

**Submission of the
World Federation for Culture Collection (WFCC)
World Data Centre for Microorganisms (WDCM)
& Transparent User-friendly System of Transfer programme (TRUST)**

for Notification SCBD/ABS/VN/KG/jh/86849

This submission is related to **paragraphs 4 and 5 of decision CBD/NP/MOP/DEC/2/10:**

- Paragraph 4 *situations in which it is not possible to grant or obtain prior informed consent in relation to in situ or ex situ genetic resources and associated traditional knowledge*
- Paragraph 5, **the way forward in relation to article 10 and mechanism facilitating benefit sharing on a global multilateral level**

This submission is a summary of decades of work with continuous improvement based on experience of many WFCC collections of living microorganisms operating in both hemispheres and acting as facilitators of access to microbiological material for all purposes, research, education and application in all fields of biotechnology.

WFCC supports its members in implementing the Nagoya Protocol by **developing adapted procedures and updating the structure of the culture collections' databases** with the minimum data set to meet the requirements of the Nagoya Protocol in terms of ABS relevant information.

Since the creation of the International Federation for Culture Collections seventy years ago, as predecessor to the World Federation for Culture Collections, the mission of culture collections members of the WFCC match closely the provisions of *CBD article 9* regarding *ex situ* conservation. Microbial culture collections are instruments for *Each Contracting Party [...] to adopt measures for the ex-situ conservation of components of biological diversity, preferably in the country of origin [...]*

Like CBD article 9 (b) culture collections are "*facilities for ex-situ conservation of and research on [...] micro- organisms, preferably in the country of origin of genetic resources;*"

In support to CBD article 9 (d) specifying that Contracting parties shall "*Regulate and manage collection of biological resources from natural habitats for ex-situ conservation purposes [...]*" collections maintain and organize collections of living microorganisms.

Like CBD article 9 (e) individual collections and WFCC as a formal multidisciplinary federation under the International Union of Microbial Societies "*Cooperate in providing [...] support for ex-situ conservation [...]*

In the same way WFCC member collections continually work together to organize a global system that help support the ABS principles and implement the Nagoya Protocol provisions in microbiology.

Concerning decision CBD/NP/MOP/DEC/2/10, WFCC and its members have designed guidelines and an internet based system organizing the online catalogues of public culture collections.

Concerning paragraph 4 of decision CBD/NP/MOP/DEC/2/10

[...] situations in which it is not possible to grant or obtain prior informed consent in relation to in situ or ex situ genetic resources and associated traditional knowledge [...]

Such situations may happen when *in situ* sampling occurred before the entry into force of the Nagoya Protocol but no documentation is available except the fact that the microorganism was deposited before this date.

Other such situations occur when a third party wants to deposit material in a culture collection but has no documentation concerning the date and place of sampling. In that case, rather than rejecting material that may have great scientific value, although not having evidence of legality, a culture collection may accept the material but inform the authorities *a posteriori*. That is what MOSAICC and TRUST call a "regularising procedure". Such procedure allows a possible benefit sharing with the putative country of origin.

When no country of origin is unambiguously identifiable (for instance because the microbial material is ubiquitous) a global multilateral benefit sharing mechanism may be useful as long as it is cost efficient.

Already in 1999, the MOSAICC code of conduct included a regularising procedure for the cases where no information or evidence of date and place of original collecting are available.

[...] Many ex-situ MGRs are not yet covered by a PIC because individuals as well as institutions, including ex-situ resource centres, have sometimes acquired and are still acquiring MGRs without a PIC. MOSAICC recommends that a regularising procedure will be followed for these ex-situ MGRs that have been in the past acquired/isolated from in-situ conditions without a PIC. This regularising procedure consists of the applicant providing the competent authority with an inventory of indexed strains in pure culture, whether identified

or not, kept at its facilities. This correcting measure will fulfil the need to identify the in situ origin of the strains by recording and transferring the adequate information. [...]

In the updated 2011 version MOSAICC stipulates:

[...] Complementary to the recording of basic information at key point of the micro-organisms life, the use of Global Unique identifiers (GUIDs) will help retrieve the necessary minimal information and more. Many ex situ MGRs are not yet covered by a PIC because individuals as well as institutions, including ex situ resource centres, have sometimes acquired in the past, and in particular cases are still acquiring MGRs without a PIC.

MOSAICC recommends that a regularising procedure will be followed for these ex situ MGRs that have been acquired / isolated from in situ conditions without a PIC. This regularising procedure consists of the applicant providing the competent authority with an inventory of indexed strains in pure culture, whether identified or not, kept at its facilities. This correcting measure will fulfil the need to identify the in situ origin of the strains by recording and transferring the adequate information. This measure must remain exceptional.

It is intended to get back into the regular circuit MGRs that have for any reasons bypassed the standard procedure.

The regularising procedure applies also in the context of fast-track procedure (see Nagoya protocol Article 8 (b) regarding present and imminent emergencies). Amongst the strains kept ex situ, those used in standards for assays and proficiency tests are called reference strains, and the strains that underpin taxonomy and nomenclature are defined as Type strains. The availability of these strains is of central importance in a comparative science, it is essential that access and exchange of these reference strains and Type strains is not impeded to facilitate microbiological systematic research.

The emergence of individuals and organisations attempting to restrict use, access or protect intellectual property threatens this access, and runs contrary to CBD Article 15.2. MOSAICC recommend that the States exercise their sovereign rights upon their natural resources to request ex situ MGRs providers such as culture collections in which such strains are deposited to make these available without restriction, a reasonable costs fee, to facilitate future research and enable proper identification. [...]

At present the combination of TRUST and the Global Catalogue of Microorganisms (GCM) make an electronic handling of the regularising procedure possible.

GCM structures its information in such way that data relevant for ABS can be directly passed through to the ABSCH. The Global Catalogue of Microorganisms is described in the following paragraphs.

Concerning paragraph 5 of decision CBD/NP/MOP/DEC/2/10

[...] views on the way forward in relation to Article 10 [...]

(About mechanism facilitating benefit sharing on a global multilateral level, complementary to bilateral benefit-sharing)

Much of the recommendations of TRUST are based on experience and guidelines of the WFCC members. Since 1999, the basic principle of MOSAICC and TRUST is to always link the original source(s) of material with the end uses, among others by means of Global Unique Identifiers (GUID). The development of the Global Catalogue of Microorganisms improves dramatically the possibility to monitor the origin and the transfers of microbiological genetic resources stored *ex situ* via the common access to online catalogues of culture collections. Catalogues of culture collections have a minimum data set about every strain

The Global Catalogue of Microorganisms is an initiative of the World Data Centre for Microorganisms combined with TRUST. TRUST is published on the ABSCH. To explain the context in microbiology and to describe the system set up by the WFCC community we may refer to the introduction of the TRUST reference document:

[...] TRUST 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 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). 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 is a voluntary Code of Conduct. It was developed to facilitate access to microbial genetic resources (MGRs) and to help partners to make appropriate agreements when transferring MGRs, in the framework of the Convention on Biological Diversity (CBD), and other applicable rules of international and national 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 microbial genetic resources (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". MOSAICC was first issued in spring 1999, two years before the Bonn Guidelines. 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 and GCM offer 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) may be issued as proof.
2. When the MGR is deposited in an *ex situ* conservation facility usually called "culture collection" (CC), it receives a Globally Unique Identifier (GUID). This code is kept throughout transfers and is connected to the GUID of the sample. The Deposit of MGRs into a collection is made under a Material Deposit Agreement (MDA) 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 terms¹⁷ of the contracts can be short or very detailed.

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 Deposit Agreement (MDA). ("Deposit" or "Accession" are terms both used when somebody deposit a strain into an ex situ conservation facility).
- 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). (In the culture collections community, the term MTA designates usually the transfer from culture collection to users).

TRUST also may help competent authorities of countries of origin of MGRs by suggesting procedures or connecting GCM with national or international official ABS website:

- 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 (GCM)** 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)** created originally in Australia:

- The WFCC database system registers the CCs in its official directory CCINFO. CCINFO assigns a unique acronym and numerical identifier to each CC.
- WFCC members are expected 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.

WFCC supports its members in implementing the Convention on Biological Diversity and the Nagoya Protocol. WFCC works on continuous optimisation of its internet-based global network.

More information concerning MOSAICC, TRUST and GCM can be retrieved on the ABSCH (<https://absch.cbd.int/search/referenceRecords?schema=modelContractualClause>) or on their respective website:

MOSAICC at <http://bccm.belspo.be/projects/mosaicc>

TRUST at <http://bccm.belspo.be/projects/trust>

GCM at <http://gcm.wfcc.info/>

Questions can be forwarded to

The coordinator of TRUST, Philippe Desmeth. Email: desp@belspo.be

The secretary of the WFCC permanent secretariat, Anne Depauw. Email: depa@belspo.be

The Director of WDCM, Juncai MA. Email: ma@im.ac.cn
