

**NAGOYA PROTOCOL
USER MANUAL**

According **TRUST**
TRansparent **U**sers-friendly **S**ystem of **T**ransfer

Based on **MOSAICC**
Micro-**O**rganisms **S**ustainable use and **A**ccess regulation **I**nternational **C**ode of **C**onduct

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

TRUST - Transparent User-friendly System of Transfer

- The purpose of TRUST is to facilitate access, study and exploitation of the microbial realm by organizing the transfers of Microbiological Genetic Resources (MGRs) and by managing all related data.
- TRUST assumes that a system based on trustworthy accurate information increases transparency and legal certainty. A simple cost efficient procedure applied on a voluntary basis is attractive and therefore more likely to be abided than a coercive system; it is *in fine* more effective.
- TRUST integrates the MOSAICC recommendations.
- TRUST uses the [Global Catalogue of Microorganisms](http://gcm.wfcc.info) (<http://gcm.wfcc.info>).
- TRUST applies the legal obligations set by the following laws:
 - Convention on Biological Diversity (CBD, Rio de Janeiro, 5 June 1992),
 - Nagoya Protocol to the CBD on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity,
 - Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure,
 - Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS Agreement, Marrakech, 15 April 1994),
 - as well as other applicable laws ruling importation & exportation of goods, biosafety & biosecurity, etc.
- TRUST combines facilitated transfers of microbiological material and effective monitoring of the flows managed by the culture collections (CC) members of the World Federation for Culture Collections (WFCC).
- The operating principles are:
 - a. Identification of the point of origin:
 - the *in situ* origin is initially recorded via initial Prior Informed Consent (PIC) deliverance,
 - a Minimum Data Set (MDS) including the reference of the PIC is recorded at the time of deposit in a culture collection,
 - the MDS always accompany the MGRs along the transfers.
 - b. Monitored transfers of MGRs:
 - by use of two kinds of contracts:
 - Material Accession Agreement (MAA) for the deposit of MGRs in collections,
 - Material Transfer Agreement (MTA) for the distribution of MGRs to users.
 - by computing and concatenate all relevant data.
- The Global Catalogue of Microorganisms is an initiative of the World Data Centre for Microorganisms (WDCM) to merge all the collections' catalogues data to make them searchable and accessible at once. All these catalogue references are in turn linked to all published scientific data.

Once a MGR 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)” sets up a robust system to organise transfers of MGRs, 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 MGRs, including information related to the origin and movements of the resource.

- More information and explanations are detailed in the TRUST Guidelines document accessible online at the BCCM website <http://bccm.belspo.be/projects/trust> .

TRUST General Procedure

IN SITU - Sampling

Isolation
from
in situ

Purposes: Obtaining sampling authorization - Exercise Due Diligence - Identification of *in situ* origin

Document(s): **Prior Informed Consent (PIC)**

Action: Prior to sampling *in situ*, microbiologists exercise due diligence:

- Inquire on the official website of the ABS Clearing House (ABSCH) <https://absch.cbd.int/> regarding the country's Competent National authority (CNA);
- Check the information with the National Focal Point (NFP) indicated on the country's fact sheet published on the ABSCH;
- Make significant efforts to get a PIC from the CNA and other authorization from possible rights holders.

Information: The Minimum Data Set (MDS) for scientific & for legal and administrative purposes,

Due diligence info

"What?" = Kind of sample

"Where?" = Provenance

"When?" = Time of sampling

EX SITU - Deposit & preservation

Deposit
in
collection

Purpose: Deposit and registration in a culture collection

Document(s): **Accession Form:** record all necessary scientific and technical information for unambiguous identification and optimal preservation of the microbiological material

Material Accession Agreement (MAA): legal document, contract specifying the rights and duties of depositor and collection

Action:

- Depositor provides the necessary information requested in the Accession form;
- Depositor agrees with the terms of deposit (MAA);
- Collection assigns a reference code that is a GUID or is connected to a GUID;
- If no PIC shown than follow the **Regularising procedure** (see TRUST guidelines).

Information: All information recorded in the PIC + scientific information relevant for due diligence

"What?" = Scientific name of MGRs

"From whom?" = Depositor

Reference of Internationally Recognized Certificate of Compliance (IRCC) when any,
Reference of MGRs and GUID,

Technical data related to the method and place of conservation of MGRs,

All these data are published or referenced in the catalogue of MGRs of the CC.

EX SITU - Transfers & Utilisation

Distribution,
transfers in
general

Purposes: Purchasing microbiological material from culture collection (recipient's perspective)
Providing microbiological material (provider's perspective)

Document(s): **Material Transfer Agreement (MTA)**

Action: Use: Standard MTA - non-modifiable terms implicitly accepted when placing order;
Model MTA - set of provisions selected according to needs;
Tailored MTA - contract is written using a check list.

Information: Catalogue reference (GUID) of microbiological material,
Due diligence info

"To whom?" = Recipient of MGRs

MTA provisions = agreed upon conditions of distribution = Mutually Agreed Terms

All uses permitted. Commercial use requires prior notification of recipient and written authorization of provider. "To whom" is not public information.

EX SITU - Commercial Use

Isolation
from
in situ

Purposes:	Ensure legal certainty Make future benefit sharing possible (non-monetary benefit possible from all kind of use)
Document(s):	Material Transfer Agreement - MTA Written consent from provider (collection)
Action:	Recipient notifies intended commercial use to the provider; Provider records the intent of commercial use the information and send written consent; Exchange of information about the intent of the recipient is strictly confidential. The information may become public when the user places a service or a product on the market, takes proprietary rights via patent or licence.
Information:	Notification of user with confirmation of the legality of the planned activity that shall not affect the safety of people and property nor contravene ethics Catalogue reference of the MGRs (GUID) MTA provisions = agreed upon conditions of distribution

MTA Contents Check List

Transfer of
MGRS

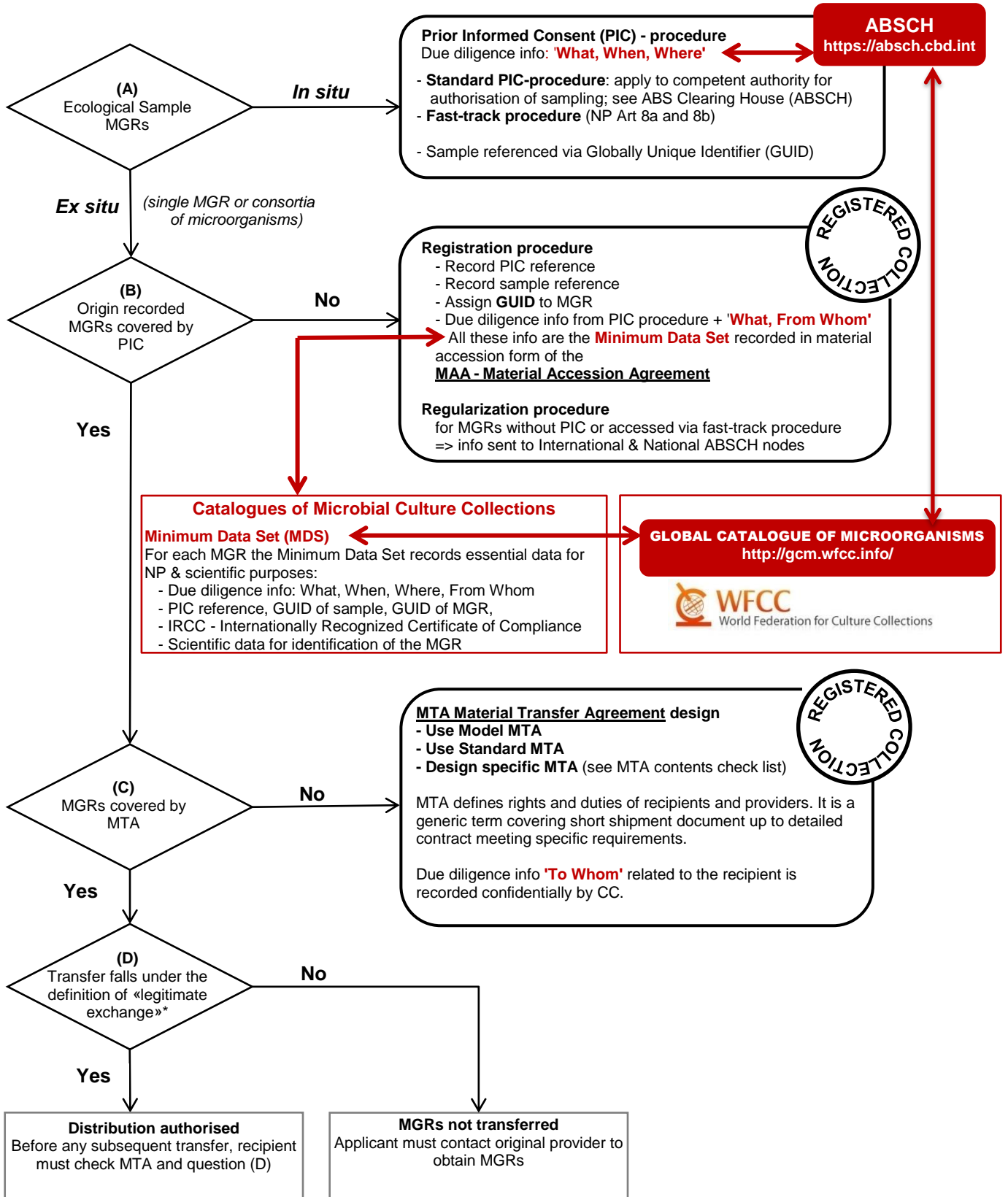
Transfer of
Technology

Transfer
(sharing) of
Benefits

Purposes:	Reduce transaction costs and save time Ensure legal certainty
Contents:	Minimum Data Set for scientific, legal & administrative purposes The Minimum Data Set includes due diligence information "What?" = Scientific name of MGRs "Where?" = Provenance "When?" = Time of sampling "From whom?" = Depositor "To whom?" = Recipient of MGRs + GUID <u>Definitions</u> Unambiguous definitions are essential. "Commercial use" is handled differently from all other cases. The Frascati Manual OECD (2015) is an objective reference to support appropriate use of terms concerning research, R&D, R&I, experimentation, etc. Another approach is to consider 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. <u>Contractual terms</u> setting rights and duties of recipient and provider of MGRs, concerning: <ul style="list-style-type: none">- IPR related to MGRs and derived technology;- Terms on benefit sharing, preferably non-monetary options such as training, technical and scientific co-operation, transfer of technology, exchange of information and publication policy;- Monetary terms, up-front payment, milestones payment and/or royalties. Financial arrangements should be designed as complement to non-monetary activities that have more lasting effects;- Partnerships involving other stakeholders than provider and recipient of MGRs, including indigenous and local communities;- Distribution of MGRs by the recipient to third parties is prohibited by default. Monitoring of the transfers of the MGRs is limited to the registration of one recipient. This also guarantees the quality of the MGRs. Distribution to 3rd parties is only allowed in case of "legitimate exchanges". Activities where MGRs are used as commodities are not subject to the Nagoya Protocol in the contrary of material that is studied in R&D and R&I processes.

LOGICAL FLOW CHART - Operating the Nagoya Protocol in Microbiology

In red: essential data & data flow



* 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

LIST OF ABBREVIATIONS

ABC	Analysers 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

