Consortium of European Taxonomic Facilities (CETAF)

ANNEX 1 to the CETAF Code of Conduct on ABS

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 *Regulation 511/2014 of the European Parliament and 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 Utilisation in the Union* (hereafter the "EU Regulation") and the subsequent *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* (hereafter the "Implementing Act") to guide Institutions on the implementation of the Code of Conduct. It supports CETAF members to establish ABS measures[1], the policies and practices herein are not, however, restricted in applicability to the EU Regulation[2].

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1) CETAF General Meeting approved the CoC and BP in October 2015

2) CETAF Members are from EU countries as well as from EU associated countries

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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 resulting from the implementation of the Nagoya Protocol on Access and Benefit Sharing in the Provider and User Countries in which it operates;
- it can negotiate and enter into relationships with Providers of genetic resources, biological material and associated Traditional Knowledge, and deal with any contractual matters that may result from such agreements;
- its staff, authorised visitors and associates abide by appropriate national and international laws and regulations when working in or on behalf of the Institution. If Genetic Resources (GR) and particularly Traditional Knowledge associated with Genetic Resources (TKaGR) are obtained from indigenous and local communities, the views and position of the indigenous

and local communities holding the GR or TKaGR should be taken into account and may be reflected in mutually agreed terms, even if this is not required by the national legislation[3]

- the Institution, its staff, authorised visitors and associates[4] comply with the EU Regulation, the Implementing Act, and the relevant National legislation;
- biological material and associated Traditional Knowledge[5] 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 to enable its retention, rapid retrieval and compliance with its terms.

Tools in this Best Practice fit closely to the requirements of the EU Regulation, while offering necessary flexibility for adaptation under national laws of the home countries of CETAF Members inside and outside the EU.

In order to comply with ABS regulations and function effectively, Institutions[6] and their staff[7] should:

1. **Acquire** only biological material and associated Traditional Knowledge (TKaGR) that has been legally accessed[8] (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;
3. **Use**[9] biological material and TKaGR only in a way that is consistent with the terms and conditions under which it 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 Mutually Agreed Terms (MAT), permit conditions and analogous contracts;

[3] The requirements of Providing Countries in regard to indigenous communities and the legal status and official recognition of customary laws of such local communities may differ from country to country. *In-situ* collecting in areas with indigenous communities should only be carried out with prior consent of such communities.

[4] i.e. 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, and anyone authorised to use the name of the Institution in their activities.

[5] Although the wording of the Nagoya Protocol refers to 'traditional knowledge associated with genetic resources' such TK tends to be accessed into collections associated with biological material, irrespective of whether that material contains functional units of heredity, or not.

6) In the following the term "Institution(s)" refers to those bodies adhering to the CETAF Code of Conduct and Best Practice.

7) 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 authorised to act in the name of the Institution are informed and abide by relevant ABS policies, regulations and legislation.

8) See Annex 3 - Glossary for a definition of "Access".

9) See "Statement of Use of Biological Material" for a description of the spectrum of "use".

6. **Seek new Prior Informed Consent** (PIC) and **renegotiate Mutually Agreed Terms** (MAT) in case of proposed change in utilisation 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 collections[10].

Tools to assist organisations and individuals understand ABS and the Nagoya Protocol are given on the Practical Guidance (**Annex 5**) Sections *"Getting Started"* and *"Institutional Management"*.

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 (e.g. collections inside or outside the original Providing Country), 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 utilise have been accessed in accordance with applicable ABS legislation or regulatory requirements[11]. Section 2.1 lists the information required to be able to exercise due diligence in this regard according to the EU Regulation and Implementing Act.

When signing agreements such as MAT or Material Transfer Agreements (MTA), Institutions should refer to the legal framework governing the collections and ensure that it can accommodate requirements of those agreements, including persistent obligations (i.e. those which will persist for the lifetime of the specimens being in the custody of the Institution, which may extend indefinitely).

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[12].

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

11) 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.

12) For example, the Natural History Museum in London (NHMUK) requires Memoranda of Cooperation to be signed by the Director of Science, but individual staff may be permitted to sign collecting permits (or PIC and MAT) in Providing Countries. NHMUK also has a Registrar with the responsibility of overseeing all legal agreements and providing advice to staff.

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 Entry[13], 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).

For practical guidance see **Annex 5** Section *"Acquiring GR from in-situ or ex-situ sources in Providing Countries (including field collecting)"*.

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[14], and seek to obtain the relevant documentation from the Competent National Authority within the Providing Country [15]. Institutions and staff should be aware, when contacting the Competent National Authority, that other offices might need to be contacted as well (e.g. separate export or research permits may be required), 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 and that no permits for access of biological material were required or have been issued[16].

Indigenous and Local Community customary laws and community protocols should be taken into account and reflected in mutually agreed terms, even if this is not required by the national legislation.

13) Objects may include biological material but also substances that could contain biological material, such as soil samples.
14) Set procedures should include use of the ABS Clearing House and seeking advice from National Focal Points, among others. For example see recommendations at the following link: http://nagoyaprotocol.myspecies.info/node/16
15) With pending international and national ABS legislation inside and outside the EU, Institutions and particularly individual researchers and curators 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/).
16) e.g. by recording positive replies of respective Competent National Authorities.

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 Institution[17]. 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 by CETAF members. 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 National 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 (and) 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 fieldwork[18]. 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

17) 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 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.

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

or other use, including on behalf of or for sale to Third Parties, should be prohibited by the Institution[19].

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.

Internal policies or procedures should set out conditions under which loans of material from outside the Institution received by staff or associates of the institution can be accepted in the context of ABS. Staff should not utilise such genetic resources[20] if the original permit conditions of the material are unclear, in which case clarity from the source should be sought. This will reduce the risk of breach of terms under which genetic resources were accessed if appropriate documentation is not transferred with the material, or of utilising genetic resources if they were illegally collected.

Two additional scenarios regard (I) material brought in by guest scientists for examination in the Institution including through research falling within scope of the EU Regulation, and (II) material sent in for sequencing from users not associated with the Institution, where the Institution is acting purely for others[21] or as a collaboration partner offering established analytic pipelines. In neither of these cases does the material pass under the ownership of the Institution. While the broad solution is the same for each, they can be considered separately:

I. Visiting scientist bringing material for examination. If the material is to be utilised within the scope of the EU Regulation or other appropriate legislation[22] there should in all cases be a formal agreement between the visitor and the host Institution setting out (i) who has the responsibility to ensure that due diligence has been done in regard to the material being utilised; (ii) who has responsibility to submit a due diligence declaration, if required. It should also specify what is to happen to any material left by the visitor (see 1.4 below). This should be set out in a written agreement[23] or covered in MoUs between the hosting and home Institution of the guest researcher as discussed in Section 3.3. below.
    a. If the utilisation is part of a collaborative project involving the Institution, the host Institution should ensure that due diligence is carried out, i.e. by delegating this responsibility to an individual staff member hosting collaborators, or through a written agreement[23] with external collaborators that obliges them to meet all necessary legal ABS requirements when utilising genetic resources in the Institution.

[19] 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.

[20] Utilisation in the sense of Nagoya Protocol as defined in the Glossary

[21] Including formal subcontracting

[22] Where the institution implementing these Best Practices is outside the EU.

[23] See also Annex 6.4: Agreement for guest researchers bringing biological material to facilitate their own research at hosting institutions

If a due diligence declaration is required, the person responsible for the submission must also be agreed; the submission should be made by either (i) the supervising custodian within the institution, (ii) the Project Co-Ordinator, if based in another EU institution[24], or (iii) the hosted external collaborator, as appropriate. If the external collaborator is deemed to be responsible for submitting a due diligence declaration but is visiting from outside the EU, a submission of a declaration is still required if the utilisation is in scope of the EU Regulation[25]. The Institution should satisfy itself that the person responsible for submitting a declaration is named clearly in the written agreement.

b. If the host Institution (i) has no collaborative interest in the research and has not received research funding for it, or (ii) the guest researcher is not employed via external funding by the host Institution or its agents, the host Institution can reasonably take the view that due diligence obligations in relation to the research carried out and any submission of a due diligence declaration is the responsibility of the visitor. However, this needs to be supported by a formal agreement. It is important that visitors are made aware that if the utilisation happens inside the EU, their utilisation may be within scope of the EU Regulation and, if so, they are legally bound to carry out due diligence and submit a due diligence declaration if required. The host Institution should support visitors in undertaking due diligence, providing information on the requirements and the means of fulfilling them[26]. Annex 6.4 provides a template for the agreement between host and visitor.

II. When the host Institution is sequencing on request for an external user[27] and has no involvement in the research, and the relationship between the host Institution and the legal person carrying out the research is governed by contract, the host Institution is not regarded as a user, but the legal person contracting the work is. The contract between this legal person and the host Institution should make clear who is legally responsible to exercise due diligence and submit due diligence declarations if required for compliance with the Nagoya Protocol under user country Regulations. The contract should also specify that there is no transfer in rights to the host institution, and state either the return or the destruction of any material left.

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.

[24] As set out in the EU Implementing Regulation Art 5(3)
[25] See Implementing Regulation Art 5(1)
[26] See also Annex 5: Practical Guidance on GR Entering the Institution Section F
[27] Often termed 'subcontracting'

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 force[28], 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). 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.[29]

If biological material is acquired from a commercial supplier and might be utilised immediately or in the longer term, the Institution should be aware that this could constitute a change of use which could require seeking 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"[30] for use with any material not collected by staff (see Section 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.

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. To reduce risks of potential non-compliance, the Institution should in all cases exercise due diligence, which will include (but not necessarily be limited to) requiring from the donor appropriate documentation (permit or equivalent) or a statement providing clarification why such

28) 12th of October, 2014 (http://www.cbd.int/abs/)
29) NHMUK has developed a separate MTA explicitly for the receipt of such material.
30) See CETAF MTA templates, here specifically MTA 3 (Annex 6.3)

documentation was not required. Annex 6.3 provides a template to file and document such information on the condition. Material left by visitors should be returned to the visitors or clarity on its legal provenance sought as for unsolicited donations[31].

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 utilisation of cultures and other captive-bred and propagated organisms in collections. These will need to be recognised in policies.
c. Research and ABS. Policies may be needed to govern internal access to and utilisation 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.
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 or in the central administration), especially if subsamples of a single individual organism

[31] See also CETAF MTA 4, warranty of guests bringing material to an institution for research / analysis (Annex 6.4)

(Genetic Resource) are stored in separate collections, different buildings, etc. An accessible digital archive of these documents can offer valuable support, and has been developed by some CETAF members. Digital images of permit documents can be held within specimen or other collection management databases in some implementations. During planning of such electronic systems, institutions should carefully check the legal requirements under national and European law to archive such sensitive data in electronic form and which measures must be taken to protect such data from illegal access of third parties.

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. The items below may be considered as outline requirements of such a system.

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

- acquisition of biological material, including core data associated with Genetic Resources such as[32]
    - *a description of the GR* (at appropriate taxonomic level)
    - *the date*[33] *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.
    - Conditions of the Prior Informed Consent / permit
    - *Mutually Agreed Terms*, including benefits shared
    - *Presence or absence of rights and restrictions, including commercialisation and third party transfer.*
- the *utilisation of Genetic Resources and Traditional Knowledge associated with Genetic Resources* and, if utilised, *the person or entity utilising them*[34] at the Institution or through a

32) In this list the items in italics are those that are required for submitting a due diligence declaration to a Competent Authority (Checkpoint) under the EU Implementing Act, and for transmission to other users under the EU Regulation (see Article 4, paragraph 3). Outside the EU, the same information may be required by Checkpoints.

33) Retain both the date of actual access and the date when the permit was given.

34) Although the EU Implementing Act requires that the recipient of research funding involving utilisation of genetic resources submits a due diligence declaration, it might be that it is not the recipient of funding that is

subcontracted entity (see also point 3) and whether this was funded by external sources (grants) or internal resources[35];

- utilisation carried out at the Institution when the Institution was sequencing on request from an external user, including relevant contracts (see section 1.2. above – to evidence that due diligence was not the responsibility of the Institution);
- any *supply to Third Parties*, whether on loan or permanent supply (see also point 4);
- any benefits derived from the use/utilisation as agreed in MAT and shared with the Provider/Providing Country (see also point 5);
- de-accessioning, 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 any associated traditional knowledge that entered the collections (including utilisation 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 utilisation 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 utilisation").

carrying out the research (e.g. in the case of PhD students). In this case it is important that the person responsible for submitting a due diligence declaration is documented in the institution. The institution should also keep a record of the person who utilised the genetic resources, if these are different.

[35)] The source of funding might have relevance in combination with the ABS Implementing Act or the EU Regulation and should be critically reviewed for each utilisation (including multiple use of same samples); for external sources of funding due diligence declaration might be required;

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. Utilisation of Genetic Resources

This section, as well as the entire document, addresses occasions which institutions should consider as response to applicable ABS laws, e.g. how to manage uses of genetic resources which would constitute utilisation[36]. While the text provides guidance for compliance with the EU Regulation, it is suitable for CETAF members and others outside the EU.

3.1. Clarification of conditions affecting utilisation

Biological material should not be sampled for utilisation 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 utilisation 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. Such mechanisms might require addition of labels indicating the restrictions, barcodes or document numbers or similar IDs on the specimen labels linking to respective database entries and filed documents, or simply procedures requiring users to check the records.

If the information associated with the material is insufficient, clarification of the legal status of the biological material should be sought, e.g. by contacting the National Focal Point of the original sourcing country of the biological material in question. If so required for legal access, additional permits such as an access permit or its equivalent might be needed and Mutually Agreed Terms established with the Providing Country; these should be established before utilisation takes place.

3.2. Inappropriate utilisation

If utilisation is taking place but the information is found to be insufficient to provide certainty about the legality of access and utilisation, individuals should discontinue utilisation. Insufficient

[36] As most CETAF members have to respond to the EU Regulation, “utilisation” should be understood to refer to the activities within scope of the EU Regulation.

information might be indicated if the relevant information required to submit a due diligence declaration under Article 7(1) of the EU Regulation is not all available [see also EU Regulation Article 4(5)].

An Institution should have clear and robust policies and procedures on how it handles inappropriate utilisation (whether inadvertent or deliberate) by staff and other users. Policies and procedures should be put in place to halt the inappropriate utilisation when discovered, prevent its reoccurrence, and address any problems it may have caused with the Providing Country. Such systems might include the following structured response:

a. In all cases utilisation ceases until it is clear that it can be done legally.
b. In cases where attention has been drawn to apparent non-compliance by the Providing Country:
    i. The situation is reviewed to discover whether the concern is justified.
    ii. The complaint is responded to with an explanation, and apology if an infringement has taken place.
c. PIC is sought and MAT agreed with the Providing Country for the utilisation undertaken, and covering further utilisation if required.
d. If the utilisation is being carried out by a third party on material borrowed from the Institution, inform the third party of the situation and request that utilisation ceases, referring to EU Regulation Article 4(5) if appropriate;
e. If an infringement has taken place, review policies and procedures to avoid its recurrence. If helpful, discuss with National Competent Authority of your country.
f. If internal policies and procedures reveal obvious gaps arising from the implementation of these Best Practices, inform CETAF of the issues, so they can be addressed.

3.3. Reporting on utilisation

Institutions should be aware that any utilisation[37] of GR within their facilities may fall under the reporting responsibility of that Institution, both to the Providing Country and under user country regulations, including submitting a due diligence declaration under Articles 7(1) and 7(2) of the EU Regulation[38]. Section 2.1. above lists the information that will be required to submit a due diligence declaration in the EU. Because the EU requirements concerning information in due diligence declarations are based on Article 17 of the Nagoya Protocol, the information required by

37) "Utilisation" here is used in the sense of the Nagoya Protocol (see **Annex 3** - Glossary)

38) The 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 at the stage of final development of a product, specifying the provisions of Articles 7(1) and 7(2) of the EU Regulation.

Checkpoints[39] in other Parties to the Nagoya Protocol to complete a "*Checkpoint Communiqué*"[40] is likely to be the same. Declarations are required in the EU when utilisation concerns GRs:

i. that were accessed from a country that was a Party to the Nagoya Protocol at the time of access,
ii. from a Party that exercises its sovereign rights over GR and TKaGR inside their national territory,
iii. that has implemented its national access laws
iv. the utilisation is carried out inside the EU and is funded by a grant[41], and also at the stage of final development of a product developed through utilisation[42]

and consequently the utilisation falls under the scope of the EU Regulation

Members of CETAF are unlikely to be reporting under Article 7(2) of the EU Regulation but may well under Article 7(1)[43].

The declaration at the stage of research funding must be made after the first instalment of funding has been received and all the GR and TKaGR that are utilised in the funded research have been obtained, but no later than at the time of the final project report (or if there is no such report, at the project end) (Implementing Act article 5). Further information is given in the CETAF Practical Advice document (**Annex 5**). For utilisation that happens inside the EU, the time of submission of such declaration may be further specified by national authorities. Reports must be made to the Checkpoint in the EU Member State where the user is based (in the EU these are the Competent Authorities in individual EU Member States, who are responsible for implementation of the EU Regulation). If the research project is funded from more than one source or involves more than one recipient, a single declaration may be made on behalf of the users, which should be made by the project co-ordinator to the Competent Authority of the Member State in which the project coordinator is based[44]. If the project co-ordinator is not based in the EU, the declaration should be made to the Competent Authority of one of the Member States in which the research is carried out.

[39] In this document the term 'Checkpoint' refers to authorities identified by Parties to the Nagoya Protocol under Article 17 of the Nagoya Protocol inside and outside the EU.
[40] This will be relevant to users of these Best Practices based in Parties to the Nagoya Protocol outside the EU.
[41] EU Regulation article 7(1)
[42] EU Regulation article 7(2)
[43] Switzerland, which has very similar regulations, does not have a checkpoint at the stage of research funding.
[44] Implementing Act Art 5(3). If the Project Co-Ordinator is based outside the EU a project member in the EU could take on the role, or all users make separate declarations. If the project does not have a Co-ordinator, then one could be identified in the research agreement between collaborators for this purpose.

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, Article 4, paragraph 3, sets out requirements for retention and transfer of relevant information. These are based on the information that users in any Party to the Nagoya Protocol (that has established compliance measures) will have to provide to their respective Checkpoints on utilisation. CETAF members are well advised to understand the provisions of the EU Regulation not only as necessary for material accessed after October 2014, but also as general best practice to be applied to all material. The relevant paragraph reads:

"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 utilised;

(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 by the EU Regulation to be submitted to Checkpoints in reports of utilisation of GR (i.e. when reporting due diligence under the EU Regulation and the Implementing Act). 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 utilising genetic resources) that information on their utilisation will be retained for reporting purposes.

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 CETAF MTAs[45] to establish a new agreement to cover temporary Third Party transfers. These may be adapted to meet institutional requirements.

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 utilisation of such material (which may occur either inadvertently or purposefully) by Third Parties.

Records should be maintained of specimens or samples borrowed by Third Parties, including utilisation 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 MAT[46]. Details of PIC and MAT should be transferred with the material (see also EU 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 utilise 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.

45) See MTA templates, here specifically MTA 1 (Annex 6.1)

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

5. Benefit-sharing

Institutions should implement procedures to share benefits arising from their utilisation 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 on data management). Institutions are advised to keep a record of benefits shared.

Wherever possible benefit-sharing agreements should be negotiated in such a way that allows for directing the benefits 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 Annex 4), since this will support record management by use of a standard vocabulary.

Publications resulting from the utilisation of Genetic Resources, and other use of biological material, should acknowledge the Providing Country. Ideally, publications should also include an identifier such as a document number referring to respective documents (permits or equivalent) on file at the Institution. Such permits or similar agreements, where these exist[47], should cover the collecting (access to) and use of the specimens, 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.

Institutions should strive to implement procedures to share any benefits arising from the new utilisation 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.

[47] This would not be required for genetic resources collected from countries that at the time of collection were not Party to the Nagoya Protocol or had no requirements for access permits or issuance of PIC; it should be good practice to reference and document these conditions, as access laws could change.

6. Institutional Policies and Procedures

Clear policy statements will assist institutions in managing compliance with provisions arising from the Nagoya Protocol, the EU Regulation and Implementing Act, and other applicable national ABS regulations and legislation. 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, emeritus posts); 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 policies[48]). Harmonised policies and procedures 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 Regulation, Implementing Act 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).

On developing the policies institutions should also ensure that practices are developed to ensure the policies are sufficient.

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. Should also identify responsibility for signing 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, how this is assessed and recorded, and 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:

48) It is advisable to develop policies and clear procedures for utilisation 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)

a. Documents required (e.g. PIC, MAT, MTA, donation letter, Transfer of Title document[49]), and how these are managed;
b. Identification of the individual (e.g. Director, Head of collections etc.) within the Institution responsible for authorising accession.

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 – Utilisation of cultures and other bred and propagated organisms in collections; living material sourced from commercial suppliers[50]; 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 utilised for scientific research such loans may require ABS permits (including for TKaGR).[51]
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 utilisation.

49) Legal document managing the formal change of ownership of an object from one person or organisation to another.
50) If a change of use is involved, e.g. from pet trade to utilisation of genetic resources.
51) They also may be required to comply with additional requirements such as CITES compliance.

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 utilisation by a borrower;
    c. Loans are considered personal and are not transferable by the borrower.
13. Research and ABS – governs access to GR, utilisation 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 disposals[52] (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.

7. Staff training and awareness-raising

CETAF members should appoint a member of staff as institutional Focal Point on ABS, to liaise with the CETAF Legislation and Regulations group. This will be the main conduit for information between the Institution and the expert group, and with other CETAF members.

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. Institutions should ensure at least one member of staff should have sufficient expertise to deliver such training. It would be advantageous if institutions would identify a small number of staff for detailed training, e.g. to allow holiday replacement. These colleagues could act as local "super-users" able to advise their peers.

A handbook to the Institution's policies and processes regarding ABS should be made available digitally or in hard copy. RBG Kew has made their policy available on the web at https://www.kew.org/science/who-we-are-and-what-we-do/policy-work/cbd-and-nagoya-protocol.

Developing an institutional web-site may be helpful. The Natural History Museum, RBG Kew and RBG Edinburgh have collaborated to develop a web-based resource centre at http://nagoyaprotocol.myspecies.info/. The German Natural History Collections united under the DNFS consortium acknowledged the CETAF Code of Conduct for the implementation of internal ABS procedures on 27 March 2017. The ABS group of the DNFS is tasked to support DNFS members during in their implementation and to offer guidance, first members like the SNSB (Bavarian Natural History Collections) offer web-based tools at http://www.snsb.mwn.de/index.php/de/allgemeines-zu-abs. NHM has put some of its training material on this site as well as providing links to other sites (http://nagoyaprotocol.myspecies.info/node/12).

Kew has an intranet area focussed on ABS and available only to staff.

A regular (e.g. annual) audit of the Institution's ABS skills and procedures should be undertaken.

52) e.g. PCR and cycle sequencing products