

ELABORATION AND DIFFUSION OF A CODE OF CONDUCT FOR THE ACCESS TO AND
SUSTAINABLE USE OF MICROBIAL RESOURCES WITHIN THE FRAMEWORK OF THE
CONVENTION ON BIOLOGICAL DIVERSITY

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MOSAICC

MOSAICC
MICRO-ORGANISMS SUSTAINABLE USE AND ACCESS REGULATION
INTERNATIONAL CODE OF CONDUCT

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Louis Pasteur: “ The role of the infinitely small is infinitely large ”

BCCM

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INTRODUCTION

MOSAICC is a voluntary Code of Conduct. It is developed to facilitate access to microbial genetic resources (MGRs)¹ and to help partners to make appropriate agreements when transferring MGRs, in the framework of the Convention on Biological Diversity (CBD)² and other applicable rules of international³ and national⁴ 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.

Access to MGRs is a prerequisite for the advancement of microbiology and world-wide sustainable development. 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. Therefore, MOSAICC combines the need for easy transfer of MGRs and the need to monitor the transfer of MGRs. It proposes a system that works through two operating principles:

1. The *in situ* origin of the MGRs is identified via initial **Prior Informed Consent (PIC)** procedure providing authorisation for sampling. The *in situ* origin of the MGRs is always mentioned when transfer occurs.
2. The transfer of MGRs is monitored and occurs under **Material Transfer Agreement (MTA)** which terms are defined by both recipient and provider. MTA is a generic term that covers 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. According to the use and intended distribution of the MGRs, mutually agreed terms can be short or very detailed.

MOSAICC aims to assist microbiologists:

- to obtain Prior Informed Consent-PIC (CBD art.15.5) ;
- to establish Material Transfer Agreement (MTA) for access to and transfer of MGRs, access to and 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).

MOSAICC aims to assist countries providing MGRs by suggesting procedures:

- to issue PIC for access to MGRs;
- to monitor the transfer of such MGRs, to enable a fair and equitable sharing of the possible benefits arising from their utilisation.

MOSAICC includes recommendations to microbiologists. These recommendations should be considered as guidelines for an optimal implementation of the CBD. National and international legal requirements developed in or outside the framework of the CBD remain compulsory (CBD art.22). As the implementation of the CBD is ruled at national level, some suggestions to countries are also included as well as some model forms in section II of this document. As it is not the purpose of MOSAICC to analyse thoroughly the terms and principles of the CBD, readers are advised to check the bibliography and consult other documents for more information about the CBD.

¹ Definition of microbial genetic resources (MGRs) derived from the CBD definition of genetic resources: *any microbial genetic material of actual or potential value* (art.2).

² 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).

³ A/o 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) and the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS Agreement, Marrakech, 15 April 1994). See also CBD article 22.

⁴ 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, an 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.

SECTION I. TERMS OF ACCESS to MGRs

I.1. Prior Informed Consent: definition and contents⁵

In the system proposed by MOSAICC, the “*prior informed consent*” (PIC) is a document that officially identify the *in-situ* origin of MGRs and authorise the access to *in-situ* MGRs. It is the result of a procedure put in place to monitor the access to and the transfer of MGRs.

The PIC must be: - acquired prior to accessing the MGRs ;

- based on legally correct and trustworthy information provided by the applicant;
- granted by a competent authority of the country providing the MGRs and according to the national legislation and procedures. (For the purpose of MOSAICC, the competent authorities that are entitled to provide the authorisation for access to MGRs will be called “PIC-providers⁶”).

MOSAICC recommends that, in all cases, the PIC-document should contain⁷ (see section II for model PIC):

- 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 description of MGRs to be accessed);
- a 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;
- a reference to a Material Transfer Agreement, if any⁸;
- and , if necessary, in annexe, the permission of the landowner and/or usufructuary.

⁵ 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);
- « *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).

⁶ There are different kinds of 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 such as the MOSAICC model form (see section II).

⁷ 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 attainment of the general objectives of the Convention on Biological Diversity (CBD articles 1 and 15.2).

⁸ The transfer without MTA of *in-situ* MGRs to *ex-situ* conservation facilities is possible when the present depository has itself isolated the MGRs directly from *in-situ* conditions and stored them at its facilities. In any other cases transfer of MGRs without MTA is extremely inadvisable.

I.2. Procedure for access to *in-situ* MGRs⁹

Prior Informed Consent

MOSAICC recommends that microbiologists, wishing to access *in-situ* MGRs, endeavour in all cases to apply for a **Prior Informed Consent** (PIC) both in countries that have or have not yet designated a competent « PIC-provider » within the framework of the CBD¹⁰.

Because “PIC-providers” are not always identifiable where access to *in-situ* MGRs is required (see remark 6 page I.2), MOSAICC recommends that microbiologists:

- make efforts to identify the competent « PIC-provider » and to acquire a PIC before accessing MGRs;
- keep the files proving their efforts made to acquire PIC;
- when wishing to access *in-situ* MGRs¹¹, always attempt to acquire written permission from the landowner and/or the usufructuary of the land or sea area before accessing this area and its genetic resources;
- use the MOSAICC model PIC-application form as model (see Section II model documents);
- ask “PIC-providers” to use the MOSAICC model PIC-document (see Section II model documents).

The PIC gives access to *in-situ* MGRs; it authorises sampling of MGRs under certain conditions. Subsequently, for each MGR isolated during the specific field survey / sampling campaign it covers, the PIC proves that the MGR has been isolated in a legitimate way and identify officially the *in-situ* origin of the MGR.

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 MGRs.

Given the flexibility of the CBD¹² concerning the PIC requirement and the need for appropriate procedure for special cases, countries could put in place a fast-track procedure with shortest possible administrative delay according to the level of urgency, giving access to *in-situ* MGRs on basis of minimum information about the purpose of the purchase. This procedure should still enable the monitoring of the distribution and utilisation of the MGRs. In the system proposed in this Code of Conduct, fast-track procedure will match with the contents of Material Transfer Agreement excluding further distribution of MGRs and use-category I or II (see types and contents of Material Transfer Agreement on page I.5).

⁹ Given the provisions included in CBD article 15, and the use of terms for the purposes of the CBD (article 2), which 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”.

MOSAICC defines *in-situ* MGRs as micro-organisms or material of microbial origin containing functional units of heredity, as existing within ecosystems and natural habitats, and, in the case of domesticated or cultivated species in the surroundings where they have developed their distinctive properties. Note: This definition excludes MGRs having acquired their distinctive properties in *in-vitro* conditions, outside their ecosystems and natural habitats (laboratory conditions).

¹⁰ 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 and 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. (Hendrickx/Koester/Prip, The Convention on Biological Diversity – Access to Genetic Resources: A legal Analyses, 23 Environmental Law and Policy 250 (1993)).

¹¹ The country where the *in-situ* MGRs were accessed is the country of origin.

¹² As already mentioned in point 10 here above, 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 would not only be suicidal for a country to deny or delay access to MGRs and so impeding international aid, but also probably counter 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».

I.3. Procedure for access to *ex-situ* MGRs¹³

Prior Informed Consent

MOSAICC recommends that microbiologists wishing to access *ex-situ* MGRs:

- endeavour in all cases to get, at least, the country of origin or a reference that leads 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* collections¹⁴ (see also recommendation for regularising procedure).
- keep files of correspondence when dealing with *ex-situ* resource centres, including possible Material Transfer Agreement (see definition of MTA, page I.4).
- check that the ***necessary minimal information*** regarding the MGRs is attached.
- always mention provider, strain reference number and country of origin in their scientific papers/publication.

MOSAICC recommends that the provider of the MGRs transfer them with the ***necessary minimal information*** 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;
- a strain reference number;
- if available, the species name identifying the strain;
- 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 Material Transfer Agreement.

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. This correcting 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.

¹³ Given the provisions included in CBD article 15, and the use of terms for the purposes of the CBD (CBD art. 2), which state:
-“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 microbial origin containing functional units of heredity, that is kept outside its natural habitat (such as *in-vitro* or laboratory conditions).

¹⁴ *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.

I.4. Settlement of Material Transfer Agreement

MOSAICC recommends that all transfers of MGRs (*in-situ* MGRs to *ex-situ* conditions and transfers of *ex-situ* MGRs) occur under **Material Transfer Agreement (MTA)** the terms of which are mutually agreed¹⁵ upon between the provider and the recipient.

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 (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. For usual transfers, such as delivery of test strains and exchanges between scientists, etc., partners are advised to use widely accepted MTA model forms.

When a more custom-made agreement is needed, partners are advised to use the MTA check list¹⁶ 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 CBD.

The contents of the MTA are defined by two main criteria:

1. the kinds of use of the MGRs.
2. the possibility to distribute the MGRs to third parties, or not ;

¹⁵ "Access, where granted, shall be on **mutually agreed terms** and subject to the provisions of this Article" (CBD art. 15.4).

¹⁶ **Material Transfer Agreement contents :**

- Accompanying terms
 - Mention of the country of origin, reference to the original PIC; previous MTA-terms if any.
- 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 recipients).
 - Information about provider and recipient : names, addresses.
- Use-specific terms
 - Category 1**: Use for test, reference, bioassay, control and training purposes. No commercial use. No IPRs 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 IPRs on MGRs, derived technology and information.
 - Category 3**: Commercial use. Need for more precise MTA provisions on IPRs, information feedback, patent application and benefit-sharing (see additional terms).
- Additional terms
 - 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.

1. MOSAICC divides the possible uses of MGRs into three categories:

- Category I: Use for test, reference, bioassay, control and training purposes.
- Category II: Use for research purposes
- Category III: Commercial use

These categories of use will determine use-related terms to include in each MTA. Potential use and intentions may shift accordingly to results of R&D programmes and subsequent perspectives of new applications (actually, all micro-organisms have the potential to be of commercial interest). In this context all agreements to be signed between the different parties should clearly indicate the need that changes of categories must be negotiated and agreed with the rightful owner or provider. In order to help the partners make the appropriate choice between the categories of use, non-ambiguous definitions and clear descriptions of the uses listed above are needed, especially the definition of “commercial use” with regard to the need for more precise terms for sharing of financial benefits. “**Commercial use**” of MGRs includes but is not limited to the following activities : sale, patenting, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or licence, product development and seeking pre-market approval.

2. MOSAICC recommends to distinguish between two types of material transfer.

- I. Transfer where further distribution is excluded (MTA excluding distribution to 3rd parties)
- II. Transfer where further distribution is allowed (MTA allowing distribution to 3rd parties)

The choice between these two types of transfer will be determined by the capacity of the users as well as of the suppliers for keeping records of the individuals or institutions from where or where to they transfer MGRs¹⁷.

I. When they choose a MTA **excluding distribution to 3rd parties**, provider and recipient agree that the recipient cannot distribute the MGRs to anybody 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. This option is recommended for transfers between individuals or institutions who’s primary mission is not the *ex-situ* conservation and valorisation of MGRs^{17.I}. The MTA excluding distribution to 3rd parties will also be used in case of fast-track procedure (see page I.2).

¹⁷ I. MTA **excluding distribution to 3rd parties** is recommended in the following cases :

- Deposition of *in-situ* MGRs in a culture collection, when the depositor impose restriction of distribution (e.g.: patent deposit, some safe deposits). Take care that this does not run counter the principles of CBD art.15.2. “*facilitated access to MGRs*”.
- Deposition of *in-situ* MGRs in a laboratory other than a culture collection, in a laboratory that is not used to record information about the transfers it does.
- Transfer of *ex-situ* MGRs from an individual or an institution that is not a culture collection to a culture collection, when the depositor imposes restriction of distribution (e.g.: patent deposit, some safe deposits).
- Transfer of *ex-situ* MGRs from a culture collection to individuals or institutions that are not used to record information about the transfers they do.
- Transfer of *ex-situ* MGRs between individuals or institutions that are not used to record information about the transfers they do.
- Fast-track procedure (see page I.2).

II. MTA **allowing distribution to 3rd parties** can be used in the following cases :

- Deposition of *in-situ* MGRs in a culture collection (CBD art.9 (a) « *preferably in the country of origin* »)
- Transfers of *ex-situ* MGRs between culture collection, between microbial genetic resource centre who’s primary mission is the *ex-situ* conservation and valorisation of MGRs; with terms according to specific collaborative agreements between these institutions.

II. MTA allowing distribution to 3rd parties is in use when MGRs are transferred to a recipient that is a culture collection or when both recipient and provider are culture collections^{17.II}. 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.

This system 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 : The type of MTA covering a particular transfer depends on the terms of a previous MTA when it exists (see page I.6 and related diagram). It also depends on the terms of the PIC because national legislation takes precedence over any specific terms that runs counter the law.

I.5. Monitoring the distribution and utilisation of MGRs

There is a need for a simple administrative system that enables easy circulation of MGRs. Such a system must also monitor the distribution and the utilisation of MGRs, 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) because they have contributed to the conservation and sustainable use of the MGRs,,

MOSAICC proposes a system that meets both these needs and:

1. allows easy circulation of MGRs at the first level of distribution and
2. limits the further distribution to third parties, in order to shorten the chain of distribution along which the monitoring of the transfer of MGRs may be lost.

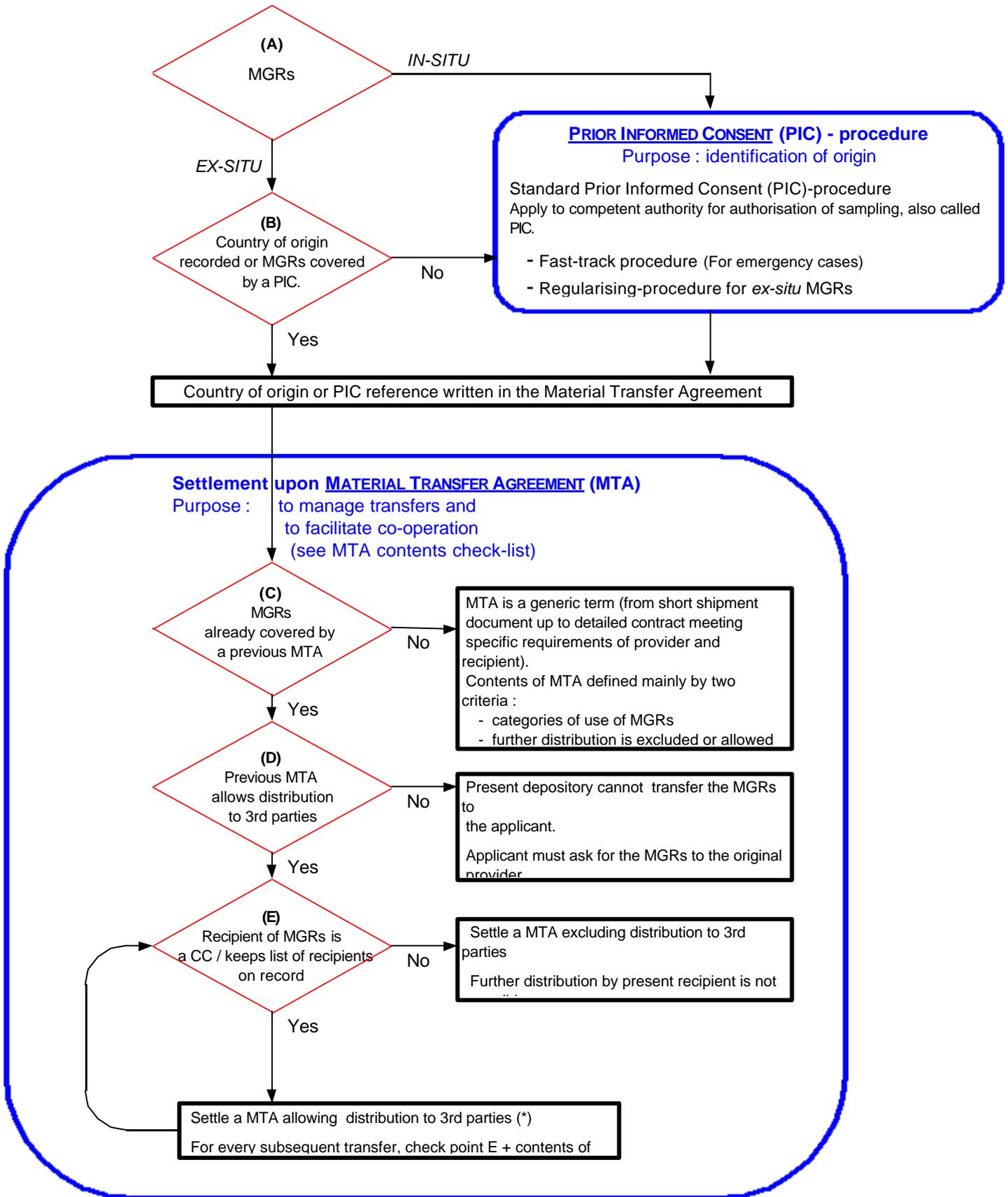
The system works through the adequate choice of MTA terms governing the conditions of transfer (see page I.6), these terms being mutually agreed upon between the provider and the recipient. The expectations of provider and recipient, the available trustworthy information, the legal context (national and international laws) and the contractual context (terms of possible previous agreements) will determinate the contents of the MTA.

More specifically, a balanced use of the options governing -allowing or excluding- the further distribution of the MGRs will help to arrange the flows of MGRs. To make the appropriate choice, to use the adequate option governing the further distribution of the MGRs, provider and recipient will check the following options when they want to transfer MGRs (see figure 1):

- 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. If there is a previous MTA, it may be
 - either** a MTA excluding distribution to 3rd parties. A transfer under MTA excluding distribution to 3rd parties is not followed by a next transfer.
 - or** a MTA allowing distribution to 3rd parties.
- E. A transfer under MTA allowing distribution to 3rd parties is possible if the MGRs are transferred to a recipient that is a culture collection or when both recipient and provider are culture collection. If the MGRs is transferred to a recipient that is not a culture collection or to individuals or institutions that are not used to record information about the transfers they do, then the transfer of MGRs will be covered by a MTA excluding distribution to 3rd parties.

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.

Figure 1. : Procedure of transfer of Microbial Genetic Resources (MGRs)



(*) Successive MTA's allowing distribution to 3rd parties are not recommended except in the case where provider *and* recipient are culture collections. In all cases transfers should be recorded by both suppliers and recipients for future tracking purposes.

I.6. Terms of agreement on benefit sharing, access to and transfer of technology, scientific and technical co-operation as well as technology transfer.

MOSAICC recommends the partners signatory of a MTA to include additional clauses, if applicable, in order to facilitate benefit sharing as foreseen by the CBD¹⁸, especially scientific and technical co-operation as well as access to and transfer of information and technology.

CBD art. 15.7 terms "... *sharing in a fair and equitable way...*" imply that the return for each partner should correspond fairly with the time, money and intellectual and inventive effort 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 additional terms-package agreement.

When agreeing upon the terms of the MTA, the partners can decide either to wait until benefit arise 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. MOSAICC recommends the partners signatory of a MTA to come to a preliminary agreement about financial benefit sharing.

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 it is recommended that the partners come to an agreement, as far as wished for, and as far as possible, about the following topics :

• IPRs related to MGRs and derived technology¹⁹

Terms of agreements on IPRs related to MGRs and derived technology are recommended use-specific terms when commercial use is involved. MOSAICC recommends partners:

- to agree on the IPRs 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;

¹⁸ Article 15.7 : " ... *the aim of sharing 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 with the Contracting Party providing such resources* "

Apart from the basic terms and the use-specific terms included in the Material Transfer Agreement standard model, MOSAICC foresees the possibility to have complementary mutually agreed terms dealing specifically with benefit sharing, transfer of technology, scientific and technical co-operation and technology transfer (technology including biotechnology). 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.

¹⁹ MOSAICC refers to 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, have to be 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 micro-organisms, as well as of derived products, technology and processes, and this as far as the criteria of invention, novelty 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.

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 IPRs 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 policy²⁰**
 - 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 data²¹.
 - **Place and ways of conservation of MGRs²²**

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.

- **Partnerships involving stakeholders other than provider and recipient of MGRs, including indigenous and local communities²³**

²⁰ **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* ».

²¹ Dr. Cletus P. Kurtzman - US Nat'l Committee for the IUMS and Ms Robin Schoen - US Nat'l Academy of Sciences / National Research Council

²² 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*”.

²³ Apart from suggesting that recipients of MGRs cooperate with , among others, governmental institutions and the private sector of the country providing the MGRs (CBD art. 16.4) and/or the appropriate international and national institutions (CBD art. 18.1), the CBD also makes reference to indigenous and local communities (CBD art. 8 j). However, the CBD does not provide its users with a definition of these communities or guidelines on how to deal with them.

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) 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**²⁴

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**²⁵

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 a 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.

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.

²⁴ Monetary terms can be broadly split into, on the one hand, terms concerning initial payments (e.g. up-front payments) that are made independently of, as well as before, any possible successful commercial use of the MGRs concerned; and on the other hand, royalty payments that are only made in the exceptional cases of successful commercial use of MGRs.

²⁵ In this category, we can consider the normal fees applied by most *ex-situ* resource centres and payable by the recipients of the MGRs after 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.

SECTION II. MODEL DOCUMENTS

List of documents that should « cover » the MGRs in order to guarantee a transfer consistent with the principles of the CBD.

ACCESS TO *IN-SITU* MGRS

- **Prior Informed Consent - PIC** obtained from a competent authority
- Optional: permission of the landowner and/or usufructuary
- **Material Transfer Agreement - MTA**

ACCESS TO *EX-SITU* MGRS

- **Material Transfer Agreement - MTA**
- **Reference to the country of origin or reference of the PIC** or equivalent document delivered when the MGRs were originally isolated from *in situ* conditions and deposited in *ex situ* collections (See pages I.2, I.3 and I.4)

MOSAICC recommends that each document (PIC-application, PIC, MTA):

- 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 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.

MOSAICC proposes:

- a model of Material Transfer Agreement;
- a PIC-application model form for access to *in-situ* MGRs;
- a model of PIC for access to *in-situ* MGRs.

MATERIAL TRANSFER AGREEMENT – MTA

²⁶ The RECIPIENT will respect, if applicable, the accompanying PIC-terms and the terms laid down in the previous Material Transfer Agreement (see annexes).

²⁷ The RECIPIENT will use the MGRs described and listed in annex, in a sustainable way, for *bona fide* purposes and in full respect of the principles of the Convention on Biological Diversity and other applicable rules of international and national laws.

²⁸ The RECIPIENT will not distribute the MGRs delivered.

The RECIPIENT may distribute the MGRs, provided that the following conditions are observed:

The RECIPIENT will keep records of the full co-ordinates of all downstream recipients of the MGRs concerned. This information will be available on request (= monitoring the transfers).

The RECIPIENT will transmit to the PROVIDER, as far as applicable, information (e.g. intentions for commercial use,) provided by the downstream recipient(s) of the MGRs concerned (= information feedback);

²⁹ The RECIPIENT and the PROVIDER distinguish the following categories of use of MGRs:

Category 1: Use for test, reference, bioassay and control (covering only their use within the framework of the corresponding official (inter)national test-, bioassay and control protocols); use for training purposes;

Category 2: Use for research purposes;

Category 3: Commercial use. Commercial use of MGRs includes but is not limited to the following activities : sale, patenting, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or licence, product development and seeking pre-market approval .

For categories 1 and 2 uses:

The RECIPIENT will not claim ownership over the MGRs received, nor seek intellectual property rights over them or related information. If the RECIPIENT wishes to utilise or exploit such organisms commercially he will first inform the PROVIDER ; suitable and adequate recompense to «*names of those entitled to be rewarded* » and the country of origin will be discussed in the spirit of the Convention on Biological Diversity.

THE RECIPIENT will ensure that any individual or institution to whom the RECIPIENT makes samples of the MGRs available, is bound by the same provision.

(See Terms of Material Transfer Agreements for access to *ex-situ* MGRs on page)

²⁶ Accompanying terms: Reference of PIC, mention of the country of origin; previous MTA-terms if any

²⁷ 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. Information about provider and recipient: names, addresses Scientific feedback : publication will mention provider, strain reference number and country of origin. .

²⁸ Key-terms that differentiate MTA excluding or allowing distribution to 3rd parties

²⁹ Use-specific terms Category 1: Use for test, reference, bioassay, control and training purposes.

- No commercial use ;
- No IPRs on MGRs, derived technology and information ;
- The recipient has to follow the protocols of standard test and reference procedure.

Category 2: Use for research purposes

- No commercial use ;
- No IPRs on MGRs, derived technology and information ;

Category 3: Commercial use

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

For category 3 uses,

In order to ensure adequate benefit sharing with the country of origin and « *names of those entitled to be rewarded* », according to the principles of the Convention on Biological Diversity, the RECIPIENT will immediately inform the PROVIDER and the country where the MGRs were originally accessed, of the intended commercial use(s) of the MGRs and/or derived technology and/or related information. The terms upon which benefit sharing with the stakeholders takes effect are laid down in annex.

For all categories of uses,

The RECIPIENT will mention the PROVIDER, the strain reference number and the country of origin in publication presenting scientific results and related information resulting from the use of the MGRs.

MTA ADDITIONAL TERMS CHECK LIST

• IPRs related to MGRs and derived technology

Different regimes³⁰ of IPR-ownership could 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-ownership of the MGRs
IPR-ownership of the derived technology

• Terms on training, technical and scientific co-operation, technology transfer, exchange of information and publication policy³¹

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. 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.

• 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 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 resources centres³².

• Partnerships involving other stakeholders 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 the community is:

- owner or usufructuary of the area where the *in-situ* MGRs were accessed;
- represented by officially recognised representative(s) and
- willing to preserve and maintain her knowledge, innovations and practices relevant for the conservation and sustainable use of MGRs (cf. CBD-article 8 (j)).

³⁰ For instance : - single ownership or co-ownership of the IPRs;

- a single or different regimes of IPR-ownership, and the latter depending on the category of MGRs.

³¹ 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. It is to remember that scientific publications should always mention provider, strain reference number and country of origin.

³² In this case, a country could transfer *ex-situ* MGRs to (an) *ex-situ* resource centre(s) in (an) other country(ies). This transfer should be covered by a 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.

- **Monetary terms**

MOSAICC 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, but this always independently of 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 MGRs³³.

- 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 always make reference to net royalties³⁴.

³³ For example : local community participating or not to field survey, costs of maintenance of *ex-situ* MGRs, etc.

³⁴ 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 marketing the application.

PIC application form for access to *in-situ* MGRs

(Date)

(Name and address of the PIC-provider)

Dear (.....),

According to article 15 of the Convention on Biological Diversity (CBD) stating that *«the authority to determine access to genetic resources rests with the national governments and is subject to national legislation »* and that *«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 »*, as well that *«access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources »*;

and, as ratified by (Name of the Country where one wants to access MGRs),

I would like to acquire access to (Name of the field survey area), as well as to its genetic resources, with your prior informed consent (PIC), during the period and under the conditions specified in annex.

To this end, I have annexed a model form of PIC-certificate to be used if you agree to provide me with such a PIC according to the principles and rules laid down in the CBD.

(closing salutation)

(Name, address and signature of the PIC-applicant)

PIC certificate for access to *in-situ* MGRs.

(Name and address of the CBD PIC-provider)

(Date)

Dear (Name of the PIC-applicant),

In reply to your PIC-application of (date of written demand), having as a reference (reference), and as annexed;

as well as, according to article 15 of the Convention on Biological Diversity (CBD) stating that «*the authority to determine access to genetic resources rests with the national governments and is subject to national legislation* » and that «*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* », as well that «*access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources* »;

and, as ratified by (Name of the Country providing the MGRs), on (Date of ratification);

as well as, in conformity with the national laws and rules referred to in annex;

We, the undersigned, being (within the framework of the CBD)*, on behalf of (Name of the country providing the MGRs), the competent authority for surveying *in-situ* access to the genetic resources of (Name of the geographical area of competence), have the pleasure to provide you, exclusively for the annexed PIC-application, with the required PIC.

This PIC for access to *in-situ* MGRs from (Name of the field survey area) grants access to this area from (date) to (date). This PIC is not transferable from one organisation to another without written agreement of the undersigned authority.

(closing salutation)

(Place and date of issue, official administrative seals and signature of the CBD PIC-provider.)

N.B.: PIC = Prior Informed Consent

* when applicable