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Utilization of genetic resources and associated traditional knowledge in academic research

A good practice guide for access and benefit-sharing

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Utilization of genetic resources and associated traditional knowledge in academic research

A good practice guide for access and benefit-sharing

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Note: This Good Practice Guide is not intended to replace any legally binding obligations for researchers according to domestic ABS legislations or regulatory requirements in countries providing genetic resources, or in countries where such resources are utilised.
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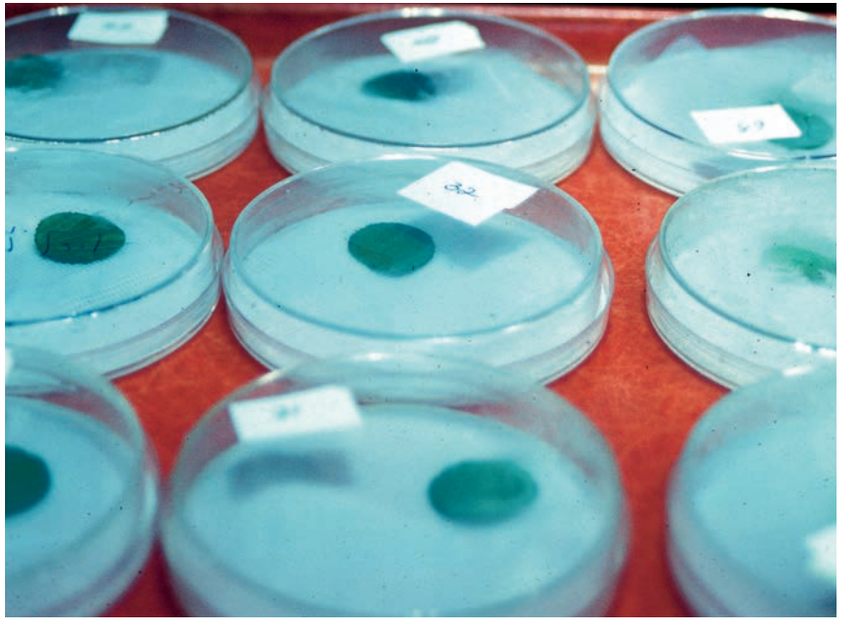
Contents



Abbreviations and Acronyms

Access and Benefit Sharing/ABS	Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization
Art., Arts.	Article, Articles
Associated Traditional Knowledge/ATK	Traditional Knowledge Associated with Genetic Resources
Bonn Guidelines	Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization
CBD	Convention on Biological Diversity
CETAF	Consortium of European Taxonomic Facilities
CGIAR	Consultative Group on International Agricultural Research
CITES	International Convention on the Trade with Endangered Species
FOEN	Swiss Federal Office of the Environment
GR	Genetic Resources
IARC	International Agriculture Research Centres
IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO)
International Treaty	International Treaty on Plant Genetic Resources for Food and Agriculture
IPEN	International Plant Exchange Network
MAT	Mutually Agreed Terms
MTA	Material Transfer Agreement
Multilateral System/MLS	Multilateral System for ABS of the International Treaty
Nagoya Protocol/NP	Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity
NCHA	Federal Act on the Protection of Nature and Cultural Heritage (NHG, LPN)
PGRFA	Plant Genetic Resources for Food and Agriculture
PIC	Prior Informed Consent
SMTA	Standard Material Transfer Agreement
WIPO	World Intellectual Property Organization

Foreword

It is a great privilege and pleasure to write a few lines to welcome the new good practice guide for academic research on access and benefit sharing (ABS). Having followed the scientific and political process on ABS for more than two decades, it is gratifying to see this guide move the discussion on ABS and its implications for academic research into the reality of scientific enquiry and pursuit in our societies.

In 1992, the international community of states established the Convention on Biological Diversity (CBD). The ABS principles stipulated in the CBD reached more operational specificity in the Nagoya Protocol in 2010. There the measures to implement the CBD principles are well specified. Moreover, in 2004, the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty) complemented the conceptual and operational thinking on ABS. This guide is based on these three pillars. Through its wide-spread and thoughtful application in daily academic practice, it will be validated for its applicability and efficiency.

Governed by the present guide, sensitivity to ABS will become an essential part of enabling ethically and societally responsible academic research in partnership across systems and cultures by taking into account the prevailing realities of our societies and the countless global challenges. Clearly, the guide helps ensure good scientific practice that is compatible with our Swiss legislation; it specifies procedures and approaches to integrate ABS in day-to-day research and to effectively meet the requirements of the implementation of the Nagoya Protocol in the framework of the Swiss legal order.

ABS is strongly based on a contractual understanding in which interests and concerns of users and providers are not only discussed but reconciled for a responsible, ethically acceptable and science-enhancing way forward. Consequently, living according to ABS in such a forward looking way removes bottlenecks or overt contradictions and builds trust among all partners, thus rendering partnership even more effective.

I sincerely congratulate the authors and their teams who have carefully established the guide through an effective process of consultation that will assure acceptance and application. Application will – in turn – contribute to the continuous and harmonic validation of the guide, already supported by the three conceptual and legal pillars, the CBD, the Nagoya Protocol and the International Treaty but challenged by the changing dynamics of science, research and development. It is only through the continuous assessment and validation of our scientific practice that we remain responsible and ethically coherent to the societies and partners with whom we have the privilege to work.

It is in this spirit, that I thank you for disseminating this ABS guide. I wish you stimulating reading and discussion as you consult its valuable content and translate it into your daily academic practice.

Marcel Tanner
President SCNAT

1 Purpose of the Manual

Academic research needs to comply with ABS requirements

The access and benefit-sharing (ABS) principles were agreed upon by the international community of States in the Convention on Biological Diversity[1] (CBD) in 1992. In 2010, the parties to the CBD adopted the Nagoya Protocol[2] that spells out in more detail the measures its Parties should take to implement ABS principles. The third instrument covering ABS measures is the International Treaty for Plant Genetic Resources for Food and Agriculture[3] (International Treaty, 2004). These instruments need to be implemented on the domestic level by their Parties. Therefore, when accessing genetic resources (GR) or associated traditional knowledge, and utilizing them in research in states that are Parties to these conventions, scientists must respect the domestic legislation and regulatory requirements of the providers of the resources or knowledge as well as those of Parties where research is carried out.

The rules on "Access and Benefit-sharing"[4] apply to commercial as well as to non-commercial research. A scientist doing basic or applied research on biological material or traditional knowledge associated to this material, must comply with the respective regulations. The goal of this manual is to enable researchers to act in conformity with these regulatory requirements. It provides information on the background, the procedures in access and benefit-sharing and the responsibility of academic research. It explains the steps to be taken when accessing genetic resources for research purposes abroad, *in-situ* in the country of origin, or *ex-situ* in public collections, within a research institution, or from third persons. It presents the legal obligations of non-commercial academic researchers according to the Swiss legislation and the ethical principles of good scientific practice where the former do not apply.

These guidelines are addressed to researchers as well as research managers and heads of departments; they provide essential information for the responsible organizational units in academic institutions.

Switzerland has ratified the CBD, the Nagoya Protocol and the International Treaty. Corresponding legislation is in place and applies also to academic research.

Benefits of ABS for research

A set of accepted and operational protocols is essential for researchers working across international borders and will enhance collaborative research among countries. Access to genetic resources and associated traditional knowledge for academic research may become easier as the procedures increase transparency and encourage trust between stakeholders.

How to use this brochure

This Good Practice Guide gives a general overview of the ABS system and its implications for academic research. It intends to provide comprehensive information to assist scientists and research institutions in planning and executing research projects that include genetic resources and associated traditional knowledge.

Note: The Good Practice Guide contains recommendations. They do not replace legally binding obligations for researchers according to domestic ABS legislations or regulatory requirements in countries providing genetic resources.

1 www.cbd.int
2 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity www.cbd.int/abs
3 www.planttreaty.org
4 "Access to genetic resources and the fair and equitable sharing of benefits arising from their utilization."

2 Essentials of Access and Benefit-sharing for academic research

2.1 What is Access and Benefit-sharing?

The CBD recognizes that States have sovereign rights over the genetic resources found within their national jurisdiction. Therefore they are entitled to define the modality of access to such resources for research purposes and for their subsequent utilization. This includes the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. In turn and in line with Article 15 of the CBD, the parties should do their best to facilitate access to their genetic resources "for environmentally sound uses". These principles are substantiated in the Nagoya Protocol and implemented in the domestic legislation and regulations of the countries providing the genetic resources. It is up to the countries to decide whether they require the fulfilment of ABS obligations for accessing their genetic resources.

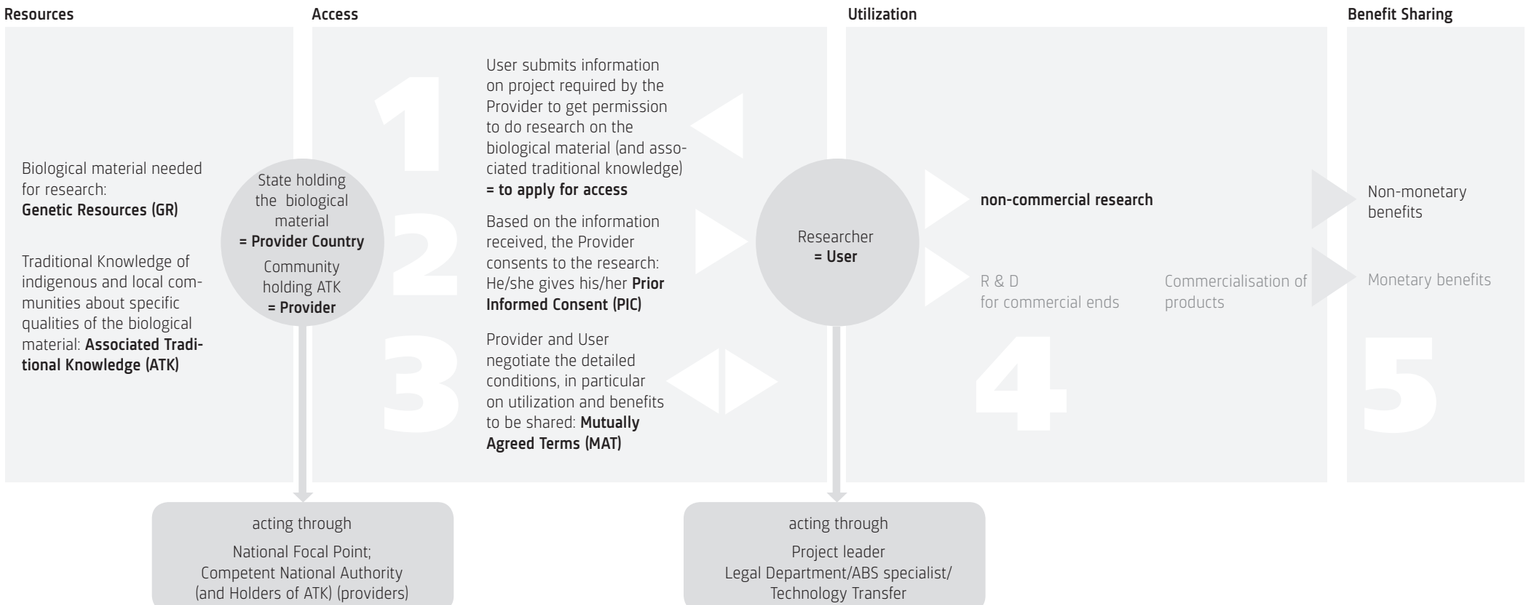
If you intend to do research on genetic resources and/or associated traditional knowledge in a country requiring ABS procedures for academic research, your research needs to be covered by the Prior Informed Consent (PIC) and the Mutually Agreed Terms (MAT) of the provider country. If your research includes associated traditional knowledge, the PIC and possibly MAT of its holders may be required too. The respective conditions depend on the domestic legislation or rgulatory requirements of the provider country.

Never utilize genetic resources before verifying the conditions for access and utilization

This is true whether you access the genetic resources *in-situ*, from the field, or *ex-situ*, from an institution or third person.

The following graph gives a simplified overview of the persons and the steps involved in access to genetic resources and associated traditional knowledge. It also introduces the pertinent terminology.

Table I: Overview of the stakeholders involved in Access to Genetic Resources and Associated Traditional Knowledge and steps to take.



The ABS system covers genetic resources and associated traditional knowledge situated in any provider country that is party to the CBD or to the CBD and the Nagoya Protocol. The provider country acts through special institutions, namely the National Focal Point and one or more Competent National Authorities. In the case of associated traditional knowledge, the Indigenous and Local Communities that are holders of the knowledge are also involved.

You, as the User, check on the ABS Clearing House website[5] and inquire with the ABS Focal Point about conditions for access and the respective procedures, and apply for access to the genetic resources and/or associated traditional knowledge. The provider country, acting through its Competent National Authority, gives its Prior Informed Consent (PIC); together user and provider negotiate the Mutually Agreed Terms (MAT).

5 https://absch.cbd.int

Key to ensuring good ABS practice is to understand the implementation of the ABS provisions by the country that provides the resources.

The **Prior Informed Consent** is, in most cases, a unilateral administrative permit given by the Competent National Authority of the provider country and – if applicable – by additional providers, such as an indigenous or local community, to an individual or an institution prior to accessing genetic resources. Depending on the domestic legislation or regulatory requirements of the provider country, it might be required *in addition* to the research permit (cf. Appendix I).

On this basis, in a second step, the **Mutually Agreed Term**s are negotiated. The MAT are a bilateral (private law) contract between providers and users. They establish the conditions of access and utilization of the resources and the benefits to be shared. The contract needs to respect the regulatory requirements of the country providing genetic resources and/or associated traditional knowledge and of the country where such resources or knowledge will be utilized.

Overview of main actors and instruments:

Provider country: Party providing genetic resources that is the country of origin of such resources or that has acquired the resources in accordance with the CBD (Art. 15 CBD, Art. 6 NP).

Provider: Institution that, according to the domestic legislation or regulatory requirements of a provider country, has the competence to grant access. It may be different from the Competent National Authority (i.e. an institution delegated by the competent authority) or it may act in addition to the Competent National Authority (Holders of ATK, decentralised agency).

National Focal Point: Provides information on authorities/communities to contact, conditions for access and procedures to observe.

Competent National Authority: Agency in the provider country that is entitled to grant access, namely to issue the PIC and to negotiate and conclude the MAT according to its national regulatory requirements.

Prior Informed Consent: Unilateral permission issued by the Competent National Authority to an individual or institution seeking access to genetic resources.

Mutually Agreed Terms: Agreement between provider country/provider of genetic resources and traditional knowledge and the users, on the conditions of access and utilization of the resources and on the benefits to be shared.

Useful tip

The SCNAT's publication "Agreement on Access and Benefit-sharing for Academic Research"[6] offers a toolbox to help set up the Mutually Agreed Terms. It contains Model Contractual Clauses and is designed for the use by providers of genetic resources and associated traditional knowledge and for academic researchers.
The toolkit covers the essential elements that need to be considered in the case of access for academic research. It aims to meet the needs of both the providers and the users of the genetic resources. The kit includes optional clauses allowing to adapt a Mutually Agreed Terms contract to various cases of biodiversity research and to the different needs of providers.
The "ABS-Agreement toolkit" is meant to serve as a template that can be applied to fill the gap where no national tools are available. The text may also be used as a checklist for items that need to be agreed upon when negotiating Mutually Agreed Terms.

2.2 Steps involved in ABS: where to find the pertinent information

The following list gives a brief overview of the steps involved in access to genetic resources by academic researchers. The numbers refer to the chapters of this manual. For detailed step-by-step recommendations, refer to chapter 2.5.

Accessing Genetic Resources *in-situ* and/or Associated Traditional Knowledge

	Chapters
1. Assess the relevance of ABS for your intended research	2.1; 5.3-5.5
2. If your research falls under ABS, go to the ABS Clearing House to:	5.6
a. Obtain the contact details of the focal point of your provider country;	
b. Check whether the provider country is Party to the Nagoya Protocol and has ABS regulation in place (relevant for the application of the Swiss legislation).	3

6 www.naturalsciences.ch/organisations/biodiversity/abs/publications

3. Contact the ABS National Focal Point of your provider country and inquire about:	5.6
a. Conditions to apply for PIC and MAT;	2.1; 5.6
b. Other specifics of the national legislation/ regulation (e.g. specific conditions for utilization, benefit-sharing).	
4. Inquire which additional permits may be necessary (e.g. research permits, exportation permits).	Appendix I
5. Apply for PIC.	
6. Negotiate MAT.	
7. During research, comply with MAT and the legislation of your provider country. Comply with Swiss legislation, if applicable.	3
8. Share benefits as agreed in the MAT.	Appendix III
9. After finalization of the research, proceed with the collected material as agreed in the MAT. When transferring material to *ex-situ* facilities or third persons, include relevant ABS documentation.	3

Additional points when accessing genetic resources *ex-situ*

1. Inquire with the *ex-situ* facility about the ABS conditions for the genetic resource you intend to access:	2.4; 2.5
a. From a non-registered facility, verify its legitimate acquisition, the right of the facility to transfer the genetic resources, and whether your intended research is covered by the PIC and MAT of the provider.	
b. From a registered facility, verify whether PIC and/or MAT of the provider covers your intended research.	2.5; 3.1
c. If your research is covered, comply with PIC and /or MAT. If not, apply for new PIC and MAT with the provider country.	2.1; 5.6
2. Comply with the MTA of the collection.	

Additional obligations according to the Swiss legislation (Due Diligence)

1. Store proof of legitimate access (PIC, MAT) according to the requirements of Due Diligence.	3.1
2. Hand over all relevant documentation to subsequent users.	3.1

2.3 The meaning of fundamental terms[7]

In the context of ABS, the term **genetic resources** has a broad meaning: It refers to "any material of plant, animal, microbial or other origin containing functional units of heredity and that is of actual or potential value" (Art. 2 CBD). These genetic resources fall under the rules on ABS if they are **utilized** to "conduct research and development on the genetic and/ or biochemical composition of genetic resources, including through the application of biotechnology …" (Art. 2[c] NP). Accordingly, ABS does not apply to biological material containing genetic resources that is used as commodity.

The genetic resources can be wild, domesticated or cultivated. ABS applies to access to genetic resources *in-situ* as well as *ex-situ* (Art 2 CBD). Human genetic resources are not covered by the CBD.

Utilization of genetic resources means to conduct research and development on their genetic and/ or biochemical composition

The **Plant Genetic Resources for Food and Agriculture (PGRFA)** are defined as any "genetic material of plant origin of actual or potential value for food and agriculture" (Art. 2, International Treaty). They are subject to the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty).

The ABS-system also applies to access to **traditional knowledge associated with genetic resources that is held by indigenous and local communities**. There is no internationally legally binding definition of traditional knowledge. The term according to international declarations refers to "the traditional knowledge, innovations and practices of indigenous and local communities embodying lifestyles relevant for the conservation and sustainable use of biological diversity".[8]

7 For more information refer to chapter 5 and Appendix II.

8 Akwé: Kon voluntary guidelines for the conduct of cultural, environmental and social impact assessment regarding developments proposed to take place on, or which are likely to impact on, sacred sites and lands and waters traditionally occupied or used by indigenous and local communities, II. Use of terms, par.6, let. h. www.cbd.int/traditional/guidelines.shtml

2.4 Which legal framework applies to your research?

At the international level, different legal frameworks exist for the utilization of genetic resources, in particular the CBD, the Nagoya Protocol and the International Treaty. These frameworks have to be implemented at national level by their Parties. Yet, not all states are Parties to all three Conventions. Also, there are countries that do not require ABS procedures for access to their genetic resources and associated traditional knowledge. This leads to different legal situations for ABS.

The international legal framework that applies to your research, as well as its implementation on the national level, is bound to influence the ease of access. The following decision trees can help you identify which one applies to your planned research. They may assist your strategic decisions regarding the choice of country and source of biological material for your research.

The first decision tree in Table II (see p. 19) depicts different scenarios regarding *in-situ* access to genetic resources abroad, namely in

1. Countries that are party to the CBD and the Nagoya Protocol *with* ABS regulation in place;
2. Countries that are party to the CBD and the Nagoya Protocol *without* ABS regulation in place;[9]
3. Countries that are party to the CBD only (CBD-only countries) with ABS regulation and/or infrastructure in place;
4. Countries that are party to the CBD only (CBD-only countries) without ABS regulation and/or infrastructure in place.

Useful tip

Countries that have ratified and implemented the Nagoya Protocol may have the most transparent procedures for access and legal security. Researchers may expect challenges in CBD-only countries that lack ABS regulation and corresponding administrative infrastructure.

9 This is relevant for the application of the Swiss Due Diligence requirements that only apply to utilization of resources in countries that are parties to the Nagoya Protocol *and* that have ABS regulatory requirements in place.

The second decision tree in Table III (see p. 20) illustrates access *ex-situ* to genetic resources hosted in collections. Here, there is a difference between

1. Access to PGRFA and access to all other genetic resources;
2. Access to PGRFA that are included in the "Multilateral System of Facilitated Access" (Multilateral System) and all other PGRFA.

The Multilateral System of Access and Benefit-sharing of the International Treaty

The International Treaty established the **Multilateral System of Access and Benefit-sharing**. It provides easy access *ex-situ* to selected crop and forage varieties (listed in Annex I of the International Treaty[10]) for research, breeding and training in collections that are part of the Multilateral System[11]. Only the Standard Material Transfer Agreement (SMTA) needs to be signed.

For *ex-situ* access to genetic resources not included in the Multilateral System, users have to follow the national ABS regulation of the country where the collection is located. In such cases, access will probably be simpler in countries that have ratified the Nagoya Protocol.

If you do research with PGRFA listed in Annex I of the International Treaty, the easiest approach is to access the biological material through a collection that is part of the Multilateral System (see chapter 2, Appendix II; Appendix IV).

Useful tips

Some countries may establish a system of "registered collections" (see chapter 3.1) that manages their hosted genetic resources according to ABS requirements to facilitate compliance.
Other networks of collections provide facilitated access and exchange within their own organisation (for instance the International Plant Exchange Network, IPEN).[12]

10 See www.planttreaty.org/content/crops-and-forages-annex-1
11 See www.planttreaty.org/inclusions
12 www.bgci.org/policy/ipen

Useful information sources for collections

- Consortium of European Taxonomic Facilities (CETAF) Code of Conduct and Best Practices for Access and Benefit-sharing; includes three types of Standard Material Agreements; available at http://cetaf.org/taxonomy/publications
- World Federation for Culture Collection; TRUST – transparent user-friendly system of transfer; based on MOSAICC MICROORGANISMS SUSTAINABLE USE AND ACCESS REGULATION INTERNATIONAL CODE OF CONDUCT; September 2014; available at http://bccm.belspo.be/projects/trust
- Global Genome Biodiversity Network; Best Practice for Access and Benefit-sharing; Code of Conduct; Standard Material Transfer Agreements; revised June 2015, available at http://wiki.ggbn.org/ggbn/Documents

2.5 Recommendations on how to proceed

Step by step recommendations on access to genetic resources *in-situ* and *ex-situ*

Table IV (see p. 26) suggests the necessary steps for the implementation of a research project utilizing genetic resources. It branches off depending on whether the user acquires the genetic resources from the field (*in-situ*) or from an institution or a third person (*ex-situ*).

Researchers or users should inquire in the planning phase about the ABS conditions in the prospective provider country if they plan to access the biological material *in-situ*. If accessing genetic resources from an *ex-situ* facility, application for new PIC and MAT with the provider country may be required if the documents that come with the biological material do not allow the transfer to a third person or the intended utilization.

Table IV focuses on academic research for non-commercial use. Nevertheless, it includes action for research and development of potential commercial use to illustrate the genetic resources value chain and changes of research intent.

Table II: Access to genetic resources *in-situ*

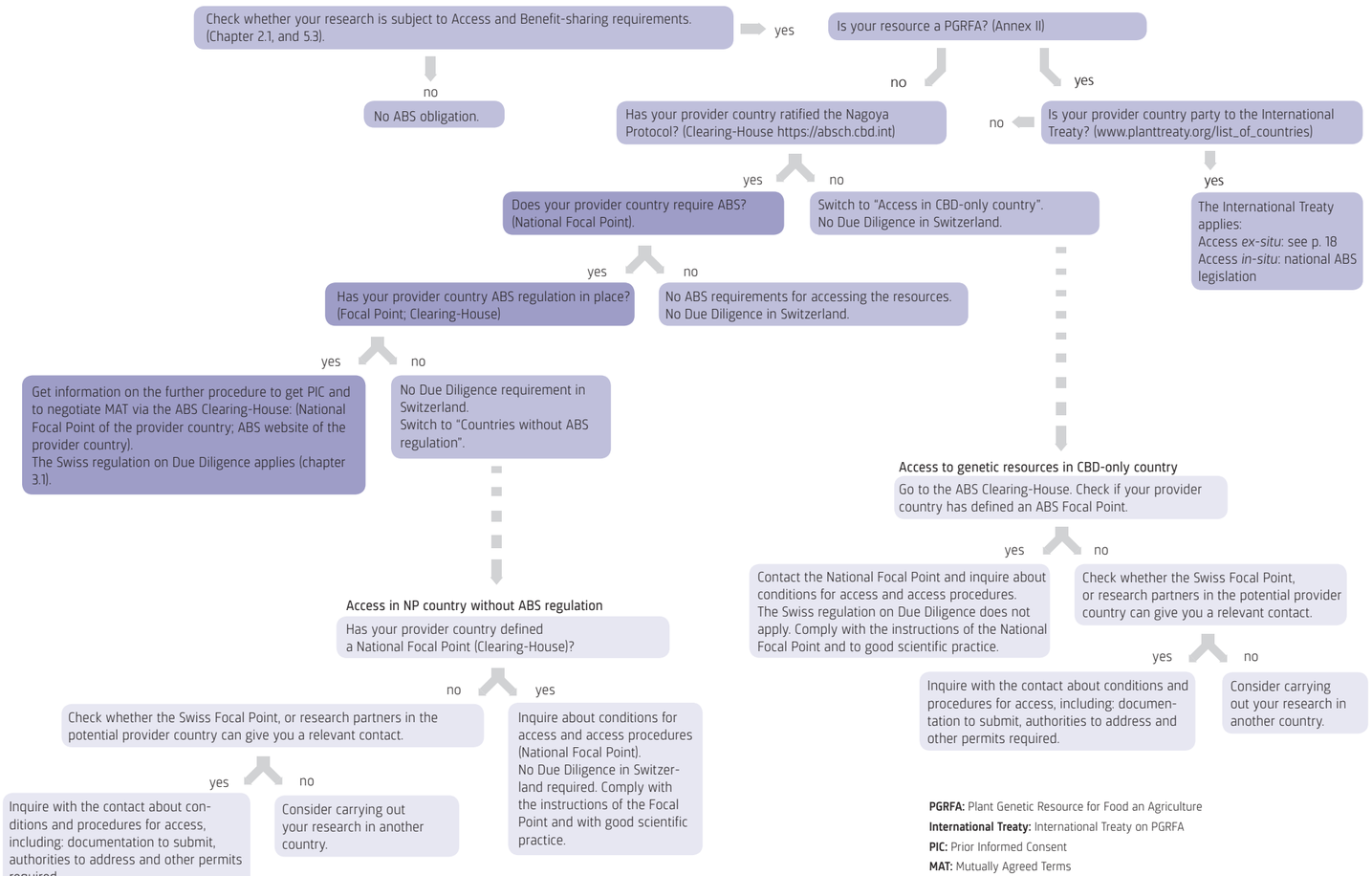
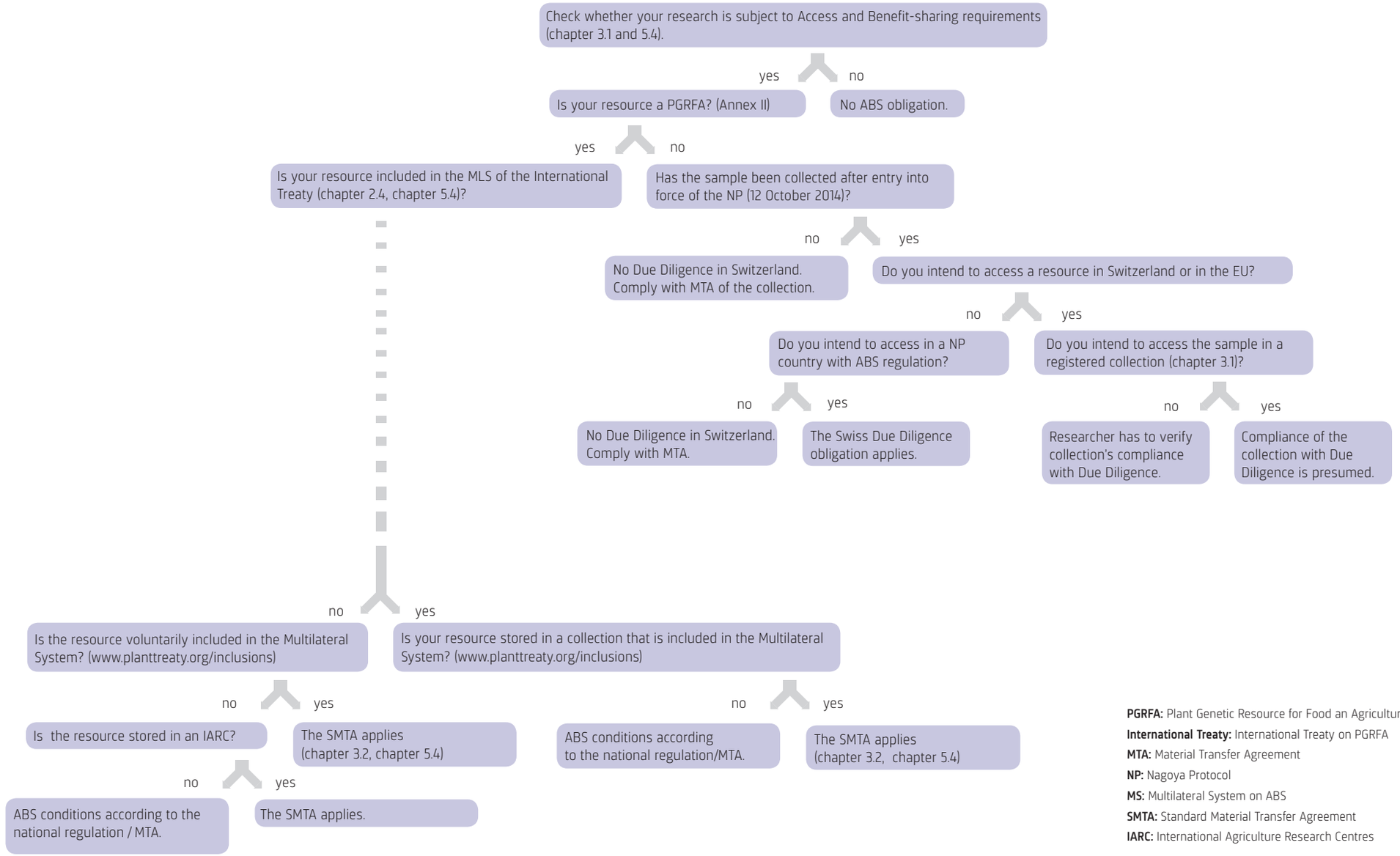


Table III: Access to genetic resources *ex-situ*



PGRFA: Plant Genetic Resource for Food an Agriculture
International Treaty: International Treaty on PGRFA
MTA: Material Transfer Agreement
NP: Nagoya Protocol
MS: Multilateral System on ABS
SMTA: Standard Material Transfer Agreement
IARC: International Agriculture Research Centres

The genetic resource value chain and changes in the utilization (change of intent)

It is possible that a genetic resource accessed for basic research is, at a later stage, utilized for research and development in a commercial context.

Different scenarios are possible: The transfer of the genetic resources that are promising for further research might, 1) occur directly between researchers, 2) between different departments of a research institution, 3) between cooperating institutes, or 4) via internal or public collections. A consecutive project may be an immediate follow-up to the previous one, or be taken up only after some time has elapsed.

In ABS terms, this is called "change of intent." While these cases are not frequent, in the event of future commercialization, the corresponding PIC and MAT is imperative.

Access to Traditional Knowledge Associated to Genetic Resources

In many countries access to Associated Traditional Knowledge requires the PIC of its holders. Even in a country where there are no formal ABS requirements, ethical principles need to be respected. Therefore, when your research involves access to Associated Traditional Knowledge:

- Determine early whether the type of knowledge you want to access is subject to ABS for access to Associated Traditional Knowledge in the provider country.
- Respect international law and ethical principles on rights of indigenous peoples; e.g. the United Nations Declaration on the Rights of Indigenous Peoples (2007),[13] the International Labour Organization Convention 169 (1989),[14] professional ethical codes such as the Code of Ethics of the International Society of Ethnobiology.[15]
- Design your research to match the interest of the involved communities. Prepare to communicate your results clearly and in a non-scientific way adapted to the customs of the community.
- Clearly inform the involved community about your planned research and the expected results.
- Record all ABS relevant steps; store the respective documents.
- Respect the customary law, customs, traditions, values and practices of the holders of the Associated Traditional Knowledge.
- Respect the wish of the holders of Associated Traditional Knowledge to keep specific parts of their knowledge confidential, for instance, for spiritual reasons, to prevent the loss of genetic resources and/or to prevent unsafe or hazardous uses.
- Respond to requests for information from the involved communities and present the information in a suitably adapted form.
- Reflect on options for benefit-sharing (solutions and ideas of the holders of associated traditional knowledge may seem unorthodox to you). Sharing of results in an academic form may not be adequate.

Publication of results and data

- Acknowledge the provider country and/or the collection supplying the genetic resources as the source of the genetic resources in all publications arising from their utilization. This includes written and electronic publications and reports, including sequence data stored in online databases in the public domain.[16]
- When depositing sequence data, unique identifiers associated with the provider (such as an Internationally Recognized Certificate of Compliance code) should also be submitted.
- If in the PIC/MAT for access to the genetic resources utilized non-commercial use is specified, publication of the data should be accompanied by a statement that for uses other than non-commercial, the author/depositor of the data must be contacted and/or permission from the original provider of the genetic resources must be sought.
- When publishing the results of research including Associated Traditional Knowledge, acknowledge its source, unless otherwise agreed upon with the holders of that knowledge. Additional conditions of the provider country or the holders of the knowledge, such as clauses regarding sharing of the benefits resulting from the utilization of the knowledge, must be added. In order to give their informed consent, the holders of the knowledge must be clearly informed that the knowledge will be published. They must be given the opportunity to declare specific information as confidential for instance, for spiritual reasons, to prevent the loss of genetic resources and/or to prevent unsafe or hazardous uses.

13 https://daccess-ods.un.org/TMP/8351190.68622589.html
14 www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:12100:0::NO::P12100_ILO_CODE:C169
15 www.ethnobiology.net/what-we-do/core-programs/ise-ethics-program/code-of-ethics/code-in-english

16 CETAF, Code of Conduct and Best Practice for Access and Benefit-Sharing, 2015. Accessible at http://cetaf.org/taxonomy/publications

Recommendations for institutions

The adoption of the Nagoya Protocol and its implementation by its Contracting Parties is expected to increase legal security and transparency for access and benefit-sharing and ease access procedures for academic research. Its monitoring and compliance measures are essential to promote the confidence of providers.

Since its inception, ABS has been based on bilateral relations between providers of genetic resources and their users. This means that a key element of the system is a contract between providers and users that stipulates the mutual rights and duties and the conditions for access.

The complexity of these contracts varies in relation to the project setting and the access situation: from simple Material Transfer Agreements to complex contracts, for instance if decentralized entities (such as decentralised authorities or holders of traditional knowledge) need to be included or if access contracts are combined with contracts on research partnerships.

Negotiation and conclusion of contracts with external partners is not new for most research institutions. Thus the conclusion of ABS agreements can be integrated into the existing organizational and procedural settings and order of competencies.

However, in comparison with other contracts, access and benefit-sharing presents some specific features. These are worth considering in order to streamline the application for access and avoid time-consuming procedures at the expense of research time. This will also minimize administrative costs for the institution and alleviate the administrative burden for project leaders and researchers.

Among these features are the following:
First, ABS formalities, i.e. the application for the Prior Informed Consent and the negotiation of the Mutually

Due to the need to track the resources in the downstream research and value chain, documentation is crucial. While documentation of the resources used in research is part of the scientific routine, Swiss (and EU) ABS legislation include some specific requirements (see chapter 3) regarding content, storage and transfer of the documentation. In case of inquiries, e.g. by the provider country, the ABS documentation needs to be accessible via the institution.

In sum, the following tasks arise during the lifespan of a research project:[17]

1) During the planning period, the relevance of ABS for the project needs to be assessed; in the affirmative case, and if there is flexibility regarding the sourcing of the genetic resources, the optimal partners (country, collection) ought to be evaluated and benefit-sharing options discussed.
2) In the preparatory period, the access procedure needs to be managed. This includes building contacts to the relevant authorities; inquiring about requirements and conditions; applying for PIC and concluding the MAT; storing the pertinent documents and/or concluding other relevant contracts.
3) During and after the conclusion of the research, compliance with the MAT (in particular the benefit-sharing obligations) is essential.
4) The relevant documentation needs to be stored and maintained; if the genetic resource is stored, it needs to be safely linked to the documentation (see chapter 3).

ABS is not only a legal challenge. Its implementation in an institution may also include strategic reflections and organisational measures.

ABS procedures may be complex. A good overview of the ABS situation in the prospective partner countries and know-how in obtaining relevant information and experience are valuable assets.

17 See also Table IV.

Table IV: How to proceed

Type of Research	Phase	ABS Requirements		Action	Recommendation
Basic Research	Planning			Check at an early stage the ABS requirements of the targeted country for your planned research	Follow the scheme in Table II. Check also the conditions of the provider country regarding the exportation of your material.
			Access *in-situ*	Define schedule and budget for the preparatory phase. Define options and budget for benefit-sharing, in order to discuss possibilities with your institution and to submit a funding request to the research funding agency, together with your project. Inquire about information to be submitted for PIC and modalities for negotiating MAT (focal point, internet).	ABS negotiations might take some time; additional funds might be needed. If there is more than one option regarding the location of the study area, choose a country in which you have established contact with the authorities and/or university institutes and/or choose a country that provides an organized ABS infrastructure and facilitated access for non-commercial research (e.g. Party to the Nagoya Protocol with ABS regulation in place).
			Access *ex-situ* including acquisition from/ transfer through third persons	Inquire for the best way to obtain GR *ex-situ* for your project. Inquire if the utilization planned in your research is covered by the ABS conditions documented for the GR. If not, apply for new PIC and MAT from the provider country.	Follow Table III. If you obtain the resources from an intermediary (e.g. third person or *ex-situ* institution), ensure that the PIC and MAT of the original holder of the material, or the Material Transfer Agreement of the *ex-situ* facility allows the transfer of the material and your intended utilization.
	Preparation of research	Mutually Agreed Terms (MAT)	Field work (PIC and MAT)	Apply for PIC: submit the required information to the identified entry points and stakeholders of the provider country. According to the regulation of the provider country and your planned research, PIC may need to be obtained from: – The Competent National Authorities; – The relevant stakeholders, such as indigenous and local communities; – Different levels of government (central State government, decentralised authorities, etc.).	Apply for access as early as possible as the formalities may be time-consuming. Check whether you need to apply for other types of permits (exportation, research, access to protected areas ...).
				After PIC is granted, negotiate MAT. Negotiate MAT with the ABS Competent National Authority. Comply to these terms throughout the research.	– For elements and possible clauses to be included in MAT, refer to the Model Clauses at www.naturalsciences.ch/abs. – For ABS-negotiations, seek support from your institution's ABS officer, technology transfer unit or legal service department. – Document the application for PIC and all decisions regarding the granting of access to genetic resources and the MAT in written form. Store all data documenting the PIC and MAT processes also if there is no Due Diligence obligation.
	Research			Before starting your research acquire PIC and agree on MAT, including the benefits to be shared. Adhere to the agreed research plan; if this is not possible, renegotiate PIC and MAT. Respect local and national laws and regulations. Respect the customs, traditions, values and customary practices of indigenous and local communities. Respect the principles of conservation and sustainable use of biological resources.	For a list of possible benefits arising in the context of academic research, refer to Appendix III.
				Cooperate with local researchers, research institutions. Engage local research assistants.	A large part of the sharing of benefits may have to be carried out during the research itself. It might be necessary to carefully explain that academic research does not lead to economic benefits in most cases.
	Results and Benefit-sharing		Benefit-sharing (BS)	Share the results with stakeholders of the providing country. Respond to requests for information from local people; communities, institutions. Make documentation of the research findings available to the ABS authority (and other interested agencies) of the provider country; Provide your research partners with access to the research findings.	
	Continuation of research			If you transfer resources to a third party, verify that this is covered by PIC and that the conditions of the initial MAT are known by the recipient. If you transfer rights or processed research material to another institution, ensure that this transfer is covered by the issued PIC and that the specified conditions (MAT) are met. Pass on the documentation on PIC and MAT to the subsequent user.	
Research and Development	Preparation			Access *ex-situ* including acquisition from/transfer through third persons	Inquire for the best way to obtain GR from *ex-situ* for your project. Inquire if your planned research is covered by the ABS conditions related to the resource. If not, apply for new PIC and MAT from the provider.	Follow the scheme in Table III. If you obtain the resources from an intermediary, ensure that the PIC of the original holder of the material covers the transfer of the resource and your planned research intent.
					PIC and MAT for academic research are frequently issued for basic research only. Therefore in case of R&D for a potential commercial product, as a rule, new PIC and MAT have to be applied for in the initial provider country.	The MAT need to include agreements on Intellectual Property Rights and on monetary benefit sharing.
	Research				Seek research and development cooperation with the provider country. Respect any restrictions or limitations on the use of the genetic resources as defined by the provider(s). If your findings lead to essential changes in the project, obtain new consent (PIC and MAT).	
	Results and BS				Share any economic and/or academic benefits resulting from the valorization of the research findings.	When applying for a patent in Switzerland, you need to disclose the source of your GR and ATK. Economic benefits may e.g. result from license fees.
Commercialization				Access *ex-situ* or from third parties	Check whether in PIC and MAT include a potential commercialization of the product is included. If not you need to have a new PIC and negotiate MAT.	There are different triggers to flag "commercialization" (Patenting; applying for market permits ...). The trigger chosen by your provider country needs to be specified in the MAT.
					Promote participation of the providers of the genetic resource in the product development. If possible, develop products in the provider country.	
					Concurrently apply for market admission or commercialization, and notify your Due Diligence compliance to the Swiss Federal Office for the Environment.	
					Share monetary (and non-monetary) benefits according to the MAT.	

Agreed Terms, need to be concluded before accessing the resources. Otherwise, if the legal and administrative situation in the intended provider country is not clear, precious project time is lost to complicated negotiations before the resources can even be accessed.

Second, it is up to the countries how they implement ABS. Therefore, the legal and procedural situation in the provider countries may differ: It might be clearer in countries that are Parties to the Nagoya Protocol and have implementing legislation or regulation and institutions in place than in CBD-only countries and/or Parties to the NP that don't have legislation/regulation and institutions in place (see 2.4). If there is a choice regarding the geographical location for access, it may be preferable to choose a "well-organized" country or a country offering easy access for academic, basic research.

An alternate solution might be to access the resources from a Swiss or European *ex-situ* facility – in particular from a registered collection (see 3.1) – if this is compatible with the research concept.

Third, the administrative organisation of the ABS procedures is up to the countries. The respective competencies and duties may be assigned to an authority that is not familiar with matters of scientific research, for instance to a ministry responsible for trade matters. This means that more background information has to be offered than when negotiating with partners closer to sciences and research. Established relations with responsible people and good experiences help, as well as established cooperation with institutions in the provider country.

The finances necessary for benefit-sharing may need to be integrated into the application for the funding of the project. That means that at an early stage of the planning process it must be clarified what benefit-sharing is possible; this may include early negotiations with prospective partners.

Therefore, it might be commendable to create an ABS specialised function, complementary or joined to the legal competence that is capable of assisting the research units at an early stage in the project. This would allow for accumulating and concentrating knowledge, experience and, over time, could establish a partner network with providing countries. This specialised function could then operate as a pivotal point between researchers and prospective providers, thus unburdening the research units and providing support for developing the best ABS strategy. Tasks of the ABS specialist would include gathering information on relevant contacts and the legal and administrative situation and required procedures in the envisaged provider country; identifying possible alternate solutions and the ensuing obligations. It would be up to the project leaders to assess the relevance of ABS at an early stage of the project and know how to proceed internally. To this end, they need to have a general overview on Access and Benefit-sharing and ensuing obligations.

The following measures are recommended:

- Define research units that are affected by ABS and provide for raising awareness and building capacity. The leaders of these units ought to be able to identify research with potential ABS relevance and take further steps, i.e. inquiry with the ABS specialist.
- Assign the function of ABS specialist to a member of a defined administrative unit. Allow for his/her capacity building. This specialist would assist the principal investigators in all questions related to ABS.
- Organize storage and transfer of the required and additional documentation on the legitimacy of access.

Advantages of institutions as partners in ABS

For the providers/provider country it is important and advantageous to partner with an institution that is able to take responsibility for research, research products and utilization of genetic resources on a long-term basis. This secures control over the utilization of the genetic resources in case of a change of staff in the research units and/or in case of a "change of intent" – i.e. of the transition of research results into industrially-oriented R&D.

3 Implementation of the Nagoya Protocol and the International Treaty in Switzerland

3.1 Implementation of the Nagoya Protocol

Overview

Switzerland ratified the Nagoya Protocol on 11 July 2014, after the adoption of the respective legislation for its implementation, an amendment of the Federal Act on the Protection of Nature and Cultural Heritage (NCHA)[18] (cf. in particular Arts 23n to 23q NCHA). This amendment of the NCHA entered into force with the Nagoya Protocol on 12 October 2014. The related Nagoya-Ordinance[19] was adopted by the Federal Council on 11 December 2015 and entered into force on 1 February 2016.

The Swiss ABS regulations introduce the following measures:

1. A Due Diligence requirement to assure that those who utilize genetic resources according to the Nagoya Protocol, or benefit directly from their utilization, respect the domestic legislation or regulatory requirements of the Party to the Nagoya Protocol that provides the resource and, if required, agree on conditions for benefit-sharing.
2. A requirement to notify compliance with the due diligence obligation to the Federal Office for the Environment (FOEN) before market authorization has been obtained or, if such authorization is not required, before the commercialization of products that have been developed on the basis of utilized genetic resources.
3. The Due Diligence and notification requirements also apply to traditional knowledge of indigenous and local communities associated with genetic resources unless such traditional knowledge is already freely available to the public.
4. A requirement to document resources accessed in Switzerland and the notification to the FOEN before market authorization has been obtained or, if such authorization is not required, before the commercialization of products developed on the basis of these genetic resources.

The Swiss obligations of Due Diligence and notification apply to:
genetic resources that (Art. 23n para 2 and Art. 25d NHCA):
- Have been accessed after 12 October 2014 (the entry into force of the Nagoya Protocol and of the NCHA);
- Originate from a country that
  - Is a Party to the Nagoya Protocol and
  - Has domestic access and benefit-sharing regulatory requirements in place.

Associated Traditional Knowledge not freely available to the public (Art. 23p NHCA).

Due Diligence and notification: useful details

In case of **access *in-situ* in countries requiring PIC**, the Due Diligence obligation requires that the user must store information related to the access and the utilization of genetic resources and/or Associated Traditional Knowledge. This information may be contained in the Internationally Recognized Certificate of Compliance or the documentation of PIC and MAT. This information must be passed on to subsequent users and – in case of commercialization – included in the notification to the FOEN.

Certificate of compliance

The Internationally Recognized Certificate of Compliance serves as evidence that Prior Informed Consent has been granted and Mutually Agreed Terms on benefit-sharing have been concluded. It is constituted by a permit or its equivalent, issued by the provider country at the time of access and made available to the Access and Benefit-sharing Clearing-House (ABSCH) according to a specified template. The certificate is published on the ABSCH.

18 Of 1 July 1966 (Status as of 12 October 2014) Classified Compilation (SR) 451. www.admin.ch/opc/en/classified-compilation/19660144/index.html

19 Of 11 December 2015, SR 451.61. www.admin.ch/opc/de/classified-compilation/20150120/index.html

If the user **accesses the genetic resource *ex-situ***, he/she has to make sure that the collection, institution or third person has lawfully accessed the genetic resources. If the resources are accessed from a Swiss Registered or EU Registered Collection, compliance with Due Diligence is facilitated, as the *ex-situ* collections will provide you with the necessary documentation. In both cases, the user has to verify that the PIC of the provider covers transfer of the material to a third person as well as the planned research. If this is not the case, he/she has to obtain new PIC and MAT from the provider country corresponding to the planned utilization, or desist from utilizing the genetic resource.

Registered Collection

Collections can be important providers of genetic resources and associated traditional knowledge. In this function they can promote compliance of the users with ABS regulations. Collections that guarantee that the resources have been legally accessed and are well documented can be included in the voluntary register maintained by the FOEN.

All information must be stored
- For ten years after having completed the utilization or after the generation of benefits and
- As long as the resource or the resulting product is stored (Art. 3 para 5 Nagoya-Ordinance).

In case of an obligation to notify (see above p. 34, 2.) this information must be notified to the FOEN. The user is obliged to submit all relevant documents as specified in Art. 4 of the ordinance.

In addition, when *applying for a patent in Switzerland*, the patent applicant has to declare the source of the genetic resource (and/or of the ATK) (Art. 49a Patent Law).[20]

For research not leading to a commercial product, notification to the FOEN is voluntary.

20 Federal Act on Patents for Inventions of 25 June 1954, classified compilation 232.14. www.admin.ch/opc/en/classified-compilation/19540108/index.html

Useful Tip

- Document your access procedure and store the documentation. In case of transfer of material to a third person/entity, hand over all corresponding documentation, even if there is no Due Diligence obligation for the accessed resources.
- The precise information that needs to be recorded, stored, passed on to subsequent users and, if a commercialization is involved, also included in a notification to the FOEN, is defined in Art. 3 and 4 of the Nagoya-Ordinance.[21]
- Comply with the Due Diligence obligation, although the authorities will verify compliance with Due Diligence by basic research only sporadically. Correct ABS documentation will be crucial in cases when research on genetic resources turns out to be of commercial interest.

Access to Genetic Resources located in Switzerland

For access to genetic resources located in Switzerland no PIC and MAT is required. But all Swiss and foreign researchers are obliged to document access as follows:
- Name and address of the user, description of the genetic resources and their utilization, date and location of access. If a resource is acquired through a third person, document the name and address of this person and the date of acquisition have to be documented.
- If a genetic resource accessed in Switzerland is transferred to another user, the first user has to document name and address of this person and the date of the transfer.

This information has to be notified to the FOEN before market authorization has been obtained or, if such authorization is not required, before the commercialization of a product developed on the basis of a utilized genetic resource accessed in Switzerland (Art. 8 para 3 Nagoya-Ordinance).

A voluntary notification of the research is possible.

21 For details, see Art. 3 of the Nagoya Ordinance at www.admin.ch/opc/de/classified-compilation/20150120/index.html

3.2 Implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture

Switzerland has implemented the International Treaty in its Law on Agriculture[22] (Arts. 147a and 147b) and the Ordinance on the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture[23] (entry into force on 1 January 2016).

Switzerland has included all material of the National Gene bank in the Multilateral System of the International Treaty

According to this ordinance, material of the collections (e.g. Agroscope Changins-Wädenswil[24]) being part of the National Gene bank is available for research for food and agriculture, as well as for breeding and development and the creation of propagating stock. Access to plant genetic material is provided after the user signs the Standard Material Transfer Agreement (SMTA) of the Multilateral System of the International Treaty. If the material is to be used for other purposes, a specific agreement has to be concluded between the user and the Federal Office of Agriculture. This means that access to all material contained in the National Gene bank for non-commercial, academic research for food and agriculture is quite straightforward. Benefits are shared through results of the research (by publication) (see chapter 5.5)

22 Bundesgesetz über die Landwirtschaft vom 29. April 1998, SR 910.1. www.admin.ch/opc/de/classified-compilation/19983407/index.html

23 Verordnung über die Erhaltung und nachhaltige Nutzung von pflanzengenetischen Ressourcen für Ernährung und Landwirtschaft vom 28. Oktober 2015, SR 916.181. www.admin.ch/opc/de/classified-compilation/20151992/index.html

24 www.agroscope.admin.ch/aktuell/00198/00199/04681/index.html?lang=en

4 Case Studies

This chapter presents cases to exemplify various types of research and possible ABS procedures. They have been selected according to the types of genetic resource and utilization. The exemplified types of research are Botany, Ecology, Agriculture, Medicine and Ethnobotany, including Associated Traditional Knowledge.

Note that the conditions for access are defined by the provider country, so details of the access procedure will vary from country to country.

4.1 Botany: Inventory of flora and vegetation in a tropical region

The project will conduct inventories of the flora and vegetation in an area of the tropics where botany has not previously been studied in detail. The objective is to prioritize areas for conservation and to reach a better understanding of the area's phytogeography. The work will include the following steps: *in-situ* collection of wild plant material; preparation of dried herbarium specimens; taxonomic identification of plants using reference herbarium specimens and molecular techniques; the sending of collected plant material to specialists in different countries for the purpose of identification. It is expected that several new species will be discovered.

This species-level work will yield a floristic inventory of the analysed region. Surveys of vegetation will be conducted in the field and will include analysis of satellite images. Vegetation maps will be drawn using Geographic Information System technology. A distribution analysis of target taxa will also be carried out. In accordance with general practice, it was agreed to deposit identified duplicate samples in a herbarium of the country in which the plant collection occurs.

Genetic resource	Wild plant material
Access	*In-situ* collection
Utilization	Taxonomic identification of plants using morphological-anatomical characterization and molecular techniques, including DNA-Barcoding. It includes sending *in-situ* collected material to taxonomy specialists in other countries.
Stakeholders involved in ABS-procedures	Research institution in user country and the Competent National Authority in the provider country
Steps	Apply for PIC; negotiate MAT. Inquire about export permits.
Notes	MAT: record in writing that the plant material will be sent to specialists for taxonomic identification. Transfer the plant material with a Material Transfer Agreement (MTA) and under the same conditions as the Mutually Agreed Terms (MAT) negotiated with the provider country.

4.2 Ecology: Experiment on tree species diversity in a tropical forest

Logged Dipterocarp forests are being replanted with three levels of tree species diversity for the purpose of investigating how forest diversity affects wood production, carbon storage and other ecosystem processes in tropical regions. The replanting is being carried out using monocultures, low-diversity mixtures similar to those in commercial reforestation areas and using a full mixture of species reflecting the natural diversity of the primary forest.

The aim of the project is to compare community and ecosystem processes in low and in high species diversity plots. The focus of the analysis is on diversity and wood production (carbon sequestration), biogeochemical and hydrological variables, and levels of biodiversity. The field research is being carried out at a state-owned research station of the provider country. Samples of tree litter will be collected for biomass quantification. No material, only data, are exported to Switzerland.

Genetic resource	Tree litter (leaves and twigs)
Access	*In-situ* collection of plant material
Utilization	Weighing of plant biomass, spherical densiometer measurements of canopy coverage.
Stakeholders involved in ABS-procedures	(no ABS case)
Steps	Inquire about necessary research permits, export permits.
Notes	This research project doesn't involve molecular or biochemical analyses of genetic resources and, therefore, it doesn't fall under ABS regulations of the NP. However, check the ABS requirements of the provider country.

4.3 Agriculture: Isolation and assessment of local mycorrhizal fungi for the improvement of yam growth

Yam is the second most important tuber crop in West Africa. Annual demand is constantly increasing, while annual production per hectare has declined considerably. This is mainly due to the prevalence of pests and diseases. Arbuscular mycorrhizal fungi (AMF) have been shown to act as antagonists to pests (e.g. nematodes) and diseases. They also increase the efficiency of soil nutrient uptake and water use, particularly in suboptimal soil conditions, and thus help to increase crop yield.

As a novel approach to protect yam seed material against pathogens, the proposed project assesses the occurrence and diversity of AMF in two African countries.

Soil samples that include arbuscular mycorrhizal fungal communities will be collected jointly by Swiss researchers and researchers from the provider country. The material will be used to analyse soil chemical parameters (pH, organic carbon, and phosphate content). Also, AMF spores will be isolated and identified. Isolated AMF species will be grown together with yam plants in single pots.

The screening of AMF isolated for their potential to improve yam growth will be carried out in collaboration with the International Institute of Tropical Agriculture (IITA) in Benin. Techniques include soil sieving to collect fungi spores, species identification based on morphological characterization and molecular polymerase chain reaction (PCR). Part of the screening will be carried out in Switzerland. AMF cultures will be sent to IITA for future uses.

Genetic resource	Arbuscular mycorrhizal fungi (AMF)
Access	*In-situ* collection of soil samples
Utilization	Isolation and screening of AMF. This includes soil sieving to collect fungi spores, species identification based on morphology and molecular PCR. Cultivation of yam plants in pots together with AMF.
Stakeholders involved in ABS-procedures	Swiss Research Institute and Competent National Authorities of the two provider countries. The involvement of the research institute of the provider country in the ABS negotiations depends on the national regulation of the provider country.
Steps	Apply for PIC and negotiate MAT for the research on the AMF; inquire for conditions of the IITA for utilizing yam tubers.
Notes	Yam is a PGRFA. Therefore, access to the tubers falls under the International Treaty. It is included in Annex I of the International Treaty. Yet, access *in-situ* of Annex I varieties is defined by the provider country.

4.4 Agriculture: Growth and bioactives of native potatoes under drought stress

Decreased water availability under the scenario of climate change will have a significant impact on potato tuber yield, growth and quality. In contrast to commercial potatoes, native potatoes in general have higher tolerance to drought stress, contain higher levels of bio actives (e.g. antioxidants, polyphenols, carotenoids, anthocyanins) and display a wider range of key nutritional compounds (e.g. starch, proteins). Taking into account the ever-increasing importance of potatoes in the agro food industry, this project offers an excellent opportunity to bring scientific research into practical applications. The project aims at (1) assessing the effect of drought stress on tuber induction and growth dynamics in native potatoes by means of computed tomography; (2) quantifying changes in phytochemicals (bioactives) and key nutritional compounds of native potato tubers under drought stress.

Genetic resource	17 native (South American) genotypes of potato (*Solanum tuberosum*)
Access	*Ex-situ:* The material is provided by the Genebank IPK Gatersleben, (Leibniz Institut für Pflanzengenetik und Kulturpflanzenforschung) Germany.
Utilization	Analysis of tolerance to environmental stress, plant physiology and assessment of bioactive and overall nutritional content in potato tubers.
Stakeholders involved in ABS-procedures and steps	Standard Material Transfer Agreement (SMTA) signed by user on behalf of collection
Notes	Potato (*Solanum tuberosum*) is listed in Annex 1 of the International Treaty. Germany is party to this Treaty; IPK Gatersleben is a public gene bank and, accordingly, the potato samples are accessible through the Multilateral System. If – in contrast – the user accesses the potato genetic resources on the private field of a farmer, the national regulation of the provider country applies. The user may have to comply with national ABS legislation/regulatory requirements.

4.5 Medicine: Evolution and epidemiology of tuberculosis

Tuberculosis (TB) causes many deaths and is rapidly increasing in sub-Saharan African countries. The aim of this project is to identify population-based clinical and molecular determinants of tuberculosis epidemiology and ascertain new evidence of the evolutionary pathway of TB in humans and livestock.

The project will establish a molecular characterization and clustering of TB strains in relation to prevalence, animal-human transmission and resistance to antibiotics. Repeated observational field studies will be conducted in close collaboration with the national tuberculosis programme in an African country. Tuberculosis patients will be offered treatment within the framework of national

tuberculosis programmes. Livestock carcasses will be collected in abattoir surveys for the cultivation of *Mycobacterium tuberculosis* complex. Region-deletion polymerase chain reaction and sequencing of single-nucleotide polymorphism of genes responsible for antibiotic resistance of all isolated TB strains will provide specific information on the evolutionary pathways of TB at the interface between humans and live-stock and between West and East Africa.

Genetic resource	*Mycobacterium tuberculosis* complex: *M. tuberculosis*, *M. bovis*
Access	*In-situ:* Livestock carcasses containing Mycobacterium sp. Collecting of bacteria in carcasses and in humans.
Utilization	Isolation and cultivation of *Mycobacterium tuberculosis*; identification of strains with region-deletion polymerase chain reaction, and sequencing of single-nucleotide polymorphism.
Stakeholders involved in ABS-procedures	Research institute and Competent National Authority.
Steps	Apply for PIC and negotiate MAT for access to the micro-organisms.
Notes	Only microbial genetic resources are accessed. Human genetic resources are not included in the CBD.

4.6 Ethnobotany: Ecological impact of repeated harvesting of wild plants

The project focuses on the mutual influence of biological diversity and local indigenous cultural diversity in a biodiversity hotspot in Asia. Five ethnic groups in a remote mountain region will be examined as part of a comparative ethnobotanical survey. The researchers will investigate the differences in plant use and study plant resource management of cultivated and collected wild species among the ethnic communities. The main question to be addressed is whether plant use is influenced by the accessibility of certain species or by the traditional culture of an ethnic group. The ecological impact of repeated harvesting of wild plants on different habitats will be analysed (sustainability of use).

Field work will involve interviews about medicinal plant use, the assessment of plant diversity around the villages, identification of different plant taxa and the impact of repeated plant harvesting. The work will include *in-situ* collection of wild plant material and taxonomic identification of plants using reference herbaria. Modern inventory techniques relating to plant diversity will be applied. Current statistical software tools will be used for the analysis of the semi-structured interviews and participatory observation data.

Genetic resource	Wild plant material
Associated Traditional Knowledge	Knowledge of indigenous and local communities about their use of the plants
Access	Interviews with members of the indigenous and local communities about plant use. *In-situ* collection of plants
Utilization	Taxonomic identification of plants, analysis of interviews and publication of results
Stakeholders involved in ABS-procedures	Research institute, local communities and Competent National Authority
Steps	Apply for PIC of the provider country; inquire with the National Focal Point about conditions for access to Associated Traditional Knowledge; follow instructions to get PIC and MAT of the indigenous and local communities; negotiate MAT with the provider country.
Notes	The term "traditional knowledge associated with genetic resources" is not clearly defined. Here, we assume that it is knowledge about the traditional use of plants. Accordingly, location of plants, harvesting methods and frequency do not fall under the term. This would need to be verified with the Competent National Authority.

Examples of national ABS regulations

Provider countries have sovereign rights over their genetic resources and, accordingly, national regulations have their singularities. Some of them are exemplified below. In any case, users must adhere to the national regulations of the provider country.

In certain countries:

- Access for certain types of basic research do not fall under ABS.
- No PIC and MAT is needed for access to the genetic resources.
- Cooperation with a research institution in the provider country is a precondition for applying for PIC and MAT.
- When issuing PIC, the Competent National Authority can set the prerequisite that a (specific) national institution in the provider country is involved in the research project.
- PIC will be granted solely to national (research) institutes in the provider country, which have to apply for PIC directly.
- PIC and MAT have to be negotiated by the user's research institution and not by an individual researcher.
- Individual researchers can apply for access but only with a letter of guarantee from the Competent National Authority of their home country.
- Researchers have the obligation to apply for PIC and MAT for access to genetic resources and ATK in their own country.
- Only researchers from a foreign country need apply for PIC and MAT.

5 In-depth information on ABS

5.1 The rationale of ABS

Global biodiversity is not evenly distributed over the planet, a fact that is essential to Access and Benefit-sharing. An important part of the global biological diversity occurs in the "countries of the South" where genetic and biochemical compounds found in nature are sought for industrial research. They serve as a basis for research potentially leading to marketable products such as pharmaceuticals, cosmetics and nutritional supplements. The richness in diversity of living species is also of great interest for research and education in the academic world that contributes essential information for the conservation of biodiversity and its sustainable use.

The problem is that the means and technology needed for studying and for adding value to the genetic resources are also unevenly distributed over the globe. Many biodiversity-rich countries lack the technological and economic means to profitably and sustainably exploit their riches, yet are nevertheless responsible for their conservation and sustainable use.

Responsibility for conservation and sustainable use is given to the states on whose territory the biological material is located. However, the entire global community of states has the responsibility to cooperate to this end. For the industrialized countries this means supporting the biodiversity-rich but often economically-poor countries in the endeavour. The keywords in this context are technology transfer and cooperative research. The CBD contains rules that clarify the rights and responsibilities of all parties involved.

In the CBD, biodiversity-rich and technology-rich countries have joined forces for conservation and sustainable use of biodiversity

This scenario of inequality has been aggravated by cases where researchers from both academia and industry have collected, exported and developed genetic resources without the consent of the countries that provided them, and without sharing resulting benefits. This has led to distrust and misgivings vis-à-vis each form of research and to accu-

sations of "biopiracy" from biodiversity-rich countries. It has been particularly egregious where genetic resources were commercially used for products that were patented and profitably marketed without consent of the countries where they were accessed.

It is at this point that the CBD and its system on ABS come into play. By providing a framework for access and utilization of genetic resources and the sharing of benefits arising from their utilization (Art. 15 CBD), it combines the aim of maintaining and conserving biological diversity with economic objectives. Concurrently, it strives to create a balance between the interests of the biodiversity-rich and the technology-rich countries.

It is a give-and-take to facilitate access and equitably share benefits

ABS must be seen against the background of sovereign rights of states over their natural resources, which is confirmed in the CBD. Accordingly, the ABS article of the CBD (Art. 15) establishes that States providing genetic resources have the authority to determine access to their biological resources. This competency of the provider state is counterbalanced by its obligation to create conditions to facilitate access by potential users.

The objective: cooperation between provider and user of a genetic resource

The objectives and rules of the CBD and the Nagoya Protocol apply to accessing and utilizing genetic resources in both commercial contexts and academic research. The focus in this manual is on academic research.

Through the CBD its Parties have explicitly attributed value to the genetic and biochemical components of biodiversity. The utilization of these components for research or for the development of a commercial product is now linked to a permit to access the biological material and to sharing the resulting monetary profits or non-monetary advantages.

5.2 The responsibility of academic researchers

Academic research – including basic research – is an important stakeholder in the ABS scenario. It not only generates relevant new knowledge for conservation and sustainable use of biological diversity, but also a series of benefits for academic researchers themselves, including scientific experience, knowledge and enhanced professional careers. Likewise, academic research generates non-monetary benefits such as education, training, capacity-building, technology transfer and, not least, collaborative research for the provider countries.

Research in a commercial context frequently builds upon results of basic academic research on organisms collected abroad. Therefore, it is essential that the genetic resources are well documented with regard to ABS, in order to provide needed information to potential future users. **When transferring genetic resources to third persons or to storage, researchers are responsible for the transfer of all relevant documentation.**

Solid partnerships with research institutions and local partners from provider countries are not only a way of sharing the benefits of academic research, but also provide support for complying to the ABS requirements of the provider country.

Useful tip

Appendix III contains a list of non-monetary benefits resulting from academic research.

5.3 Key terms: Genetic Resources, Access and Utilization and Benefit-sharing

The term **genetic resources** in the CBD is closely linked to the "genetic revolution" in the second half of the 20th century that brought new insights to the inherent potential of material contained in all organisms. Advances in science have opened new avenues that use genetic information to develop a wide range of products and services in many sec-

tors, *e.g.* agriculture, pharmaceuticals, cosmetics, environmental services and techniques.

It is in this broad sense that the CBD defines genetic resources as genetic material, i.e. material containing functional units of heredity that is of actual or potential value (CBD Art. 2.10). According to the Nagoya Protocol, biochemical compounds contained in organisms are subsumed under this term even if they don't contain functional units of heredity.

As the CBD definition also includes the potential value of such resources, almost all biological material falls under the provisions of the ABS system.

The ABS system covers all types of genetic resources, wild or domesticated, of animal, plant, microbial or other origin, located on private or public land or waters within the territories of CBD Parties. ABS obligations apply to research on resources that are located and collected *in-situ* or procured from *ex-situ* facilities or from academic partners. Excluded from the scope of application of the CBD are human genetic resources.

The term **"access"** is not defined in the CBD or in the Nagoya Protocol. Thus, its meaning depends on the interpretation of each provider country. The Nagoya Protocol, in its Art. 6, links "access to genetic resources" to the PIC of the provider country, and sets **"utilization of genetic resources"** as the trigger for the benefit-sharing obligation. Utilization of genetic resources means to "conduct research and development on the genetic and/or biochemical composition of genetic resources, (Art. 2(c) NP). **"Research and development"** is not defined in the Nagoya Protocol. It includes all types of research in academic and commercial contexts: basic research as well as research and development aimed at new and potentially profitable products or procedures.

Plant Genetic Resources for Food and Agriculture (PGFRA) are defined as any genetic material of plant origin of actual or potential value for food and agriculture. The term "genetic material" includes reproductive and vegetative propagating material containing functional units of heredity (Art. 2 International Treaty). National legislation may define in more detail which resources are subject to the International Treaty (e.g. wild relatives of domesticated varieties or medicinal plants).

The requirement to **share fairly and equitably the benefits resulting from the utilization of genetic resources and/or associated traditional knowledge** sets out from the premise that every utilization of genetic resources and/or associated traditional knowledge in the sense of the CBD and the Nagoya Protocol generates economic or non-economic values. Principles of equity demand that these values are shared in a fair way with the custodians of the underlying biological diversity and traditional knowledge.

5.4 International legal framework

The international legal framework of ABS consists in the CBD (primarily its Article 15), the Bonn Guidelines on Access and Benefit Sharing (Bonn Guidelines) and the Nagoya Protocol, as well as the International Treaty on Plant Genetic Resources for Food and Agriculture.

The CBD and the Nagoya Protocol

The mechanism linking access to genetic resources to the sharing of benefits resulting from their utilization has been first laid down in the **CBD**. However, Art. 15 of the CBD only includes the basic principles of ABS. In order to facilitate the implementation of the ABS system in the Parties, the **Bonn Guidelines** (BGL) were elaborated and adopted by the Conference of the Parties to the CBD in 2002. The BGL are voluntary and intended to guide both providers and users of genetic resources in the implementation of ABS. They are a useful source to help understand the mechanism.

In 2010 the **Nagoya Protocol** was adopted by the parties to the CBD. It entered into force on 12 October 2014. To date

(July 2016) it has been ratified by 74 States;[25] Switzerland is among them.

The Nagoya Protocol substantiates the CBD's ABS provisions. It aims at providing greater legal certainty and transparency for both providers and users of genetic resources. It sets out core obligations for its Contracting Parties to take measures in relation to access to genetic resources, benefit-sharing and compliance. It defines roles and responsibilities of the providers and users of genetic resources and includes measures to facilitate access and to promote compliance. How Parties implement the system at the national level depends on the political decision of each individual Party.

The Nagoya Protocol also applies to academic research. The Nagoya Protocol explicitly recognizes the importance of research for conservation and sustainable use of biological diversity. Parties should, therefore, create conditions to promote this type of research, including simplified measures with regard to access for non-commercial purposes. The Nagoya Protocol specifies that if facilitated access for research is granted, the possibility of a "change of intent" needs to be addressed (Art. 8 [a] NP). For example, a change of intent occurs with the transition of a resource from the academic to the commercial field.

The ABS system is also applicable to the **Traditional Knowledge of Indigenous and Local Communities Associated with Genetic Resources** (Associated Traditional Knowledge). If research involves Associated Traditional Knowledge, indigenous and local communities are to be involved in the ABS procedures.

The obligations of the Nagoya Protocol are applicable to genetic resources and associated traditional knowledge that have been accessed *in-situ* after its entry into force on 12 October 2014.[26]

25 Update available on the ABS Clearing House (absch.cba.int)

26 The interpretation of the temporal scope is still under discussion among the parties to the Nagoya Protocol.

For parties to the CBD that have not (yet) ratified the Nagoya Protocol, only the basic obligations of the CBD are applicable. Researchers who access resources in these countries must comply with their national legislation or regulatory requirements but are not subject to the Swiss ABS legislation.

The International Treaty on Plant Genetic Resources for Food and Agriculture

The International Treaty applies the principles of access and benefit-sharing to plant genetic resources for food and agriculture.

Agricultural crop-breeding depends on easy access to and exchange of crop varieties. The implementation of the full bilateral ABS system of the CBD would hamper plant breeding. Therefore, in the International Treaty on PGRFA the Multilateral System of Access and Benefit Sharing (Multilateral System) was negotiated to facilitate access and benefit-sharing to a series of the most important varieties of crops.

The goal was to create a system that is efficient, effective and transparent. The Multilateral System offers a standardised procedure for access to the PGRFA and the sharing of benefits resulting from their utilization.

The Multilateral System establishes a global approach of granting everyone access to the genetic resources of (at least) 64 crop and forage species that are selected according to their importance for food security and their interdependence. It also aims to ensure the fair and equitable sharing of benefits arising from the utilization of these genetic resources in order to promote conservation, sustainable use and further development of agriculture (in the developing world). The crops are listed in Annex I of the International Treaty.[27] For specified utilizations – conservation, research and breeding – users of genetic resources simply sign the International Treaty's Standard Material Transfer Agree-

27 www.planttreaty.org/content/crops-and-forages-annex-1

ment (SMTA) issued by a gene bank that participates in the system. Accordingly, there is no need to either verify legitimate access of the gene bank, to track the origin of the accessions or to negotiate individual agreements.

The Multilateral System of the International Treaty offers a standardized system for access to PGRFA and benefit-sharing

In terms of benefits, the user agrees to share the results of his research/breeding. If the user develops a commercial product and concurrently limits access to the product (by intellectual property rights), a percentage of the commercial product profit must be paid into a common funding pool.

The Multilateral System consists of collections that include varieties

- that are under the control and management of governments of the contracting parties;
- that belong to private or legal persons that have been voluntarily included in the system;
- that are stored in the International Agriculture Research Centres (IARCs) of the Consultative Group on International Agricultural Research (CGIAR).

Non-Annex I varieties can be included voluntarily into the Multilateral System by the contracting parties, for instance Switzerland has done this.

For information on which set of international rules applies to your research, see Tables II and III in chapter 2.4.

Useful tips

In the following cases, access to PGRFA is subject to the ABS legislation/regulation of the provider country:

- Access *in-situ*;
- Access *ex-situ* to varieties that are not listed in Annex I of the International Treaty (and not included in the Multilateral System by the provider country);
- Access *ex-situ* in countries that are not party to the International Treaty
- Access *ex-situ* to all varieties in collections that are not included in the Multilateral System.

Useful sources for access to PGRFA

- Parties to the International-Treaty: www.planttreaty.org/list_of_countries
- National Focal Points: www.planttreaty.org/nfp
- Collections included in the Multilateral System: www.planttreaty.org/inclusions

5.5 Associated Traditional Knowledge

Traditional Knowledge Associated to Genetic Resources

The CBD and the Nagoya Protocol do not provide a definition of the term "Traditional Knowledge Associated to Genetic Resources". It is left to the parties to define thze term in their implementing measures. The following definition is adapted from the definition used in the discussions of the World's Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore:

> Associated Traditional Knowledge is knowledge resulting from intellectual activity in a traditional context that is specific or general in its relationship to genetic resources. It includes know-how, practices, skills and innovations. It can be found in a wide variety of contexts, including: agricultural knowledge; scientific knowledge, technical knowledge, ecological knowledge, medicinal knowledge, including related medicines and remedies; and biodiversity-related knowledge.
> www.wipo.int/tk/en/resources/glossary.html#50

Access to Associated Traditional Knowledge

According to the Nagoya Protocol, details of the procedure for access to Associated Traditional Knowledge have to be determined by the countries that are Party to the Nagoya Protocol, within the borders of which the indigenous and local communities are located. The countries are to ensure that Associated Traditional Knowledge held by indigenous and local communities is accessed with PIC or approval and involvement of the communities, and that MAT are nego-

tiated. They also must establish mechanisms and instruments to inform potential users of Associated Traditional Knowledge about their obligations. In some countries, governments are working together with the communities to set up the respective systems and procedures.

In the CBD this principle is less clear. But also in countries that are only Party to the CBD, ABS with regard to associated traditional knowledge depends on the national legislation/regulation of the country where the associated traditional knowledge provider is located.

1. Associated Traditional Knowledge can only be accessed with PIC or approval and participation of the involved indigenous and local communities. MAT must also be established.
2. Respective steps and procedures are fixed in the legislation/regulation of the provider country.
3. The provider country, the ABS Focal Point and/or Competent National Authority must supply information to potential users.

The same principles apply in cases where communities have an established right to grant access to the genetic resources situated on their territory (Art. 6.2. Nagoya Protocol).

Ongoing international developments

In two international organizations there are ongoing participatory processes to implement the CBDs/NPs rules on access to Associated Traditional Knowledge.

In 1998, the Conference of the Parties to the CBD appointed the **Ad-hoc Working Group on the implementation of Art. 8(j)** (of the CBD)[28] **on traditional knowledge of indigenous and local communities.**[29] At present, this working group is developing guidelines that include assisting Contracting Parties in creating mechanisms to ensure 1) that indigenous and local communities obtain a fair and equitable share of benefits; 2) that entities interested in using Associated Traditional Knowledge obtain the PIC of the indigenous and local communities.[30] **The World Organization on Intellectual Property – in its IGC**[31] – "is undertaking text-based negotiations with the objective of reaching agreement on (a) text(s) of an international legal instrument(s), which will ensure the effective protection of traditional knowledge (TK), traditional cultural expressions (TCEs) and genetic resources (GRs)".[32]

28 This article introduces the basic elements of ABS to ATK.

29 Ad Hoc Open-ended Inter-sessional Working Group to address the implementation of Article 8 (j) and related provisions; www.cbd.int/traditional/intro.shtml. Cf Decision IV/9 of the Conference of the Parties, www.cbd.int/decision/cop/default.shtml?id=7132.

5.6 Elements of the ABS procedure: Authorities and instruments

According to the Nagoya Protocol, countries as providers are free to decide whether they want to control access to and utilization of the genetic resources on their territory. Also it is in the discretion of the Parties to decide on the details of the procedures for access to genetic resources and Associated Traditional Knowledge.

The CBD, in its Art. 15, spells out the basic elements of the ABS procedure: Prior Informed Consent, Mutually Agreed Terms, and Fair and Equitable Sharing of Benefits arising out of the utilization of genetic resources.

The Nagoya Protocol, in order to enhance efficacy and transparency of the ABS procedures and to facilitate the monitoring of the utilization of the resource, clarifies and specifies the procedural requirements and proposes an institutional structure for the Parties: National Focal Points, Competent Authorities and Checkpoints. On the international level it establishes the ABS Clearing House and – in order to facil-

30 For the respective draft guidelines, see the Annex of Recommentdation 9/1. Adopted by the Working Group on 7 November 2015, UNEP/CBD/WG8J/REC/9/1, accessible at www.cbd.int/recommendations/wg8j/?m=wg8j-09; CBD programme of work on the implementation of Art. 8(j) and related provisions of the Convention on Biological Diversity; accessible at www.cbd.int/traditional/pow.shtml;

31 Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

32 www.wipo.int/tk/en/

itate the administrative burden for users – provides for an Internationally Recognized Certificate of Compliance.

Prior informed consent, Mutually Agreed Terms and the Sharing of Benefits

Prior Informed Consent is a unilateral declaration of the authority defined by the national legislation/regulation of the provider country. In many cases this will be the Competent National Authority.

PIC means, in principle, that the provider country has been informed of the planned research as part of the application process and that it gives its consent prior to the start of the research.

The prior informed consent is a prerequisite for access to biological resources. In many cases, the required information and the procedure are specified in national regulations. Under national regulation it may also be necessary to include stakeholders involved at various intermediary levels in the PIC process, especially if your research involves ATK.

According to the Nagoya Protocol, the National Focal Points are to provide information on procedures for PIC and MAT, including procedures of access to ATK, and on addressing competent national authorities and other relevant stakeholders (Art. 13.1 NP).

Mutually Agreed Terms are a contract negotiated between the users and providers of genetic resources. This contract defines the conditions for access to genetic resources and grants permission for their utilization. And, crucially, it incorporates an agreement on how to share the benefits arising from the utilization of the genetic resources. The regulatory requirements of the provider country and the complexity of the proposed research influence the elements of MAT. Countries may have official standard formats for the MAT. The Swiss Academy of Sciences offers a MAT toolkit for non-commercial academic research that is meant to serve as a template that can be applied to fill the gap where no national tools are available (s. Chapter 2.1).[33]

The fair and equitable sharing of benefits arising from the utilization of genetic resources and/or Associated Traditional Knowledge is one of the main rationales of ABS. The CBD, in its Art. 15.7., explicitly spells out that this includes "sharing … the results of research and development and the benefits arising from the commercial and other utilization of genetic resources…". Accordingly, the principle of fair and equitable sharing of benefits extends to academic research. Although this type of research yields benefits that are non-monetary as a rule, they nevertheless are of value to the provider country, particularly for conservation and sustainable use of biological diversity. Academic research benefits include the research results, education and capacity building, technology transfer and the establishment of permanent academic networks and cooperation (see Appendix III). With these tools, science and research can help bridge the North-South divide through the transfer of urgently needed knowledge and technology.

Responsible public agencies on national level: National Focal Point; Competent National Authorities and Checkpoints

The **National Focal Points** are the first contact point for researchers or other applicants seeking access to genetic resources and/or Associated Traditional Knowledge. They are meant to provide information on procedures for obtaining PIC and negotiating MAT, including from holders of Associated Traditional Knowledge; and to advise how to address the authorities, indigenous and local communities and other involved stakeholders. Contact information on the National Focal Points can be accessed on the ABS Clearing House.[34]

The **Competent National Authorities** are responsible for granting access and for issuing written evidence that the user has

33 Accessible at www.naturalsciences.ch/organisations/biodiversity/abs/publications

34 absch.cbd.int

met the access requirements, ideally in the form of an internationally recognized certificate of compliance. In many cases, the Competent National Authorities are the primary partners for the negotiation of the MAT.

Checkpoints

Checkpoints are a means to enhance transparency about the utilization of genetic resources and to support compliance. Their task is to monitor the utilization of genetic resources. Parties are to designate one or several checkpoints. The checkpoints collect or receive relevant information related to (1) prior informed consent, (2) the source of the genetic resources, (3) the establishment of mutually agreed terms and/or the utilization of genetic resources (NP Art. 17).

Checkpoints transfer a summary of the information collected or received (except confidential information) to the ABS Clearing House where it is published (checkpoints communiques). Thus, information on the provided genetic resources becomes accessible for the providers/providing countries. For instance, the Swiss Checkpoint can submit selected (non-confidential) information to the ABSCH that it receives in connection with the Swiss obligation of notification that its users have (see Art. 23o 2 NCHA).

Useful tip

National authorities and their competences, as well as conditions and requirements for granting access, are specified in the national law and regulations of the provider countries. The National Focal Points are meant to provide respective information.

The designation of these administrative structures is not required in CBD-only countries!

Assistance to transparency and information flow: The ABS Clearing House and the International Recognized Certificate of Compliance.

The **Access and Benefit-sharing Clearing-house** (ABSCH) is an internet-based, global information portal and database to facilitate access to and exchange of information on ABS. It is a key tool for facilitating the implementation of the Nagoya Protocol.

The purpose of the ABSCH is to enhance legal certainty and transparency on procedures for access, and for monitoring the utilization of genetic resources along the value chain. It thus builds a bridge between the needs of providers and users by supplying relevant information on parties to the Convention on Biological Diversity and the Nagoya Protocol.

The ABSCH is established by the Nagoya Protocol (Art. 14) and maintained by its international secretariat. The Protocol identifies the information that Parties either must or may submit to the Clearing-House. It provides information that is relevant for providers and users of genetic resources and Associated Traditional Knowledge:

What users seek	Information on the ABSCH
Access to GR and ATK – A clear understanding of how to access – Legal certainty for utilization of the GR and TK	– Status (Party to the NP or not) of a country – Contact data of the Focal Point and the Competent National Authority – Legislative, administrative or policy measures – National websites and databases – Internationally Recognized Certificate of Compliance

What providers want	Information on the ABSCH
Monitoring of compliance: – Control over of GR and ATK – Ensure that users comply with MAT – Assurance of entitled benefits arising from utilization	– Checkpoints contact data – Checkpoint communiques that allow the provider to monitor the utilization of the resource

Useful tip The ABSCH is a/the first point of information when planning research on Genetic Resources and/or associated Associated Traditional Knowledge in the provider country.

The **Internationally Recognized Certificate of Compliance** is meant to ease the documentation of the legitimate access to the genetic resources and/or Associated Traditional Knowledge throughout the value chain. It is issued by the provider of the genetic resource and/or Associated Traditional Knowledge according to a format defined and registered by the ABSCH. The certificate serves as evidence that the genetic resource it covers has been accessed in accordance with (1) prior informed consent and (2) mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of genetic resources through the value chain.

Appendix

I Additional permits for research on Genetic Resources

Research on genetic resources might require additional permits either at the national level from the provider country (i.e. research permits, export permits, phytosanitary certificates) or at the international level (permits based on the International Convention on the Trade with Endangered Species of Wild Fauna and Flora [CITES]).

National level

Research permit

A research permit is a unilateral order from the appropriate ministry (e.g. research, education) of the host country. It frequently has a standardized form. It might be required in addition to the Prior Informed Consent. Researchers should inquire whether a specific research permit must be applied for.

If you access resources in a country without ABS legislation or procedures, legal security is increased if some essential ABS elements are included in your research permit to make it compatible with ABS requirements. To this end it is recommended that you indicate benefits to be shared (e.g. cooperation with…); include permitted use (e.g. no commercialization) and a clause about intellectual property rights (e.g. no patenting of the research results).[35]

Export permit

Many countries require permits for the exportation of samples of natural resources; there might be a ban on the exportation of specific varieties/organisms. If you plan

35 For more information, see "Agreement on Access and Benefit-sharing for academic research Annex IV.
Accessible at www.naturalsciences.ch/organisations/biodiversity/abs/publications.

to analyse samples in your home institution, at an early planning stage inquire about conditions for exportation. There are also countries (e.g. Brazil) where the export permit is included in the PIC and MAT.

Phytosanitary Certificate

Plant protection certificates are issued after phytosanitary control by official plant protection services of the exporting countries in compliance with international standards (IPPC-International Plant Protection Convention). In Switzerland, such certificates are required for import/export of virtually all the plant material from/to non-EU countries. Plant protection certificates for exports are issued by the Plant Protection Services of Agroscope and FOEN/WSL (Swiss Federal Institute for Forests, Snow and Landscape Research).[36]

International Level

Under the CITES agreement, any crossing of national borders by live animals and plants and all parts and products are defined as trade; the CITES obligations, therefore in most cases, apply to academic research

International Convention on the Trade with Endangered Species of Wild Fauna and Flora (CITES)

The CITES is a trade agreement. The convention intends to ensure that international trade in species at risk is limited to the extent permitted by their natural stocks as agreed by its over 180 Parties.

Any crossing of national borders by live animals and plants and all their parts and products is defined by CITES as trade; the CITES obligations are, therefore in most cases, applicable for academic research. A precondition for all CITES permits is that the specimens have been legally obtained. This includes compliance with the ABS regulatory requirements of the provider country.

There exists an exemption from the CITES permits for non-commercial loan, donation or exchange of herbarium specimens and for other preserved, dried or embedded museum specimens, and live plant material between registered scientific institutions. No export permit is needed if the specimens carry a label issued or approved by a CITES Management Authority, and if they are transferred among *registered scientists or scientific institutions*. This implies that both the sending and the receiving institutions have been registered by their corresponding CITES Management Authorities. For registration, these institutions need to meet requirements for state-of-the-art collection and curation.[37]

Trade in species *threatened with extinction* (Appendix I) is permitted only in exceptional circumstances. Both an export permit issued by the CITES Management Authority from the state of export, and an import permit issued by the Management Authority from the state of import are required.

Appendix II includes species not necessarily threatened with extinction, but in which trade must be controlled in order to avoid utilization incompatible with their survival. An export permit or re-export certificate issued by the Management Authority of the state of export or re-export is required and, in most countries, an import permit is also required.

A country can ask other CITES signatories for assistance in controlling the trade (Appendix III). In this case, an export permit issued by the Management Authority of that state, a certificate of origin from other states within the range of distribution of the species concerned and, in cases of re-exports, a CITES re-export certificate are required. Some countries also require import permits.

36 www.phytosanitarycertificate.ch/?action=page&page=HOME

37 The list of registered institutions is accessible under www.cites.org/eng/common/reg/e_si.html

II Glossary

Term	Description
ABS Clearing-House	The term refers to the global information portal that is established by the Nagoya Protocol and maintained by its International Secretariat. The Protocol identifies information that Parties either must or may submit to the Clearing-House. The ABS Clearing-House is an important information-hub for ABS (Glossary for Europe[28]).
Access (to genetic resources)	The term "access to genetic resources" is not defined in the CBD and, therefore, varies according to national legislation/regulation and practices. Researchers must verify with the provider country which of their activities are subsumed as access in the national regulations.
Benefit (monetary/ non-monetary)	Economic or academic advantages arising from research on/utilization of genetic resources and/or Associated Traditional Knowledge
Benefit-sharing Fund	A common fund to support conservation and further development of agriculture, particularly in the developing world. The fund is fed by the payment of a percentage of benefits resulting from the commercialization of genetic resources (protected by Intellectual Property Rights) under the Multilateral System.
Biochemical compound	Biochemically active part of (plant) genetic resources. Research on the biochemical composition is included in the term "utilization of genetic resources" that triggers ABS, according to the Nagoya Protocol (Art. 2 [c] Nagoya Protocol).
Biological diversity/ Biodiversity	Variability that exists among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part. This includes diversity within species, between species and their ecosystems (Art. 2.1 CBD).
Biological material, Biological resources	Biological resources include genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity (Art. 2 CBD).
Change of intent	The alteration of intended use of resources accessed under MAT for basic research (no commercialization) to that for research and development for potential commercial use. In case of such "change of intent," new PIC and MAT of the providers is needed.
Commercialization	Commercialization means to sell products developed on the basis of utilised genetic resources or of utilised associated traditional knowledge, as well as other legal transactions in connection with utilised genetic resources or with utilised traditional knowledge that result in monetary benefits, in particular licences, pledge agreements or similar legal transactions (Nagoya-Ordinance, Art. 2e)
Competent National Authority	Agency in the provider country that is entitled to grant access, namely to issue the PIC and to negotiate and conclude the MAT according to its national legislation and regulatory requirements
Contracting Party	State that has ratified an international convention and thus has to implement its obligations on national level
Due Diligence	According to the Swiss legislation (Art. 23n) due diligence in access and utilization of GR requires that resources are accessed lawfully and that MAT are established. The exercise of due diligence "appropriate to the circumstances" is the responsibility of the user.
Ex-situ	Cf. *in-situ*
Genetic resources	Genetic materials, i.e. any material of plant, animal, microbial or other origin containing functional units of heredity that is of actual or potential value (Art. 2 CBD. The value need not be commercial [i.e. monetary]), but may be scientific or academic in nature.
Genetic resources value chain	The term is used to describe the totality of typical steps taken to create environmental, social and economic value from genes and naturally occurring bio-chemicals found in nature. The genetic resources value chain starts with the collection of some material and possibly ends with the successful commercialization of a final product. Typical progression is from the collection of genetic resources, the storage of collected material, basic research on genetic resources, applied research on genetic resources, the development of products and eventually the commercialization of products. Not all these steps will necessarily be taken for each sample collected in the wild. Not all collected material is stored in collections. In a few cases, material is collected by an agent of a company specifically interested in a sample of a known organism. Most basic research will not result in concrete applications; much applied research ends without moving to the development of a product. Additionally, many development efforts never make it to the product approval stage (Glossary for Europe).
Indigenous and local communities	The CBD and the Nagoya Protocol do not define this term. It is left to the Parties of the Protocol to define this term in their implementing measures. In the context of the Nagoya Protocol the term 'indigenous and local communities' is generally understood to encompass communities living close to nature and holding genetic resources and traditional knowledge associated with genetic resources (Glossary for Europe).
In-situ/ex-situ	Genetic resources can be wild, domesticated or cultivated. *'In-situ'* genetic resources are those found within ecosystems and natural habitats. *'Ex-situ'* genetic resources are those outside their normal ecosystem or habitat, such as in botanical gardens or seed banks, or in commercial or university collections (CBD Secretariat Information Kit[37]).
International Plant Exchange Network (IPEN)	IPEN is a voluntary registration system intending to facilitate plant exchanges of member botanical gardens in accordance with the CBD provisions.
Internationally recognized certificate of compliance	A certificate issued by the provider of the genetic resource and/or Associated Traditional Knowledge, according to a format defined by the ABSCH and registered by the ABSCH. The certificate serves as evidence that the genetic resource it covers has been accessed in accordance with (1) prior informed consent and that (2) mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of genetic resources through the value chain.

38 Glossary for Europe: Glossary of key terms used in the context of "Access and Benefit-sharing" ec.europa.eu/.../Glossary%20for%20Europa.pdf

37 CBD Secretariat InformationKit: Access and benefit-sharing information kit. Introduction to access and benefit-sharing, glossary. www.cbd.int/abs/information-kit-en

Material Transfer Agreement (MTA)	Contract that governs the transfer of tangible research materials between two organizations when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.
Multilateral System of ABS (MLS)	The Multilateral System establishes a global approach of simplified access to specified PGRFA and sharing of benefits from their utilization in order to promote conservation and sustainable use (www.planttreaty.org).
Mutually Agreed Terms (MAT)	An agreement between provider country/provider of genetic resources and traditional knowledge and the users, on the conditions of access and utilization of the resources, and on the benefits to be shared between both parties (CBD Secretariat Information Kit).
National Focal Point	Agency established by the state that provides information on authorities/communities to contact, on conditions for access to genetic resources and Associated Traditional Knowledge, and procedures to observe.
Party see	Contracting Party
Plant Genetic Resources for Food and Agriculture (PGRFA)	Any genetic material of plant origin of actual or potential value for food and agriculture. "Genetic material" means any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity (Art. 2 International Treaty).
Prior Informed Consent (PIC)	Permission given by the Competent National Authority of a country to an individual or institution seeking to obtain access to genetic resources, complying with an appropriate legal and institutional framework (CBD Secretariat Information Kit)
Provider country	Party providing genetic resources that is the country of origin of such resources or that has acquired the resources in accordance with the CBD (Art. 15 CBD, Art. 6 NP)
Provider	Institution that according to the domestic legislation or regulatory requirements has the competence to grant access. It may be different from the Competent National Authority (institution with delegated competence) or act in addition to the Competent National Authority (Holders of ATK, decentralised agency).
Traditional Knowledge (associated to genetic resources)	Associated Traditional Knowledge is knowledge resulting from intellectual activity in a traditional context that is specific or general in its relationship to genetic resources. It includes know-how, practices, skills and innovations. It can be found in a wide variety of contexts, including: agricultural knowledge; scientific knowledge, technical knowledge, ecological knowledge, medicinal knowledge, including related medicines and remedies; and biodiversity-related knowledge. www.wipo.int/tk/en/resources/glossary.html#50
User of genetic resources	In the academic context, all researchers who access genetic resources (cf. above) and/or make use of genetic resources
Utilization of genetic resources	To conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology… (Art. 2(c)NP)

III Benefit-sharing in the context of academic, non-commercial research[40]

Sharing of Academic benefits

- Provide access to scientific data resulting from the research, including the necessary infrastructure
- Provide access to *ex-situ* facilities
- Integrate partners into the reviewing process
- Co-publish research findings with research partners
- Support the academic careers of research partners
- Maintain institutional and professional relationships

Capacity building, scientific cooperation, participation, technology transfer

- Train local researchers in the field and in the laboratory
- Share samples
- Secure finance for maintenance of collections
- Provide research infrastructure (e.g. laboratory equipment)
- Provide communication infrastructure
- Integrate local researchers into scientific and practical work
- Integrate local assistants into practical work
- Implement research on a cooperative basis: cooperative project design; cooperative project implementation

Increased availability of information and knowledge

- Provide ongoing information about research, progress and expected results
- Inform all involved stakeholders about results in a form that is adapted to the target audience
- Maintain contact with (local) representatives of administration, government agencies and research institutes

40 Adapted from the Bonn Guidelines and the Nagoya Protocol.

Application, research and development, patenting

- Develop research directed at the practical needs and problems of the provider country
- Promote participation in product development
- Establish joint ownership of relevant intellectual property rights based on the level of contribution
- Share economic benefits (e.g. resulting from license fees)

Useful tips

- Benefits should be aimed at conservation and the sustainable use of biological diversity.
- Benefits should be shared fairly and equitably between all those who have contributed to the resource management and scientific and/or commercial process.
- Differences exist in benefit-sharing options between basic research, applied research and research and development for commercial uses.
- It may be necessary to explain carefully that academic research does not lead to economic benefits in most cases.
- A large part of the sharing of benefits may have to be carried out concurrently with the research itself.
- There are benefits that can only be shared once research has been accomplished.

IV Links and Sources

Switzerland

- Swiss Federal Office for the Environment (FOEN): www.bafu.admin.ch
- FOEN ABS website:
  - e: www.bafu.admin.ch/Nagoyaprotocol
  - d: www.bafu.admin.ch/NagoyaProtokoll
  - f: www.bafu.admin.ch/protocoleNagoya
  - i: www.bafu.admin.ch/protocolloNagoya
- Swiss Information System Biodiversity (SIB): www.sib.admin.ch/en/index.html
- Bundesamt für Landwirtschaft (BLW); www.blw.admin.ch
- BLW, International, Agrobiodiversität und genetische Ressourcen: www.blw.admin.ch/themen/00009/01779/01808/index.html?lang=de
- BLW, Agroscope, Schweizer Forschung für Landwirtschaft, Ernährung und Umwelt, Pflanzengenetische Ressourcen: www.agroscope.ch/ressources-phytogenetiques/index.html?lang=de
- Swiss Academy of Sciences (SCNAT), Information on ABS for academic research: www.naturalsciences.ch/organisations/biodiversity/abs
- Swiss Academy of Sciences (SCNAT), Agreement on Access and Benefit-sharing for Non-commercial Research – Sector specific approach containing Model Clauses: www.naturalsciences.ch/organisations/biodiversity/abs/publications

Convention on Biological Diversity (CBD)

General website: www.cbd.int
CBD text: www.cbd.int/convention/text
Nagoya Protocol, general website: www.cbd.int/abs
Nagoya Protocol, text: www.cbd.int/abs/text/default.shtm
ABS Clearing-House: http://absch.cbd.int
CBD Secretariat (2011) Access and benefit-sharing information kit: www.cbd.int/abs/information-kit-en

International Treaty on Plant Genetic Resources for Food and Agriculture

General website: www.planttreaty.org
ITPGRFA Text of the Convention and Annex 1:
www.planttreaty.org/content/texts-treaty-official-versions
Collections included in the Multilateral System on Access and Benefit-sharing: www.planttreaty.org/inclusions

World Intellectual Property Organization

Searchable database of actual and model biodiversity-related access and benefit-sharing agreements with particular emphasis on the intellectual property aspects of such agreements:
www.wipo.int/tk/en/databases/contracts/index.html

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

CITES general website: www.cites.org
CITES convention text:
https://www.cites.org/eng/disc/text.php
CITES convention, Annexes:
https://www.cites.org/eng/app/appendices.php
CITES Management Authority in Switzerland:
Federal Food Safety and Veterinary Office FSVO
www.cites.org/eng/cms/index.php/component/cp/country/CH
www.cites.ch
Register of scientific institutions entitled to the exemption for non-commercial donation, exchange or loan of listed species: www.cites.org/eng/common/reg/e_si.html

European Union

EU ABS website includes: Legislation, registered collections, background material and links:
http://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm

Germany

Bundesamt für Naturschutz, ABS Deutschland:
www.bfn.de/index_abs+M52087573ab0.html
German Research Foundation
Supplementary Instructions for Funding Proposals Concerning Research Projects within the Scope of the CBD:
www.dfg.de/formulare/1_021e/1_021e.pdf

Other Guidelines and Sources

Botanic Gardens

International Plant Exchange Network (IPEN), general website:
www.bgci.org/policy/ipen
Botanic Gardens Conservation International:
learning modules for botanic gardens:
www.bgci.org/policy/abs_learning

Micro-organisms Sustainable use and Access regulation International Code of Conduct

http://bccm.belspo.be/documents/files/projects/ → mosaicc
http://bccm.belspo.be/documents/files/projects/ → mosaics
http://bccm.belspo.be/documents/files/projects/ → trust

International Institute for Sustainable Development

ABS Management tool. Best Practice Standard and Handbook for Implementing Genetic
Resource Access and Benefit-sharing Activities. A handbook that provides voluntary guidance to the users and providers of genetic resources and focuses on commercial research.
Provides useful guidance on negotiating partnerships:
www.iisd.org/library?keys=ABS+Management+Tool+

V National Focal Point

Swiss National Focal Point to the Nagoya Protocol
Soil and Biotechnology Division
Federal Office for the Environment (FOEN)
3003 Bern
Switzerland
E-mail: contact.np @bafu.admin.ch

The purpose of this manual is to inform the academic community about the system governing access to genetic resources and Associated Traditional Knowledge and the sharing of the benefits arising from their use as established by the Convention on Biological Diversity and its Nagoya Protocol. The brochure explains the steps that researchers must take when accessing biological resources for research purposes and it informs about the ABS legislation in Switzerland.
The manual is a Good Practice Guide in the sense of Art. 20.1 of the Nagoya Protocol.

Who are we?

The Swiss Academies of Arts and Sciences link sciences regionally, nationally and internationally. They specifically engage in the fields of early warning and ethics and advocate for an equitable dialogue between science and society.

The Swiss Academies of Arts and Sciences is an association of the four Swiss scientific academies
– Swiss Academy of Sciences (SCNAT)
– Swiss Academy of Medical Sciences (SAMS)
– Swiss Academy of Humanities and Social Sciences (SAHS)
– Swiss Academy of Engineering Sciences (SATW)

as well as the centres of competence
– Centre for Technology Assessment (TA-SWISS)
– Foundation Science et Cité

SCNAT – network of knowledge for the benefit of society

The Swiss Academy of Sciences (SCNAT) and its network of 35 000 experts works at the regional, national and international level for the future of science and society. It strengthens the awareness for the sciences as a central pillar of cultural and economic development. The breadth of its support makes it a representative partner for politics. The SCNAT links the sciences, provides expertise, promotes the dialogue between science and society, identifies and evaluates scientific developments and lays the foundation for the next generation of natural scientists. It is part of the association of the Swiss Academies of Arts and Sciences.

The Swiss Biodiversity Forum of the SCNAT is the scientific center of competence for biodiversity in Switzerland.