Microbial Resource Research Infrastructure

Best Practice Manual on Access and Benefit Sharing

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1. Introduction

MIRRI[1] is a pan-European distributed research infrastructure that provides facilitated access to high quality microorganisms for research, development and application and connects public microbial domain Biological Resource Centers (mBRCs) with researchers, policy makers and other stakeholders to deliver biological material and services more effectively and efficiently to meet the needs of innovation in biotechnology. The infrastructure has developed a legal operational framework by which it can assure compliance of its partner mBRCs with the Nagoya Protocol[2] on Access to Genetic Resources and the fair and equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity[3]. The associated Regulation (EU) No 511/2014[4], henceforth referred to as 'the Regulation', governs user compliance measures and benefit sharing within the European Union. It is complemented by the Commission Implementing Regulation (EU) 2015/1866[5] providing detailed rules as regards the register of collections, monitoring user compliance and best practices.

MIRRI developed a Policy statement[6] on how MIRRI partner mBRCs commit themselves to contributing to reaching the main objectives of the CBD while operating in compliance with all applicable national and international laws on ABS and regulatory requirements.

This MIRRI Best Practice Manual has been developed in response to Article 20 of the Nagoya Protocol and Article 8 of the Regulation. It provides guidance for the mBRCs[7] in implementing their ABS institutional policies with regard to genetic resources and associated traditional knowledge, and working procedures for the acquisition of material[8], including accession, i.e., formal acceptance of new material in the public collections of the mBRCs, for transfer of material including supply to third parties and the delivery of other services. It also aims to increase transparency on how the mBRCs themselves conduct research on their holdings and lawfully utilize[9] the genetic resources and associated traditional knowledge.

This best practice manual was primarily designed for the management of collections of living microbial strains and their derivatives (e.g., DNA samples), but could be useful for all who receive microorganisms, use and supply them to colleagues or others outside their institutions for further

[1] Microbial Resource Research Infrastructure; http://www.mirri.org/
[2] http://www.cbd.int/abs/
[3] http://www.cbd.int/intro/default.shtml
[4] "Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union"; http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511 (applies from 12 October 2014, i.e. the date of entry into force of the Nagoya Protocol for the EU)
[5] "Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices", also referred to as the "implementing act"; http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866 (entered into force 9 November 2015)
[6] MIRRI Policy on Access and Benefit-sharing (ABS)
[7] The legal entity representing the mBRC may also include other departments, where staff are working with material that may be holdings of the mBRC Collections or not, for example material kept in a working collection of a research group. This best practice should be understood to apply to all staff, authorized visitors and other associates working within or on behalf of the same legal entity as mBRC staff.
[8] Throughout this document the term 'material' refers to any biological material. The term 'genetic resource' is used when specifically referring to 'utilization' within the scope of the Nagoya Protocol. Definitions of these terms are provided in the Glossary (Chapter 3).
[9] "Utilize" ("Utilization") as here and elsewhere used in this text, means activities which can be regarded as conducting research and development in the sense of the Nagoya protocol and the EU Regulation 511/2014, for which PIC and MAT may be required. For an explanation see the EC Guidance on scope (see footnote 11).

use. Some mBRCs may also keep collections of dead natural specimens, e.g., in herbaria or fungaria[10]. In the text-boxes included in this best practice all minimal requirements are presented. MIRRI strongly recommends mBRCs adhere strictly to these requirements, which should minimize the risk of non-compliance.

The scope of the Nagoya Protocol has been much debated. The definitions of terms like 'utilization of genetic resources' and 'country of origin' provided in the text of the CBD, and also 'research and development' as used in the Regulation, left room for interpretation. In order not to add to the confusion, the terms used in the current text are in agreement with those in the CBD, Nagoya Protocol and Regulation text. These terms, their definitions with their source indicated, are listed in the Glossary (Chapter 3). Additional interpretations of certain terms have been added for clarification only where this is regarded absolutely necessary for a correct understanding of MIRRI practices.

With regard to determining whether access and use of a genetic resource or traditional knowledge are within or outside scope of the Regulation, the following elements are of importance: geographic, temporal, kind of material and utilization ('research and development'), personal scope and intent of acquisition. If for one or more of these elements the conditions do not apply, the Regulation does not apply. More details on the scope of the Regulation are provided in the Guidance document[11] published by the European Commission, henceforth referred to as 'the EC Guidance'.

As the European Commission explains in its Guidance on scope[11], the Regulation applies to genetic resources that were accessed on or after October 12th, 2014 from a country of origin that is a Party to the Nagoya Protocol (mostly by collecting *in situ* in that countries territory), or from another provider country that is a Party to the Nagoya Protocol (for example, through exchange with another mBRC). For example, a strain deposited in an mBRC in 2012 is and remains outside the scope of the Regulation even if the provider country later becomes a Party to the Nagoya Protocol. Still, national legislation or regulatory requirements of the provider country (even when in place before the Nagoya protocol entered into force), may apply to such material, in which case all users are expected to follow them. Besides law governing ABS, national environmental protection law prohibiting or restricting collecting of biological material may also apply to the geographical area where collecting took place (for instance, in National Parks).

The MIRRI Policy statement, minimal requirements, and Best Practice resulted from activities in Work package 9, Task 9.1, of the Preparatory Phase Project MIRRI[12]. These tools were developed by participants from the MIRRI partner institutes in consultation with external experts, and are based on their understanding of the operational practices of mBRCs and their understanding of the Nagoya Protocol and its implementation, the Regulation, and the EC Guidance[11]. Tools developed for implementation of the Nagoya protocol by other projects and associations of users and keepers of biological collections were also taken into account, particularly those of the MICRO-B3 project and CETAF[13].

[10] For herbarium material which is sent on loan temporarily it is advised to also consult the Consortium of European Taxonomic Facilities (CETAF) Code of Conduct and Best Practice for Access and Benefit Sharing. Draft document (8-12-2014)
[11] Guidance on the EU ABS Regulation implementing the Nagoya Protocol - Guidance on the scope of application and core obligations.
[12] The Preparatory Phase Project MIRRI was funded by the EU Seventh Framework Programme (Grant Agreement no 312251)
[13] Consortium of European Taxonomic Facilities; http://www.cetaf.org/

2. MIRRI Best Practice on Access and Benefit Sharing

2.1 Managing acquisition of biological material for accession into the public collection or other purposes

MIRRI-mBRCs are often embedded in larger institutes. Material entering the institute may or may not be intended or suitable for accession into the collections of the mBRC. Most mBRCs mainly acquire new biological material directly through transfer from external depositors (i.e., from another legal entity) to the curators or other staff dedicated to collection management. However, there are also other possible routes of entry for new material into the mBRC.

For example, mBRC staff or other scientists working in the same institute may collect material in the field. ABS legislation in the country where the fieldwork is planned should be strictly followed, including (if so decided by the Country) the requirement to obtain from the competent national authority in that country appropriate permits, typically including PIC and MAT, before starting the field work. Seeking early collaboration with local scientists for planned field work is recommended. Annex 1 provides a flowchart for scientists who want to collect material in the field in compliance to the Nagoya Protocol and the EU Regulation 511/2014.

In other cases, scientists in the institute may acquire material for (taxonomic) research from collaborating third parties, or as unsolicited samples for identification, etc. They may utilize the genetic resources in ways falling within the scope of the Nagoya Protocol. Guidance for such scientists is provided in the flowchart of Annex 2.

To assure compliance with applicable ABS legislation and regulatory requirements for all activities throughout the institute, due diligence or "reasonable care"[11] should be exercised in all cases and preferably at the moment of entry of the material, meaning that the documents should be collected that are required to prove that the material was legally accessed and which may also determine uses permitted and terms of benefit sharing (see Box 1 iv-ix).

If such documents are at hand from the moment of entry of the material, this will not only provide legal certainty to the users in the institute, but also promote expeditious accession of the material into the mBRC collection once the need to do so becomes evident. Breaches or delays during the accession procedures caused by missing documents are thus more likely to be avoided. In short, the requirements listed in Box 1 for accession into the pubic collections of the mBRC and best practices presented here should as far as appropriate also be followed for other biological materials entering the institute.

Each institute should formulate and implement its own policy on ABS, and make clear who are authorized to negotiate and sign agreements, and responsible for training and awareness-raising among staff across the institute.

2.1.1 Accession forms and Material Accession Agreements (MAA)[14]

The MIRRI mBRCs should use a 'strain accession form' with a minimal set of obligatory fields that the depositor must complete (see Box 1) for each item of biological material. It is essential that the

[14] This agreement could be based on a model Material Accession Agreement used by the mBRC, or take the form of a Material Transfer Agreement between de depositor and the mBRC.

depositor must clarify the geographic origin of the material, and also provide a minimal amount of information that allow the mBRC to determine, as far as reasonably can be expected, if any ABS legislation or regulatory requirements apply to the material or not, in other words, to exercise due diligence. If information concerning only one of the elements of scope (see Introduction) already allows to conclude that the material is out of scope of the Nagoya Protocol and Regulation, then information on other elements of scope would not be necessary for that purpose. However, if the information provided remains insufficient to determine if material is within scope, the material should not be accepted for deposit and not be retained by the mBRC.

Further recommendations are provided in Box 1, to ascertain that the depositor and mBRC will understand what can and cannot be done with the material once accessioned into the public collection. The form should at least be signed by the depositor; otherwise the responsibility and any liability for the deposit could be placed entirely on the mBRC.

In case the material is deposited with associated traditional knowledge, the receiving mBRC should only make this traditional knowledge publicly available if this is in agreement with terms in the MAT. For example, this may be relevant for material used in fermented beverages from indigenous communities.

Proof of consent from the competent authority in the country of origin for the act of deposit of the material in the foreign receiving mBRC must be provided where such is required by applicable legislation of the country of origin of the material. In case of doubt, the mBRC should ask the depositor about this and/or contact the appropriate authority to check.

In case the standard MTA of the mBRC is used for supply to third parties, the depositor should be informed of this. Any objections the depositor might have on the content of the MTA should be discussed and resolved between the mBRC and depositor before the material can be distributed.

Depending on the depositor's and the receiving mBRC's wishes, a Material Accession Agreement (MAA) could also be used, instead of a sole accession form. Whichever document is chosen for the deposit, the document must be a legally valid agreement between the mBRC and the depositor and signed by both parties. National ABS law in certain Parties to the CBD may demand that a model MTA of the competent authorities (in the country of origin) is signed between the authority or the depositor and the receiving mBRC.

Note 1: Third parties in the context of MAA may be users of materials in academia or private companies, and the use they make of these materials varies. Such use may or may not be considered as 'utilization' within the scope of the Nagoya Protocol.

Note 2: The Regulation includes special provisions for genetic resources of pathogens (see Article 4, par. 5a) in case of a present or imminent public health emergency of international concern.

Note 3: Where an accession form to be completed and signed by the Depositor would be a legally acceptable alternative for an MAA, the MIRRI-mBRC should include the points above in the text of the accession form.

Box 1 - Deposit of material in a public collection - Accession Form and Material Accession Agreement (MAA) minimal requirements, due diligence steps and recommendations

Minimal information needed to exercise due diligence

The information fields in the below table shall be included in the accession form, and/or in the MAA or its annex, whichever is appropriate. Indicated is whether provision of the information is obligatory for the depositor or not.

Fields used by the mBRC to assess the status of the material under applicable ABS law	To be completed by depositor	Remark
Depositor's identifier for the material (e.g., lab strain number)	Always	
The taxonomic designation (scientific name)	If available	
Space to fill in the unique strain identifier issued by the mBRC	No	To be completed by the mBRC
Date of original collecting *in situ* ('access')	Always	
Place of original collecting *in situ* (preferably with geographic coordinates), including the country of origin	Always	Country not applicable if collecting from an area beyond national jurisdiction; in the case of collecting on high seas, the name of the vessel could be recorded
Name of the individual(s) who collected the sample from *in situ* conditions and the name of the institution (legal entity) that employed the individual at the time of the collecting of the strain	Always	

Fields needed to collect proof of legal access in the country of origin and information on agreed terms for use	To be completed by depositor	Remark
The Internationally Recognized Certificate of Compliance (IRCC) number	If available	
PIC and MAT[B1.1], and any relevant MTA(s) or other legal documents	Always when such documents cover the material, and IRCC is not available; also in case an IRCC is available but does not provide information on content of mutually agreed terms relevant for mBRC and future users	Copies should be provided with the information on the material for deposit, or be requested by the mBRC , whichever is appropriate

Due diligence steps

Always determine the status of the material, i.e. whether it is within scope of the Nagoya Protocol and EU Regulation 511/2014 (as part of due diligence), or any other ABS law.

Does the material originate from a country that is a Party to the Nagoya Protocol? Check the country information in the ABSCH.

- At the time of *in situ* access of the material, was there legislation in place in the country of origin and does it apply to the material? Check the country information in the ABSCH.
- If unsure, or none can be found, ask the depositor to contact the National Focal Point in the country of origin for clarification and to provide a copy of any answer received.

Box 1 - continued

- If no clarification is provided by the depositor, and there are reasons to believe that applicable access legislation may exist, contact the NFP in the country of origin to seek clarification. Keep copies of e-mails sent and any answers received as proof of due diligence.
- For the above, always follow the EC Guidance11
- If documents are provided by the depositor, refer to "Checking documentation" (2.1.3).

Recommendations

MIRRI recommends the addition of more fields to the accession form to allow the recording of information relevant for ABS, such as tracking the history of the transfers of the material, in the direct chain from collection of the material *in situ* to the moment of deposit in this mBRC.

MIRRI also recommends that the mBRC includes the following in the accession form and/or MAA model:

(1) a brief statement to explain (a) the mission of the receiving mBRC and (b) that the mBRC adheres to the MIRRI-approved ABS policy and best practices;

(2) a list of terms and their definition, preferably consistent with those used in CBD, Nagoya Protocol, and the Regulation. It is recommended to use the terms listed in the glossary.

(3) a section in which the depositor declares that he/she:

- has acquired the material legally and in compliance with applicable legislation;
- assures as far as reasonably possible the accurateness, truthfulness, and completeness of (scientific and non-scientific) information and the authenticity of the documentation relevant to ABS provided to the receiving mBRC and that the documentation applies to the material;
- declares that by depositing the material the depositor does not infringe any rights of third parties, including intellectual property rights, or any terms of MTAs to which the material is subject.

For transparency MIRRI recommends to also include article(s) in the accession form and/or MAA which clarify:

(4) Terms for use and benefit sharing by third parties that will receive the material from the receiving mBRC, after it has been released for distribution.

Note: Simple reference to standard MTA used by the receiving mBRC for such purposes may suffice, and MTA included in annex to the MAA (mBRC may change its standard MTA at any time, but the terms that will apply are those provided with the material at the time of supply).

(5) The rights the mBRC will acquire over the material.

Note: It is important that both parties to the agreement understand that the receiving mBRC acquires certain rights over the material upon accession, that are compatible with original PIC and MAT, or other previous and applicable agreements. These typically include the right to use the material for (a) preservation, (b) distribution, (c) research, including work on the genetic resources for the purpose of quality control, identification and characterization (if necessary define what type of use is intended), and the right to publish the results thus obtained (e.g. sequence data, images), and (d) removal from collection when necessary.

(6) Duration of the contract – in principle this would be indefinite.

(7) Clauses for disputes.

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Footnote

B1.1 This is the PIC and MAT issued by a competent national authority in the country of origin prior to the *in situ* access of the material there, or any other document type valid under applicable ABS law.

2.1.2 Tracking information

At the time material is offered for deposit, the mBRCs will make reasonable effort to collect information to track back to the origin of that material including any intermediary transfer(s), before accepting it as a novel deposit in the Collection.

- The mBRC will make the depositor aware of the need to clarify the origin of the material and, if the data available indicate that such is required, ask the depositor to provide the mBRC with all relevant documents providing evidence that the material was legally accessed *in situ* in the country of origin, including the original PIC, and MAT where appropriate, and also subsequent agreements if any were made.
- If the material itself is not listed as the 'subject matter' on the Internationally Recognized Certificate of Compliance, PIC, or other permit[15], and there is no evident affiliation between the depositor and the PIC-applicant mentioned in these documents, then the mBRC will ask the depositor for an explanation. The mBRC is advised to keep this correspondence as proof of having exercised due diligence.

2.1.3 Checking documentation provided by the depositor

The Internationally Recognized Certificate of Compliance will be checked by the mBRC. It should be accessible in the ABS-CH, and the mBRC should check the information available as far it is public. If the Certificate is available, the mBRC should add the Certificate's unique identifier to the material documentation and add it to the record of the material in the mBRC database (and include it in the strain catalogue).

In the absence of an Internationally Recognized Certificate of Compliance, the mBRC should check other relevant documents at its disposal that have been issued by the competent authority (access permit, PIC, MAT) in the country of origin. This authority should be listed in the ABSCH and on the NFP webpages of the country of origin. In case it is not listed there, the legality of the documents may be unclear and MIRRI recommends it should be confirmed by the NFP before the mBRC can accept the material for deposit.

> *Note 1 :* In case the material is not itself listed as 'subject matter' in the Internationally Recognized Certificate of Compliance [16], it is recommended to note this in the records of the mBRC (for example, if the subject matter is a soil sample, from which one or more strains were isolated that are not listed as such on the certificate).
>
> *Note 2:* The mBRC should make available in the holdings catalogue the reference numbers of the above documents, or the documents contents as far as it is not confidential.

2.1.4 Special cases

Article 8 of the Nagoya Protocol on special considerations encourages each Party to implement simplified measures for providing access to genetic resources for non-commercial research, and to

[15] See Nagoya Protocol, Art. 17, par. 4(f); for microbial genetic resources (strain, isolate) it will in fact be very rare that the resource would be listed under the subject matter

[16] See Nagoya Protocol Art. 17 par. 4 (f).

pay due regard to situations of present or imminent emergencies that threaten human, animal or plant health, by implementing expeditious access and benefit sharing procedures. The MIRRI mBRCs should be aware of their responsibility and work with the authorities to address such situations.

Post-accession problems

While at time of deposit the mBRC had no reasons to doubt the correctness of information provided or the legality of access, proof could emerge later that the information provided by the depositor on a certain material was false or incorrect. In such a case, the mBRC should immediately contact the depositor to discuss the matter and request for the correct documentation. Should it remain unclear whether the material was legally accessed in the country of origin or not, then the mBRC should immediately inform the competent authority in the country where the mBRC is located, and (confidentially) any third parties that may have been supplied with the material since the accession by the mBRC. In consultation with this competent authority appropriate measures should be taken by the mBRC and any third parties mentioned above informed of these if appropriate. Such measures may include deaccessioning of the material from the collection, or trying to resolve the problem.

2.1.5 Setting terms for utilization by the mBRC and third parties

The mBRC can decide to use the standard MTA of the mBRC for distribution to third parties if for the material no original PIC and MAT were legally required, and also no additional terms were expressed by the depositor (through MTA/MAA/accession form) that would be incompatible with the standard MTA. The mBRC is advised to inform the depositor about this decision[17].

> *Recommendation: Terms for permitted use of the material and benefit sharing are laid down in the mBRC's standard MTA for distribution, and therefore should be already listed (or accessible) in the strain accession form model used by the mBRC. When completing the accession form, the depositor should explicitly have to approve these terms (in paper or online through a click-wrap procedure).*

If the original PIC and MAT provide terms for use, or a MAA/MTA has been provided by the depositor, then the mBRC should compare these documents to its standard MTA for supply to third parties. If the standard MTA is fully compatible with terms laid down in these documents, then the standard MTA can be used for future distribution from the mBRC, and the depositor should be informed about this. If terms are incompatible, the mBRC could consider asking the depositor or the competent authority if distribution under the standard MTA of the mBRC would be allowable. If this is not allowed, or if the mBRC agrees with these terms put forward by the depositor, the mBRC can set up a specific MTA for supply of the material meeting all stakeholders' requirements, or simply use the (core of) MTA provided by the depositor for future supply to third parties.

If terms on benefit sharing need to be specifically agreed between the depositor and the mBRC as a utilizer of the genetic resource, emphasis could be on non-monetary benefits including research collaboration, training and capacity building in taxonomy and microbiology in general; referring to the policy statement or best practice may suffice. This pertains to the type of use mentioned under 2.3 (ii b).

[17] This can simply be done by referring in the accession form to the standard MTA for supply to third parties as the one being used in such cases.

To clarify what the mBRC itself can do with the material, a brief statement or clause could be inserted into the strain accession form or MAA (see Box 1, recommendations). Any restrictions the depositor may wish to impose with regard to use of the material by the mBRC could be taken into consideration at the time of deposit, but it is stressed that MIRRI regards the use rights as listed in Box 1 recommendation 5 c as the minimal requirements for good practice in collection management, necessary to fulfil MIRRI's aims[18] and basic to a proper implementation of the OECD Best Practice guidelines for Biological Resource Centres[19].

2.1.6 Material acquired temporarily

If the material is unsolicited and acquired temporarily, for example to perform an identification service, during which time it is not sent to any third party or subcontractor as part of performing the service, and is not used for research purposes by the mBRC, it can be considered outside the scope of the Regulation. The material should be returned to the sender or destroyed after the end of work.

2.2 Managing transfer of material from the public collection to other mBRCs and third parties

2.2.1 Transfer of material between mBRCs (exchanges)

A separate standard MTA for exchange between mBRCs may or may not be required[20].

Transfer of material from one mBRC to another will have to be in agreement with terms under which the material was acquired by the supplying mBRC. For the exchanged materials, further distribution by the receiving mBRC is under MTA conditions equivalent and compatible to those in place at the supplying mBRC, but never more lenient (without renegotiating terms with the competent authority in the country of origin, that is). MIRRI-mBRCs should use compatible MTA for distributing to third parties, so it can be expected that, with few exceptions, the exchanges within MIRRI will be compliant also under the mBRCs own standard MTA. The exchanging mBRCs should inform each other about all relevant ABS documentation associated with the exchanged material and properly file these in their records.

> *Note*: *Simplified mechanisms for transfer between mBRCs that are members of MIRRI, as other recognized regional networks or associations (ECCO, WFCC, so at any level), should be favoured. This will also depend on their success to get recognition of best practice with the CBD and EU.*

[18] Typically, the mBRC staff and others at the same institute will not be allowed to use the material for research until it has been published and released for distribution.

[19] Organisation for Economic Co-operation and Development (2007) http://www.oecd.org/sti/biotech/oecdbestpracticeguidelinesforbiologicalresourcecentres.htm

[20] This may depend for example on the mBRC policy for exchange of material, or requirements by national ABS law in the country where the mBRC resides.

2.2.2 Transfer to third parties

Material should always be supplied by the mBRC to third parties under an MTA. MIRRI minimal requirements for such an MTA are presented in Box 2. A standard MTA may suffice for most materials. Specific MTAs may be used where appropriate or required. Best practice for setting up specific MTAs for distribution are provided in par. 2.1.5.

Recommendation 1: If the mBRC receives a request from an interested third party to obtain material for expressed use that is not allowed under the current terms for use in the MAT (and MTA), then it should not provide the material to this third party before this party is able to deliver proof that it has reached a new agreement with the country of origin and other rightful stakeholders, allowing such new use. Also, in other cases[21] where the mBRC foresees a considerable risk of non-compliant utilization, this recommendation applies.

Recommendation 2: Material which is not part of the mBRC holdings, e.g., material in a research collection, should only be sent to third parties outside the institute by properly trained personnel, typically by a certified safety officer who also handles and oversees all the administrative and practical preparations for the shipment of cultures and other materials ordered from the mBRC[22]. The scientist who is responsible for the material must hand over to the staff who is responsible for the shipment along with the material proper MTA signed by both parties to the agreement (so also the Recipient), and in case it is required by applicable ABS law or regulatory requirements, also documents providing proof that the material was legally accessed (Internationally Recognized Certificate of Compliance, or PIC and MAT, or an equivalent permit; see also Box 2, iv). Staff responsible for ABS implementation within the institute should be consulted in case of doubt.

2.2.3 Material collected post-CBD and pre-Nagoya

mBRC holdings may include material originating from an area of jurisdiction of a Party to the NP, collected on or after 29th December 1993 (date of entering into force of the CBD) and before 12 October 2014 (date of entering into force of the Nagoya Protocol) yet without a permit (PIC and MAT), and for which the mBRC was unable to determine if any (provisionary) national legislation in the country of origin was applicable at the time of *in situ* access.

Although such material is not subject to the Regulation, the MIRRI-mBRC is advised to only distribute (or continue distributing) such materials to third parties under an MTA that obliges recipients who want to utilize the genetic resource for research and development with commercial intent, to contact at least the appropriate authority in the country of origin of the resource, in advance of such utilization, to negotiate in good faith on the terms of any benefit sharing.

Note 1: Since 2009, several mBRCs have used an MTA based on the ECCO Core-MTA[23] for the supply of all strains in the public collection; also for holdings that were accessioned prior to 1994. The key article 7 reads: "If the RECIPIENT desires to use the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSE(S),

[21] Authorities may see as a typical example of this a request by a commercial company for material that is available for non-commercial purposes only.

[22] This recommendation will be in line with practice already in place at most mBRCs where a certified safety officer is responsible for all material leaving the institute is shipped in accordance with applicable rules, including export control, dangerous goods and quarantine regulations.

[23] Janssens D, Tindal B, Green P, Garay E, Fritze D, Stalpers J, Smith D, Bimet F, Desmeth P (2009). The ECCO core Material Transfer Agreement for the supply of samples of biological material from the public collection. The MTA text is available here: http://www.eccosite.org/.

it is the responsibility of the RECIPIENT, in advance of such use, to negotiate in good faith the terms of any benefit sharing with the appropriate authority in the country of origin of the MATERIAL, as indicated by the COLLECTION's documentation." It is up to the mBRC to decide if it continues such practice.

Note 2: MIRRI recommends that the ECCO Core-MTA phrasing "…desires to use … for COMMERCIAL PURPOSES..." is changed to "...desires to utilize … for research and development with commercial intent...", or change the definition of the COMMERCIAL PURPOSES accordingly.

2.2.4 Tracing user information

As laid down in Art. 4 par 3 b (iii) of the Regulation, users of genetic resources should not only keep information on the source from which the resources (or traditional knowledge associated with these resources) were directly obtained, but also information on subsequent users. mBRCs shall thus keep records of all transfers of material from the mBRC to the primary recipients. Tracing of further transfers down a user chain starting with these primary recipients is not required for collections under the Regulation.

2.2.5 Transfer to third parties by recipients

MTA for supply of material from the public collection to primary recipients (the requestors or 'mBRC customers') should not allow third party transfer. An important reason for this is that there is a risk that the resources will be transferred by the primary recipients to such third parties without the documentation, raising the chances of non-compliant use. It is also noted that the authenticity and identity of microbial strains cannot be assured along a user chain, and such practice is therefore generally not recommended for microbial materials.

A user not employed by the same legal entity as the signatory to the MTA should be regarded as a third party, even if they collaborate under a 'defined joint project'[24]. Such a third party user is not contractually engaged vis à vis the provider (the mBRC) and is thus not authorized to use the material. Moreover, the legal status of parties collaborating in a single defined joint project can be different, e.g., contractors, subcontractors etc.

Under the condition that the MTA and annexes are always transferred along with the material, the following exceptions can be made:

(i) the recipient can share the material with colleagues (employed by the same legal entity);

(ii) the recipient can also share the material with scientists working in the same consortium, where in a consortium agreement the control of access to material is clearly defined to meet the terms in applicable MTAs;

(iii) in situations where scientists employed by different legal entities (for example, a research institute or a university) work in permanently shared laboratory facilities and collaborate, it is allowed to make an arrangement that these scientists can also share material.

[24] "Legitimate exchange" will only include exchange between mBRCs, and the exceptions (i-iii) below. In the ECCO-Core MTA the term also includes exchange between researchers collaborating in "a joint defined project", but MIRRI advices against such practice.

Box 2 - Supply of material from a public collection to other mBRCs or third parties - Material Transfer Agreement (MTA) minimal requirements and recommendations

Consider if a standard MTA for pre-CBD and post-CBD materials is needed – in relation to the decision to be taken by MIRRI partners if and what type of MIRRI-MTAs will be needed.

Minimal information to be included

In the MTA, or in annex thereof, or in the packing list for the supplied material, whichever is appropriate, the following minimal information is to be provided:

(i) full names and addresses of the institutes or other legal entities that are parties to MTA;

(ii) full names and capacities of persons signing on behalf of the provider mBRC and the Recipient;

(iii) information on the material(s) supplied under the MTA:

- strain identifier (Global Unique Identifier, Accession number of the supplying mBRC);
- scientific name;
- country of origin, if applicable;

(iv) if required by applicable ABS law or regulatory requirements, copies (electronic or paper) of the relevant documents, including:

- the Internationally Recognized Certificate of Compliance (IRCC) number and information on the content of mutually agreed terms[B2.1] or,
- if no IRCC is available, the original PIC and MAT[B2.2] or,
- if these are not available, any other legally valid documentation[B2.3], providing proof that the material was legally accessed in the country of origin, and providing information on terms for use (including previous MTAs if applicable) additional to terms here agreed on (in this MTA).

Furthermore, to support Recipient's compliance, articles should also be included which clarify

(v) what kind of transfer of the material is permitted by the recipient to third parties/other users under the MTA (if allowed, see also par. 2.2.5).

Note: 'Legitimate Exchange' can be defined in the MTA; MIRRI recommends that third party transfer will not be allowed under the standard MTA of the mBRC.

(vi) that the recipient will acknowledge the country of origin and the provider mBRC as sources of the material in any and all publications that reference the material using the mBRCs' accession number.

(vii) that the recipient is expected to use the material in a legal and sustainable way, and that the recipient will fully respect national ABS legislation of the country where the recipient resides, also when such legislation goes beyond the requirements of the EU Regulation or the terms in the MTA covering the material (see ix below if the use is outside that specified in the MAT).

For example: "The Recipient undertakes to use the material in compliance with all applicable national and international laws and regulations, including those on Access and Benefit Sharing under the CBD and the Nagoya Protocol. Activities involving the use of the material by recipient should be supportive and not run counter to the objectives and principles of the CBD."

(viii) the kinds of use that are allowed under the MTA, especially with regard to:

- non-commercial and commercial use of the material;

Box 2 - continued

- filing for patents or other ways of securing intellectual property developed using the material;
- the reporting requirements if any, and how benefits are to be shared.

Note 1: Such provisions should always be within the limits of terms under which the provider mBRC acquired the material (or the latest valid agreement); see also par. 2.1.5.

Note 2: Recipient's may be required by applicable national law in the country where they work on the genetic resource, to declare at checkpoints (their domestic competent authorities) on certain utilization or reaching steps in a process of research and development. Additional reporting requirements may also exist for the recipient of the material as per MTA.

Note 3: The ECCO Core MTA phrasing is generally useful: "RECIPIENT may use the MATERIAL in any lawful manner for the purpose of scientific research, teaching or quality control (QC) purposes or any such other purposes agreed in writing with Provider mBRC".

Note 4: As laid down in par. iv for the MIRRI Policy statement, MIRRI will in general promote commercial utilization of genetic resources they provide.

(ix) what is expected of the Recipient in case he/she wishes to use the material in other ways than allowed under the MTA and original PIC and MAT.

For example: "If the recipient is interested in utilizing the genetic resource in a manner different from the conditions as set out in this MTA and original PIC and MAT, recipient will seek a new access permit and settle MAT with the competent authority in the country of origin before commencing such utilization. If the recipient reaches an agreement with this competent authority, recipient will immediately inform and supply the provider mBRC with electronic or hard copies of this new agreement."

Note 5: The provider mBRC may assist in this process on the Recipients request, and if the mBRC wishes to do so.

Recommendations

MIRRI recommends that the mBRC includes in the MTA:

(1) a brief statement to explain (i) the mission of the mBRC and (ii) that the mBRC adheres to the MIRRI-approved ABS policy and best practices;

(2) a list of terms and their definition, preferably consistent with those used in CBD, Nagoya Protocol, and the Regulation. It is recommended to use the terms listed in the glossary;

(3) for recipients of the material within the EU, to keep this MTA and all other documents relevant to ABS for at least twenty years after the end of the period of utilization.

(4) duration of the contract.

(5) date and place. In case of electronic standard ordering systems the date of approving the procedure will legally suffice.

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Footnotes:

B2.1: The MAT need not be physically transferred, the essential info could be transferred: art 4 (3) a of the Regulation: "the internationally Recognised Certificate of Compliance, as well as information on the content of the mutually agreed terms relevant for subsequent users".

B2.2: As far as the information in PIC and MAT is not confidential. Instead of the physical transfer of the MAT, the transfer of "information on the content of mutually agreed terms" (Reg. art. 4 (3) a), will probably suffice.

B2.3: The validity needs to be determined in close consultation with the national authorities in the country where the mBRC resides.

2.3 Access, internal use of material and benefit sharing by the mBRC

Criticism of the user community on the rather vague definition of utilization of genetic resources, viz., "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology " (see Glossary) has not resulted in a more concrete definition, nor a list of specific activities it is supposed to cover. Instead users are expected, as part of the due diligence obligation, to assess whether the activities they undertake should be considered as utilization in the sense of the Protocol and the Regulation or not.

The EC Guidance[11] stresses the importance of so-called "upstream" activities, i.e. activities typically following closely the access to a genetic resource. Such activities are recognized for their contributions to the conservation of biodiversity, and should therefore not be unnecessarily burdened under ABS legislation and regulatory requirements. The handling and storing of biological material and describing its phenotype are specifically mentioned in the EC Guidance as examples of such upstream activities. The preservation of microorganisms in *ex-situ* collections is also an upstream activity, which typically, besides work on the phenotype, will also have to include work on the genotype in order to accurately identify these organisms and effectively contribute to their conservation.

For the purpose of this best practice, two principal types of activities by MIRRI-mBRCs (and other departments residing under the same institute) are distinguished:

(i) *Activities not falling under the definition of 'utilization' of the Nagoya Protocol and Regulation*: Maintenance and management of the mBRC collection for conservation purposes, including storage of material, quality checks, and verification of material upon acceptance (including pursuing correct and up-to-date identification);

(ii) Research proper, viz.:

(a) *Activities potentially falling under the definition of 'utilization' of the Protocol and Regulation:* activities such as generating data which add value to the material, and will be made available in the public domain;

(b) *Activities falling under the definition of 'utilization' of the Protocol and Regulation*: activities that can be seen as conducting 'research and development' on the genetic resource, for various purposes including, but not limited to, commercial purposes.

Note 1: Since the technologies for genotypic characterization of microorganisms advance rapidly and continuously, it would be impractical to make a list of specific techniques and activities on genotype that should be considered as outside scope of the Regulation. Instead, the mBRC should as part of its due diligence assess whether activities listed above under ii(a) fall under the term utilization in the meaning of the Protocol and Regulation.

Note 2: MIRRI will encourage CBD and regional, and national authorities to have the types of use (i) and (ii a) recognized as 'accepted use' for the common good, providing non-monetary benefits to the Countries of Origin of these resources as well as the global scientific community[25].

The mBRC should keep records of all deliveries of material (holdings) to users (non-mBRC staff) working within the same institute, and inform these users about the conditions for use of the material and all obligations under the MTA.

The minimal requirements are listed in Box 3.

The mBRC or its institute should implement a policy or put other measures in place clarifying under what conditions and terms staff, visiting scientists and other authorized visitors to the institute, are allowed to use the genetic resources present in the mBRC collection(s) or in working collections within the institute (but not in the mBRC's collections) for their research, and how it handles incidents of inappropriate utilization. MIRRI can advise on such a policy statement, but the content will be the responsibility of the individual mBRCs.

Staff wanting to utilize a genetic resource for which PIC and MAT are not available but ABS legislation or regulatory requirements (likely) apply, should first contact the relevant authorities in the country of origin of the genetic resource and/or other appropriate stakeholders to obtain PIC and negotiate MAT[26].

During a research project without commercial intent opportunity for the successful commercialization of a genetic resource may arise unexpectedly. If the mBRC wishes to explore further, it should immediately inform the country of origin of the genetic resource and other rightful stakeholders to negotiate the terms for benefit sharing, at least if such is required according to terms under which the resource was acquired by the mBRC or under applicable national ABS law.

In any scientific collaborative project where the mBRC enters into a written contract with other non-private or private partners, a paragraph should be included in the contract stating that all signatories will utilize the genetic resources in compliance with all applicable ABS legislation and regulatory requirements.

[25] mBRCs should discuss with their national competent authorities their regular practice of preservation and quality control that fall (or could fall) within the definition of "research and development" in the Regulation. For example, DNA extraction and sequencing for the purpose of identification and quality control could be typical activities, as maybe also MALDI-TOF. For example, if a mBRC is successful in entering into the Register of collections (Regulation Art.5), it would be good to have put on paper what type of utilization will be exempt from user obligations as defined in the Regulation Art. 4). Any additional burden for mBRCs from "user obligations" that is only the result of work the mBRCs needs to do to contribute to the conservation of GRs (in support of the CBD primary goal), can and must be avoided. MIRRI will also advocate that these types of use therefore should be exempt from the Regulation.

[26] According to the ECCO-Core MTA published in 2009 (see footnote 23), this would not be necessary. Only if a "positive hit" is found and actual commercialization can be expected, making contact with the country of origin is required.

Box 3 – Research activities of the mBRC - Minimal requirements for utilization of genetic resources by the mBRC

(i) Utilization by the research staff of the mBRC[B3.1] shall fully comply with original PIC and MAT, and additional terms that may be laid down in MAA, if applicable. Such utilization should also comply with any applicable national ABS legislation in the country where the mBRC resides. If the mBRC wishes to utilize a genetic resource in other ways than set out in original agreement, it shall renegotiate PIC and MAT with the country of origin, the depositor and/or other stakeholders if applicable.

(ii) It should be clear which data on the genetic resource the mBRC is allowed to publish, and under which conditions, if any. Such data could include DNA sequences for reference and clarifying the taxonomy of material, which may be published in open access databases or in other ways (normally after release of the material for distribution). The importance of this point lies in the fact that third parties may then access the data and utilize them. See also the minimal requirement for MAA in Box 1.

(iii) The mBRC catalogue of holdings and any publications citing a strain must state the country of origin as the original source of the material.

Note: For ways in which MIRRI-mBRCs typically handle material and utilize the genetic resources thereof, see par. 2.3 of the best practice.

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Footnote

B3.1: and other persons of the same institute (see footnote 7)

Benefit sharing

Benefits resulting from the utilization of the genetic resources by the mBRC will be shared with the rightful stakeholders according to the agreed terms.

MIRRI mBRCs are investing in the safe-keeping of genetic resources and also add value to the resources through research. The result of their research on genetic resources may directly or indirectly contribute to successful commercialization of such resources, in which case fair and equitable sharing by the mBRC in the benefits can be justified. The mBRCs have the option to include a condition in their MTA for supply, which states that they need to be informed when a recipient is going to commercialize a genetic resource obtained from the mBRC, so that the mBRC, if interested, can join in the negotiations on sharing benefits with other stakeholders entitled, e.g., the country of origin.

Charging fees for supply of material

mBRCs will normally supply material to third parties against payment, and this is sometimes mistaken by others for a commercial activity. The mBRCs that charge fees for furnishing material are recommended to explain what these funds are used for. Most mBRCs use the revenues for supplementing public funds, to cover costs made for the delivery, and/or to support the mBRC in general in fulfilling its mission including conservation of biodiversity. Moreover, activities such as

keeping the identification of material up-to-date, and publishing data in the public strain catalogue, can be seen as non-monetary benefits provided by the mBRC to the Countries of Origin and society in general.

2.4 Managing documentation and data

The mBRC should develop a data management policy to assure that all data and documents relevant to ABS for all holdings are properly curated, and readily accessible to authorized staff. Besides the material in the holdings of the mBRC, other material may be kept by other departments or laboratories in working collections. MIRRI recommends that the fields used by the mBRC to implement ABS requirements in its strain collection databases, are also introduced in the various other institutional databases where information on biological material is managed, to reach harmonization across the institute.

(i) Whenever possible, legal documents should be digitized and saved in a central storage facility (if an electronic database of collection holdings is present in the mBRC). Where possible, electronic files of documents should be linked to the main record of the material. Procedures for management of data storage and back-up, access to and security of stored data should be set out and implemented. All authorized staff should be able to view relevant documentation as far as it is not confidential.

(ii) As far as feasible, the mBRC should also make non-confidential ABS information available in the holdings catalogue.

(iii) Some information in the legal documents that are provided by depositors might be treated as (i) confidential, i.e., only for internal use by the mBRC, or as (ii) sensitive, i.e., only to be shared with recipients of the material if necessary. Each mBRC should determine which type of information should be treated as confidential or sensitive, and such information should be stored in fields to which internet users have no access. Any terms in the MAA for deposit concerning confidentiality of information should be respected by the mBRC.

(iv) The mBRC should use unique identifiers of legal document(s) whenever available, such as for the Internationally Recognized Certificate of Compliance, and if possible provide direct links to relevant information on the genetic resources in other data repositories including the ABSCH database.

(v) The mBRC should make the accession numbers (or the associated GUIDs) it issues for accessioned materials available to repositories and/or the ABSCH as part of its standard operating procedures, when such a repository is recognized by the CBD Secretariat in future for the purpose of formal registration of microbial genetic resource GUIDs and linking these to particular Internationally Recognized Certificate of Compliance record in the ABSCH.

2.5 Training and awareness-raising

The managers of the mBRC should set up communication procedures to train staff and raise awareness among all institutional staff of their responsibilities concerning ABS, particularly as regards appropriately sharing monetary or non-monetary benefits arising from the utilization of genetic resources with the country of origin of the genetic resources and other rightful stakeholders.

2.6 Managing secured collections

The views below reflect discussions held in previous stakeholder workshops. It is necessary to confirm these views during the process of creating the EC sector-specific guidance including practice of microbial collections.

Deposits under the Budapest Treaty. These deposits are not within the scope of the Regulation. The mBRCs that are International Depository Authority are therefore not required to keep any ABS relevant data or documents on material deposited under the Budapest Treaty. Appropriate measures are expected from the competent authorities under (national) patent law[27].

Safe deposits. These deposits are also not within the scope of the Regulation. The mBRC is not required to keep any ABS relevant data or documents on material accepted for Safe deposit[28].

> *Note*: Privately held genetic resources may be subject to the Regulation depending on national ABS legislation in the country where these resources are kept *(EC Guidance)*

[27] The utilization of the genetic resources and associated traditional knowledge may be within the scope of the Nagoya Protocol, but this does not affect IDA activities.

[28] Safe deposits are understood to be material deposited in the secured collection of the mBRC through a signed contract, where all rights over the material remain exclusively with the depositor, is confidential, and is never transferred to third parties or used for research by the mBRC. Any transfer to third parties on explicit request by the depositor will be subject to applicable ABS law and regulatory requirements. Any such transfers can be dealt with by the depositor.

3. Glossary

Access - the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol (from the Regulation)

Note: The EC has made clear[29] that access only pertains to the moment when the genetic resource is acquired through collecting or otherwise in the country of origin under in situ conditions. Later acquisitions in the user chain, or acquisition from an ex situ collection, are not regarded as access in the sense of the Regulation. However, countries exercising sovereign rights over their genetic resources may regard acquisition of such resources kept ex-situ in collections within their jurisdiction also as access.

Association of users - an organization, established in accordance with the requirements of the (Member) State in which it is located, that represents the interests of users and that is involved in developing and overseeing the best practices referred to in Article 8 of the Regulation (from the Regulation)

(Biological) material – all strains of microorganisms, and specimens or samples (environmental samples, extracts) of living or dead organisms in MIRRI member collections, regardless if it contains 'functional units of heredity' or not

Biotechnology - any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use (from CBD)

Collection - a set of collected samples of genetic resources and related information that is accumulated and stored, whether held by public or private entities (from the Regulation)

Country of origin (of genetic resources) – the country where a particular microbial genetic resource was taken from *in-situ* conditions, in a natural habitat or from its original non-natural source (for example, in a fermenter, or a human-made substrate or matrix); see also Provider country.

Note: The definition provided in the CBD, reading "the country which possesses those genetic resources in in-situ conditions", is difficult to apply in the case of microorganisms that mostly have distribution ranges including territories of several or multiple Party States.

Derivative - a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity (from NP)

***Ex-situ* conservation** – the conservation of components of biological diversity outside their natural habitats (from CBD)

Genetic material – any material of plant, animal, microbial or other origin containing functional units of heredity (from CBD)

Genetic resources - genetic material of actual or potential value (from NP)

Habitat - the place or type of site where an organism or population naturally occurs (from CBD)

[29] Ms Alicja Kozlowska (ICNP, ABS, NFP for the European Community) during the International Chamber of Commerce Workshop "Working out ABS", 24-25 November 2014, Paris, France

***In-situ* conditions** - 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 (from CBD)

Internationally Recognized Certificate of Compliance - a permit or its equivalent issued at the time of access as evidence that the genetic resource it covers has been accessed in accordance with the decision to grant prior informed consent, and that mutually agreed terms have been established for the user and the utilization specified therein by a competent authority in accordance with Article 6(3)(e) and Article 13(2) of the Nagoya Protocol, that is made available to the Access and Benefit-sharing Clearing House established under Article 14(1) of that Protocol (from the Regulation)

Provider country - the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country (from CBD); the country of origin of the genetic resources or any (other) Party to the Protocol that has acquired the genetic resources in accordance with the Convention (EC Guidance)

Traditional knowledge (associated with genetic resources) - traditional knowledge held by an indigenous or local community that is relevant for the utilization of genetic resources and that is as such described in the mutually agreed terms applying to the utilization of genetic resources (from the Regulation)

User - a natural person or legal entity that utilizes genetic resources or traditional knowledge associated with genetic resources (from the Regulation)

Utilization of genetic resources - to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology (as defined in Article 2 of the Convention; from the Regulation)

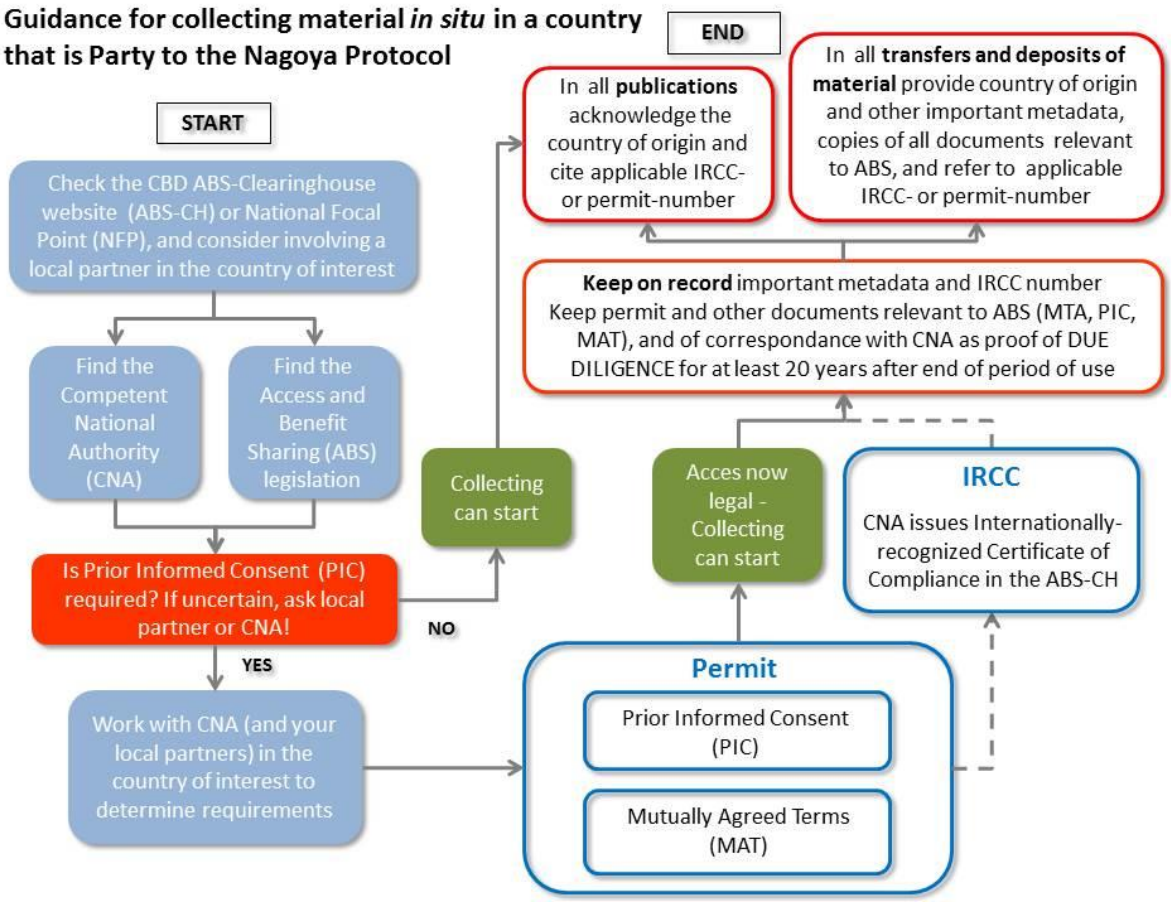
Working collection – a collection that is kept by staff of an institute for research purposes, and is not part of the public collections held by the mBRC of the same institute

4. Abbreviations

ABS	Access and Benefit Sharing
ABSCH	ABS Clearing House
CBD	Convention on Biological Diversity
CETAF	Consortium of European Taxonomic Facilities
EC	European Commission
ECCO	European Culture Collections Organization
IDA	International Depository Authority
MAA	Material Accession Agreement
MAT	Mutually Agreed Terms
MIRRI	Microbial Resource Research Infrastructure
mBRC	microbial domain Biological Resource Centre
MTA	Material Transfer Agreement
NFP	National Focal Point (normally with reference to ABS)
NP	Nagoya Protocol
PIC	Prior Informed Consent
WFCC	World Federation for Culture Collections

5. Annexes

Annex 1: Guidance for collecting material *in situ* in a country that is party to the Nagoya protocol



Annex 2: Guidance for accepting material form external providers for study