

**CETAF**

**Consortium of European Taxonomic Facilities**

**CODE OF CONDUCT & BEST PRACTICES**

for the

**Nagoya Protocol on  
Access and Benefit-Sharing**

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## CODE OF CONDUCT & BEST PRACTICES

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**The Code of Conduct on ABS was adopted by the CETAF members at their 35th General Meeting in May 2014 in Oslo. This Code of Conduct and its annexes, including Best Practice, together with complementary documents, has been developed by the CETAF Legislations and Regulations Liaison Group.**

**This is the original version of the CETAF Code of Conduct as adopted by the Senckenberg Gesellschaft für Naturforschung (SGN), including the options in Annex 1 which apply to the SGN.**

## INTRODUCTION

CETAF, the Consortium of European Taxonomic Facilities, is a networked consortium of non-commercial scientific institutions in Europe formed to promote training, research and understanding of systematic biology and palaeobiology. Together, CETAF institutions hold very substantial biological (zoological and botanical), palaeobiological, and geological collections and provide the resource for the work of thousands of researchers in a variety of scientific disciplines. As a response to Article 20 in the Nagoya Protocol, and Articles 8 and 13 of the *European Regulation 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* CETAF has developed and adopted this Code of Conduct for Access and Benefit-Sharing, together with the annexed Best Practice. Also annexed is a 'Statement of Use of Biological Material' to provide clarity on how CETAF members use and treat samples of biological material.

The principles and practices stated below are designed to fully support CETAF members' operations as taxonomic collection-holding and non-commercial biological research institutions in complying with Access and Benefit Sharing (ABS) legal and ethical requirements. The documents (i) outline the Code of Conduct governing principles under which collections are managed and collection-based research conducted in CETAF member institutions; (ii) provide details of best practices to ensure implementation of those principles; (iii) explain to both Providers and users how biological specimens are used by CETAF institutions, which will support the negotiation of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) with Providers.

The CETAF Code of Conduct was developed by CETAF's *Legislations and Regulations Liaison Group*. They drew on their understanding of the processes and practices of their institutions, their understanding of the Nagoya Protocol and its implications, and a wide range of existing Codes of Conduct and Best practice documents, including particularly the *Principles on Access to Genetic Resources and Benefit-Sharing* for Botanic Gardens (<http://www.bgci.org/resources/article/0007/>), the Swiss Academy of Sciences model Agreement on Access and Benefit Sharing for Non-Commercial Research (<http://abs.scnat.ch/downloads/index.php>), and the Code of Conduct of the International Plant Exchange Network (IPEN, [http://www.bgci.org/resources/Description\\_of\\_IPEN/](http://www.bgci.org/resources/Description_of_IPEN/)).

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## CETAF CODE OF CONDUCT FOR ACCESS AND BENEFITSHARING

CETAF Member Institutions commit themselves to the following Code of Conduct on access to genetic resources and benefit-sharing. This Code of Conduct applies to biological material<sup>4</sup> that is accessed, i.e. acquired newly from a Providing Country, after the entry into force of the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity* (hereafter referred to as the *Nagoya Protocol*).

### 1. CONVENTION ON BIOLOGICAL DIVERSITY AND LAWS RELATED TO ACCESS TO GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE AND BENEFIT-SHARING

Participating institutions will:

- Honour the letter and spirit of the Convention on Biological Diversity (CBD), The Nagoya Protocol, and other relevant international agreements.
- Abide by international and national laws and regulations relating to Access and Benefit-sharing<sup>6</sup>.
- Comply with Prior Informed Consents (PIC), Mutually Agreed Terms (MAT) and other agreements entered into with the Providing Country and Providers within that country.

### 2. ACQUISITION OF BIOLOGICAL MATERIAL

Participating institutions will:

- In order to obtain Prior Informed Consent, provide a full explanation of the purposes for which biological material will be used and how genetic resources will be utilised (within current technical understanding).
  - When acquiring biological material from *in situ* conditions, where possible, (i) obtain information on the Providing Country's access laws and the procedures for obtaining Prior Informed Consent and relevant permits, and for agreeing Mutually Agreed Terms, and (ii) obtain Prior Informed Consent and relevant permits from the Government of the Providing Country and other relevant stakeholders as required under national law, and (iii) agree terms, according to applicable law and best practice.
  - When acquiring biological material from *ex situ* collections, agree terms with the body governing the *ex situ* collection under which the material can be used.
  - When acquiring or otherwise receiving biological material from *ex situ* sources, whether from scientific collections, commercial sources or individuals, evaluate available documentation and, where necessary, take appropriate steps to ensure, as far as is reasonably possible, that the biological material was acquired in accordance with applicable law.
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### 3. UTILISATION OF GENETIC RESOURCES

Participating institutions will:

- Utilise genetic resources on terms and conditions consistent with those under which they were accessed or otherwise acquired. Renegotiate Prior Informed Consent and Mutually Agreed Terms if the participating institution wishes to utilise genetic resources in a different way to those set out in the original agreements.

### 4. SUPPLY OF BIOLOGICAL MATERIAL TO THIRD PARTIES

Participating institutions will:

- Supply biological material to Third Parties on loan only on terms and conditions consistent with those under which it was acquired.
- Supply biological material for subcontracted work on genetic resources, such as to sequencing companies, only with a contract excluding utilisation not in compliance with the terms and conditions under which they were acquired.
- Transfer biological material permanently to Third Parties only on terms and conditions consistent with those under which they were acquired and with copies of the documentation showing agreements with the Providing Country, where applicable, including Prior Informed Consent, Mutually Agreed Terms or other relevant documents.

### 5. USE OF WRITTEN AGREEMENTS

Participating institutions will:

- Acquire biological material using written agreements providing legal certainty and ensuring that there is a record of relevant documents such as Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT).
- Supply biological material to Third Parties using written Material Transfer Agreements (MTAs), setting out the terms and conditions under which the biological material may be acquired, used and supplied and resulting benefits shared.

### 6. TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

Participating institutions will:

- Acquire Traditional Knowledge associated with genetic resources using written agreements providing legal certainty and ensuring that there is a record of relevant documents such as Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT).
  - Use and supply Traditional Knowledge associated with genetic resources only in accordance with the terms and conditions under which it was acquired.
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## 7. BENEFIT-SHARING

Participating institutions will:

- Share benefits arising from their utilisation of genetic resources fairly and equitably with the Providing Country and other appropriate stakeholders<sup>7</sup>.
- Strive to share benefits arising from the new utilisation of genetic resources 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<sup>8</sup>.

Benefits may include any of those listed in the Annex to the Nagoya Protocol, although because of the not-for-profit nature of the work of the Participating Institutions are most likely to be non-monetary, *inter alia*: scientific training, education, capacity building, transfer of technologies, collaboration on scientific work programmes, and the mutual sharing of research results and of associated publications (see Annex 4 to this document).

## 8. CURATION

Participating institutions will:

- record the terms and conditions under which biological material is accessed or otherwise acquired;
- record relevant information on the utilisation of genetic resources, and benefits arising from that utilisation;
- record supply of biological material to Third Parties permanently or on loan, including the terms and conditions of supply; and
- record when and how biological material passes permanently out of custodianship, including complete consumption of samples or disposal.

## 9. POLICIES

Participating institutions will:

- Prepare, adopt and communicate institutional policies setting out how the Participating Institution will implement this Code of Conduct.
- Prepare a transparent policy on utilisation of genetic resources.

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<sup>4</sup>The term '*biological material*' is used throughout the documents because it describes all material in CETAF Member Institution collections, regardless if it contains 'functional units of heredity' or not. 'Genetic resources' is used when specifically referring to 'utilisation' within the scope of the Nagoya Protocol. The CBD and the

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Nagoya Protocol define '*genetic resources*' as 'genetic material of actual or potential value', and '*genetic material*' as 'any material of plant, animal, microbial or other origin containing functional units of heredity'.

<sup>5</sup> While reasonable efforts will be made, no responsibility is accepted for any retroactive claims, such as benefit-sharing.

<sup>6</sup> In case of conflict between national law in the home country of the institution and the CETAF code of conduct, national law will take precedence.

<sup>7</sup> as agreed in Prior Informed Consent and Mutually Agreed Terms at the time of Access, or as renegotiated following a subsequent change of use

<sup>8</sup> While reasonable efforts will be made, no responsibility is accepted for any retroactive claims, such as benefit-sharing.

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## ANNEX 1: STATEMENT OF USE OF BIOLOGICAL MATERIAL

This statement sets out the typical ways in which biological material, accessioned into the collections of the Senckenberg Gesellschaft für Naturforschung (“SGN”), may be used and genetic resources may be utilised. This includes use both in facilities managed or owned by the SGN and in facilities owned or managed by others but mandated for specific purposes (for example external DNA sequencing facilities). If Providers of biological material do not wish their material to be treated in this way or wish to place any specific restrictions, this needs to be expressly set out in writing when granting access, when donating or exchanging material, or providing unsolicited material such as for identification. If the Provider does not place any express written restrictions, then the material will be accessioned and used under the conditions set out below.

SGN is a member of the Consortium of European Taxonomic Facilities (CETAF) and subscribes to the CETAF Code of Conduct on Access and Benefit Sharing and Best Practice.

### 1. USE OF BIOLOGICAL MATERIAL

**Research at SGN:** Any biological material at SGN may be made available to its staff and authorised visitors as well as to the staff of cooperating institutions or cooperating individuals for non-commercial research such as systematics, ecology, conservation, genetics, morphology, physiology, molecular biology, genomics, environmental genomics and science supporting sustainable use. Such work may involve making anatomical and cytological preparations, carrying out isotope analysis, and sampling for pollen, spores, and/or chemicals. DNA, RNA, proteins or other biomolecules may be sequenced or otherwise analysed. Such analyses may result in complete destruction of the material.

**Research results:** Results of research will be made available to the public domain through publication in printed or online form (such as books, scientific journals, publically-available databases, published images or internet sites). DNA sequence data will be deposited in publicly available databases such as GenBank and, where possible, referenced to the respective biological specimens stored at SGN.

**Information and images:** As a scientific institution involved in biodiversity research and conservation it is important that SGN makes its collections as accessible as possible to its direct counterparts and to the wider community. This may involve the digital representation (e.g., images and / or 3D models) of specimens and of associated data, and publication of such representations and information to be freely available in the public domain. Images and data may also be presented in research publications.

**Loans:** SGN may lend biological material (specimens) to Third Parties for identification, scientific research or for educational purposes subject to the Loan Conditions of SGN and consistent with the terms and conditions under which the material was acquired from the Provider.

**Permanent Supply to Third Parties:** SGN may supply biological material to other scientific research institutions and/or to individual scientists for scientific research or for educational purposes,

including through donation and exchange for other specimens or samples or parts thereof, subject to the terms and conditions under which the material was acquired from the Provider. Transfer will be effected when the recipient institution or individual has signed a “Material Transfer Agreement” with SGN.

**Propagation and public display:** Living specimens may be propagated / bred at the institution. Any specimens grown from such propagation / breeding, or otherwise acquired, may be put on public display at SGN. SGN will maintain data records on any specimens grown from such propagation / breeding to enable its origin and associated records such as PIC and MAT to be retrieved.

## 2. TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

If there is Traditional Knowledge associated with the Genetic Resources when accessed by SGN, it will be managed and used according to the terms and conditions agreed with the Provider.

## 3. COMMERCIALISATION

SGN is a not-for-profit institution and is only rarely involved in commercialisation of collection-based genetic resources. However, as part of its mission, SGN investigates organisms, genomic samples and their constituents for taxonomic and other scientific research. This research may lead to the discovery of potential commercial uses of certain genetic resources. In such cases, if not already covered by the terms and conditions agreed with the Provider, SGN will initiate renegotiation of the terms and conditions.

## 4. BENEFIT-SHARING

SGN will share benefits arising from its utilisation of genetic resources fairly and equitably with the Providing Country and other appropriate stakeholders<sup>11</sup>. It will strive to share benefits arising from the new utilisation of genetic resources 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<sup>12</sup>.

Benefits may include any of those listed in the Annex to the Nagoya Protocol, although because of the not-for-profit nature of the work of the SGN, these are most likely to be non-monetary, *inter alia*: scientific training, education, capacity building, transfer of technologies, collaboration on scientific work programmes, and the mutual sharing of research results and of associated publications.

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<sup>11</sup> As agreed in Prior Informed Consent and Mutually Agreed Terms at the time of Access, or as renegotiated following a subsequent change of use.

<sup>12</sup> While reasonable efforts will be made, no responsibility is accepted for any retroactive claims, such as benefit-sharing.

## ANNEX 2: 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.

### 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;
- biological material entering the collections is obtained with appropriate legal certainty and can legally be retained; and
- the documentation legally required in this process is managed effectively.
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Implementation of specific parts of this Best Practice may not be relevant or applicable for all institutions<sup>13</sup>.

In order to comply with ABS regulations and function effectively, Institutions<sup>14</sup> and their staff<sup>15</sup> should:

1. **Acquire** only biological material that has been legally accessed<sup>16</sup> (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**<sup>17</sup> biological material in a way that is consistent with the terms and conditions under which the material was acquired;
4. **Supply biological material** to Third Parties for their use only on terms and conditions that are consistent with those under which the material was acquired;
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 utilisation from that previously agreed;
7. **Develop institutional policies;** and
8. **Train staff** and inform authorised visitors and associates.

This Best Practice applies to biological material accessed after the entry into force of the Nagoya Protocol (12 October 2014)<sup>18</sup>.

## 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 transfer (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<sup>19</sup>. Ideally this is done when the material is acquired. 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 might consider designating 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.

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<sup>20</sup>, 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), sometimes combined in a permit. Staff may have to negotiate and agree these with the Providing Country prior to the start of fieldwork. Institutions should develop systems so that staff is aware of the permissions and legal documentation required, and seek to obtain the relevant documentation from the Competent National Authority within the Providing country<sup>21</sup>. 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 issued<sup>22</sup>.

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 authorised 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<sup>23</sup>.

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.

Where possible and appropriate, fieldwork should be conducted as part of a collaborative venture with a museum, botanic garden, university or other recognised scientific research organisation in the Providing Country. Such collaboration can be included in the MAT as a direct benefit arising from the fieldwork<sup>24</sup>. 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 Institution<sup>25</sup>.

### **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.

An internal policy may be helpful that sets out conditions under which loans received by staff or associates of the Institution can be accepted in the context of ABS. This is important since there is a risk of breach of terms under which genetic resources were accessed if appropriate documentation is not transferred with the material, or of illegally utilising 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, except with the express consent of an appropriate outside authority. For biological material accessed after the Nagoya Protocol came into force<sup>26</sup>, 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)<sup>27</sup>.

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. To manage acquisition of material from *ex situ* sources, Institutions may wish to develop or adapt their internal policies for documentation covering incoming material. The Institution will need

documents covering requirements and permissions associated with the material and demonstrating its provenance (e.g. PIC, MAT, MTA) where these are available, or a statement as to why they are not available or not required. These might usefully be attached to a document confirming transfer of title to the Institution, including any conditions. A tool to facilitate this might be a standard ‘Material Access Agreement’<sup>28</sup> for use with any material not collected by staff (see ‘1.1 Acquisition from in-situ sources’).

This might also be used 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. 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 donations<sup>29</sup>.

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.
- 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. Of particular importance is management of restrictions and requirements agreed with the Providing Country (MAT).
- e. Traditional Knowledge associated with genetic resources – covering aspects of the Institution’s acquisition, documenting, digitisation, 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 might be 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 as<sup>30</sup>:
  - *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-Recognised 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 utilisation of Genetic Resources* and, if utilised, *the person or entity utilising them* at the Institution or in a subcontracted entity (see also point 3) and whether this was funded by external sources or internal<sup>31</sup>;
- *any transfer to Third Parties*, whether on loan or permanent transfer (see also point 4);
- *any benefits derived from the use/utilisation and shared with the Provider/Providing Country* (see also point 5);
- *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 that is in the Institution's collections, and provide staff or authorised visitors with

information on any terms and conditions of use;

- b) track the use of biological material that entered the collections (including utilisation or transfer to Third Parties).

To accomplish this, the data management system ideally will 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 transfer 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”).

## **2.2. DEACCESSION AND DISPOSAL OF COLLECTIONS**

As with other aspects of collection management, one or more harmonised internal policies may 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**

Institutions should be aware that any utilisation<sup>32</sup> of GR within their facilities may fall under the reporting responsibility of that Institution<sup>33</sup>. 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 utilisation of Genetic Resources if this is prohibited by 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 .

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 utilisation persist, Institutions should either obtain an access permit or its equivalent and establish Mutually Agreed Terms with the Providing Country, or discontinue utilisation.

Records should be kept of utilisation of Genetic Resources. An Institution should have clear and robust policies on how it handles inappropriate utilisation (whether inadvertent or deliberate) by staff and other users.

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 of the permit or other agreement covering the collecting (access to) and use of the specimens, where these exist, 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.

#### 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 transferred).

The EU Regulation 511/2014, Article 4, paragraph 3, sets out requirements that encompass EU institutions:

“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 may also be required within the EU by national checkpoints under the EU Regulation 511/2014 on ABS. 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. This would form part of a standard MTA.

#### **4.1. TEMPORARY TRANSFER (E.G. LOANS/SHARING OF TISSUES/DNA SUBSAMPLES)**

This section deals with temporary transfer 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 MTAs<sup>34</sup> 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 that allowed the original 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. 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 utilisation of GR if it takes place.

#### **4.2. PERMANENT TRANSFER TO THIRD PARTIES**

Biological material 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<sup>35</sup>. 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 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 utilisation of GR 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.

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 utilisation of GR 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 GRs 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 aspect of ABS and be used as a reference in other policies<sup>36</sup>). Harmonised policies and the processes<sup>36</sup> 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 and subsequent Regulations on Access and Benefit-Sharing. Aspects that may be considered for separate policy statements include:

### 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 document<sup>37</sup>), 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<sup>38</sup>; 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).<sup>39</sup>
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.
- 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** <sup>40</sup> (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

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.

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<sup>13</sup> 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.

<sup>14</sup> In the following the term “institution(s)” refers to those bodies adhering to the CETAF Code of Conduct and Best Practice.

<sup>15</sup> 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.

<sup>16</sup> See glossary for a definition of ‘Access’.

<sup>17</sup> See ‘Statement of Use of Biological Material’ for a description of the spectrum of ‘use’

<sup>18</sup> While reasonable efforts will be made, no responsibility is accepted for any retroactive claims, such as benefit-sharing.

<sup>19</sup> 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 organisations. Therefore it is recommended to include an agreed definition in all legal documents.

<sup>20</sup> Objects may include biological material but also other material that could contain biological material, such as soil samples.

<sup>21</sup> 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/>).

<sup>22</sup> e.g. by recording positive replies of respective Competent National Authorities

<sup>23</sup> 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.

<sup>24</sup> It is advisable to list under the MAT all benefits that are to be delivered and to record all benefits being delivered.

<sup>25</sup> 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.

<sup>26</sup> 12<sup>th</sup> of October, 2014 (<http://www.cbd.int/abs/>)

<sup>27</sup> Legal exemptions such as materials seized by customs and deposited at the institution may apply.

<sup>28</sup> See joint GGBN / CETAF MTA templates, here specifically MTA 3

<sup>29</sup> See CETAF MTA 4, warranty of guests bringing material to an institution for research / analysis

<sup>30</sup> 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).

<sup>31</sup> This might have relevance in combination with the ABS Implementing Act or the EU and should be critically reviewed for each utilisation (including multiple use of same samples)

<sup>32</sup> 'Utilisation' here is used in the sense of the Nagoya protocol (see Glossary)

<sup>33</sup> See Nagoya Protocol, Article 15, and the European Commission Implementing Regulation for the Implementation of Regulation (EU) No. 511/2014.

<sup>34</sup> See joint GGBN/CETAF MTA templates, here specifically MTA 1

<sup>35</sup> 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 utilisation not in compliance with the terms and conditions under which the biological resources were acquired

<sup>36</sup> It might be 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)

<sup>37</sup> 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).

<sup>38</sup> If a change of use is involved, e.g. from pet trade to utilisation of genetic resources.

<sup>39</sup> They also may be required to comply with additional requirements such as CITES compliance.

<sup>40</sup> e.g. PCR and cycle sequencing products

## ANNEX 3: GLOSSARY

### **Access:**

The acquisition of Genetic Resources or of Traditional Knowledge associated with Genetic Resources from a Providing Country. Note that this term has not been defined in the Convention on Biological Diversity or the Nagoya Protocol, and may be used differently by some countries or organisations. The EU Regulation defines access as ‘the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol’.

### **Access and Benefit Sharing Clearing House:**

Information sharing mechanism developed under the Convention on Biological Diversity to make information available on national contacts, national legislation and other matters relevant to Access and Benefits-Sharing generally and the Nagoya Protocol in particular. It is on the internet at <https://absch.cbd.int/>.

### **Accession:**

The addition of specimens and samples to a collection, by which process they pass under the ownership or custodianship of the Institution, including long-term loans and material held in trust. See also *Object Entry*.

### **Benefits arising from the use of genetic resources:**

Not defined by the CBD or the Nagoya Protocol, but may include: (1) Monetary benefits when research and developments leads to a commercial product (e.g. royalties, milestone payments, licensing fees); (2) Non-monetary benefits (e.g. technology transfer, enhancement of research skills, sharing research results, research partnerships, Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies, etc.). Examples are given in the Annex to the Nagoya Protocol (attached in Annex 4 to this document).

### **Biological material:**

All specimens and samples of or subsamples from living or dead organisms, regardless if they contain ‘functional units of heredity’ or not. See also ‘Genetic material’ and ‘specimen’.

### **Biorepository:**

A repository that collects, processes, stores, and distributes biological specimens to support future scientific investigation. See also *Collection*.

### **Biotechnology:**

Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity).

### **Collection :**

A group of specimens or samples that can be seen, studied, and kept together. They are generally associated through sharing some feature, e.g. being of the same taxon (e.g. mammals, insects, sharks), from the same general locality or ecosystem, or collected by the same collector or on the same expedition. Collections are maintained by collection-holding institutions. The term *biorepository* or *biobank* may also be used, to include specimens which are not necessarily of whole organisms.

### **Commercialisation and Commercialise :**

Applying for, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or licence or in any other manner, commencement of product development, conducting market research, and seeking pre-market approval and/or the sale of any resulting product based on utilisation of the original genetic resource. Handling fees (e.g. for providing DNA samples), entrance charges etc., fall under the scope of management and/or administration of public research facilities, do not involve the utilisation of Genetic Resources, and are not considered as a commercialisation of research activity on Genetic Resources.

### **Competent National Authority:**

The body or individual in a country authorised to sign ABS agreements.

**Data:**

Unless otherwise stated, information, including locality and other collecting information, permits and other agreements, and any other information provided by the supplier with the material.

**EU Regulation:**

Where used in this document, this refers to Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, which entered into force for Europe on 6 Jun 2014.

**Exchange:**

Also 'Transfer', and 'Permanent supply'. Permanent transfer of specimens to a Third Party to the original agreement; note that 'exchange' implies a receipt of items in return for providing or transferring items. This is somewhat different from a straight transfer.

**Genetic material:**

Any material of plant, animal, microbial or other origin containing functional units of heredity (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity).

**Genetic Resources :**

Genetic material of actual or potential value (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity).

**Internationally Recognised Certificate of Compliance:**

A record generated when the Competent National Authority of a Providing Country publishes a permit or equivalent (e.g. PIC and MAT) on the ABS Clearing House. This is given a unique identifier by the Clearing House and provides legal surety of the genetic resources covered. It may also be used to simplify reporting.

**Material Transfer Agreement (MTA):**

An agreement between two institutions stipulating the terms and conditions for transferring specimens or samples, including genetic material.

**Memorandum of Cooperation (MoC):**

An agreement between two or more institutions to cooperate. In the context of the CETAF Code of Conduct and Best Practice this will include reference to ABS.

**Mutually Agreed Terms (MAT):**

An agreement reached between the Providers of genetic resources and users on the conditions of access and use and the benefits to be shared between both parties.

**Object Entry:**

The point at which a specimen, sample or collection enters the institution, whether temporarily as a loan or being carried by a visitor for study, or with the intention of it coming into ownership or custodianship of the institution. At this point decisions based on ABS compliance and responsibilities may be taken. See also *Accession*.

**Participating Institution:**

A member of CETAF which has signed the CETAF Code of Conduct and agreed to follow CETAF Best Practice.

**Prior Informed Consent (PIC):**

The permission given by the Competent National Authority of a Providing Country to a user prior to accessing genetic resources, in line with an appropriate national legal and institutional framework; i.e. what a user can and cannot do with the material.

**Providing Country:**

The country supplying genetic resources collected from *in situ* sources, including populations of both wild and domesticated species, or taken from *ex situ* sources, which may or may not have originated in that country (definition from Article 2 of the Convention on Biological Diversity).

**Research :**

The systematic investigation into and study of materials and sources in order to establish facts and reach new

conclusions. This does not include any development of commercial applications.

**Specimen:**

This includes any type of biological material.

**Traditional Knowledge (TK):**

There is currently no generally accepted definition of TK at an international level. WIPO defines it as “knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity.” It also notes that “TK in the narrow sense refers to knowledge as such, in particular the knowledge resulting from intellectual activity in a traditional context, and includes know-how, practices, skills, and innovations.” (<http://www.wipo.int/tk/en/tk/>). The Nagoya Protocol and EU Regulation cover TK associated with Genetic Resources (TKaGR), not TK as a separate element.

**Use :**

The purposes to which samples and specimens (biological and genetic material) are put, including but not limited to ‘utilisation’ in the sense of the Nagoya Protocol.

**Utilisation (of GR) :**

To conduct research and development on the genetic and/or biochemical composition of Genetic Resources, including through the application of biotechnology as defined in Article 2 of the Convention (definition from the Nagoya Protocol).

## ANNEX 4: MONETARY AND NON-MONETARY BENEFITS

As listed in the Annex to the NAGOYA PROTOCOL (NP) of 29 October 2010, on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their utilisation, to the CONVENTION ON BIOLOGICAL DIVERSITY (CBD).

### 1. MONETARY BENEFITS

May include, but not be limited to:

- (a) Access fees/fee per sample collected or otherwise acquired;
- (b) Up-front payments;
- (c) Milestone payments;
- (d) Payment of royalties;
- (e) Licence fees in case of commercialisation;
- (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
- (g) Salaries and preferential terms where mutually agreed;
- (h) Research funding;
- (i) Joint ventures;
- (j) Joint ownership of relevant intellectual property rights.

### 2. NON-MONETARY BENEFITS

May include, but not be limited to:

- (a) Sharing of research and development results;
- (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
- (c) Participation in product development;
- (d) Collaboration, cooperation and contribution in education and training;
- (e) Admittance to ex situ facilities of genetic resources and to databases;
- (f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilisation of biological diversity;
- (g) Strengthening capacities for technology transfer;
- (h) Institutional capacity-building;
- (i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
- (j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;

- (k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
- (l) Contributions to the local economy;
- (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
- (n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
- (o) Food and livelihood security benefits;
- (p) Social recognition;
- (q) Joint ownership of relevant intellectual property rights.

## COMPLEMENTARY DOCUMENTATION

### DATA USE STATEMENT & MATERIAL TRANSFER AGREEMENTS (MTAS)

#### *DATA USE STATEMENT*

The data on genetic material released to the public domain by the abovementioned authors is published for non-commercial use only. Utilisation by third parties for purposes other than non-commercial scientific research may infringe the conditions under which the genetic resources were originally accessed, and should not be undertaken without contacting the *[corresponding author of the paper / depositor of the sequence data]* and/or seeking permission from the original provider of the genetic material.

#### *MATERIAL TRANSFER AGREEMENT (MTAS) TEMPLATES*

In the following pages, you'll find templates for 3 different kinds of transfer agreements, which are also available for download at [www.cetaf.org](http://www.cetaf.org):

- **MTA1 - Standard MATERIAL TRANSFER AGREEMENT for PROVISION OF MATERIAL with no change in ownership** ([www.cetaf.org/abs-mta1](http://www.cetaf.org/abs-mta1))
  - **MTA2 - Standard MATERIAL TRANSFER AGREEMENT for PROVISION OF MATERIAL with change in ownership** ([www.cetaf.org/abs-mta12](http://www.cetaf.org/abs-mta12))
  - **MTA3 - Standard MATERIAL TRANSFER AGREEMENT (MTA 3) for RECEIPT OF MATERIAL with change in ownership** ([www.cetaf.org/abs-mta13](http://www.cetaf.org/abs-mta13))
-