



Consortium of European Taxonomic Facilities (CETAF)

ANNEXES 1 to 4 to the CETAF Code of Conduct on ABS

ANNEX 1:

CETAF BEST PRACTICE on Access and Benefit-Sharing

This Best Practice on Access and Benefit-Sharing (the “Best Practice”) has been produced in response to Article 20 of the Nagoya Protocol and Article 8 of the EU Regulation 511/2014 and subsequent EU Implementation Act to guide Institutions on the implementation of the Code of Conduct.

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Preamble

These Best Practice components are designed to assist Institutions in implementing the CETAF Code of Conduct on Access and Benefit-Sharing. The Best Practice gives practical guidance for the day-to-day work of the institution, so that:

- it can fulfil its legal obligations and understand its rights and responsibilities under the appropriate treaties and relationships with Providers of biological material;
- its staff, authorised visitors and associates abide by appropriate national and international laws and regulations when working in or on behalf of the institution and, where required, respect Indigenous and Local Community customary laws and community protocols;
- biological material and associated Traditional Knowledge entering the collections is obtained with appropriate legal certainty and can legally be retained;
- temporary and non-temporary supply of specimens to any Third Parties is documented as required to meet relevant legal and contractual obligations; and
- the documentation legally required in this process is managed effectively.

Implementation of specific parts of this Best Practice may not be relevant or applicable for all institutions¹.

In order to comply with ABS regulations and function effectively, Institutions² and their staff³ should:

1. **Acquire** only biological material and associated Traditional Knowledge (TKaGR) that has been legally accessed⁴ (whether from *in situ* or *ex situ* sources);
2. **Manage** collections and associated data in a way that the Provider of the biological material, including any subsamples, can be traced and that any related terms and conditions are easily accessible;

¹ Depending on Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) at the time of access and documentation requirements laid down in relevant national or international law.

² In the following the term “institution(s)” refers to those bodies adhering to the CETAF Code of Conduct and Best Practice.

³ In the following the term “staff” is used as a general term, but Institutions should make sure that not only employees but also associates and any other individuals acting in the name of the Institution are informed and abide by relevant ABS policies, regulations and legislations.

⁴ See glossary for a definition of ‘Access’.

3. **Use⁵** biological material and TKaGR in a way that is consistent with the terms and conditions under which the material was acquired;
4. **Supply biological material and associated traditional knowledge** to Third Parties for their use only on terms and conditions that are consistent with those under which the material was acquired, and with relevant documentation;
5. **Share benefits** with the Provider as agreed in negotiated terms;
6. **Seek new Prior Informed Consent (PIC) and renegotiate Mutually Agreed Terms (MAT)** in case of proposed change in utilization from that previously agreed;
7. **Develop institutional policies;** and
8. **Train their staff** and inform authorized visitors and associates.

This Best Practice applies to biological material accessed after the entry into force of the Nagoya Protocol (12 October 2014). CETAF members and other participating Institutions are encouraged to apply this Best Practice, as far as reasonably possible, also to all other biological material in their collections⁶.

1. Acquisition of biological material

There are different ways of acquiring biological material: collecting in the field (*in situ*) and acquisition from *ex situ* sources, either by permanent (e.g., exchange, donations, sharing of tissue or DNA samples) or temporary supply (e.g., loans).

Institutions should exercise due diligence to ascertain that Genetic Resources (GR) and Traditional Knowledge associated with Genetic Resources (TKaGR) which they utilize have been accessed in accordance with applicable ABS legislation or regulatory requirements⁷. Section 2.1 lists the information required to be able to exercise due diligence according to the EU Regulation.

When signing agreements such as MAT or Material Transfer Agreements (MTA), Institutions should consider the legal framework governing the collections and how this can accommodate requirements of those agreements, including persistent obligations.

In order to facilitate this, Institutions should designate one or more individuals (e.g. director, conservator or any other technical staff) to handle such legal matters and authorise agreements such as MAT or MTAs.

⁵ See 'Statement of Use of Biological Material' for a description of the spectrum of 'use'

⁶ While reasonable efforts will be made, no responsibility is accepted for any retroactive claims, such as benefit-sharing.

⁷ Note that the term 'access' has not been defined in the Convention on Biological Diversity or the Nagoya Protocol, and may be used differently by some countries or organizations. Therefore it is recommended to include an agreed definition in all legal documents.

Institutions should make sure that their internal policies and procedures relating to material entering their premises cover the following ABS aspects, if applicable:

- a. Field Collecting (see section 1.1.)
- b. Object Entry⁸, governing what legal documentation is required by the Institution when biological material is received, either unsolicited (see section 1.4), temporarily (see section 1.2) or permanently (see section 1.3).

1.1. Acquisition from in situ sources (fieldwork)

Permission from the Providing Country to undertake fieldwork and collect biological material will typically include Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT), which may be combined in a permit. Staff may have to negotiate and agree these with the Providing Country prior to the start of fieldwork, depending on the applicable laws and regulations of the Providing country, and whether or not the fieldwork is taking place as part of a larger project for which negotiations have already taken place. Institutions should develop systems so that staff are aware of the permissions and legal documentation required, and seek to obtain the relevant documentation from the Competent National Authority within the Providing Country⁹. Institutions and staff should be aware, when contacting the Competent National Authority, that other offices might need to be contacted as well, depending on the Providing Country's legislation. If a providing country grants free access, institutions are advised to positively document that access was not restricted then and no permits for access of biological material have been issued¹⁰.

Indigenous and Local Community customary laws and community protocols should be respected where these apply to the work undertaken.

Staff should not start any fieldwork until the required permits are agreed and finalised, or appropriate written guarantees received. Fieldwork in a Providing Country is to be carried out only in accordance with the laws and regulations of that country.

Institutions should draw up guidelines to assist staff in this formal process, including clear rules on who is authorized to sign any agreements. Staff should only sign MAT (e.g., conditions in permits) if the Institution is able to meet the terms agreed. When negotiating PIC and MAT, the Institution or its staff must be clear about the purposes for which the material will be used at the Institution¹¹.

⁸ Objects may include biological material but also other material that could contain biological material, such as soil samples.

⁹ With pending international and national ABS legislation inside and outside the EU, Institutions should carefully check and compare laws as soon as they enter into force to determine if specific access restrictions and reporting obligations need to be considered. Relevant information on national ABS legislation and Competent Authorities can be obtained from the ABS clearing house website (<https://absch.cbd.int/>).

¹⁰ e.g. by recording positive replies of respective Competent National Authorities

¹¹ It is advisable to consider and cover – as far as foreseeable and possible – any potential future uses beyond current specific research projects for which PIC & MAT are negotiated. The proposed use should be as

Institutions and their staff are encouraged to refer to the CETAF 'Statement of Use of Biological Material', because it sets out the typical ways in which biological material may be used. This document (see Annex 2) is intended for use in discussions with Providers of biological material when seeking access. It might also be used in donations or exchanges of material, or when material is provided unsolicited such as for identification. By its use ambiguities or uncertainties regarding uses of the material can be avoided. It should be provided to Competent Authorities in Providing Countries, and with their agreement annexed to an agreement. If Providers do not wish their material to be treated in a way listed in the document, or wish to place any specific restrictions, staff should ensure that this is expressly set out in writing in the agreement or permit, or the relevant elements of the document deleted. Written restrictions and conditions in a permit or equivalent will always take precedence over the text of the use statement.

Where possible and appropriate, fieldwork should be conducted as part of a collaborative venture with a museum, botanic garden, university or other recognized scientific research organization in the Providing Country. Such collaboration can be included in the MAT as a direct benefit arising from the fieldwork¹². In cases where an institution conducts long-term or repeated projects in a Providing Country, it might be beneficial to develop framework agreements with the Competent National Authority of that country.

Activities that involve collecting specimens or samples by staff and associates, and any other individuals using the name of the Institution, should be carried out only for and in the name of the Institution responsible for the fieldwork; any additional acquisition of biological material for private or other use, including on behalf of or for sale to Third Parties, should be prohibited by the Institution¹³.

1.2. Temporary acquisition from *ex situ* sources

This covers all cases where material is not transferred into ownership of the Institution and/or is not accessioned into its collections. This might include incoming loans of material for research or exhibition or temporary use, e.g. material brought in by guest scientists for analysis in the DNA lab of the Institution or specimens brought in by visitors for examination in the Institution.

Internal policies or procedures should set out conditions under which loans received by staff or associates of the Institution can be accepted in the context of ABS. This will manage the risk of

broad as possible and not be limited to a specific technique, keeping in mind that samples persist in collections (if not consumed by the current project). This could help to avoid new negotiations being triggered due to novel analytical and technical advances even though the purpose of the research is unchanged.

¹² It is advisable to list under the MAT all benefits that are to be delivered and to record all benefits being delivered.

¹³ Institutions are advised to develop or revise procedures to train and inform independent or contracted individuals or organisations who collect and supply biological materials or who do fieldwork for and in the name of that institution.

breach of terms under which genetic resources were accessed if appropriate documentation is not transferred with the material, or of illegally utilizing genetic resources if they were illegally collected.

1.3. Permanent acquisition from *ex situ* sources

This covers all cases where material is not collected in the wild by the Institution, but is transferred from other collections or any other *ex situ* sources into the ownership or custodianship of the Institution, by means such as purchase, donation, bequest, exchange, submission as unsolicited samples, etc.

Institutions must exercise due diligence (see section 1 *Acquisition of biological material* above) so that they do not acquire biological material without being confident that they can retain the material legally.

Institutions should not knowingly acquire, by any direct or indirect means, any biological material that has been collected, sold or otherwise transferred in contravention of any national or international law or treaty at the time of original collection or thereafter. For biological material accessed after the Nagoya Protocol came into force¹⁴, Institutions should accept biological material only with appropriate documentation providing evidence that the genetic resources and the related information were accessed in accordance with applicable access and benefit sharing legislation or regulatory requirements and, where relevant, with Mutually Agreed Terms (see also Sections 1 and 2.1)¹⁵. An exception may be appropriate when material known or suspected to be illegally obtained is submitted by an outside authority such as police, customs or quarantine officials for temporary or permanent deposition.

If biological material is acquired from a commercial supplier, the institution should be aware that this could constitute a change of use which could require PIC and MAT from the original provider. Institutions are advised to check the provenance and legal status of this material before acquiring it.

Institutions will need to ensure their policies and procedures address management of documentation associated with acquisition of material from *ex situ* sources. The Institution will need documents covering requirements and permissions associated with the material and demonstrating its provenance e.g. the number of an Internationally Recognised Certificate of Compliance, or PIC and MAT (or a statement as to why they were not required if they are not provided). These might usefully be attached to a document confirming transfer of title to the Institution, including any conditions. A tool to facilitate this is a 'Material Transfer Agreement'¹⁶ for use with any material not collected by staff (see '1.1 Acquisition from in-situ sources'). This is also of use in cases where material is offered to the Institution and a commitment to accept is required prior to donation.

¹⁴ 12th of October, 2014 (<http://www.cbd.int/abs/>)

¹⁵ Legal exemptions such as materials seized by customs and deposited at the institution may apply.

¹⁶ See joint GGBN / CETAF MTA templates, here specifically MTA 3

1.4. Unsolicited acquisition

Objects may arrive at the Institution without being solicited. Examples include submissions for identification, donations from researchers in other institutions, and material abandoned by visitors. The Institution should develop or adapt policies and practices to address each circumstance. For unsolicited donations the donor should be asked for appropriate documentation or a supported statement that such documentation was not required. Material left by visitors should be returned to the visitors or clarity on its legal provenance sought as for unsolicited donations¹⁷.

Material sent for identification or analysis similarly cannot be retained without appropriate documentation (including, if appropriate, clarity that it was not legally obtained in the first place but for some reason, such as submission by national border authorities, it can be legally held by the Institution). Sequence or other data from objects submitted for identification should not be published without clarity on whether this is legally appropriate.

2. Curation and Data management

Institutions should make sure that their internal policies and procedures consider ABS aspects where relevant. Internal policies may need to address:

- a. Harmonisation of policies, management and record keeping protocols across all collections and research groups in the Institution. Separate or newly-developing collections (e.g. frozen tissue and DNA collections) and public exhibition collections may have different protocols and policies from the more traditional collections; harmonising policies will reduce management problems and uncertainty among staff.
- b. Living collections – Special conditions may apply to living collections, including utilization of cultures and other captive-bred and propagated organisms in collections.
- c. Research and ABS. Policies may be needed to govern internal access to and utilization of Genetic Resources and publication of results, during research activities by institution staff and others. This may be covered by other ABS policy elements, or in a separate policy, depending on how closely research and collection management are integrated.
- d. Destructive and invasive sampling – covers any form of sampling or subsampling including that intended for DNA extraction. It is particularly important to manage restrictions and requirements agreed with the Providing Country (MAT).
- e. Traditional Knowledge associated with genetic resources – covering aspects of the Institution's acquisition, documenting, digitization, archiving and release of TKaGR. This should include how it is stored, who can access it, and conditions under which it can be made public.
- f. Databasing, data (including images) and document management, publication of data associated with biological material (see section 2.1); digital linkages between collection data records and corresponding MAT, PIC and MTAs.

¹⁷ See CETAF MTA 4, warranty of guests bringing material to an institution for research / analysis

- g. Internal Collections Audit – Monitoring or audit system (preferably digital) in order to determine if the Institution is managing its ABS documentation effectively, compliance with agreements and associated processes, and improvements, if required and feasible.

It is advisable to register and store relevant legal documentation at one central point (e.g. with a registrar), especially if subsamples of a single individual organism (Genetic Resource) are stored in separate collections, different buildings, etc. An easily accessible digital archive of these documents can offer valuable support.

See section 6 (Institutional Policies) for further details.

2.1. Record-keeping and data management

Institutions must manage their collections and associated information so that biological material is used only in a way consistent with the terms and condition under which the material was acquired from the Providing Country.

For that purpose, Institutions should **keep records** on

- acquisition of biological material, including core data associated with Genetic Resources such as¹⁸
 - *a description of the GR* (at appropriate taxonomic level)
 - *the date and place of access of GR and TKaGR*
 - the *Provider* from whom the GR or the TKaGR were directly obtained
 - references to associated legal documentation (*Number of the Internationally-Recognized Certificate of Compliance (if issued), permits, PIC, MAT, etc.*) and scanned or physical copies where possible, including the *authority responsible for granting PIC, the date of its granting and the person or entity to whom PIC was granted*. There should be a flag or indicator inside the documents that PIC was granted.
 - *Mutually Agreed Terms, including benefits shared*
 - *Presence or absence of rights and restrictions, including commercialisation and third party transfer.*
- the *utilization of Genetic Resources and Traditional Knowledge associated with Genetic Resources* and, if utilized, *the person or entity utilizing them* at the Institution or in a subcontracted entity (see also point 3) and whether this was funded by external sources or internal¹⁹;
- any *supply to Third Parties*, whether on loan or permanent supply (see also point 4);
- any benefits derived from the use/utilization and shared with the Provider/Providing Country (see also point 5);

¹⁸ In this list the items in italics are those that may be required for reporting to a checkpoint under the Nagoya Protocol and under the EU Regulation (see Article 4, paragraph 3).

¹⁹ This might have relevance in combination with the ABS Implementing Act or the EU and should be critically reviewed for each utilization (including multiple use of same samples)

- deaccessioning, disposal and loss, including consumption of tissues or DNA for analysis or degradation of material.

and are advised to **implement appropriate data management** systems that allow the Institution to

- a) keep records of the origin, provenance and provider of any sample or specimen of biological material and TKaGR that is in the Institution's collections, and provide staff or authorized visitors with information on any terms and conditions of use;
- b) track the use of biological material, and associated traditional knowledge that entered the collections (including utilization or supply to Third Parties).

To accomplish this, the data management system should provide the following elements:

- Means to discover rapidly what legal documents, requirements and restrictions are associated with a specimen or sample (as set out, for example, in the MAT) and, if necessary, efficiently transfer this information to a user in another institution when the specimen or any subsample, part or derivative of it is transferred;
- Means to discover rapidly all records on the use of biological material that entered the collections (including utilization or supply to Third Parties); this should include the establishment of unique identifiers (e.g., collection catalogue numbers) that allow tracking of specimens or samples;
- Means to link different data and information obtained from the use of biological material (such as DNA sequence information, images, or other digital representation) to the original sample or specimen;
- Means to retain all relevant records and legal information covering Genetic Resources for an appropriate period of time (e.g. to comply with the EU Regulation, those shall be kept at least 20 years after "end of utilization").

2.2. Deaccession and Disposal of collections

As with other aspects of collection management, one or more harmonized internal policies and/or procedures will be helpful here (see Section 6). Disposal should only take place if it is in accord with the terms and conditions agreed with the Providing Country.

Mutually Agreed Terms may require that specimens be destroyed after use (e.g. DNA sent for sequencing to a third-party laboratory) or returned to the Provider. Destruction should only be carried out if congruent with all restrictions or requirements. Institutions should have a process in place to manage destruction of Genetic Resources in line with the original PIC, MAT or MTA where this is required.

3. Utilization of Genetic Resources

Institutions should be aware that any utilization²⁰ of GR within their facilities may fall under the reporting responsibility of that Institution²¹. In this context reference is also made to the Use Statement included as Annex 1 to the CETAF Code of Conduct.

Biological material should not be sampled for utilization of Genetic Resources if this is prohibited by Prior Informed Consent or Mutually Agreed Terms. Institutions should therefore develop means to associate any data indicating restrictions on the use of biological material (including utilization of Genetic Resources) with each individual (sub)sample of this material. They should also put mechanisms in place so that staff and other users, such as partners in collaborative projects, are informed about and can abide by terms and conditions regarding GR and TKaGR.

When the information on material acquired by the Institution that was accessed from the Providing Country after the Nagoya Protocol entered into force is insufficient to meet reporting requirements, or uncertainties about the legality of access and utilization persist, Institutions should either obtain an access permit or its equivalent and establish Mutually Agreed Terms with the Providing Country, or discontinue utilization.

Records should be kept of utilization of Genetic Resources. An Institution should have clear and robust policies on how it handles inappropriate utilization (whether inadvertent or deliberate) by staff and other users. Systems should be put in place to halt the inappropriate utilization when discovered, prevent its reoccurrence, and address any problems it may have caused with the providing country.

Publications resulting from the utilization of Genetic Resources, and other use of biological material, should acknowledge the Providing Country. Ideally, publications should also include an identifier of the permit or other agreement covering the collecting (access to) and use of the specimens, where these exist²², and should list references to specimens or samples studied. ‘Publication’ includes paper and electronic publications, as well as online databases in the public domain, such as GenBank.

In the event of complaints from providing countries about inappropriate utilization or other related matter, the institution should have policies or procedures that deliver a structured response, such as:

- a. Utilization ceases until it is clear that it can be done legally.

²⁰ ‘Utilization’ here is used in the sense of the Nagoya protocol (see Glossary)

²¹ The European Commission Implementing Regulation for the Implementation of Regulation (EU) No. 511/2014 sets out the requirements for reporting due diligence at the stage of research funding and of putting on the Union Market, under Articles 7(1) and 7(2).

²² This would not be required for genetic resources collected from countries that at the time of collection had no requirements for access permits or issuance of PIC

- b. The situation is reviewed to discover whether the concern of the providing country is justified.
- c. Justified complaints are responded to with an explanation, with an apology if an infringement has taken place and, if necessary, PIC sought and MAT agreed for the utilization being undertaken.
- d. If an infringement has taken place, to review policies and procedures to avoid its recurrence.

There may also be requirements under the user country legislation implementing the EU Regulation.

4. Supply to Third Parties

Any restrictions or requirements arising from the conditions under which the specimens were obtained or arising from institutional policy should be communicated to the Third Party. This may require paper or electronic copies of relevant Mutually Agreed Terms, collecting permits and Material Transfer Agreements in some cases (especially where the specimen, sample or (processed) subsample is being permanently supplied).

The EU Regulation 511/2014, Article 4, paragraph 3, sets out requirements that apply to CETAF members:

“For the purposes of paragraph 1, users shall seek, keep and transfer to subsequent users:

- (a) the internationally-recognised certificate of compliance, as well as information on the content of the mutually agreed terms relevant for subsequent users; or
- (b) where no internationally-recognised certificate of compliance is available, information and relevant documents on:
 - (i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources;
 - (ii) the description of the genetic resources or of traditional knowledge associated with genetic resources utilized;
 - (iii) the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources;
 - (iv) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation;
 - (v) access permits, where applicable;
 - (vi) mutually agreed terms, including benefit-sharing arrangements, where applicable.”

Some of the information listed above is required within the EU by national checkpoints when reporting due diligence under EU Regulation 511/2014 and Implementing Regulation EU No 2015/1866. Note that point (iii) above implies that this information includes records of users. It may, therefore, be appropriate to inform Third Parties (and in particular those utilizing genetic resources) that information on their utilization will be retained for reporting purposes. This would form part of a standard MTA.

4.1. Temporary supply (e.g. loans/sharing of tissues/DNA subsamples)

This section deals with temporary supply of biological material to a Third Party without change in ownership, i.e. material that is under temporary custodianship by a researcher in an institution that was not involved in the original Access. This can only take place if not prohibited by the original PIC and MAT.

Third Parties borrowing biological material should be made aware of terms and conditions governing use of that material, including both restrictions and requirements.

Institutions should use standard MTAs²³ to establish a new agreement to cover temporary Third Party transfers.

Institutions should have procedures setting out how to respond to a request from a Third Party for a change of use of material sourced from the Institution from that allowed by the original PIC and MAT or other conditions set out in the relevant MTA (loan agreement). Institutions should have clear and robust policies for how they handle inappropriate utilization of such material (which may occur either inadvertently or purposefully) by Third Parties. Such a policy might include notification of the Checkpoint or National Focal Point of the user's country.

Records should be maintained of specimens or samples borrowed by Third Parties, including utilization of GR if it takes place.

4.2. Permanent supply to Third Parties

Biological material or associated Traditional Knowledge should not be permanently transferred to another institution if prohibited under the original PIC and MAT. If transfer is not prohibited under the original PIC and MAT, biological material may be transferred to Third Parties under an appropriate MTA, at least as restrictive as the MTA signed with the Provider. By this MTA the Third Party would undertake to use the biological material only in a manner compliant with the original PIC and MAT²⁴. Details of PIC and MAT should be transferred with the material (see also EU

²³ See joint GGBN/CETAF MTA templates, here specifically MTA 1

²⁴ Where sequence or other analytical data are retained by the Third Party as a part of the logfile of the sequencer or other datasets, a contract should be agreed prior to analysis that excludes utilization not in compliance with the terms and conditions under which the biological resources were acquired

Regulation text above), and records should be maintained of specimens or samples transferred permanently to Third Parties.

If an institution is approached by a Third Party wishing to utilize the biological material or TKaGR in a manner different from the conditions as set out in the original PIC and MAT or MTA, possible responses may include denial of the request, requirement that the Third Party obtains PIC and MAT from the Provider, or partnership with the Third Party in seeking such permission.

Any commercial facility to which samples are sent as a part of research (e.g. for DNA sequencing) should be required to return or destroy residues following completion of the work.

5. Benefit-sharing

Institutions should implement procedures to share benefits arising from their utilization of GR or TKaGR fairly and equitably with the Providing Country and other appropriate stakeholders as agreed in Prior Informed Consent and Mutually Agreed Terms at the time of access, or as renegotiated with a subsequent change of use. These procedures will include maintaining appropriate records of benefits agreed in the PIC and MAT (see section 2). Institutions are advised to keep a record of benefits shared.

Where agreed with the Providing Country benefits arising from the utilization of genetic resources of CETAF members will be directed towards the conservation of biological diversity and the sustainable use of its components, in agreement with Article 9 of the Nagoya Protocol. Benefits agreed with the Providing Country are likely to include any of those listed in the Annex to the Nagoya Protocol (see Annex 4 to this document). Because of the not-for-profit nature of the work of Institutions, benefits are most likely to be non-monetary, *inter alia*: scientific training, education, capacity building, transfer of technologies, collaboration on scientific work programmes, mutual sharing of research results and of associated publications, as well as acknowledgment of the Provider when publishing data or research results. Management of benefit delivery will be facilitated if a standard list is used with the Providing Country as a basis for agreement (see Section 1), since this will support record management by use of a standard vocabulary.

Institutions should strive to implement procedures to share any benefits arising from the new utilization of GR or TKaGR accessed or otherwise acquired prior to the entry into force of the Nagoya Protocol, as far as reasonably possible, in the same manner as for those acquired thereafter.

6. Institutional Policies

Clear policy statements will assist Institutions in managing compliance with provisions arising from the Nagoya Protocol and other ABS regulations and legislation that apply. They need to govern

activities or points in workflows, where decisions have to be taken – which have an ABS implication, which are governed by ABS legislation, or where ABS concerns have to be managed.

Any policies on GR and TKaGR should make explicit who is obliged to follow them (e.g. staff, whether onsite or elsewhere, including when working as a visitor in another institution; students attached to the Institution; associates (e.g. Research Associates, Honorary Associates); volunteers; visitors working in the Institution, etc.). Special consideration may need to be given to individuals or groups working across more than one institution.

The Institution (and/or other appropriate entity) should have an overall Access and Benefit-Sharing policy (this can be an ‘umbrella’ policy covering all aspects of ABS and be used as a reference in other policies²⁵). Harmonised policies and the processes will help the institution and its staff to manage compliance with national and international ABS legislation. Where possible, policies should echo wording in accepted legal frameworks, including the EU No 511/2014, Implementing Regulation EU No 2015/1866 and any national implementing Regulation. Aspects that may be considered for separate policy statements include those listed below. There should be means either in policies or procedures to ensure compliance in each of these areas (as discussed in this document).

6.1. Acquiring new specimens

1. Field Collecting – to cover all aspects of collecting, including the requirement to obtain appropriate documents including permits, PIC and MAT.
2. Object Entry – governing what legal documentation is required by the Institution when biological material enters the Institution prior to accession, including how both entry and documentation are managed by the Institution.
3. Accession – governing the conditions required for specimens to be added to the collections and pass under the ownership or custodianship of the Institution, including long-term loans and material held in trust. The policy may need to address:
 - a. Documents required (e.g. PIC, MAT, MTA, donation letter, Transfer of Title document²⁶), and how these are managed;
 - b. Identification of the individual (e.g. Director, Head of collections etc.) within the Institution responsible for authorising accession.

²⁵ It might be advisable to develop policies and clear procedures for utilization of pre-NP specimens (collected in-situ or acquired ex-situ prior to 12 Oct 2014) and pre-CBD specimens (collected in-situ or acquired ex-situ prior to 29 Dec 1993)

²⁶ Legal document managing the formal change of ownership of an object from one person or organisation to another. Documents required (e.g. PIC, MAT, MTA, Donation letters or Transfer of Title or similar documents confirming transfer of ownership).

6.2. Managing the collection

4. Means of managing compliance with MAT – This includes accommodating continuing obligations within the legal framework governing the collections (e.g. that specimens be returned to the Providing Country). Also addresses intended change of use from that agreed in PIC and MAT.
5. Incoming loans, including DNA and tissues – Documents required (e.g. copies of PIC and MAT, MTA, loan form), and how these are managed.
6. Special or newly-developing collections within the Institution – e.g. frozen tissue and DNA collections conferred to dried or spirit collections. Should develop harmonisation of policies and record keeping.
7. Destructive and invasive sampling – covers any form of subsampling intended for DNA extraction. Management of restrictions and requirements agreed with the Providing Country (MAT).
8. Living collections – Utilization of cultures and other bred and propagated organisms in collections; living material sourced from commercial suppliers²⁷; agreements required for supply to Third Parties.
9. Traditional Knowledge associated with Genetic Resources – covering all aspects of the Institution's acquisition, documenting, digitisation, achieving of Traditional Knowledge associated with genetic resources. Should include how it is stored, who can access it, conditions under which it can be made public.
10. Incoming and outgoing exhibition loans/acquisition – although not utilized for scientific research such loans may require ABS permits (including for TKaGR).²⁸
11. Outgoing loans – conditions under which users in other institutions can borrow biological material, in compliance with terms under which material was acquired, including:
 - a. list of analytical processes (e.g. using tick boxes) loan recipients are permitted to carry out on material received and, if appropriate, what is prohibited; anything that is not stipulated in the loan form is prohibited;
 - b. requirements for documentation to be provided with loans (e.g. copies of original PIC and MAT or summary thereof);
 - c. action should commercialisation be requested by the Third Party;
 - d. action should the Third Party undertake inappropriate utilization.
12. Outgoing DNA and tissues – or products of other destructive sampling techniques (see also 6.3 below); these may include the elements from 11 above, and:
 - a. return or disposal of any residual samples/aliquots/derivatives that have not been consumed for analysis;
 - b. any subsequent utilization by a borrower;
 - c. Loans are considered personal and are not transferable by the borrower.

²⁷ If a change of use is involved, e.g. from pet trade to utilization of genetic resources.

²⁸ They also may be required to comply with additional requirements such as CITES compliance.

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13. Research and ABS – governs access to GR, utilization of GR and use and publication of results during research activities by the Institution.
 14. Data management and documentation – all data management that includes ABS-related documentation or information, including:
 - a. storage and access to ABS-related documents and associated information;
 - b. mechanism to cross reference intended use with PIC and MAT;
 - c. sharing content of ABS documents with Third Parties, including through reporting and compliance mechanism;
 - d. special treatment of sensitive information (e.g. Traditional Knowledge associated with genetic resources, information restricted under PIC and MAT);
 - e. means of keeping records of tissue and DNA subsamples congruent when physically separate, e.g. if samples (tissues, DNAs and voucher specimens) are physically stored and/or managed by different departments or entities in the Institution;
 - f. protocols for publishing additional information (e.g. Provider, permit number, restrictions on use) associated with sequence data (e.g. publication through GenBank);
 - g. record-keeping.
 15. Internal Collections Audit – Monitoring or audit system in order to determine if the Institution is managing its ABS documentation effectively, compliance with agreements and associated processes, and whether improvements are required or possible.
- 6.3. Removal of specimens from the collection, including consumption during analysis**
16. Dispatch and object exit – covering all items leaving the Institution temporarily or permanently, including:
 - a. documentation required internally, with special regard to consumption of (sub) samples and derivatives thereof;
 - b. documentation required by recipient if transferred to a Third Party;
 - c. documentation required by the Providing Country.
 17. Loss or complete consumption – the course of action to be taken with regard to ABS requirements (e.g. under MAT), including documentation, should specimens no longer be available in the collections for internal (e.g. complete consumption for DNA analysis) or external (e.g. loss of loaned specimens) reason.
 18. Deaccessioning and disposals²⁹ (including exchanges and transfers) – governing how specimens leave the ownership/custodianship of the Institution, which may be governed by Mutually Agreed Terms or a Material Transfer Agreement.

²⁹ e.g. PCR and cycle sequencing products

7. Staff training

All staff whose work involves collecting, managing and researching on specimens, including those undertaking laboratory work and managing loans to other institutions, should receive training in implementing the ABS policy and ABS aspects of other policies. An identified staff member should be responsible for coordinating delivery of training and keeping records of training being delivered. A handbook to the Institution's policies and processes regarding ABS should be made available digitally or in hard copy.