NAGOYA PROTOCOL - FIRST AID KIT

- This section is intended as a checklist for those who obtain and use Microbial Genetic Resources (MGRs) for Research and Innovation.

- It is based on guidelines developed by TRUST and MOSAICC.

- TRUST believes that accurate and reliable information increases transparency and legal certainty.

- TRUST applies the **LEGAL OBLIGATIONS** set by several legal layers:

  International agreements such as:
  - Convention on Biological Diversity (CBD),
  - Nagoya Protocol to the CBD on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization,
  - 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),
  - other applicable laws ruling importation & exportation of goods, biosafety & biosecurity, etc.

  Supra-national laws such as:
  - Regulation (EU) No 511/2014 of 16 April 2014 on compliance measures for users from the Nagoya Protocol on ABS and related laws
  - Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions

  National Laws, including the Belgian Federal and Regional laws, are listed for information -but with no guarantee of exhaustiveness- in the ABS Clearing House of the Convention on Biological Diversity.

- The **OPERATING PRINCIPLES** are:

  a. **Identification of the point of origin**:
  - the *in situ* origin is initially recorded via initial Prior Informed Consent (PIC) or similar legal document 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 following the "**Due Diligence**" **principle**.

  b. **Monitored transfers of MGRs:**
  - by use of two kinds of contracts:
    - **Material Deposit Agreement (MDA)** for the deposit of MGRs in collections,
    - **Material Transfer Agreement (MTA)** for the distribution of MGRs to users.
  - by recording and concatenating all the relevant data according to the principle of due diligence

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

The **MINIMUM DATA SET (MDS)** is a concept that is used commonly by microbiologists to define the essential data to unambiguously characterize a particular microbial strain from a particular provenance: its place and date of discovery, isolation, identification, its characteristics and eventually its storage place. In bioinformatics these technical and scientific data are digitalized in specific fields of database.

The Minimum Data Set includes information relevant for Nagoya Protocol purposes:

- The scientific name. In terms of due diligence 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 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.

The MDS developed for scientific and technical purposes is the data set necessary for accurate identification of MGRs. The scientific MDS differs depending on the kind of MGRs but the core information is similar to the minimal legal and administrative information required by the Nagoya Protocol.

The MDS may be considered as the essential data to monitor the faith of a microbial strain from its first isolation from nature to its final use and eventually or not its socio-economic exploitation. In this context these essential data are clerical ones that are also of scientific importance.

The **DUE DILIGENCE** concept is set by EU Regulation EU 511/2014, more precisely Chapter II about User Compliance, Article 4 Obligations of users : "1. *Users shall exercise due diligence* [...]".

According preamble 21 of the said Regulation " *[...] all users [...] should 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 fulfil the obligation of due diligence you need to SEEK, KEEP AND TRANSFER the **Minimum Data Set**. Doing so you work in full transparency and make sure that you did all you had to do to comply with the Nagoya Protocol when laws and regulations are unknown. By exercising due diligence, one helps organize the lawful exchanges and uses of MGRs and ultimately make possible the benefit sharing with those who have the right to be scientifically or financially rewarded for their contribution to the study, conservation and sustainable use of MGRs.

Successive stages of discovery, preservation, study and use of microbiological diversity

IN SITU - Sampling (Sampling and Isolation from *in situ*)

EX SITU - Deposit & Preservation (Deposit in collection, in biobank)

EX SITU - Transfers & Utilisation (Distribution, exchanges, transfers in general

EX SITU - Commercial Use (Socio-economic exploitation of biodiversity)

MTA Contents Check List (Transfer of MGRS - Transfer of Technology - Transfer (sharing) of Benefits)

Logical Flow Chart - Operating the Nagoya Protocol in Microbiology

List of Abbreviations

General Procedure (based on TRUST)

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)** or similar legal document

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 or equivalent 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): **Deposit Form**: record all necessary scientific and technical information for unambiguous identification and optimal preservation of the microbiological material
Material Deposit Agreement (MDA): legal document, contract specifying the rights and duties of depositor and collection

Action:
- Depositor provides the necessary information requested in the Deposit form;
- Depositor agrees with the terms of deposit (MDA);
- 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 - *ad hoc* contract 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

Socio-economic exploitation of biodiversity

Purposes: Ensure legal certainty
Make future benefit sharing possible (note that monetary benefit is more likely in case of commercial use, non-monetary benefit is possible from all kinds 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

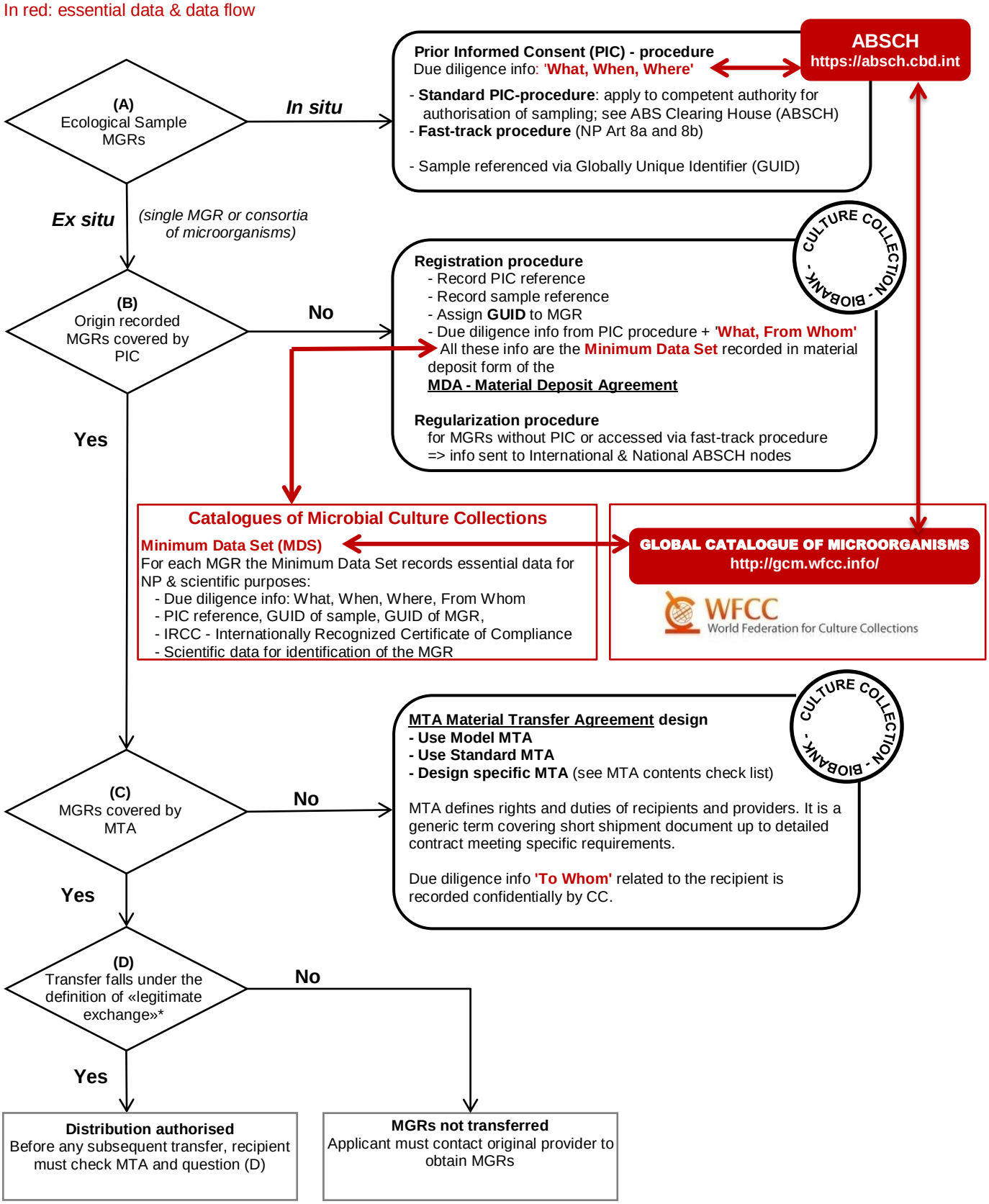
Definitions Unambiguous definitions are essential. "Commercial use" is handled differently from all other cases. The Frascati Manual OECD (2015) is an objective reference to support appropriate use of terms concerning research, R&D, R&I, experimentation, etc.
Another approach is to consider the public 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.
Contractual terms setting rights and duties of recipient and provider of MGRs, concerning:

- 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" (see definition in TRUST or in the flow chart.

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 / 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

Txt & lay-out: philippe.desmeth@BELSPO.be

LIST OF ABBREVIATIONS

ABC	Analyser of Bio-resources Citations (WDCM)
ABS	Access and Benefit Sharing
ABSCH	Access and Benefit Sharing Clearing House
BB	BioBank = other name for Culture Collections (term "Biobanking" uses in ISO 20387:2018)
BCCM	Belgian Coordinated Collections of Microorganisms
BRC	Biological Resource Centre ~ BioBank
CBD	Convention on Biological Diversity
CC	Culture Collection ~ BioBank
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
MDA	Material Deposit Agreement (previously MAA for 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
NSD	Nucleotide Sequence Data
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