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Issues of Biological Diversity of the German Research
Foundation (DFG)



Guidelines for Research and/or Development Projects Involving Access to Genetic Resources and/or to Traditional Knowledge Associated with Genetic Resources

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Abbreviations

ABS	Access and Benefit-Sharing
ABS-CH	Access and Benefit-Sharing Clearing-House
TK	Traditional Knowledge Associated with Genetic Resources
BfN	Bundesamt für Naturschutz (Federal Agency for Nature Protection)
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CNA	Competent National Authority
COP	Conference of the Parties
DD	Due Diligence
DFG	Deutsche Forschungsgemeinschaft (German Research Foundation)
EU	European Union
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	Mutually Agreed Terms
MTA	Material Transfer Agreement
NFP	National Focal Point
NP	Nagoya Protocol
PIC	Prior Informed Consent
SMTA	Standard Material Transfer Agreement

Foreword

As an interdisciplinary forum, the DFG Senate Commission on Fundamental Issues of Biological Diversity provides scientifically sound and interdisciplinary advice with regard to possible implications of non-commercial applied research and basic research. In the field of access and benefit-sharing, numerous developments have taken place in recent years which affect the current framework for research and/or development projects involving access to genetic resources and/or to traditional knowledge associated with genetic resources.

These Guidelines are intended to assist scientists who wish to carry out research projects that fall under the Nagoya Protocol. As of January 1st 2019 they replace the supplementary DFG Guidelines (DFG Form 1.021) from 2008.

The following explanations reflect the status as of 1 January 2019.

These Guidelines are intended to raise awareness of issues concerning research and/or development projects involving access to genetic resources and/or to traditional knowledge associated with genetic resources. They provide an initial overview of these issues. The explanations cannot replace legal advice, in particular from the researchers' own institutions or from specialised lawyers. Accordingly, neither the Senate Commission nor the authors assume any liability for the correctness and/or completeness of the following information in factual or legal terms.

In addition to these Guidelines, "Model Clauses for Mutually Agreed Terms on Access to Genetic Resources and Benefit Sharing"¹ were developed. They help researchers and their institutions negotiate agreements with provider countries regarding specific access conditions for research and/or development projects that involve access to genetic resources and/or to traditional knowledge associated with genetic resources.

¹ Available at: https://www.dfg.de/dfg_profil/gremien/senat/biologische_vielfalt/index.html.

Introduction

In your research project, are you planning to undertake research on biological material from a foreign country that shall be funded from public sources such as your university or the DFG? If this is the case, your project might be subject to specific regulatory requirements. Those requirements are based on two international conventions, according to which genetic resources are not – as previously often supposed – regarded as a common good but declared as belonging to the state from whose territory they are taken. The new regime defines a broad scope of research activities as “utilisation“ of genetic resources. States providing genetic resources, called “provider states”, may require that the taking of biological material for such utilisation is only allowed upon their prior consent, and that the benefits derived from the utilisation are shared with them. States where genetic resources from other countries are utilised, called “user states“, must ensure that genetic resources imported to and utilised within their territory have been acquired in accordance with provider state regulations and that benefits resulting from its use are shared with the providing state. The entire set of new requirements is thus concerned with what is commonly called “Access to Genetic Resources and Benefit-Sharing“, or ABS.

The Guidelines are structured as follows: In the first chapter the core requirements of the ABS regime are explained. The second chapter suggests how research projects should be planned in view of the ABS framework. The third chapter contains a glossary of the most important terms and concepts. In the fourth chapter frequently asked questions are posed and answers given. The relevant legal documents are noted in chapter five.

1 The core requirements of the ABS regime

After a short sketch of the relevant legal framework (1.1) the core requirements of ABS will be explained in the following order:

- The subject of ABS: Research and/or development on genetic resources (1.2)
- Access to genetic resources requiring PIC and MAT (1.3)
- Procedures of PIC and MAT (1.4)
- The permissible utilisation of the accessed genetic resources (1.5)
- Sharing the benefits of utilisation of genetic resources with the provider country (1.6)
- Tracking monetary benefits (1.7)
- Transfer and acquisition of material to/from third parties (1.8)
- Access requirements for traditional knowledge associated with genetic resources (1.9)
- Due diligence obligations of users and regulatory supervision (1.10)

1.1 The legal framework

The Convention on Biological Diversity of 1992 (CBD)² entered into force on 29 December 1993. It has three main objectives:

1. the conservation of biological diversity,
2. the sustainable use of the components of biological diversity and
3. the fair and equitable sharing of the benefits arising from the utilisation of genetic resources.

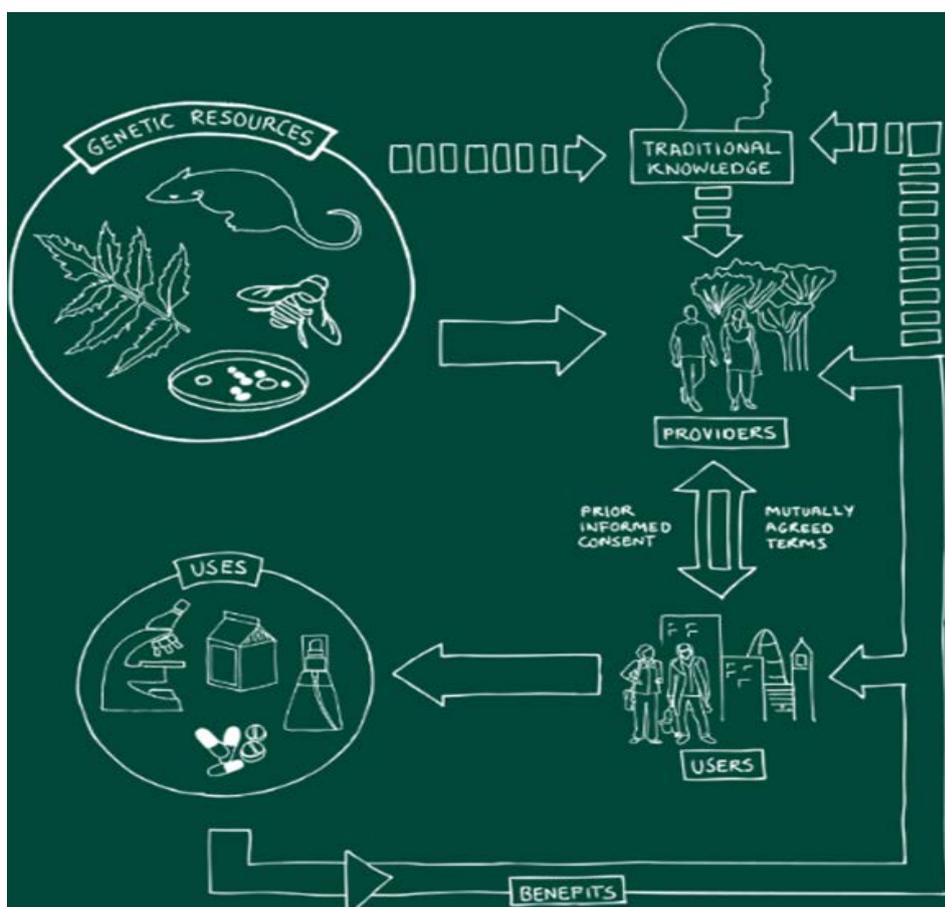
The CBD acknowledges that states have sovereign rights over their genetic resources and consequently the right to subject access to them to prior informed consent (PIC) and mutually agreed terms (MAT). In addition, states have a right to claim, likewise through MAT, a fair and equitable share in the benefits that arise from the utilisation of genetic resources. This also applies to traditional knowledge of indigenous and local communities associated with genetic resources (TK). The system of ABS was specified and reinforced by a supplementary protocol to the CBD, the Nagoya Protocol (The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation, NP). At its tenth meeting on 29 October 2010 in Nagoya, Japan, the Conference of the Parties (COP) adopted the Protocol, which after ratification by the required quorum of members entered into force in October 2014. With that the Member States to the NP committed themselves, inter alia, to support the countries of origin (of

² See below 5.1.

genetic resources) in the enforcement of their rights. Towards this aim the EU has enacted implementing legislation, in particular Regulation (EU) No 511/2014³ and the Commission Implementing Regulation (EU) 2015/1866⁴. The Regulation is directly applicable in Germany and was further specified by a German law on the implementation of the Nagoya Protocol of 1 July 2016.⁵

As a consequence, there are now important obligations for researchers and research projects laid down by the provisions of the CBD, the Nagoya Protocol, the provider states, and the user states including the EU and Germany.

The following flowchart illustrates how access to genetic resources and/or TK is subject to PIC and MAT, and how the utilisation may lead to benefits that must be shared with the provider state.



Flowchart 1: Access and benefit-sharing

© Secretariat of the Convention on Biological Diversity; Source: ABS Infokit
(www.cbd.int/abs/infokit/powerpoint/revised/brochure-en.pdf)

³ See below 5.4.

⁴ See below 5.5.

⁵ See below 5.7.

1.2 The subject of ABS: Research and/or development on genetic resources

The requirements for researchers and research projects that are dealt with here relate to the utilisation of genetic resources.

“Genetic resources” are defined as “genetic material of actual or potential value”, and “genetic material” means “any material of plant, animal, microbial or other origin containing functional units of heredity”.⁶

“Utilisation” is understood as conducting research and/or development activities on the genetic and/or biochemical composition of such genetic resources.⁷

Research and/or development using derivatives in technological applications is also included in the notion of utilisation of genetic resources.⁸ “Derivative” is defined as “a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity”.⁹

What “research and development” as comprised in “utilisation” means is not clear-cut and hence largely dependent on the interpretation of provider countries (see below). As understood by the EU, “research and development” includes any research on biological material, whether such research is basic (such as taxonomy) or applied (then being “development” according to common understanding), and whether it has or does not have commercial intentions.

1.3 Access to genetic resources requiring PIC and MAT

Access to genetic resources for their utilisation is subject to the prior approval (prior informed consent – PIC) of the competent national authority (CNA) if the regulation of the provider state so requires. In addition, an access contract (mutually agreed terms – MAT) may have to be concluded.¹⁰ The relevant regulation and the competent national authorities including the national focal points (NFP) can be found on the official website of the ABS Clearing-House (ABS-CH).¹¹

“Provider state” is the country of origin of the accessed genetic resources. It is defined as either “the country which possesses those resources in in situ-conditions”¹² or as a country “that has acquired the genetic resources in accordance with the Convention”.¹³ This refers to the country where an ex situ collection is located from which genetic resources shall be acquired. Genetic

⁶ Article 2 CBD.

⁷ Article 2(c) NP.

⁸ Article 2(c) and (d) NP.

⁹ Article 2(e) NP.

¹⁰ PIC and MAT can also be contained in one contractual document.

¹¹ Available at: <https://www.cbd.int/abs/theabsch.shtml>.

¹² Article 2 CBD.

¹³ Article 6(1) NP.

resources acquired by a collection before the entering into force of the CBD on 29 December 1993 are not subject to the access regime of the CBD.

“Access” is defined neither in the CBD nor in the NP. It is commonly understood as the “acquisition of materials”. Such acquisition usually occurs through collection of biological material in the field. However, it can also take place by buying such materials on the market or obtaining them from ex situ collections or other repositories.

Access to genetic resources is subject to PIC if it is done “for their utilisation”, which means that the researcher has the intention to conduct research and/or development on the genetic resources at the time of acquisition.

It may however occur that genetic material that was initially acquired as commodity such as fruits for consumption, animals as pets or plants for construction (so-called bulk use) later on becomes the object of research and/or development on the material as genetic resources. Is this to be construed as access, thus requiring prior consent of the state of origin of the genetic resource? This question is not addressed clearly by the current international instruments. Some provider states’ laws do qualify subsequent research and/or development as access, thus requiring PIC. In this line, the Scope Guidance Document for the EU ABS Regulation (EU) No 511/2014¹⁴ (2.3.1. Genetic Resources) takes the view that in case of subsequent utilisation “the user is expected to contact the provider country and clarify whether requirements to obtain prior informed consent and establish mutually agreed terms apply to the utilisation of such genetic resources”.

“Access to genetic resources” is sometimes even understood to cover the research and/or development with data and information taken from data bases or other publication media. Although this is a current hotspot in the political discussion, Article 6 NP clearly defines “Genetic Resources” as biological material. Hence, a provider state claiming property rights in data and information about its genetic resources and in consequence asking for PIC and MAT in such cases would go beyond the reach of its sovereign rights as they were acknowledged by the NP. The making use of published data and information does however not dispense from the obligation to observe any utilisation restrictions (such as the restriction of commercialisation) that may have been attached to them following provider states’ PIC or MAT conditions for the access to the genetic resources. Moreover, if the utilisation of the data and information generates monetary benefits, the duty of fair sharing with the provider state may apply depending on whether its regulation demands this.

A particular selection of plant genetic resources for food and agriculture (as of May 2019, 64 crops are listed) can be accessed for agricultural research through a standard material transfer agreement (SMTA). This can be done within the framework of the so-called Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) without the need to obtain the permit of the provider country. It is advisable to consult the website of the ITPGRFA for details.¹⁵

¹⁴ See below 5.6.

¹⁵ Available at: <http://www.fao.org/plant-treaty/areas-of-work/the-multilateral-system/overview/en>.

1.4 Procedures of PIC and MAT

In the procedure for an access permit, provider countries usually require the presentation of information concerning the nature, purpose, scope, implementation and possible results of the planned research and/or development. Likewise, information concerning the type of the genetic resources to be acquired/collected, e.g. plants, animals or microorganisms, and the extent of the collection will be required. The benefits that might accrue from the research project are usually specified in the access agreement. This commonly includes information on how the provider country's involvement in the sharing of the benefits will be guaranteed.

The provider state may subject access to various conditions which are usually attached to the permit and/or included in MAT.

The access permit and agreement serve as the basis for the different phases of the research and/or development, including on-site collection, export and later stages of utilisation in Germany or in another country. It also applies to transfer to third parties.

The provider state shall communicate a permit or an equivalent thereof (such as the statement of receipt of notification) to the international ABS-CH.¹⁶ Once recorded by the ABS-CH, the document constitutes an internationally recognised certificate of compliance¹⁷ that will be useful in compliance checks by supervisory authorities. Such certificate comprises the proof that the access permit was issued.

If the research project foresees the access to and utilisation of genetic resources held by indigenous or local communities, the provider state may have established additional regulations requiring the consent of the respective communities.

Often further permits must be obtained, such as for research, for entering a protected area, for the exportation of samples for research, even if these are tradable goods. They should not be confounded with the access permit. However, provider states may facilitate procedures by integrating all permits in just one document issued by one authority.

Different approaches may apply to access depending on whether the provider country has ratified the NP or not. In the former case the provider states are required to apply Article 8(a) NP and to develop simplified procedures in their access regimes if the purpose of the access is non-commercial. For instance, if the research and/or development is aimed at non-commercial purposes, the provider state may waive PIC in this case and only require that access be notified. The provider state should also streamline procedures and, for instance, provide for a so-called one-stop shop, i.e. the provision of just one permit that integrates all other required permits, e.g. for entering nature parks, for research, for exportation, etc. However, even if the provider state does not offer such simplified procedure, the researcher must nonetheless abide by its regulations as they stand.

¹⁶ Article 6(3)(e) NP.

¹⁷ Article 17(2) NP.

1.5 Permissible utilisation of the accessed genetic resources

As indicated, utilisation is understood as research and/or development. The kinds of utilisation that are permissible may be somewhat determined by the conditions of the access permit and/or access agreement.¹⁸ In particular, provider states often refuse research and/or development projects for commercial purposes or require that if the intent of the research later changes from non-commercial to commercial, new consent must be sought from the provider country.

There is no commonly accepted international definition of non-commercial or commercial research or development. Somewhat diverging from traditional understanding, it is recommended that the differentiation not be based on the content of the research or development. The reason is that the results of basic research, e.g. a gene and its functions, can be patented and thereby generate revenue. On the other hand, applied research (which is commonly understood to be development) may be undertaken without any intention of commercialisation. Therefore, the definition of commercial/non-commercial utilisation should preferably be based on the intent behind the utilisation, at the time of the establishment of the project, during its execution and afterwards, with the understanding that the intention may change. This means that if, on the one hand, utilisation aims to develop and exploit marketable information and products, it should be considered commercial research and/or development. If, on the other hand, it aims to enrich the general body of scientific knowledge and makes its results publicly available, it should be considered non-commercial. The indicator for non-commercial research and/or development should thus be the feeding of results into the public domain, no matter whether the results are objectively commercially useful or not.¹⁹

Research and/or development takes place not only through the examination of the genetic resources, but also through the processing of data and knowledge. Some provider countries require that the use of data and knowledge from accessed genetic resources also be regulated in the access contract. It is recommended to ensure during the negotiation for the access contract that the right for publication is not restricted and that sequences can be uploaded to public databases in accordance with the usual requirements. However, reference should be made in the database or any other publication medium to the provider country and any restrictions on utilisation for commercial purposes.²⁰

1.6 Sharing the benefits of the utilisation of genetic resources with the provider country

The development of the ABS system was guided by the idea that commercially significant products, in particular pharmaceuticals, could possibly be extracted from biological resources. It is in light of this idea that the requirement to share benefits with the country of origin, as laid down in

¹⁸ See e.g. clause 6 of the “Model Clauses for Mutually Agreed Terms on Access to Genetic Resources and Benefit-Sharing” (“model clauses”).

¹⁹ See further clause 2 of the model clauses with proposals for defining commercial/non-commercial intentions.

²⁰ See e.g. clauses 10 and 12 of the model clauses.

the CBD and in access laws, should be seen. However, the expected high revenues from blockbuster products are rare. As a consequence, the bilateral concept of exchanging genetic resources against monetary compensation is increasingly being replaced by the notion that enhanced benefit-sharing consists in the participation of the provider country in research and/or development and in the knowledge accruing therefrom. Possible non-monetary benefits that can be shared with provider countries are listed in the Annex to the Nagoya Protocol. Such benefits include in particular:

- a) collaborative generation of knowledge about flora and fauna and ecological interrelationships through research;
- b) access to as well as joint use of research institutions and equipment;
- c) the participation of national research institutions in the research;
- d) scientific exchange, in particular the funding of early-career researchers;
- e) cooperation in regard to research funding and the exchange of scientists;
- f) co-authorship of publications depending on the contribution of each partner in accordance with good scientific practices;
- g) the deposit of (samples of) materials from the field research in national collections and research institutions.

International research cooperation fulfils to a great extent the aims behind the ABS policy. In addition, it can significantly facilitate the execution of the relevant research projects.

The details of such sharing of non-commercial benefits will normally be laid down in research cooperation agreements concluded between the involved organisations in the provider and user state and/or between the individual researchers on both sides. The provider state may however additionally require that some core mutual rights and obligations of benefit-sharing be laid down in the access permit and/or the access agreement.²¹

1.7 Tracking monetary benefits

Should monetary benefits arise from the utilisation of genetic resources the provider state legislation will require the fair and equitable sharing of the same. Details are subject to negotiations and will be specified in the access permit and/or access agreement.

Often it will be unclear whether any monetary benefits will emerge at all, and if so, in which way and to what extent. In that case a come-back clause should be agreed upon, requiring subsequent negotiations when the benefits can be estimated.

If the chain of developing products is long, such as including intermediate steps of data and information processing through data bases and the stacking of multiple genetic resources in the final result, it can be difficult to determine what the contribution of the original genetic resource is,

²¹ See further clauses 3, 8–12 of the model clauses.

in other words, whether the benefits as such “arise from the utilisation” of the accessed genetic resources, as Article 5 NP determines. The problem of a complex and potentially negligible contribution of a genetic resource has not yet been clarified and is still under discussion. For instance, if a gene of an organism is only used in the characterisation of another organism, it may be doubted whether this would trigger the duty to share benefits. Similar doubts arise if the gene disappears in the multitude of modifications of the genome of the final product. These questions will hardly arise in common projects of basic research, but they may need to be negotiated and settled in other ones that aim at initiating complex and long chains of product development.

1.8 Transfer and acquisition of material and information to/from third parties

If genetic resources are to be acquired from collections or from other research institutions, specific conditions may apply. The collection or research institution may be bound by utilisation and benefit-sharing obligations contained in PIC and MAT for their initial access to the material. Often a so-called viral clause is also concluded, i.e. the obligation that the bilateral conditions must be transferred to third parties following the transfer of the material to them. Such terms are often part of the standard material transfer agreement (SMTA) concluded between the collection or research institution and the person acquiring the material. If the collection or research institution does not require the signing of a viral clause, the third party should nevertheless verify by checking the original PIC and MAT whether the transfer is unconditionally allowed. This is not necessary if the collection is a registered collection in terms of Article 5 of the Regulation (EU) No 511/2014.

The question how transfers and acquisitions are regulated also extends to the level of the scientific knowledge and data generated from the research and/or development. As explained above, the making use of publicly available data and information does not qualify as access to genetic resources and thus is not subject to PIC and MAT. However, any conditions of the provider state contained in PIC and/or MAT concerning the access to the original genetic resources do travel with the data and information even to the publication media and must be perceptible to the user.

Vice versa, when submitting data and information to databases and other publication media, it is advised that researchers communicate the origin of the genetic resources and communicate any utilisation and transfer conditions. The researcher should at least make best efforts to this end, even if the data base or other publication medium does not provide the possibility of registering such conditions.²²

1.9 Access requirements for traditional knowledge associated with genetic resources

The CBD also aims to enable the utilisation of traditional knowledge based on the prior informed consent of indigenous and local communities.

²² See e.g. clause 12.2 of the model clauses.

“Indigenous and local communities” are groups of communities that differentiate themselves through a particular traditional culture and lifestyle from mainstream society.

“Traditional knowledge” comprises a wide range of knowledge about plants, animals, microorganisms, about locations/sites, habitats, the ecological context, the cultivation, about metabolic products and substances and about possible practical applications. In the context of the CBD it is therefore only meaningful if it is associated with a specific genetic resource.

The labelling of this knowledge as “traditional” aims to clarify that its existence is not linked to knowledge gained by internationally recognised scientific methods, neither in relation to its generation nor in relation to its continuing importance.

The CBD and relevant national laws recognise the right of indigenous and local communities over their traditional knowledge. Consequently, in addition to the PIC and MAT of the provider state for the genetic resources, the requirement for PIC and benefit-sharing applies too in regard to TK. Therefore, not only the state’s approval must be obtained but also that of the indigenous or local community. In that regard, the rules and notions of the individual communities, which include customary laws, customs, protocols, traditions, values and practices, their councils/bodies and institutions and their decisions, are significant. The conditions of access to TK should be negotiated with appointed representatives of the communities and documented.

The inclusion of TK therefore requires considerable intercultural competences in view of the identification of the groups, their structures, rules and decisions and in regard to their modes of communication.

1.10 Due diligence obligations of users and regulatory supervision

The Nagoya Protocol provides that besides the countries of origin, all states in which genetic resources and TK are utilised should henceforth contribute towards the enforcement of ABS obligations required by provider state legislation. In the EU the rules on ensuring compliance were harmonised through EU legislation, and in particular Regulation (EU) No 511/2014. The EU ABS Regulation only applies to the utilisation of genetic resources and/or TK that originates from a state that has ratified the Nagoya Protocol and that has established ABS measures. The list of Parties is available on the ABS-CH website.

The EU decided in favour of due diligence (DD) as its mechanism for fostering enforcement by its Member States. Accordingly, users shall exercise due diligence to determine whether genetic resources and traditional knowledge associated with genetic resources which they utilize have been accessed in accordance with applicable ABS legislation or other regulatory requirements. It is also necessary to ensure that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements (see Article 4 Regulation (EU) No 511/2014). DD therefore means making best possible efforts to ascertain that access to genetic resources and TK, research and/or development thereon, the transfer of such resources and knowledge, and the sharing of benefits are taking place in the correct legal way

(1.10.1). DD imposes on the researcher certain duties of documentation (1.10.2) and declaration (1.10.3).

1.10.1 Concretizing due diligence

It is of utmost importance that the researcher ascertains the requirements of the provider state. The ABS-CH website contains information on national ABS measures, i.e. legislative or regulatory requirements that have been made available. Information on national measures, however, might not be available on the website, but the (potential) user may have reasons to believe that access legislation or regulatory requirements nonetheless exist, which might be useful to know. Conversely, the legislative or regulatory requirements although being published may be unclear. In such situations, the (potential) user is advised, as a best possible effort, to make direct contact with the provider country's designated National Focal Point (NFP). If the existence of access measures is confirmed, the NFP should also be in a position to clarify what procedures are required to access genetic resources in the country in question. If despite reasonable attempts to obtain an answer from the NFP there is none or only an insufficient one, the (potential) user must assess, whether access and utilisation are in conformity with the provider state's requirements. From the EU perspective, the necessary steps are then considered to have been undertaken.

1.10.2 Documentation

For the purpose of exercising DD the researcher has certain obligations of documentation. If the provider country requests, the user must:

- a) seek, keep and, where appropriate, transfer to subsequent users the internationally recognised certificate of compliance, as well as relevant information on the content of the MAT; or
- b) if such a certificate is not achievable, provide information and relevant documents on:
 - the date and place of access to genetic resources or to TK;
 - the description of the genetic resources or of TK utilised;
 - the source from which the genetic resources or TK were directly obtained, as well as subsequent users of genetic resources or TK;
 - the presence or absence of rights and obligations relating to ABS, including rights and obligations regarding subsequent applications and commercialisation;
 - access permits, where applicable;
 - mutually agreed terms, including benefit-sharing arrangements, where applicable.
- c) retain the documents: Users shall keep the information relevant to ABS for 20 years after the end of the period of utilisation. If necessary, this has to be settled well in advance with the institution with which the researcher is affiliated.

1.10.3 Declaration of exercise of due diligence

Users have to declare that they are exercising or have exercised DD at two stages of research and/or development: at the stage of funding and – if applicable – at the stage of final development of a product.

1.10.3.1 Declaration at the stage of funding

The declaration has to be made to the user's CNA, which in Germany is the Bundesamt für Naturschutz (BfN). A blank form attached to the Commission Implementing Regulation (EU) 2015/1866 (Annex II) should be completed and submitted to the relevant CNA.²³

The declaration shall be made after the first instalment of funding has been received and all the genetic resources and TK that are utilised in the funded research have been obtained. However, it should not be made later than the time of the final report. If a final report is not requested, the declaration should be made at the end of the project at the latest. National authorities have the discretion to further specify the time of submission of such a declaration.

One declaration is sufficient and is to be made by the project coordinator. The project coordinator shall submit the declaration to the CNA of his/her state of residence. If she or he is not a citizen of the EU and the research is carried out in the EU, the DD declaration shall be made to the CNA of one of the Member States in which the research is carried out.

1.10.3.2 Declaration at the stage of final development of a product

A form annexed to the Commission Implementing Regulation (EU) 2015/1866 (Annex III) should be completed and submitted to the CNA of the user's state of residence. This should be done once before any of the following events occurs (whichever takes place first):

- a) market approval or authorisation for the product is applied for;
- b) a notification required prior to placing a product on the EU market for the first time is made;
- c) if no approval or authorisation is required, placing of the product on the EU market for the first time;
- d) the result of the utilisation is sold or transferred in any other way to a natural or legal person within the EU for carrying out any of the three activities mentioned;
- e) utilisation of the product/result within the EU is finished or it is to be transferred to a natural or legal person outside the EU.

²³ See below 5.5.

2 Planning and performing a research and/or development project in view of ABS requirements

The following overview aims to show which questions and tasks arise for research and/or development projects if access is sought in situ. Concerning your project management, keep in mind that clarification of certain issues will require a negotiation process, which may take more time than you expect.

2.1 Collection of relevant information

Please make sure that you have adequate answers to the following questions at an early stage of the project as they might become crucial at later stages, e.g. during negotiations with the provider. See also chapter 4 with frequently asked questions (FAQs).

- a) Have I acquired a basic understanding of ABS requirements (such as through reading part 1 of these Guidelines)?
- b) What genetic resources shall be accessed, and where?
- c) Shall TK be accessed, and if so what kind and where?
- d) How shall genetic resources and/or TK be accessed (sampling in situ, acquisition from collection or otherwise)?
- e) What kind of research and/or development is envisaged (biological, chemical, etc.)?
- f) Is the research and/or development aimed at non-commercial and/or commercial purposes?
- g) Can collaboration with research institutions in the provider country be incorporated in the planned research, and if so, how?
- h) Is the provider country a party to the CBD/Nagoya Protocol?
- i) Has the provider country ABS rules in place (consult the CBD webpage, the ABS-CH and/or the CNA of the respective country)?
- j) What are the requirements of the provider state concerning ABS?
- k) What are the competent authorities in the provider state?
- l) What ABS and other permits are required (permit for access to genetic resources and/or TK, for research in general, for access to protected areas, for exportation as a CITES requirement, permit of the private landowner)?
- m) Must an access agreement be concluded? If so, with which administrative authority of the provider state?
- n) Does the provider state require that a domestic researcher must file the application for the access permit and conclude the access agreement?

- o) Are indigenous or local communities to be approached for access to their genetic resources or TK?
- p) What are the regulatory provisions for PIC of those indigenous or local communities, and what are their rules and customs? How do I ensure the CNA will accept the PIC?
- q) How much is required to cover the costs of ABS requirements and negotiations?
- r) What non-commercial benefits (capacity building, scientific collaboration, research results, publications, etc.) can be shared with domestic researchers, and how?
- s) Will commercial benefits be generated, and how shall they be shared with the provider state?
- t) Is my research institution prepared to sign the application for an access permit and also negotiate and sign an access agreement?
- u) How can it be ensured that the relevant data will be stored for 20 years after the project is concluded?

2.2 Implementation of the research project

These suggestions only apply after the project has been approved by the third-party funding agency or by the researcher's institution itself.

- a) If the ABS regulation in the provider country is unclear or overly complicated: visit the NFP and clarify the conditions; in case of non-commercial research, suggest simplification of procedures, referring to Article 8(a) NP, if the provider state is a party to the Nagoya Protocol.
- b) Prepare the application for access permit by yourself or, if the application must be made by a domestic researcher, together with your counterpart; submit the application; remind the authority after some time to move forward with the decision.
- c) Negotiate and conclude the access agreement by yourself or together with your counterpart, as appropriate. Clarify and fix intended (or future) uses of accessed genetic resources in writing.
- d) In case of access to genetic resources held by indigenous or local communities or to TK: visit the relevant community, ascertain their rules and customs, and follow their advice in order to obtain their consent.
- e) Collect or acquire the genetic resources.
- f) If applicable: collect local genetic resources and/or TK; be ready to give clarifications; respect ethical concerns.
- g) Report to the BfN using its forms when receiving the grant, or when having received (all) genetic resources/TK, or when completing the research/the project.
- h) Perform the research and/or development according to the terms of the access permit and agreement.

- i) Observe the terms of the access permit and agreement concerning transfer of material and data to third persons.
- j) Observe come-back obligations in case of change of intent from non-commercial to commercial.

2.3 Outcome of the research project

- a) Report on the research and/or development progress to the provider country according to the terms of the access permit and agreement.
- b) Share benefits (research and/or development results and publication(s)) with the provider country according to the terms of the access permit and agreement.
- c) Fulfil possible further obligations concerning the sharing of benefits.
- d) Store accessed genetic resources according to the terms of the access permit and agreement.
- e) Document and store documents according to Article 4 Regulation (EU) No 511/2014²⁴ for 20 years.

²⁴ See below 5.4.

3 Glossary

The following terms have been defined by the CBD, the NP or the Regulation (EU) No 511/2014. They are presented to convey the meaning officially agreed by countries and may be used in contract language. Nevertheless, the provider country may have adopted different terms and definitions; therefore it is important to pay attention to any deviating meaning.

Access means the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the NP (Article 3(3) Regulation (EU) No 511/2014).

Biotechnology means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use (Article 2(d) NP).

Genetic material means any material of plant, animal, microbial or other origin containing functional units of heredity (Article 2 CBD; Article 3(1) Regulation (EU) No 511/2014).

Genetic resources means genetic material of actual or potential value (Article 2 CBD; Article 3(2) Regulation (EU) No 511/2014).

Derivative means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity (Article 2(e) NP).

Internationally recognised certificate of compliance means a permit or its equivalent issued at the time of access as evidence that the genetic resource it covers has been accessed in accordance with the decision to grant prior informed consent, and that mutually agreed terms have been established for the user and the utilisation specified therein by a competent authority in accordance with Article 6(3)(e) and Article 13(2) NP, that is made available to the ABS-CH established under Article 14(1) of the Protocol (see Article 3(11) Regulation (EU) No 511/2014).

Mutually agreed terms (MAT) means the contractual arrangements concluded between a provider of genetic resources, or of traditional knowledge associated with genetic resources, and a user, that set out specific conditions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or of traditional knowledge associated with genetic resources, and that may also include further conditions and terms for such utilisation as well as subsequent applications and commercialisation (see Article 3(6) Regulation (EU) No 511/2014).

The term **provider country** as used in this document means the country of origin of the genetic resources or any (other) Party to the NP that has acquired the genetic resources in accordance with the CBD (see Articles 5 and 6 NP and Article 15 CBD).

Country of origin of genetic resources is defined as the country which possesses the genetic resources in *in-situ* conditions (Article 2 CBD; Scope Guidance Document to Regulation (EU) No 511/2014).

Registered collection means a set of collected samples of genetic resources and related information accumulated and stored by public or private entities that is registered according to Article 5 Regulation (EU) No 511/2014 and open for public use.

Utilisation of genetic resources means 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 CBD (Article 2 NP; Article 3(5) Regulation (EU) No 511/2014).

Traditional knowledge associated with genetic resources (TK) means traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources (Article 3(7) Regulation (EU) No 511/2014).

User means a natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources (Article 3(4) Regulation (EU) No 511/2014).

The EU regulation has also defined:

Illegally accessed genetic resources means genetic resources and traditional knowledge associated with genetic resources which were not accessed in accordance with the national ABS legislation or regulatory requirements of the provider country that is a Party to the NP and requires prior informed consent (Article 3(8) Regulation (EU) No 511/2014).

Collection means a set of collected samples of genetic resources and related information that is accumulated and stored, whether held by public or private entities (Article 3(9) Regulation (EU) No 511/2014).

Association of users means an organisation, established in accordance with the requirements of the Member State in which it is located, that represents the interests of users and that is involved in developing and overseeing the best practices referred to in Article 8 of this Regulation (Article 3(10) Regulation (EU) No 511/2014).

Two other useful explanations of commonly used terms:

Prior informed consent (PIC) is the permit given, by the provider country, to access specified genetic resources.

(Standard) Material transfer agreement (MTA) is a document stating the conditions of a transfer of biological or genetic material, usually, but not always, issued by ex-situ institutions, and used for loans, exchange or donations.

4 Frequently Asked Questions (FAQs) concerning applications for public funding of biological research projects

I am planning to conduct research with biological materials/objects (from) outside Germany. Do I need to obtain a permit to do this?

According to the regulations of the CBD, the materials/objects are, as of 29 December 1993, subject to the sovereign rights of the provider country (your host country). If the regulations of the country so requests, you must ask for a permit for access to the material. Germany and most other Member States of the EU grant free access to their own biological material, notwithstanding any permit requirement under environmental protection regulations (such as species and habitat protection law).

If the provider country is a member to the NP, what specific requirements do I have to respect?

In that case you are subject to specific instruments of ensuring compliance that are laid down in Regulation (EU) No 511/2014.²⁵ The German law complementing the EU Regulation entrusts powers of supervision to the BfN. The NP also specifies the terminology and conditions of access to genetic resources as well as the duty to share benefits derived from their utilisation. In addition, it addresses provider states asking for legal certainty of their domestic regulation and, in particular, for the simplification of procedures for non-commercial research. However, even if the provider state is not a Member State of the NP, it may have ABS regulations in place that must be respected.

How do I find out whether a provider country has ABS measures in place?

For more information on Member States of the NP and their ABS regulations and authorities, please consult the website of the ABS-CH provided by the Secretariat of the CBD.²⁶

Do the conditions vary depending on whether my research is basic (“academic”), applied (without commercial purpose), or research and/or development (for later commercial use)?

Although a clear answer has not yet been reached on the level of the CBD and NP, under EU and German law all kinds of research and/or development are understood as “utilisation” of genetic resources and thus are subject to the PIC and MAT if required by the provider state regulation.

The genetic resources I plan to use come from a botanical or zoological garden, a museum or another public repository. What are the conditions of access in this case?

²⁵ See below 5.4.

²⁶ Available at: <https://absch.cbd.int>.

If the material has been acquired before the entering into force of the CBD, i.e. the 29 December 1993, it belongs to the repository and its use is at the discretion of the collection, except if the material was acquired under conditions set by the provider state and agreed to by the repository. If the material was acquired after that date, you would need to clarify if the initial permits/documents include specific rules on third-party usage. If this is the case, the new usage would have to be in accordance with these arrangements. If there are no specifications about further use, you will need to contact the provider state and negotiate new permits for your project.

Are there returns for access and utilisation of a provider country's genetic resources?

If your research is commercially motivated and finally will result in revenues, the provider country, represented by your counterpart, an NGO, or an indigenous ethnic group will ask you for a share of your revenues from using their genetic resources. This requires a contract prior to getting access to the genetic resources.

If your research is basic or applied without any commercial intent, benefits for the provider country can still arise from your work. This could be agreed upon in a contract or just may be anticipated in the documents which grant you access to genetic resources and research permission (PIC). Examples of non-monetary benefits are the sharing of the data and information generated in the project, the training of local students, joint authorship of publications, if this is in accordance with good scientific practices, the deposition of samples in national collections, or providing equipment for joint use with your partner institution.

Which regulations of the NP are pertinent to my research? To what extent do I need to be familiar with the entire Protocol?

Countries are principally free in the procedures of ABS. Members to the NP (but also members of the CBD that are not members of the NP) will employ a procedure, detailed in the NP, which consists of several subsequent steps. The first is "prior informed consent" (PIC): You inform the Competent National Authority/National Focal Point (CNA/NFP) of the provider country directly or together with your counterpart about your research plan and the genetic resources you want to use, and apply for PIC if required. If PIC is granted, the next step is "mutually agreed terms" (MAT), in which details of the genetic resources as well as details of the conditions of their utilisation (e.g. number and time intervals for reports to the CNA/NFP) and milestones of benefit-sharing are described, usually in the form of an access agreement.²⁷ If you plan to take genetic resources out of the provider country or pass them on to a "third party", a "material transfer agreement" (MTA, not to be confused with MAT) is required. This can be a separate agreement or one included in the access agreement.²⁸ The MTA may also include an export licence required under the commercial laws of the providing country.

Which of these steps and documents will be required in your case depends on the provider state's regulations and your negotiations with your counterparts and/or the CNA/NFP.

²⁷ See model clauses. Sometimes MAT are required as a prerequisite for PIC.

²⁸ See clause 7 of the model clauses.

It is recommendable that you make yourself familiar with the NP in order to have a background for your applications and negotiations. It is also wise to study the relevant ABS legislation of the provider country if accessible. Otherwise, summary information may be available from the CNA/NFP and/or from more detailed information brochures published by the BfN or other institutions or consultants.

Are there restrictions to publishing my work?

Work results from DFG-funded projects must be made available to the general public in a suitable manner.²⁹ In other contexts, too, you are regularly expected to make your results available to the public. To retain data for patents is in your and your counterpart's discretion, an issue that should be addressed in the MAT negotiations. If you plan to produce "sensitive data" such as sequencing genes, it is advisable to make this known to the CNA/NFP when applying for PIC. As part of benefit-sharing, joint publication with an actively participating counterpart is self-evident, but may be mentioned in the MAT negotiations.

How long does it take from my first application until I can start my research, and do I need extra money to pay for the granting procedure?

The timeframe cannot be estimated, and since many provider countries are currently in the process of establishing authorities and adapting procedures, it may take a while, especially if you start your correspondence via e-mail. If it takes less than one year, you are really successful. However, this could improve with time. The costs are also not regulated and therefore depend upon the provider state's regulation and your negotiations. Fees can be as low as USD 10 and as high as USD 1,000 (these are actual figures). There may also be costs for the research permit, not only for the ABS procedure. In all cases, it is recommended to obtain information in advance (at the time of applying for the research grant).

Instead of or additionally to collecting and using genetic resources, what do I have to observe if I plan to ask local people about the traditional or local use of the material?

What you plan to explore may be what is termed "traditional knowledge associated with genetic resources" (TK). In principle, it should be possible to get access to that knowledge; depending on provider state legislation you will need to obtain the consent of those who hold the TK, i.e. the indigenous or local communities and or individuals or associations such as healers and healers' networks. In addition, the consent of authorities responsible for traditional culture may have to be obtained.

When making use of genetic resources in the EU/in Germany, what are the requirements imposed by the regulations of the EU and the German law?

If your provider country is not a party to the NP (i.e. has not ratified it), no EU regulations apply. If your provider country is a party to the NP, additional obligations, also for basic research projects,

²⁹ See DFG-Verwendungsrichtlinien (only available in German) (DFG form 2.00 – 11/18), section 13.

are imposed, but not difficult to fulfil. When your research project is granted, and you have obtained the envisaged genetic resources, you must inform the German Competent National Authority, i.e. the Bundesamt für Naturschutz (BfN), about your project. At the latest, this information is due when your project is concluded. There will be forms to be completed, but as the matter is still in progress, contact the BfN to be updated about details. Your documents from the provider country must demonstrate that your project complies with the regulations of the provider country and/or the NP and with the EU regulations. By submitting this report to the BfN, you are exercising “due diligence (DD)” which is one of the major stipulations of the EU and the German law.

Matters are more complicated for research and development aiming at a commercial commodity, and also if patents will be involved. This requires delving more deeply into the regulations and more paperwork.

Are there fines for not complying with all those regulatory restrictions?

Yes. Not complying with provider state regulations will be fined and may lead to termination of your research prematurely and confiscation of the genetic resources. Remember that also in a host country, the researcher is subject to public laws. Not exercising DD can also result in a premature termination of the project and, in severe cases, also to monetary penalties.

I am a laboratory biologist, ecologist, biochemist, pharmacist or medical doctor using biological samples which I receive from my cooperation partner abroad in my research. Is there anything new to be observed?

This quite familiar case requires several considerations.

1. You need information about the organismic origin of the sample. If it is human material, it is outside the scope of the CBD and the NP. Other regulations and laws apply to such research.
2. If you use the material for non-biological research (e.g. soil or water analysis), this is also outside the scope of the CBD and the NP.
3. If you use it for biological research, be sure that your provider was authorised to hand it over to a third party (you) without restrictions, or investigate potential obligations imposed on the material by the provider country. If you are the donor of the material, make sure that you are allowed to transfer it to a third party, as you are responsible for legal correctness. In case of doubt you may ask the German authority, i.e. the BfN.
4. If you purchase the material for your research from specialised traders, the responsibility for conformity with the regulations of the CBD and the NP is not only with the trader, but also with you. As part of your DD, you must enquire whether the trader or his/her provider is subject to any requirements. You may also need to contact the provider state and negotiate new permits for the project.
5. If you are using biological material as a tool, e.g. taqpolymerase, this is not considered utilisation of a genetic resource, and the ABS regulations do not apply.

6. If your research falls under the regulations of the ITPGRFA, make sure that not only the plant source but also the purpose of your research is in line with those regulations.³⁰

Does my research institution share with me the responsibility for compliance and due diligence if I use genetic resources in my research?

It must be assumed that your institution can be held accountable for your actions when conducting research with genetic resources in the sense of the CBD and the NP under Regulation (EU) No 511/2014 and the German implementing law. A decision to this effect is expected in the guidance document currently being prepared by the EU Commission and the BfN. You are advised to inform your institution of such responsibility well in advance.

³⁰ Available at: <http://www.fao.org/plant-treaty/overview/texts-treaty/en/>.

5 Relevant legal documents

5.1 The Convention on Biological Diversity (CBD)

The CBD of 1992³¹ is the major multilateral environmental agreement for the protection of biodiversity. Its three objectives are the conservation of biological diversity; the sustainable use of its components; and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.³² The third objective was agreed upon by the Parties to the Convention in order to create a mechanism for sharing the burden of conservation and sustainable use of biodiversity with its custodians as well as generating an economic incentive for them as an inducement for conservation and sustainable use. This brought to an end the earlier notion that genetic resources are a common heritage of humankind and therefore freely accessible. The system that developed from the new approach is based on a quid pro quo principle, which can be generally understood as “access (to genetic resources and TK) in exchange of benefit-sharing”. In short, this is referred to as “access and benefit-sharing” (ABS). The CBD contains a few provisions mainly under Article 15 and Article 8(j) which spell out the rights and obligations of the Parties in ABS. Accordingly, states have sovereign rights over their natural resources. Thus, each state has the authority to determine how access to its genetic resources should take place. Access is subject to the PIC of the party providing such resources and based on MAT. The party that accesses the genetic resources must share benefits arising from their utilisation with the party that provided the genetic resources. These rights and obligations form the ABS framework, which must be domestically transposed to become national law.

Article 15 CBD reads:

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

³¹ Available at: <https://www.cbd.int/convention/text/>.

³² Article 1 CBD.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

5.2 ITPGRFA

The International Treaty on Plant Genetic Resources for Food and Agriculture of 2001 (ITPGRFA)³³ is a multilateral agreement which aims at guaranteeing food security. Its objectives are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use in harmony with the CBD.³⁴ Due to the global importance of a specific number of plant genetic resources for food and agriculture listed in Annex I of the Treaty and comprising 64 crops (35 food crops and 29 forage genera), Parties to the Treaty have agreed to exempt them from the ABS regulations of the CBD when such resources are being accessed “solely for the purpose of utilisation and conservation for research, breeding and training for food and agriculture”.³⁵ For such cases they are subject to special rules of access and benefit-sharing under a common pool. The Treaty operates in line with the objectives of the CBD and hence is recognised as a specialised international instrument for ABS.

5.3 The Nagoya Protocol (NP)

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the CBD³⁶ was adopted in October 2010 and came into force in October 2014. It is a binding supplementary instrument which aims to operationalise the ABS obligations of the CBD by elaborating and concretizing them.

The main rights and obligations of the parties are spelled out under Articles 5, 6, 7, 15, 16 and 17.

³³ Available at: <http://www.fao.org/plant-treaty/overview/texts-treaty/en/>.

³⁴ Article 1 ITPGRFA.

³⁵ Article 12(3)(a) ITPGRFA.

³⁶ Available at: <https://www.cbd.int/abs/text/default.shtml>.

Article 5 requires parties to take legislative, administrative or policy measures in order to share in a fair and equitable way the benefits arising from utilisation of genetic resources and TK with their providers. It also requires sharing of benefits arising from subsequent application and commercialisation of research results.

Article 6(1) and (2) subjects access to genetic resources for utilisation to the PIC of the provider.

Article 6(3) spells out obligations of a party that subjects access to PIC. Inter alia, such a party must provide legal certainty, clarity and transparency of the domestic ABS legislation or regulatory requirements.

Article 7 highlights the aim of ensuring that TK that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities.

Articles 15 and 16 require user countries to put compliance measures in place to ensure that the utilisation of genetic resources and TK within their territories have been accessed in accordance with PIC, and that MAT have been established as required by domestic ABS legislation or regulatory requirements of the party that provided them.

Article 17 establishes control measures to support compliance. Accordingly parties shall designate checkpoints to collect or receive from users relevant information related to PIC, to the source of the genetic resources, to the establishment of MAT and/or to the utilisation of genetic resources. It also establishes that a permit or an equivalent document granted under Article 6(3)(e) shall constitute an internationally recognised certificate of compliance once made available to the ABS-CH.

5.4 Regulation (EU) No 511/2014

“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”³⁷ transposes the obligations of the NP in the EU. Member States of the EU must implement these obligations into national law. The Regulation only contains the so-called user measures, which are measures on compliance. The Regulation establishes DD as its core concept for supporting compliance under Article 4. It obliges users to declare DD of abiding by provider state regulations at the stages of research funding and prior to the marketing of developed products. The Regulation also lays down supervisory powers and obligations of competent national authorities.

The Regulation does not address the question whether the Member States should establish an ABS regime also for their own genetic resources. This is left to the Member States to decide. Some Member States did establish this, such as France, Spain, Bulgaria, Malta, Croatia, Finland and Sweden, but most of them, including Germany, refrained from doing so. They allow access

³⁷ O.J. L 150 p. 59 (2014).

to their genetic resources without PIC and do not claim the sharing of benefits. This, of course, facilitates the general research and/or development process.

Article 4(1),(2) and (3) read:

Obligations of users

1. Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements.
2. Genetic resources and traditional knowledge associated with genetic resources shall only be transferred and utilised in accordance with mutually agreed terms if required by applicable legislation or regulatory requirements.
3. 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.

5.5 Commission Implementing Regulation (EU) 2015/1866

In 2015 the EU Commission enacted the 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.³⁸

5.6 Scope Guidance Document of the EU Commission

The EU Commission in 2016 enacted a “Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the 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”.³⁹ The guidance document elaborates and clarifies the obligations under the EU regulation on ABS for users. An updated version of the guidance document with numerous application examples was published in early 2021.⁴⁰ Further guidance documents are being elaborated specifying for various non-commercial and commercial activities to what extent they are captured by the term utilisation and are thus subject to ABS requirements.

5.7 German Law Implementing Regulation (EU) No 511/2014

The “Gesetz zur Umsetzung der Verpflichtungen nach dem Nagoya-Protokoll, zur Durchführung der Verordnung (EU) No 511/2014 und zur Änderung des Patentgesetzes sowie zur Änderung des Umweltauditgesetzes vom 25. November 2015”⁴¹ largely complements Regulation (EU) No 511/2014. In particular, it determines the BfN to be the Competent National Authority (CNA). It also provides for sanctions in the case of non-compliance of users with the provisions of Regulation (EU) No 511/2014.

German political institutions do not presently plan to establish an ABS regime for Germany’s own genetic resources.

³⁸ O.J. L 275 p. 4 (2015).

³⁹ O.J. C 313 p. 1 (2016).

⁴⁰ O.J. C 13 p. 1 (2021).

⁴¹ BGBl. 2015 I S. 2092.



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