MOSAICC - Summary

- MOSAICC stands for «Micro-Organisms Sustainable use and Access regulation International Code of Conduct».
- It is a tool to support the implementation of the CBD at the microbial level, in accordance with other relevant rules of
 international and national laws. It can serve as a model when dealing with genetic resources other than microbial
 genetic resources (MGRs).
- It is a voluntary Code of Conduct.
- Its purpose is twofold: to facilitate access to microbial genetic resources (MGRs) and
 - to help partners to make appropriate agreements when transferring MGRs.
- It is subject to the relevant rules and provisions stated in :
 - the Convention on Biological diversity (Rio de Janeiro, 5 June 1992) especially the terms dealing with :
 - Prior informed consent regulating access to resources (Art. 15.1 & 15.2)
 - Mutually agreed terms on transfer of Microbial Genetic Resources (Art.15.4 & 15.7)
 - the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure (28 April 1977, amended on 26 September 1980 and Regulations);
 - other applicable rules of international and national laws.
- It combines : the need for easy transfer of MGRs
 - and the need to monitor the transfer of MGRs

This is necessary because access to MGRs is a prerequisite for the advancement of microbiology. Furthermore, monitoring the transfer of MGRs is necessary to identify the individuals or groups that are entitled to be scientifically or financially rewarded for their contribution to the conservation and sustainable use of the MGRs.

- Its operating principles are a) identification of the origin:
 - in situ origin of the MGRs is identified via initial Prior Informed Consent (PIC) procedure providing authorisation for sampling;
 - in situ origin of the MGRs is always mentioned when transfer occurs.
 - b) monitored transfer of MGRs occurring under **Material Transfer Agreement** (**MTA**) the terms of which are defined by both recipient and provider.

Material Transfer Agreement (MTA) is a generic term that can cover either a very short shipment document, a simple standard delivery notice, a standard invoice containing minimal standard requirements or a 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;
- information about provider and recipient;
- mutually agreed terms defined by two main criteria: the use of MGRs (test, research, commercial use) and the distribution of MGRs. According to the use and intended distribution of the MGRs, mutually agreed terms can be either short or very detailed.

MOSAICC general procedure

IN-SITU conditions

Isolation from in situ conditions

Identification of in situ origin Administrative requirement

Document requirement

Microbiologists wishing to access *in-situ* MGRs, will endeavour to apply to a competent authority for an authorisation for sampling microbes from in situ conditions, also called Prior Informed Consent (PIC).

<u>Information requirement</u> The document should at least contain:

- names and addresses of the PIC-applicant and the PIC-provider;

- confirmation of the authority exercised by the PIC-provider;
- confirmation of the precise scope of the PIC-authorisation (area of sampling, description of MGRs to be accessed);
- reference to the national legislation concerning the PIC, whether this national legislation is related to regulations or recommendations expressed in an international convention (such as the CBD) or not;
- reference to Material Transfer Agreement(s) which terms are mutually agreed upon between the provider and the recipient of MGRs, in compliance with CBD article 15.4. (see MTA check list below);
- and, if necessary, in annexe, the permission of the landowner and/or usufructuary.

Procedure for special cases: A fast-track procedure should be available in cases of emergency such as epidemic or for MGRs needed for biocontrol of non-indigenous pests/flora/fauna originating from the same habitat/ecosystem as the

EX SITU conservation

Administrative requirements: Acknowledgement of in situ origin;

Agreement on the conditions of the transfer;

Records, list of recipients.

Document in use: Microbiologists wishing to transfer MGRs, will use shipment document, delivery notice, invoice or elaborate contract that can be designated by the generic denomination of Material Transfer Agreement - (MTA) because it contains at least: a) information about the in-situ origin;

- b) information about provider and recipient;
- c) mutually agreed terms.

Minimal information requirement

a) Information about the in-situ origin

- reference to the original PIC or an equivalent document delivered when the MGRs were originally deposited in ex-situ collections:
- strain reference number;
- species name of the strain, if available;
- place and date of isolation as well as the name of the individual that has isolated the strain from in situ conditions or, if individual's name is not available, the name of the institution (legal entity) that employed the individual at the time of the isolation of the strain.

Procedure for special cases For ex-situ MGRs that have been in the past acquired/isolated from in situ conditions without a PIC, a regularising procedure will be followed. This regularising procedure consists of the applicant providing the competent authority with an inventory of indexed strains in pure culture, whether identified or not. This regularising measure fulfils the need to identify the in situ origin of the strains by recording and transferring the necessary information. This regularising measure should last for a transitional period, before the general procedure promoted here is widely in use. After such a transitional period normal PIC-procedure will be followed.

- b) **Information about provider and recipient**. Both users and suppliers should keep records of transfers of MGRs (names, addresses, dates, MGRs). This information is available upon request when possible sharing of benefit is contemplated.
- c) Mutually agreed terms. According to the use and intended distribution of the MGRs, mutually agreed terms can be either very short or very detailed. For usual transfers, such as delivery of test strains and exchanges between scientists, etc., partners are advised to use widely accepted MTA model forms (see also the MOSAICC MTA). When a more custom-made agreement is needed, partners are advised to use the MTA check list to avoid overlooking important terms when negotiating. Partners are free to draw up these custom-made terms according to their needs, provided that these terms are lawful and in accordance with the principles of the

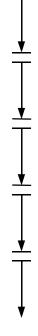




Transfer of MGRs

Transfer of technology

Transfer of benefits



Material Transfer Agreement (MTA) contents check list

1. Accompanying terms

Reference to the original PIC; Existing previous MTA-terms.

2. Basic terms

- Description of MGRs (country of origin, place and date of isolation, strain reference number, identification data, name of
 the individual that has isolated the strain from *in situ* conditions or, if individual's name is not available, the name of the
 institution (legal entity) that employed the individual at the time of the isolation of the strain);
- Bona fide and sustainable use, following the CBD-principles;
- Clause governing the payment of the costs of handling;
- Type of transfer: transfer where distribution to 3rd parties is either excluded or possible

(The choice between these two options is subordinate to the kind of use. When further distribution is possible, limited or not limited distribution are further options).

- Information about provider and recipient : names, addresses.

3. Use-specific terms

Category 1: Use for test, reference, bioassay, control and training purposes.

- No commercial use ;
- No Intellectual Property Rights (IPR) on MGRs, derived technology and information;
- The recipient has to follow the protocols of standard test and reference procedures.

Category 2: Use for research purposes

- No commercial use ;
- No IPR on MGRs, derived technology and information ;
- Scientific feedback: publications will mention provider, strain reference number and country of origin.

Category 3: Commercial use

- Terms on IPR, information feedback about patent application;
- Need for more precise terms for benefit-sharing (see additional terms).

4. Additional terms

- IPR related to MGRs and derived technology

IPR-ownership of the MGRs

IPR-ownership of the 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 considered as important 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 Royalty payments

MOSAICC ADMINISTRATIVE PROCEDURE FLOW CHART

When transferring microbial genetic resources (MGRs) check the following options:

- A. The MGRs are in-situ or ex-situ
- B. Prior Informed Consent (PIC) is available or not
- C. There is a previous Material Transfer Agreement (MTA) or not
- D. If there is a previous MTA, it may either exclude distribution to 3rd parties (D.1) or allow distribution to 3rd parties (D.2)
- E. When allowed, the distribution to 3rd parties can be not limited **or** limited.
- **F.** A transfer under MTA allowing not limited, well monitored distribution to 3rd parties could be followed subsequently by a transfer covered **either** by a MTA excluding **or** by a MTA allowing distribution to 3rd parties.

