

Good Practice Guide & Agreement Toolkit for Access to Genetic Resources & Benefit-Sharing for Non-Commercial Research

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Background

2003 Swiss Academy of Sciences received mandate of the Swiss Federal Office for the Environment (BAFU / FOEN) to develop

- Tools, program on awareness-raising and capacity-building
- implement the Bonn Guidelines within academic research in Switzerland

2004 First survey among academia about its knowledge and experiences related to ABS

First Conclusions

Low and insufficient knowledge / awareness among scientists
 Plenty of research with transnational GR

Feedback by scientists: Need fast, simple procedures for noncommercial intent

Academia largest user



All biological material containing functional units of heredity subject to ABS regulations (CBD/Nagoya Protocol)

- Collecting any GR → all research automatically falls under ABS regulations regardless of the type of utilization
- Academic research the largest user in numbers of requests for access to GR
- Not reflected in the CBD/ABS negotiations nor in its regulations
- ABS system geared towards industrial product development, with the aim of generating (monetary) benefits

Value chain

Basic research

- Blue sky research
- Curiosity-driven science to increase knowledge on foundations of phenomena and observable facts
- No return on investment expected

Research & development

- Solution-oriented approach for practical problems
- Applicable results
- Contribute to economic growth

Commercial research

Nagoya Protocol

- | | |
|--|------------------------------|
| <ul style="list-style-type: none">Utilization = doing researchWith biological material (from another country) | → Non-commercial utilization |
| <ul style="list-style-type: none">Protect results with a patentDevelop a new productPut product on the marketMake a commercial profit | → Commercial utilization |

NP also includes using the **traditional knowledge associated with genetic resources**.

→ All these activities have to be done **according to the rules / laws of the country where you want to access the biological material**.

Dual role of non-commercial, basic research ("academia")



- User of GR
 - Producer (provider) of urgently needed knowledge for the **CBD goals 1 and 2**:
 - Conservation AND
 - Sustainable use of biodiversity
- Special role of science, important stakeholder

Analysis of academic activities regarding GR



- First access to GR
- Intermediary role (transfer of knowledge and / or material GR)
 - Clear need of Provider to control flow of GR
- Academia generates (non-monetary) benefits
 - Need for increased acknowledgement and awareness by Provider

Academic (scholarly) requirements

- Fullfil a set of goals in a given time period (with public funding)
- Publication and dissemination of results and conclusions
- Disclosure of information to peers for evaluation and reproduction of results
- Storage of material and data required → repositories
- Collaboration with specialists e.g. for taxonomic identification of GR (need to transfer the GR)

Aims & requirements of Providers & Academia

Provider

- 1) Carefully assess proposal
- 2) Keep information locked, precontrol of findings (potential interest in IP by Provider)
- 3) Control the flow of GR and data
- 4) Control of utilization of GR
- 5) Control the transfer of GR to Third Party

Academia

- 1) Fulfill a set of goals in a given time period
- 2) Publication of results
- 3) Disclosure for reproduction of results
- 4) Storage of material and data
- 5) Collaboration with specialists e.g. for taxonomic identification

Background analysis

Each research situation is unique, regarding

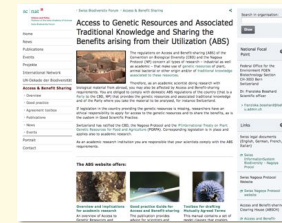
- Span of research
 - Basic (non-commercial) research → research & development R&D in an applied (and potentially commercial) context
 - Disciplines: Botany, zoology, ecology, agriculture, medicine, pharmacology, ethnobotany...
- Access situation
 - In-situ, collecting in the natural environment (,in the field')
 - Ex-situ, outside their natural habitat (repositories = storage facilities, such as germplasm collections, seed banks, botanic gardens...

Analysis of research steps concerning genetic resources in the ABS context					
Types of research with genetic resources	A	B	C	D	
ABS relevant research steps	Inventories (characterization & evaluation)		Functionality, Propagation* & Modification		[Research & Development, Commercialization]
Type of accessed resources	Preserved genetic resources (dead material)	Living genetic resources	Preserved or living genetic resources	Preserved or living genetic resources	
Overall goal of research activity	Inventories of biodiversity; knowledge increase in systematic, ecology and evolution		Identification, isolation, and characterization of active compounds	Improvement of products in agriculture, forestry, horticulture and aquaculture; development of pharmaceuticals, Biological engineering	
Use made of resources	Collection, identification, classification; phenotypic and functional characterization; measuring, basic molecular analysis (e.g. DNA sequencing, microsatellites)*		Isolation of active compounds; characterization, purification, synthesis; multiplication of organs or parts thereof (knockout); traditional biotechnological processes. Based on collection, identification, classification; basic molecular analysis	Isolation and insertion of target genes; molecular cloning and transformation of genes, structures and characteristics; multiplication of cells and/or organisms. Based on collection, identification, classification; basic molecular analysis	
Storage of samples	Researchers store samples in own lab. Storage for scientific and/or educational use in public collections (museums, herbaria)	Researchers store samples in own lab. Storage for scientific and/or educational use in public collections (pools, botanic gardens, seed banks, culture collections)	Researchers store samples in own lab or in stock centre. Culture collections**		
Transfer of genetic resources to third parties (including exchange with peers)	Scientific cooperation with peers. For identification purposes; loans for scientific work. Sharing of duplicate specimens with other collections		Scientific cooperation with peers. Stock centres, culture collections		
Products of research**	Publications, determination keys, presentations and reports. Distribution maps. Collections for scientific or educational purposes (e.g. botanical, zoological, genetic, culture collections). Organic and molecular data in private or public data bases	Publications, determination keys, presentations and reports. Distribution maps. Collections for scientific or educational purposes (e.g. botanical, zoological, genetic, culture collections). Organic and molecular data in private or public data bases	Publications, presentations and reports. Purified samples, chemical formulas, isolated and identified genes. Elaboration of new methods and technologies. Organic and molecular data in private or public data bases	Publications, presentations and reports. Isolated and identified genes, genetically modified cells or organisms. Elaboration of new methods and technologies. Organic and molecular data in private or public data bases	
Potential for further use of research results towards commercial product development**	Published results can be further developed into commercial products		Published results (e.g. chemical formulae) can be further developed into commercial products. Unmodified use after access to stock centre or stored samples		
Benefits of research (P = for providing country; S = for scientists)	Basic knowledge of the living world (PKS) Biodiversity assessment, monitoring, information for biodiversity conservation & management (PKS) Scientific cooperation with peers (S) Education and outreach material (PKS) Capacity building (P) University rankings (S) Academic career benefits (S)	Basic knowledge of the living world (PKS) Biodiversity assessment, monitoring, information for biodiversity conservation & management (PKS) In-situ and ex-situ biodiversity conservation (P) Scientific cooperation with peers (S) Education and outreach material (PKS) Capacity building (P) University rankings (S) Academic career benefits (S)	Basic knowledge of the living world (PKS) Scientific and technological advancements (PKS) Presentations (P and/or S) Scientific cooperation with peers (S) Capacity building (P) University rankings (S) Academic career benefits (S)		

*Important note: The table focuses on research activities carried out in academic institutions and does not address further research steps needed to develop commercial products.

Support for noncommercial academic research

- Good Practice Guide on ABS
- Toolbox with Model Clauses for Contracts (Mutually Agreed Terms)
- Website: abs.scnat.ch



Goal

- Good Practice Guide and Agreement Toolbox integrate different settings in their concept, structure and explanations.
- Consideration of different interests and concerns of Users and Providers (work included peer-reviewing)
- As complex as necessary but as simple as possible → Easy to understand for non-lawyers (e.g. affected scientists)
- No ready-made recipes
- Suggestions and hints on how best to proceed



The Good Practice Guide

Utilization of genetic resources
and
associated traditional knowledge
in academic research

A good practice guide
for access and benefit sharing

First version published in 2006

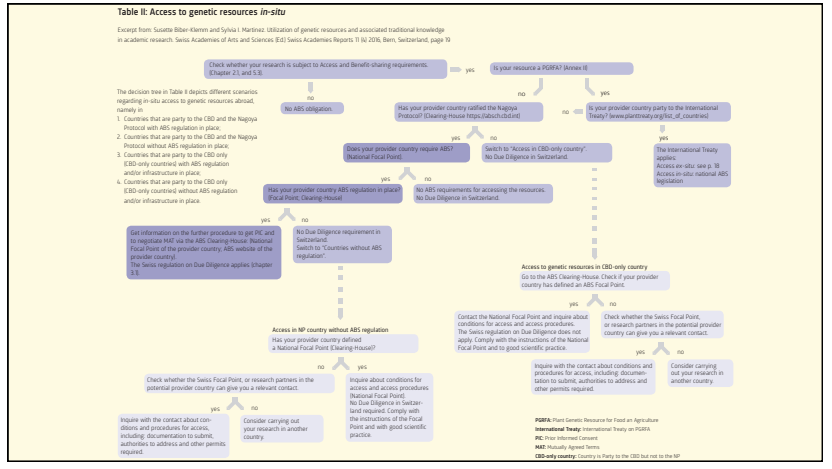
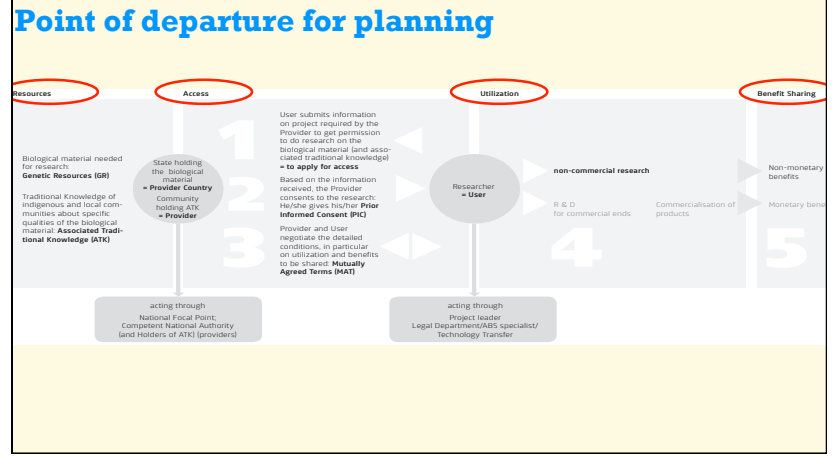


Intent

- General overview of ABS system and implications for academic research. Focuses on basic research supported by public funding
- Comprehensive information to assist scientists and research institutions in
 - planning and carrying out research projects that include GR an TK
- Presents legal obligations of scientists working in Switzerland according to the Swiss legislation and to ethical principles of good scientific practice.
- Does not replace legally binding obligations for researchers according to domestic ABS legislations or regulatory requirements in countries providing genetic resources.

Content

- 1 Purpose of the Manual
- 2 Essentials of Access and Benefit-sharing for academic research
 - 2.1 What is Access and Benefit-sharing?
 - 2.2 Steps involved in ABS: where to find the pertinent information
 - 2.3 The meaning of fundamental terms
 - 2.4 Which legal framework applies to your research?
 - 2.5 Recommendations on how to proceed
- 3 Implementation of the Nagoya Protocol and the International Treaty in Switzerland
- 4 Case Studies
- 5 In-depth information on ABS
 - 5.1 The rationale of ABS
 - 5.2 The responsibility of academic researchers
 - 5.3 Key terms: Genetic Resources, Access and Utilization and Benefit-sharing
 - 5.4 International legal framework
 - 5.5 Associated Traditional Knowledge
 - 5.6 Elements of the ABS procedure: Authorities and instruments
- Appendix
 - I Additional permits for research on Genetic Resources
 - II Glossary
 - III Benefit-sharing in the context of academic, non-commercial research
 - IV Links and Sources
 - V National Focal Point



Case-study Medicine: Evolution and epidemiology of tuberculosis

Tuberculosis (TB) causes many deaths.... This project aims to identify population-based clinical and molecular determinants of tuberculosis epidemiology, to 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...

Livestock carcasses will be collected in abattoir surveys for the cultivation of Mycobacterium tuberculosis complex. Region-deletion polymerase chain reaction (PCR) 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.

Selection of benefits to be shared, from an academic perspective

- Training of students (graduate & postgraduate), capacity building
- Training of technical staff, technology transfer
- Involve local stakeholders as field assistants
- Inform all stakeholders about research results
- Provide information in an adequate language
- Share specimens
- Involve partners as co-authors in publications, cooperation
- Facilitate access to scientific information
- Provide access to research findings
- Maintain institutional and professional relationships
- Provide research infrastructure

Evaluate the benefits your research generates → “Marketing”

Toolbox: Agreement on Access and Benefit-Sharing for Academic Research

In support of the negotiation and compilation of Mutually Agreed Terms Offers

- A basic agreement that can be used as such in simple research situations
- Optional clauses that allow to adapt and complement the agreement to the specific needs of the user and the provider

Addressees

- Users and providers
- Competent units of research institutions
- Project managers

Serves as

- Template in a country that does not have a ready-made form
- Checklist for items to take into account
- Work is available as <https://creativecommons.org/licenses/by-nc-sa/4.0/legalcode>



Basic assumptions

- GR is accessed by researcher/team under the lead of a research institution
- Primary research purpose is non-commercial
 - Results will be publicly available
 - Results have to be published according to good scientific practice
- Unexpected findings might spark reflections on utilization in a commercial context (both User and/or Provider)
- Benefits are non-monetary as a rule

Preamble.....	9
Parties to the Agreement	10
Clause 1 Use of Terms in the Agreement.....	11
Clause 2 Prior Informed Consent.....	12
Clause 3 Genetic Resources to be accessed.....	15
Clause 4 Utilization.....	16
Clause 5 Commercial Intent	16
Clause 6 Commercialization	17
Clause 7 Intellectual Property Rights	17
Clause 8 Transfer of Genetic Resources [and Associated Traditional Knowledge] to Third Parties	19
Clause 9 Storage of Genetic Resources.....	20
Clause 10 Benefit-sharing.....	21
Clause 11 Rights and Obligations of the Provider.....	23
Clause 12 Rights and Obligations of the User	24
Clause 13 Reporting	25
Clause 14 Publication.....	26
Clause 15 Duration and Termination of the Agreement.....	28
Clause 16 Handling of the Genetic Resources after Termination of the Agreement.....	29
Clause 17 Settlement of Disputes.....	29
Clause 18 Other provisions.....	30

18 Clauses



