for. Complementary information concerning relevant legislation is recommended. The PIC certificate must be reported to the ABSCH.

SECTION III. CONCLUSIONS & PERSPECTIVES

The ABS principle and the Nagoya Protocol is a social contract to ensure sustainable exploitation of the microbiological realm through generations.

TRUST represents an effort of the culture collections community. It cannot be efficient without the collaboration of all responsible socio-economic stakeholders.

TRUST recommends that the role of long term preservation facilities of biological material is not diverted from their original mission: providing solid ground to life sciences by offering reliable microbiological material for research and developments.

The best way to achieve ABS with effective socio-economic profit is to build on existing procedures, to make the appropriate linkages between the various actors and systems, provide the necessary incentives to the users so that ABS is effectively more beneficial to all and does not require coercive measures or penalties. In that way, the use of biological material will be more profitable for all parties, including the providing parties.

Cost efficiency is essential for the national strategies put in place to implement the Nagoya Protocol, including article 17 "Monitoring the utilization of genetic resources". Otherwise most of the benefits will be diverted just to feed the system, not to generate additional means for conservation of MGR, and genetic resources in general.

How much the system will cost and by whom it will be financed must be thought through in advance by the national decision makers. Funding is first needed at national level, then at international level to ensure the global functioning.

At first glance, to implement ABS in the existing structures and procedures there is a need for investment in hardware combined with maintenance of servers and computers. Software development and database management will necessitate permanent ICT staff, in addition to those who are already working to maintain the system for scientific purposes.

The experience of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR)[35] shows that the return of investment of the ABS system will be delayed as long as it is necessary to proceed from access to biological material until the actual benefit sharing. That must also be integrated in the national funding plan.

In R&D where time is also money, access delayed by lengthy administrative procedure will result in decreased profit, hence benefit-sharing.

Thus, countries willing to profit from the Nagoya Protocol ABS principles must invest in cost-efficient systems favouring academic and industrial research based on sustainable exploitation of (micro) biological resources and related knowledge.

The writer underscores that TRUST is a collaborative effort of many individuals and institutions in life sciences and human sciences (see list of major contributors hereunder). TRUST is conceived as flexible, adaptable and improvable.

The digital version of TRUST is available at http://bccm.belspo.be/projects/trust

Readers are welcome to forward comments and suggestions to the TRUST Task force, at philippe.desmeth@belspo.be

LIST OF ABBREVIATIONS

ABC	Analyser of Bio-resources Citations
ABS	Access and Benefit Sharing
ABSCH	Access and Benefit Sharing Clearing House
BCCM	Belgian Coordinated Collections of Microorganisms
BRC	Biological Resource Centre
CBD	Convention on Biological Diversity
CC	Culture Collection
CNA	Competent National Authority
GCM	Global Catalogue of Microorganisms
GUID	Globally Unique Identifier
IDA	International Depository Authorities
IPR	Intellectual Property Rights
IRCC	Internationally Recognized Certificate of Compliance
MAA	Material Accession Agreement
MAT	Mutually Agreed Terms
MDS	Minimum Data Set
MGRs	Microbial Genetic Resources
MOSAICC	Micro-Organisms Sustainable use and Access regulation International Code of Conduct
MOSAICS	Microorganisms Sustainable use and Access management Integrated Conveyance System
MTA	Material Transfer Agreement
NFP	National Focal Point
NP	Nagoya Protocol
OECD	Organisation for Economic Co-operation and Development
PIC	Prior Informed Consent
R&D	Research & Development
R&I	Research & Innovation
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TRUST	Transparent User-friendly System of Transfer
WDCM	World Data Centre for Microorganisms
WFCC	World Federation for Culture Collections

LIST OF FIGURES & BOXES

NOTES

[1] Since the infancy of microbiology, scientists struggle to ensure long term *ex situ* conservation of living microbial material for further uses. This specialised work essential to build microbiological research on solid ground is performed by culture collections (CC). CCs are infrastructures specialised in long term conservation and management of microbial resources and related data. Their mission is to provide facilitated access to - technically and legally- fit-for-use microbiological resources of consistent quality with regard to the material itself as well as related data.

Culture collections evolve constantly, not only contributing to the scientific and technical progresses but also facing the growing pressure of socio-economic, legal and political constraints. The shift of terminology reflects this evolution: while in the past, "Culture Collections - CC" were essentially seen and run as mere centres of conservation and distribution of microbiological material, "Biological Resources Centres - BRC" are conceived now as the sources of all essentials for Research and Development in Life Sciences. The concept of Biological Resource Centres (BRC) was thought up as early as 1946, at UNESCO, on the set up of the MIRCEN - Microbial Resources Centres Network – program, to establish microbial resource centres in developing countries and to strengthen several threatened treasure houses of microbial diversity through mutual support within a network. In 1999, the Organization for Economic Co-operation and Development Working Group on BRC initiated the development of the concept into the 21st century. To fulfil their role of basic infrastructure for biosciences in Knowledge Base Bio-Economy, they must implement quality management system in a constant search for improvement of their management and scientific expertise.

The ISO organisation has eventually set up Technical Committee 276 to design a norm dedicated specifically to BioBanks, including microbial BioBanks. Originally the word "BioBank" meant the stock of materials of human origin, at present the word applies to all types of biological material. One will specify whether it is about human biobank, microbial biobank, etc. This wording emphasizes the economic role played by collections, next to their scientific and technical importance.

TRUST uses the original "culture collections (CC)" term.

[2] http://absch.cbd.int

[3] Internationally Recognized Certificate of Compliance

[4] See annex 2 of information document https://www.cbd.int/doc/meetings/abs/np-mop-01/information/np-mop-01-inf-08-en.pdf

[5] Regulation EU 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, and its Implementing Act, the Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices.

[6] BCCM=Belgian Coordinated Collections of Microorganisms , BIOTEC= Thailand National Center for Genetic Engineering and Biotechnology, CBS= Netherlands Centraalbureau Schimmelcultures, JBA=Japan Bio-industry Association, KCTC=Korean Collection for Type Cultures, NBRC=Japan NITE Biological Resource Center, UNU=United Nations University, WDCM=World Data Centre for Microorganisms, NHML=Natural History Museum London, WFCC=World Federation for Culture Collections.

[7] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, adopted on the 10th meeting of the Conference of the Parties on 29 October 2010, in Nagoya, Japan. http://www.cbd.int/abs/text/

[8] http://bccm.belspo.be/projects/mosaicc

[9] 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).

[10] 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. At the time MOSAICC was issued the Nagoya Protocol that set in rules the CBD principles mentioned above was not even negotiated. TRUST is based on MOSAICC and focus on the Nagoya Protocol.

[11] Among others the Budapest Treaty on the International Recognition of the Deposit of Microorganisms 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.

[12] 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.

[13] Concerted action n° BIO4-CT97-2206 (DGXII - SSMI). The MOSAICC project involved twelve partners.

[14] 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)

[15] 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. Note that not all identifiers are global and unique.

The characteristics of a Global Unique Identifier (GUID), to be fully operational, are the following:

1. Persistent (no 404 error messages): always retrievable;
2. Actionable: can be used to activate algorithms, search and concatenation;
3. Unique at global level: global unique label linked to the sample.

In terms of level of uniqueness of an identifier, one can list in ascending order of efficiency the following:

- Label = what is assigned to a physical sample.
- Code = label (usually alphabetical or numerical) included in a list.
- Identifier = number that can be retrieved in a list for internal use.
- Unique identifier = identifier that is assigned to one and only one object, but may lead to many related data/information.
- Globally Unique Identifier = persistent, actionable and unique at global level label.

[16] The GUID issued for the sample collected *in situ* is linked to the GUID issued for the MGR deposited in a repository (collection, botanical garden, etc.).

[17] "Mutually agreed terms" is considered here as a general expression defining terms of a contract, for instance terms like those made under private laws. It is not limited to the definition of articles 6 and 7 of the Nagoya Protocol in the context of PIC deliverance.

[18] WDCM is the ICT centre of WFCC. http://www.wdcm.org.

[19] http://www.wfcc.info/ccinfo/

[20] 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.

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

[22] Provisions included in CBD article 15, and the use of terms for the purposes of the CBD (article 2) 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* ".
In case of microorganisms, "*surroundings*" may include laboratories where MGRs have acquired distinctive properties in *in vitro* condition. That means that for this kind of MGRs the country of origin will be the country where the laboratory is located. Examples of such MGRs are microorganisms that have undergone spontaneous or induced mutations, microorganisms that have evolved after many subcultures, via sexual or asexual reproduction, recombinant plasmids, constructs, weakened microbial host strains for plasmids, etc.

[23] 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);
- "*Provide for a clear and transparent written decision by a competent national authority, in a cost effective manner and within a reasonable period of time"*. (Nagoya Protocol. Art. 6.3d)
- « *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).

[24] There are different kinds of National Competent Authorities and 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. PIC providers must be registered and accessible via the ABS Clearing House website http://absch.cbd.int and via every ABS National Focal Point.

[25] 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 objectives of the Convention on Biological Diversity (CBD articles 1 and 15.2) and more specifically counter the Nagoya Protocol.

[26] The transfer of *in-situ* MGRs to *ex-situ* conservation facilities (generally called "microbial cultures collections", or "microbial biobanks") is covered by a MAA setting the conditions of deposit. When receiving MGRs to conserve, culture collections also ask the depositor to fill in an "accession form" where basic information is recorded. The accession form is an integral part of the MAA. The MAA is usually one of the first official documents recording the trail of movements of a MGR, alongside any scientific paper describing the MGR and its properties. This procedure also make possible the due diligence principles of getting answers on three questions:
What? = What do you access? + When? = When did you get access? + Where? = Where has the MGRs been accessed?

[27] 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. 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. There are countries where access is free such as Denmark.

In the case of countries members of the European Union, access is ruled at the national level while compliance measures for users are set by Regulation (EU) NO 511/2014 and its Implementing Act, the Commission Implementing Regulation (EU) 2015/1866 (see also note 5)..

[28] The principle of due diligence does not imply a reversal of the burden of proof, where it then would be borne by the user of accessed biological material while on the contrary it must remain the responsibility of the public prosecutor.

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

[30] In microbiology, the microbiota of a sample, that is the microbial population of a sample, may be studied either via isolation and grow in culture or via metagenomics. Although experienced technicians may presume what the microbial population is made of, they never know exactly the composition of the population before more or less lengthy, complex and sophisticated investigation.

[31] As already mentioned in footnote 27, 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*». MOSAICC has already proposed this fast-track procedure in its original version of 1999, precluding the decision of the Bonn Guidelines and NP article 8b.

[32] As mentioned in appendix II of the Bonn Guidelines, in COP Decision VI/24 Annex II, in the Nagoya Protocol Annex about Monetary and Non-Monetary Benefits and in Nagoya Protocol article 22 on Capacity, 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.

[33] 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

[34] A strain is a genetic variant or subtype of a microorganism , for instance, a "flu strain" is a certain biological form of the influenza or "flu" virus. In culture collections one speaks about conservation of "strains", "type strains", "reference strains", a vial of a particular strain, a subculture of a strains, etc.

[35] Wu et al.: Global catalogue of microorganisms (gcm) a comprehensive database and information retrieval, analysis, and visualization system for microbial resources. BMC Genomics 2013 **14**:933

[36] Given article 15 and article 2 of the CBD, respectively stating that:
-"*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 microbiological origin containing functional units of heredity that is kept outside its natural habitat, in laboratory conditions, under *in vitro* conditions.

[37] *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.

[38] http://www.jsmrs.jp/journal/No30_2/No30_2_85.pdf

[39] 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.

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

[41] http://www.eccosite.org/ecco-core-mta/

[42] www.planttreaty.org

[43] 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

[44] 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

[45] 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.

[46] OECD (2015), *Frascati Manual 2015: Guidelines for Collecting and Reporting Data on Research and Experimental Development*, The Measurement of Scientific, Technological and Innovation Activities, OECD Publishing, Paris. DOI: http://dx.doi.org/10.1787/9789264239012-en

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

[48] Reichman, J.H., Uhlir, P.F., Dedeurwaerdere, T. (2016) Governing Digitally Integrated Genetic Resources, Data, and Literature, Global Intellectual Property Strategies for a Redesigned Microbial Research Commons. Cambridge University Press. ISBN 9781107021747

[49] Nagoya Protocol Objective. Article 1. "*The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components."*

[50] 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 are 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 microorganisms, as well as of derived products, technology and processes, and this as far as the criteria of invention, novelty, non-obviousness 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.

[51] Article 23 of the Nagoya Protocol refers to the articles 15, 16, 18 and 19 of the CBD. MOSAICC also cites article 12 of the CBD. (Note that Nagoya Protocol article 22 on Capacity is related to capacity to organise and manage the ABS system at national and regional level. It is different from biotech related efforts. It must be handled as well but with different experts and institutions.)
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* ».

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

[53] 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".*

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

[55] This category includes the regular fees applied by most *ex-situ* resource centres and payable by the recipients of the MGRs for 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.

[56] Source: Prof. Gerd Winter, University of Bremen

[57] https://www.cbd.int/abs/doc/commonformats/ABSCH-IRCC.doc

[58] Usufruct is a civil law principle equivalent to common law life estate. This concept is particularly adequate when applying the concept of "bundle of rights" to the biological material.

[59] 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. Scientific publications should always mention provider, strain reference number and country of origin.

[60] In this case, a country could entrust its microbial diversity 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.

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

[62] 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 putting on the market the product or the service.