ABS
MANAGEMENT TOOL

Best Practice Standard and Handbook

for

Implementing Genetic Resource Access and Benefit-Sharing Activities

Updated May 2012

Developed by

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With the support of the
Swiss State Secretariat
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ACKNOWLEDGEMENTS

Preface to the 2012 Update

Since the ABS Management Tool (ABS-MT) was originally published in 2007, international law has been developed to regulate the utilization of genetic resources and associated traditional knowledge. The *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 (the Protocol)* was adopted in late 2010, opened for signature on February 2, 2011, and will enter into force when 50 instruments of ratification are in place. With the support of the Swiss State Secretariat for Economic Affairs, the authors have updated the ABS-MT to accommodate new language of the Nagoya Protocol and to assist the users and providers of genetic resources to apply current best practices. The updated ABS-MT includes a new section providing guidance to the Parties to the Convention on Biological Diversity (CBD) to prepare for the introduction and further implementation of the Nagoya Protocol.

The authors have further updated the original text and re-structured the ABS-MT in light of the growing body of practical experience in ABS since the Management Tool's original publication.

Acknowledgements:

The authors thank the members of the Advisory Committee[1] for their invaluable contributions to the content and structure of this document. Similarly, the authors would like to thank IUCN – the International Union for Conservation of Nature – for their advice and review of the ABS-MT. And finally, the authors would like to thank Switzerland's State Secretariat for Economic Affairs for supporting the ongoing development and improvement of the ABS-MT.

Disclaimer:

The content and views expressed in the updated ABS Management Tool are those of the authors and do not necessarily reflect the views of the Government of Switzerland.

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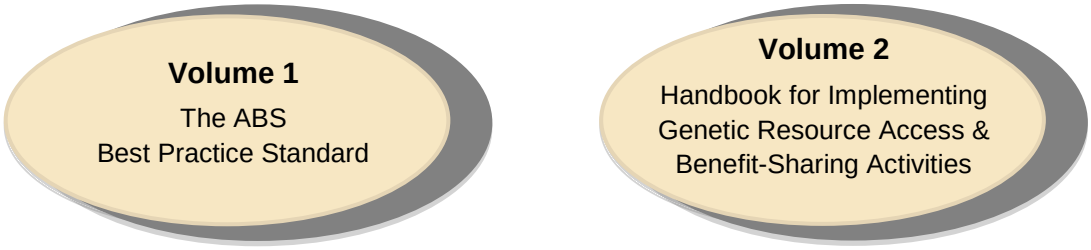
VOLUME I

THE ABS BEST PRACTICE STANDARD

1 GETTING STARTED

1.1 Introduction

This document is divided into two volumes:



Volume I
ABS Best Practice Standard

Section 1	presents an overview of why ABS is important and how the ABS-MT can provide assistance to users and providers of genetic resources (GRs), as well as to governments.
Section 2	presents the ABS Best Practice Standard for users and providers of genetic resources.
Section 3	presents guidance to governments to support implementation of the Nagoya Protocol.
Section 4	provides guidance to users of the ABS-MT on how to improve existing or how to develop new management procedures to implement ABS activities.

Volume II
Handbook for Implementing Genetic Resource Access and Benefit-Sharing Activities

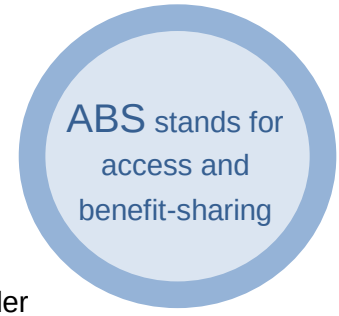
Part I:	Good Practice Guidance provides a summary of good practice steps for applying the ABS-MT standards.
Part II:	Supporting Tools provides several supporting tools and examples for applying specific aspects of the ABS-MT.

1.2 What is ABS and Why is it Important?

ABS stands for access and benefit-sharing and describes the process of accessing genetic resources found in biodiversity and obtaining a fair and equitable share of benefits arising out of their utilization under the Convention on Biological Diversity (CBD). This process is also intended to enable some of the benefits obtained from the use of genetic resources to contribute to the conservation and sustainable use of biodiversity.

These purposes for access and benefit-sharing are reflected in the objectives of the CBD:

1. the conservation of biological diversity;
2. the sustainable use of its components; and
3. the fair and equitable sharing of benefits arising out of the utilization of genetic resources.[2]



This third objective of the Convention has since developed into a field of practice – and a set of legal requirements – which are known as "access to genetic resources and benefit-sharing" or "ABS".

Over the decade following its entry into force in 1993, the Parties to the CBD developed this field of practice into voluntary, non-binding guidelines to assist governments and stakeholders to meet their ABS obligations under the Convention. These are the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization* (adopted in 2002). The Bonn Guidelines primarily address the steps involved in the process of obtaining access to genetic resources and ensuring benefit-sharing, namely: informed consent for access (prior informed consent [PIC]); and, terms of access and and terms of benefit-sharing (mutually agreed terms or MATs).

The legal framework of ABS was further developed in 2010 with the decision by the Conference Parties to the CBD to adopt the *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 (the Nagoya Protocol).*

The Nagoya Protocol sits within the overall framework of the CBD and is subject to its provisions. It primarily addresses obligations for Parties (national governments) to be implemented at the national level.

To provide assistance to the reader, an analytical table of Protocol provisions is provided in Section 3.2 (Volume I) of this ABS-MT. This identifies the national action required for each article and the underlying subject the article addresses.

[2] Article 9 of the Nagoya Protocol makes the connection among access and conservation and sustainable use explicit where it establishes an obligation for Parties to the Protocol to encourage providers and users of genetic resources to direct benefits to the conservation and sustainable use of biodiversity. The Annex to the Protocol includes a range of benefits which could be used to this end.

The Nagoya Protocol was expected to come into force in 2012 but 2014 seems more likely. It will take several years for it to be widely implemented. The obligations of the Protocol are set out in its terms which are legally binding, but also offer flexibility on implementation. In the meantime, the Bonn Guidelines continue to be relevant as a source of guidance for countries that do not ratify the Nagoya Protocol.

As of May 16, 2012, 92 Parties have signed the Protocol and four countries have ratified it.[3] It comes into force 90 days after the 50th Party ratifies its signature. It is the designated CBD instrument for the implementation of the Convention's ABS provisions. The exception is where a specialized international instrument has been created for specific genetic resources (Article 4), provided that the instrument is consistent and does not run counter to the objectives of the CBD and the Protocol, and covers the specific genetic resources covered and for the purpose of the specialized instrument (e.g., the International Treaty for Plant Genetic Resources for Food and Agriculture).

Many of the terms in the Protocol are legally binding – including new measures on compliance and monitoring – but are qualified to provide considerable flexibility in their application. Accordingly, providers and users of genetic resources have to pay close regard to the obligations, responsibilities, and opportunites created by the Protocol as they prepare for its implementation.

The objective of the Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

It establishes requirements for access and benefit-sharing, the use of traditional knowledge associated with genetic resources, compliance, cooperation, monitoring the utilization of a country's resources, and for national action to ensure that such resources are used in accordance with the laws of the providing country.

The Protocol does not have retrospective effect prior to its coming into force, and does not apply to material collected outside of any national jurisdiction. Nor does its implementation affect existing international obligations provided that the conditions of Article 4 are met.

[3] See www.cbd.int/abs/nagoya-protocol/signatories/

1.3 Purpose and Use of the ABS Management Tool

The ABS Management Tool (ABS-MT) is a **best practice standard and a handbook that provides voluntary guidance to the users and providers of genetic resources** – a tool on ABS practice to help companies, researchers, indigenous and local communities, and governments to comply with the ABS requirements under the Convention on Biological Diversity, including the Bonn Guidelines and the Nagoya Protocol.

Further, the ABS Management Tool has been updated **to assist governments as they consider their responsibilities, obligations, and opportunities under the Nagoya Protocol** and as they seek to determine which of the available options and flexilibities is appropriate for their national circumstances.

To implement the Nagoya Protocol, ABS legislation, regulation, policy, and/or administrative requirements are likely to change in many countries over the next few years. Therefore, it is most important that every stakeholder involved in ABS practices is informed about the legal requirements in force in relevant jurisdictions.

A key aspect of successful ABS activities is to build confidence and trust between the genetic resource provider and the genetic resource user. The ABS-MT is designed to inform and guide users and providers of genetic resources in a neutral way to help them establish the necessary relationships based on confidence and trust. Without confidence and trust, the access and use of genetic resources can result in negative impacts – to the providers of the genetic resource through, for example, poorly informed decisions on access, or insufficient sharing of appropriate benefits with the provider; and, to the user of the genetic resource, through, for example, perceptions and claims that they have acted improperly in accessing and/or using genetic resources. The introduction of measures under the auspices of the Nagoya Protocol to provide legal certainty and transparency supports the establishment of informed trust and will reduce transaction costs while encouraging research and development.

For Users of Genetic Resources

The ABS-MT is targeted to genetic resource user organizations (e.g., public and private research institutions, including: universities; small and large companies/enterprises; intermediaries who collect or use genetic resources, etc.) to enable them to:

- Voluntarily adopt an ABS standard of practice to access genetic resouces by ensuring that the ABS provisions of the Convention on Biological Diversity, the Bonn Guidelines,[4] and the ABS laws, regulations, and policies of countries are followed;
- Prepare to meet the requirements, including for compliance and monitoring, to be introduced under the Nagoya Protocol, and take advantage of the opportunities for improved legal certainty for their use of genetic resources; and
- Adopt good practices in accessing genetic resources and in providing fair and equitable

[4] The ABS-MT is intended to apply to genetic resources as defined in the Convention on Biological Diversity.

benefits from their use in accordance with the international standards set out in the Nagoya Protocol.

The utilization of genetic resources and/or associated traditional knowledge can be for different purposes, such as:

- pharmaceuticals;
- botanicals;
- cosmeceuticals;
- crop protection;
- nutraceuticals;
- climate change adaptation, mitigation, and resilience;
- biotechnology, including microbial sources of industrial products;
- biofuels; and
- horticulture, including ornamentals.

For Providers of Genetic Resources

At the same time, the ABS-MT is targeted to genetic resource providers (e.g., national or subnational government authorities, indigenous and local communities, research institutions, and intermediaries) to:

- **Assist them to understand the opportunities and responsibilities** established through the implementation of the Nagoya Protocol once it comes into force;
- **Help them make decisions about access** by increasing their understanding of the Nagoya Protocol's requirements and responsible practices; and
- **Determine expectations and requirements** in negotiating agreements for access to and use of genetic resources.

Providers include:

- governments providing or managing genetic resources;
- indigenous and local communities;
- land owners or land managers;
- public and private research institutions, including universities;
- holders of *ex situ* and *in situ* collections; and
- Intermediaries (commercial and public).

For Governments

The ABS Management Tool helps governments understand the individual provisions of the Nagoya Protocol and assists governments to address key steps and obligations under the Protocol, including to:

- Understand their obligations and opportunities following ratification;
- Decide what appropriate legislative, administrative or policy measures are required under its ABS framework;
- **Provide guidance on how to interpret the Nagoya Protocol** and its provisions at the national and international levels;
- **Establish necessary institutional arrangements** such as National Focal Points and competent national authorities;
- Deal with the use of and benefit-sharing for traditional knowledge (TK) associated with genetic resources
- **Determine whether to require prior informed consent** to access their genetic resources and, if so, to determine what measures are needed;
- **Decide the nature of simplified measures** for access to genetic resources for non-commercial purposes;
- **Determine the nature of the compliance measures** to encourage the use of specified matters in mutually agreed terms; and
- Decide the appropriate means to support technology transfer, collaboration, and co-operation.

The ABS-MT also can be used by governments and international organizations as a guide to capacity-building, particularly for the implemention of the Nagoya Protocol.

1.4 Alignment of the ABS-MT with Selected Articles of the Nagoya Protocol

Article	Section of the ABS-MT
Article 2: Use of Terms	Volume I, Section 1.5 – Definitions
Article 4: Relationship with International Agreements and Instruments	Volume II, Part II, Sections 7 & 8 – Links to Specific Guidelines and Other Useful Links and Sources Volume II, Part II, Section 1 – Road Map of Interaction between National Legal Frameworks and the ABS-MT
Article 5: Fair and Equitable Benefit-Sharing	Volume I, Section 2.0 – ABS Best Practice Standards Volume II, Part I – Good Practice Guidance on Benefit-Sharing
Article 6: Access to Genetic Resources	Volume I, Section 2.0 - ABS Best Practice Standards Volume II, Part I – Good Practice Guidance
Article 7: Access to Traditional Knowledge Associated with Genetic Resources	Volume I, Section 2.0 – Traditional Knowledge Associated with Genetic Resources Volume II, Part I – Good Practice Guidance
Article 9: Contribution to Conservation and Sustainable Use	Volume I, Section 2.0 – Conservation and Sustainable Use Volume II, Part I – Good Practice Guidance
Article 11: Transboundary Cooperation	Volume I, Section 2.0 – Access and Benefit-Sharing Volume II, Part I – Good Practice Guidance
Article 12: Traditional Knowledge Associated with Genetic Resources	Volume I, Section 2.0 – Traditional Knowledge Associated with Genetic Resources Volume II, Part I – Good Practice Guidance
Article 13: National Focal Points and Competent National Authorities	Volume I, Section 3.0 – Guidance to Governments on the Nagoya Protocol
Article 15: Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-Sharing	Volume I, Section 2.0 – Compliance Volume II, Part I – Good Practice Guidance
Article 16: Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-Sharing for Traditional Knowledge Associated with Genetic Resources	Volume I, Section 2.0 – Compliance and Traditional Knowledge Associated with Genetic Resources Volume II, Part I – Good Practice Guidance
Article 17: Monitoring the Utilization of Genetic Resources	Volume I, Section 2.0 – Compliance Volume II, Part I – Good Practice Guidance

Article	Section of the ABS-MT
Article 18: Compliance with Mutually Agreed Terms	Volume I, Section 2.0 – Compliance Volume II, Part I – Good Practice Guidance
Article 19: Model Contract Clauses	Volume I, Section 2.0 – Access, Benefit-Sharing, and Traditional Knowledge Associated with Genetic Resources Volume II, Part I – Good Practice Guidance Volume II, Part II, Sections 3–5
Article 20: Codes of Conduct, Guidelines and Best Practices/Standards	Volume I, Section 2.0 – Access and Compliance Volume II, Part I – Good Practice Guidance Volume II, Part II, Sections 7 and 8
Article 23: Technology Transfer, Collaboration, and Cooperation	Volume I, Section 2.0 – Technology and Knowledge Transfer Volume II, Part I – Good Practice Guidance

1.5 Definitions

Key terms used in the ABS-MT are explained below. Some, but not all, are defined in the Nagoya Protocol or in the CBD. Other terms were developed from national or international definitions established by different organizations and their respective processes.

Element	Definition
Best practice standard	A set of commitments to be followed by the genetic resource users and providers of genetic resources to achieve an outcome that meets the requirements of the ABS provisions of the CBD, the Bonn Guidelines, the Nagoya Protocol, and represents the current state of best practice.
Challenge tips	Potential solutions and advice on addressing challenges and uncertainties that arise during ABS negotiations and implementation of ABS agreements.
Derivative	A naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.[5]
Good practice guidance	Steps or activities to help user/acquirer and provider/source organizations carry out good ABS management practices – guidance that supports the application of the ABS best practice standards.
Holders, owners, managers, or custodians	Organizations or individuals who have a right over genetic resources (possession, property, etc.) in accordance with the legal system or customary law in place, or are in possession of the biological material that contains the genetic resources, *in situ* or *ex situ.*
Provider	Any government, organization, or group of people that is the source of the genetic resource and/or is the holder, owner, manager, or custodian of these genetic resources.
Technology transfer	Technology includes both “hard” and “soft” technology. Hard technology refers to the actual machinery and other physical hardware that is transferred; soft technology refers to technological information or know-how. Soft technology is often transferred within long-term scientific and technological cooperation including through joint research and innovation which move ideas from invention to new products, processes, and services.[6]

[5] See Article 2(e) of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity.

[6] CBD Technology Transfer and Cooperation Implementation Strategy: www.cbd.int/tech-transfer/ahtegtechnologycooperation.shtml

Element	Definition
Traditional knowledge, innovations, and practices of indigenous peoples and local communities	This term has not been defined in the CBD or the Nagoya Protocol and must be given a plain and ordinary meaning. However, a working definition of the term is in use in negotiations within WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.[7] This is set out in the footnote below.
Traditional knowledge associated with genetic resources	This term is not yet defined and must also be given a plain and ordinary meaning.[8] In common law countries. This means its meaning is found in common usage and by reference to dictionaries referred to by courts for the purposes of discerning meaning, or by reference to decisions by courts where words or phrases have been judicially defined.
User	Any organization or group of people that acquires and/or uses 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 as defined in Article 2 of the Convention.[9]

[7] "'Traditional knowledge' refers to the content of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices, and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations" (WIPO Revised Draft Provisions for the Protection of Traditional Knowledge).

[8] It should be noted that the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (IGC) was requested by its General Assembly (September 2011) to reach agreement on a text(s) of an international legal instrument(s) to ensure the effective protection of genetic resources, traditional knowledge, and traditional cultural expressions. This process and its outcomes may clarify the general understanding of the term.

[9] See Article 2 (c) Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity.

1.6 Understanding When to Apply the ABS-MT

The ABS-MT is intended to apply to **all stages of genetic resource activity**:

- establishment of legal frameworks;
- prior to access;
- access (collection and discovery);
- academic research10;
- research and development for commercial purposes;
- compliance, tracking, and monitoring;
- commercialization; and
- capacity-building, cooperation, and technology transfer.

A. Utilization of Genetic Resources

Genetic resources are defined in Article 2 of the Convention on Biological Diversity as:

> *"Genetic resources" means genetic material of actual or potential value. "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.*

The same definition applys to the Nagoya Protocol.

Anyone preparing to provide or to use genetic resources should be aware that the Protocol's benefit-sharing provisions apply to the **utilization of genetic resources** which it defines in Article 2 as an act:

> *"to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention."*

In short, "utilization" goes to intent. This also has the benefit of distinguishing genetic resource use from the wild harvest of biological materials or its use in commodity trade.

While this definition of utilization of genetic resources provides greater clarity and helps to resolve concerns about the utilization of genetic resources, some debate with regard to the extent of coverage of naturally occuring biochemical compounds ("derivatives") remains.

[10] For academic research with no commercial intent, a separate guideline – the Swiss Academy of Sciences' "Good Practices for Academic Research in Genetic Resources" – can be applied.

Research and development on the biochemical and genetic composition of genetic resources is covered by the Protocol. The reference to the biochemical compounds as well as the reference to the application of biotechnology links this provision with the definition of “derivative” as a naturally occurring compound. Therefore the “utilization of derivatives” is also covered by the Protocol, and utilization of a biochemical compound, including through biotechnology, can be understood to be covered by the Protocol if it was accessed simultaneously with the genetic resources. The definition of derivative creates more certainty about the meaning of “biochemicals” by clarifying that they may or may not have “functional units of heredity,” although this view is not universally shared.

The inclusion of the concept of utilization in the Protocol means that countries that decide to require PIC for access to their genetic resources will be expected to regulate research and development on both the genes and any naturally occurring biochemical component.

The Protocol does not contain a list of activities which could be considered as “utilization,” but it may include:

- genetic modification;
- biosynthesis (use of genetic material as a “factory” to produce organic compounds);
- breeding and selection;
- propagation and cultivation in the form received;
- conservation;
- characterization and evaluation; and
- production of compounds naturally occurring in genetic materials (i.e., extraction of metabolites, synthesis of DNA segments, and production of copies).

1.7 Basic Conditions for the Use of the ABS- MT

1.7.1 Willingness to Participate in ABS Negotiations

Both the genetic resource provider and prospective user must be willing to participate in good faith in the ABS negotiations. If there is a lack of trust between the potential parties involved in a negotiation, the possibility of reaching a successful agreement that benefits all parties will be reduced. Relationships should be based on trust, dialogue, and mutual benefit. Negotiation of access and benefit-sharing arrangements, therefore, must be established and implemented in a manner that advances participation of all relevant stakeholders, allows effective dialogue among these stakeholders, and promotes mutual accountability.

1.7.2 Capacity for Negotiation and Decision-Making

ABS negotiations can be complex. For many governmental authorities, indigenous and local communities, and other stakeholders, ABS is an unknown legal and administrative area. The lack of capacity (and the lack of faith in whatever little capacity they might have) can prevent potential providers from being engaged in ABS negotiations. The fear of making mistakes and the possible consequences if a negotiation is conducted poorly, limits the willingness of providers and users to participate in ABS negotiations. For this reason, a minimum capacity and knowledge on ABS issues/negotiations is necessary for use of the ABS-MT. The ABS-MT itself can be used as a capacity-building instrument, by addressing the relevant ABS issues a prospective user needs to address, and by providing a road map for ABS negotiations and discussing best practices.

Following the adoption of the Nagoya Protocol by the Conference of the Parties to the CBD, the CBD Secretariat has developed an ABS Information Kit and has publicized a number of web-based resources. For additional information please visit www.cbd.int/abs/awareness-raising/

1.7.3 Minimum Legal Framework in Place

Approximately 50 countries have some form of ABS measures, of which between 25 and 30 have adopted ABS-specific laws.[11] Some of these countries have developed specific implementing laws, regulations, and administrative procedures; others have developed enabling laws; and still others include ABS provisions in documents such as National Biodiversity Strategies and Action Plans (NBSAPs).

This lack of substantive ABS-specific regulatory and administrative measures creates legal uncertainty. It limits the willingness of prospective genetic resource users to seek genetic resources and negotiate agreements for access and benefit-sharing. At the same time, legal uncertainty limits the willingness and capacity of genetic resource providers (i.e., government agencies, and indigenous and local communities) to engage in ABS negotiations.

[11] The CBD Secretariat reports that there are more than 50 countries with ABS measures in place, but some of these measures are National Biodiversity Strategies, Plans, or Policies, or are enabling provisions facilitating the further development of more substantive ABS regimes.

Two main goals influenced the negotiation of the Nagoya Protocol. First: the delivery, through a legal instrument, of legal certainty to users and providers of genetic resources and any associated holders of traditional knowledge that provide access. Second: establishing clear obligations on governments to act to ensure genetic resources used within their jurisdiction are obtained and used in accordance with requirements for prior informed consent (PIC) and mutually agreed terms (MATs) for access to and use of genetic resources established by the providing country.

Volume II, Part II, Section 1 provides a simplified road map of how the ABS-MT interacts with national legal frameworks. Links to useful databases or legal studies on ABS measures are provided in Part II, Sections 7 and 8.

1.8 Structure of the ABS-MT

The ABS-MT is made up of the following components which are divided into two volumes: The Best Practice Standard and the Handbook.

This updated ABS-MT introduces two new standards: **Compliance** as a core standard and **Technology and Knowledge Transfer** as an additional standard. Compliance provisions form an essential part of the Nagoya Protocol. They focus on obligations to support compliance with the requirements of the country providing genetic resources and to establish obligations and measures to support user compliance with the mutually agreed terms established with the provider of the resource.

Technology and Knowledge Transfer has been introduced as a new additional standard as it is an increasingly important aspect of benefit-sharing, cooperation and collaboration between countries, and capacity-building.

Traditional Knowledge Associated with Genetic Resources is now a core standard. The Nagoya Protocol and national legislation in a number of countries has developed new specific obligations related to the utilization of traditional knowledge associated with genetic resources as well as to the use of genetic resources held in indigenous peoples' and local communities' territories, subject to domestic legislation.

1.9 ABS Decision-Making and Use of the ABS-MT

For Commercial Research

The ABS-MT is designed to specifically address the situations and concerns of commercial research for genetic resources (bioprospecting) or academic research that has commercial potential. It does not address the broader collection and use of biological resources for other purposes, such as commodity trade.

For Non-commercial Research

The ABS-MT also provides ABS best practices for individuals and institutions involved in genetic resources research for non-commercial (mainly academic) purposes. However, while there is no internationally agreed distinction between commercial research and academic research on genetic resources, it is recognized that such research may lead to the identification of commercial potential. This is often referred to as serendipitous discovery. The Nagoya Protocol provides for the introduction of simplified measures to facilitate academic or non-commercial research – provided that they address any change in intended use of the genetic resource.

Academic researchers may decide to use the ABS-MT if it is appropriate for the nature, scale, and type of research involved (e.g., where traditional knowledge is involved, or conservation and sustainable use of the resource to be collected needs to be considered).

Since the ABS-MT standard includes provisions for addressing commercial use of genetic resources, simplified procedures for individual academic researchers are available in other instruments. These include:

- the Swiss Academy of Sciences' "Access and Benefit-Sharing – Good practice for academic research on genetic resources"[12];
- Botanic Gardens' Principles on Access to Genetic Resources and Benefit-Sharing for Participating Institutions: Common Policy Guidelines[13];
- International Plant Exchange Network (IPEN) Code of Conduct for botanic gardens governing the acquisition, maintenance, and supply of living plant material[14];
- Micro-organisms Sustainable use and Access Regulation International Code of Conduct (MOSAICC)[15];

[12] http://abs.scnat.ch/
[13] www.bgci.org/worldwide/article/0007/
[14] www.bgci.org/files/ABS/IPEN/conduct.pdf
[15] http://bccm.belspo.be/projects/mosaicc/

- German Research Foundation – Guidelines for Funding Proposals Concerning Research Projects within the Scope of the Convention on Biological Diversity (CBD)[16]; and
- Society for Applied Anthropology (SfAA): Ethical and Professional Responsibilities.[17]

Figure 1 provides a decision-making path to guide prospective users and providers of genetic resources, including reference to specific sections of the ABS-MT.

[16] www.dfg.de/foerderung/formulare_merkblaetter/index.jsp
[17] www.sfaa.net/sfaaethic.html

Figure 1 - A Decision-Making Path to the ABS-MT **PRE-ACCESS**

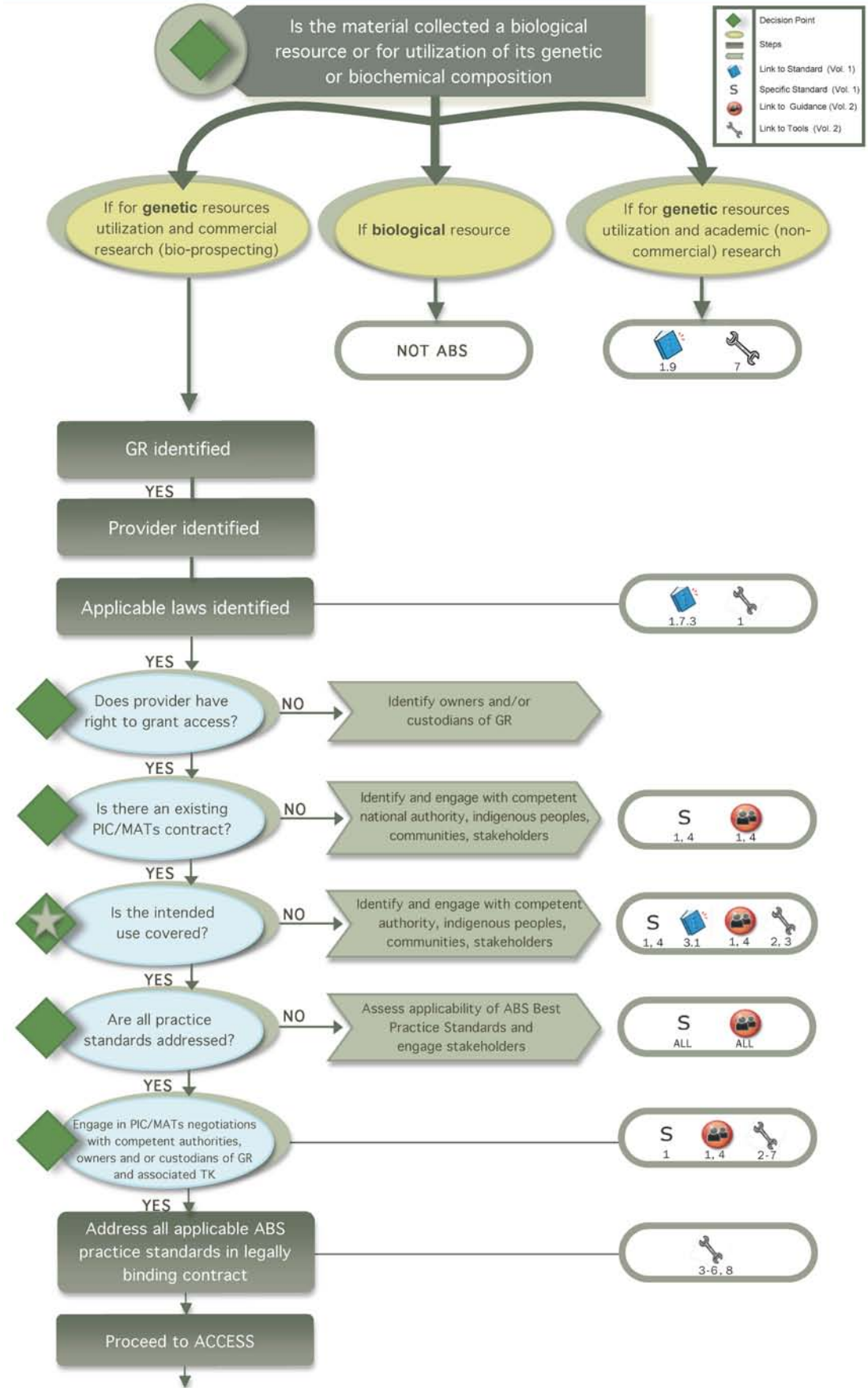


Figure 1 - A Decision-Making Path to the ABS-MT **ACCESS**

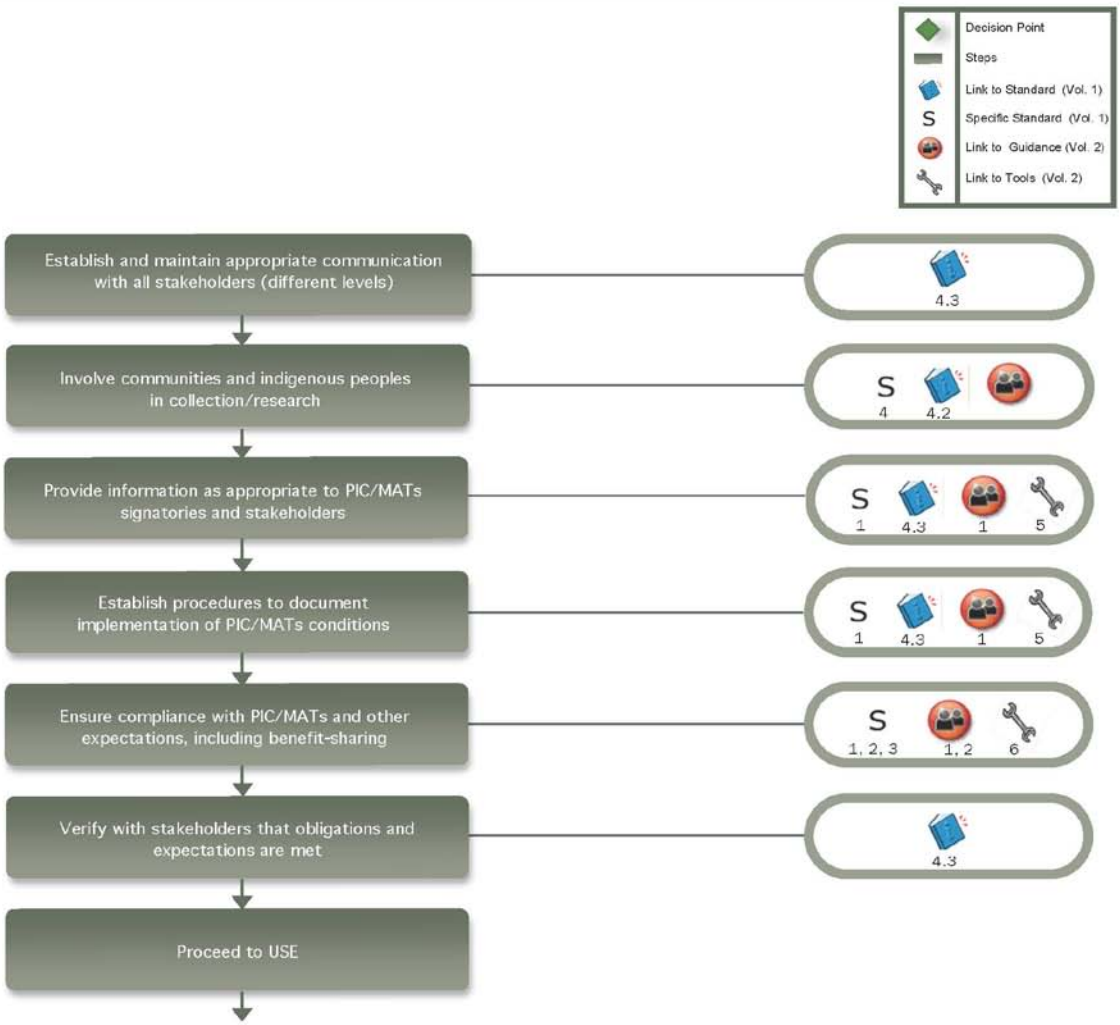
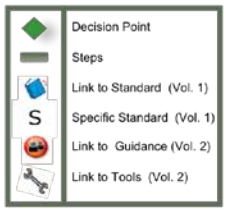
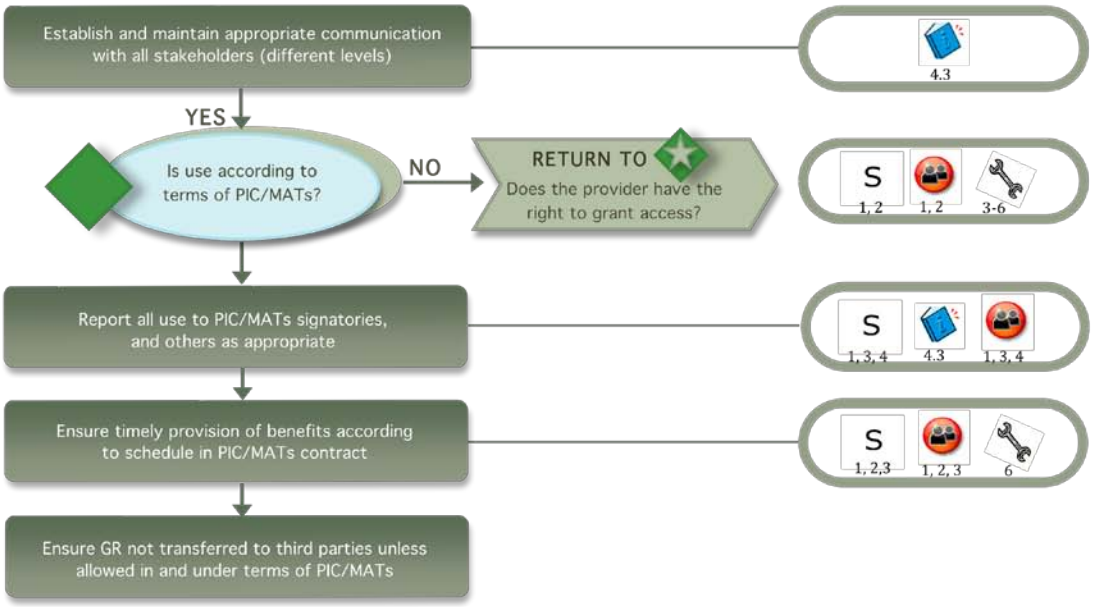


Figure 1 - A Decision-Making Path to the ABS-MT **USE**





2 ABS BEST PRACTICE STANDARDS

Core Standards for Compliance with CBD Provisions, Guidelines, and its Nagoya Protocol

BEST PRACTICE STANDARDS

STANDARD 1.0: ACCESS

A. Prior Informed Consent (PIC)

Prior informed consent (PIC) is permission obtained by the user of a genetic resource from the government and other providers, as the case may be, after fully disclosing all the required information that permits access to their genetic resources, and associated traditional knowledge, under mutually agreed terms (MATs).

1.1 PIC is prior, informed, and consented in intent and practice.

1.2 Where countries require PIC, it is obtained in writing from the competent government authority (competent national authority) and, in accordance with domestic law, from the relevant stakeholders, including indigenous and local communities where they are the holders, owners, managers, or custodians of genetic resources or traditional knowledge associated with genetic resources.

1.3 PIC is linked to a commitment to negotiate fair and equitable benefits for each stage of access and use. Once MATs have been confirmed then PIC can be granted. Genetic resources are used only for the purposes expressly outlined in the PIC documentation at the time of PIC negotiation or set out in the MATs. (The negotiation of MATs and PIC may be undertaken as separate negotiations or combined, but in any case they are linked.)

1.4 A new prior informed consent is given for any use that differs in type or scope from that originally outlined in the PIC or MATs. An agreement is concluded with the provider that reflects the terms and conditions of PIC including, *inter alia*, the establishment of terms and conditions regarding benefit-sharing (MATs)..

1.5 Where access to genetic resources acquired in accordance with the CBD is obtained from an *ex situ* collection, including from one or more intermediary, documentation is provided that appropriate PIC exists and that the transaction and intended use are consistent with that PIC – unless there is a clear and reasonable explanation that this is not feasible, for example when the provider country has decided not to require PIC (under the flexibility given at Article 6 (1) of the Protocol, in which case the PIC comes from the institution itself).

B. Mutually Agreed Terms (MATs)

Mutually agreed terms (MATs) are conditions and provisions of access and benefit-sharing, among others, negotiated between the user and the provider and involving other relevant stakeholders.

1.6 MATs are negotiated in a manner that builds confidence and a relationship of trust between the providers of genetic resources (holders, owners, managers, and custodians) and the users. Negotiations establish the basis for a long-term, transparent, and respectful relationship and communication between them. MATs are established in writing.

1.7 MATs are negotiated in good faith by users and providers, respecting the terms and understanding of prior informed consent, allowing benefits to flow to the holders, owners, managers, or custodians of the genetic resource, and facilitating access.

1.8 MATs take into account the differences in capacities and needs of the providers, including governments, and indigenous and local communities, holders of *ex situ* collections, and the intended users, to allow fair processes of negotiation and equitable outcomes in the benefits to be shared.

STANDARD 2.0: BENEFIT-SHARING

Benefit-sharing is participation in the economic, environmental, scientific, social, or cultural benefits resulting or arising from access to genetic resources and associated traditional knowledge under mutually agreed terms (MATs).

2.1 Fair and equitable benefit-sharing from the utilization of genetic resources and associated traditional knowledge is provided to support compliance with the three objectives of the Convention on Biological Diversity (the conservation of biological diversity; the sustainable use of its components; and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources), including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding. These benefit-sharing provisions are negotiated on MATs and implemented in a manner that contributes to the conservation of biological diversity including the genetic resource.

2.2 Benefits are provided according to the established MATs and may be renegotiated when the type of use is expected to change beyond the agreed PIC or as initially required under MATs. Benefit-sharing considers and provides short-, medium- and long-term non-monetary and/or monetary benefits.

2.3 Benefits are shared fairly and equitably with all those who have been identified as having contributed to the resource management of the genetic resource, and the scientific or commercial process. This may include governments at different levels, and/or indigenous and local communities and relevant stakeholders who are the holders, owners, managers, or custodians of the genetic resource (providers), and the users of the genetic resource involved in non-commercial scientific inquiry or involved along the chain of commercialization (users).

2.4 Benefits are intended to create or strengthen capacity in the providers or other stakeholders, especially through research, technology transfer, and training, relevant for the conservation and sustainable use of genetic resources.

2.5 Benefit-sharing arrangements are implemented in good faith, respecting the terms and understanding of prior informed consent agreed for use of the genetic resources collected, and the terms and conditions negotiated and mutually agreed.

Note: The Protocol at Article 5(4) anticipates a flexible and wide range of possible benefits. These possible benefits, including monetary and non-monetary benefits, are set out in the Annex to the Protocol but are not confined to this list. This is the same list that is found in the Bonn Guidelines.

STANDARD 3.0: COMPLIANCE

Compliance means meeting the requirements and obligations of national (domestic) ABS legislative, administrative, or policy measures on access to genetic resources and traditional knowledge associated with genetic resources. Similarly, compliance means meeting the requirements of national (domestic) laws and administrative or policy measures of the country in which genetic resources and associated traditional knowledge are utilized. In both cases, compliance also means meeting the requirements and obligations documented in MATs.

3.1 The legal framework existing in the country(ies) to which the genetic resources are to be used (or going to be sent) is disclosed to the provider of the genetic resource and to relevant governmental organizations by the user. Such disclosure includes any measures existing to support compliance with national ABS legislation or measures of the providing country; mechanisms in place to cooperate in cases of non-compliance; options for access to justice in such country(ies); and possibilities for recognition of foreign court arbitral awards, among others. (While not explicitly required by the Protocol, such action builds trust and supports the implementation by governments of their arrangements to discharge the Protocol's compliance and monitoring provisions.)

3.2 Users and providers respond in a timely manner and in writing to any allegations of non-compliance with the national ABS legislation or measures as well as non-compliance with MATs and PIC, and seek – in good faith – to remedy or solve any situation of non-compliance, if existing.

3.3 All relevant information regarding PIC, MATs, compliance with national legislation, and utilization of genetic resources and associated traditional knowledge, is disclosed to the appropriate checkpoints existing in the country of the provider or user country as the case may be. Any internationally recognized certificate of compliance is disclosed. If there are no officially designated checkpoints, information on the appropriate offices dealing with regulatory approvals, intellectual property rights, publications, and research and other funding, among others, are disclosed by the user – to the extent feasible and on a case-by-case basis.

3.4 National monitoring mechanisms for the use of genetic resources and associated traditional knowledge are complied with by the user to support compliance and enhance transparency, including through the ABS Clearing-House Mechanism and Internationally Recognized Certificates of Compliance where feasible.

3.5 Users report their compliance with ABS legislation or measures of the country where the genetic resources are accessed as required by the country in which they are used. Reporting includes any non-confidential information on any third-party transfers of genetic resources, and on the place where the genetic resources are kept.

STANDARD 4.0: TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

(if access involves utilization of traditional knowledge associated with genetic resources and local or indigenous communities)

Traditional knowledge, innovations, and practices is the content of knowledge resulting from intellectual activity in a traditional context and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations.

As the protection of traditional knowledge varies from country to country in accordance with national legislation, policy, and practices, it is important to consult with the competent national authorities (CNAs) when applying this standard.

4.1 The integrity of the traditional knowledge associated with genetic resources that are accessed is respected by the collector of genetic resources and other users. The collection and use of TK is made in such a way as to not affect the integrity, sense, and value of the TK, so as to not denigrate it; nor to threaten or diminish the rights of the holders of the traditional knowledge.

4.2 Fair and reasonable effort is made to preserve, respect, and maintain traditional knowledge associated with the genetic resources when that traditional knowledge is accessed and used.

4.3 Adequate compensation and sharing of benefits are provided including recognition of the community when traditional knowledge associated with genetic resources is accessed and used.

4.4 Customary laws and community protocols and procedures regulating access to genetic resources and associated traditional knowledge developed by the indigenous and local communities are recognized, respected, and followed. To the extent possible, the development of community protocols is supported.

4.5. When negotiating MATs, the content of any existing model contractual clauses for access and benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources or genetic resources is taken into account.

Additional Standards

STANDARD 5.0: CONSERVATION + SUSTAINABLE USE
(if access involves wild collection or *in situ* wild sources of genetic resources)

Conservation and sustainable use are practices that ensure, or contribute to, the maintenance of biological diversity and its components for accessed genetic and other biological resources.

5.1 The collection and/or harvest of wild genetic resources is conducted, using a precautionary approach, at a scale and rate and in a manner that does not exceed the sustainable yield and that does not impair ecosystem structure, functions, and services.

5.2 Domestication and cultivation/captive breeding of genetic resources is conducted in a manner that does not jeopardize the genetic variation of the population or diversity of the gene pool.

5.3 Species listed in Appendix 1 of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and species considered to be globally or locally threatened according to the IUCN Red List or equivalent categories are not collected, except for the purpose of species conservation research. No collection is undertaken in legally established protected areas that prohibit collection.

5.4 Knowledge about biodiversity that arises from access to a genetic resource is shared in a manner that supports and enhances conservation management.

STANDARD 6.0: TECHNOLOGY AND KNOWLEDGE TRANSFER

Technology includes both "hard" and "soft" technology. Hard technology refers to the actual machinery and other physical hardware that is transferred, while soft technology refers to technological information or know-how. Soft technology is often transferred within long-term scientific and technological cooperation including though joint research and innovation which move ideas from invention to new products, processes, and services.

6.1 The negotiation of MATs and benefit-sharing provisions creates conditions to facilitate the access and transfer of technology by users in order to enable the development and strengthening of the capacities of the providers to add value to their genetic resources and traditional knowledge associated with genetic resources on a best-effort, case-by-case basis.

6.2 The negotiation of MATs and their implementation provides benefits and supports the development and building of a solid technical, technological and knowledge base for the provider.

6.3 Technology transfer provisions consider the needs, priorities, and self-assessment of capacities of the providers and the necessities for technology infrastructure and other needs in order to make the transfer of technology sustainable.

6.4 Technology transfer takes place in a transparent manner, based on a demand-driven/needs approach, taking into account the different situations, needs, and capabilities of each stakeholder, as well as the different types and characteristics of the genetic resources or traditional knowledge associated with genetic resources being used.

3 GUIDANCE TO GOVERNMENTS ON THE NAGOYA PROTOCOL

This chapter provides guidance to governments in their consideration of their obligations and the opportinities available under the Nagoya Protocol. It is divided into two subsections following a brief introduction.

The first subsection includes a brief explanation of the implications for national implementation including information required to address the different issues and obligations.

The second subsection provides more detailed guidance on the key issues addressed by the Protocol and aligns this information against the each ABS-MT standard.

3.1 Introduction

Concern about the perceived weakness of the Convention on Biological Diversity's provisions on access and benefit-sharing, and the 2002 Bonn Guidelines, largely arose from the absence of measures among user countries to secure compliance with the terms and requirements of countries providing access for the use of their genetic resources. This was an important driver for the development of the Nagoya Protocol. The resulting Protocol now balances the obligations of providers with obligations for users of genetic resources and users of traditional knowledge associated with genetic resources. It establishes national obligations for access and benefit-sharing. The Protocol further bridges these mutual obligations of users and providers through the creation of international certificates of compliance. It is important for all countries to be aware that the Protocol's compliance obligations apply to all countries that have ratified the protocol: whether developing or developed, and whether a country sees itself as a user or as a provider of genetic resources.

3.2 Guidance to Governments

1.0: ACCESS

A. Prior Informed Consent (PIC)

In accordance with the Protocol, the procedures established by governments that require PIC may be legislative, administrative, or policy measures.

These measures must:

- Provide information on how to apply and to whom (designated competent national authorities);
- Be fair and apply non-arbitrary rules and procedures;
- Set out criteria for PIC approval and for involvement of indigenous and local communities, where applicable;
- Provide legal certainty, clarity, and transparency; and
- Provide a copy of the grant of access to the international ABS Clearing-House.[18]

B. Mutually Agreed Terms (MATs)

In accordance with domestic law and domestic regulatory requirements, procedures established by governments for access also provide for the establishment of mutually agreed terms, negotiated under clear rules and procedures and set out in writing.

These may include:

- Agreed applicable law under which the agreement is to be understood and administered[19];
- A dispute settlement clause, including options for alternative dispute resolution[20];
- The jurisdiction under which the dispute resolution process is to be conducted[21];
- Terms on benefit-sharing including intellectual property (IP) rights;
- Ensure Indigenous and local communities' PIC or approval is upon mutually agreed terms, in accordance with domestic legislation[22];
- Terms for any subsequent third-party use[23]; and
- Terms for changes in intended use, where applicable.[24]

[18] Refers to Article 6 of the Nagoya Protocol.
[19] Refers to Article 18(1)(b).
[20] Refers to Article 18(1)(b).
[21] Refers to Article 18(1)(b).
[22] Refers to Article 7 and 5(2) of the Nagoya Protocol.
[23] Refers to Article 6 of the Nagoya Protocol.
[24] Refers to Article 6 of the Nagoya Protocol.

All governments have a common responsibility to encourage the development and use of model clauses in MATs together with ABS codes of conduct, guidelines, and best practices and /or standards.

Governments have a responsibility to encourage the use of dispute resolution provisions in MATs. This is complemented by the obligation to provide access to their legal systems to resolve disputes about MATs and to respond to issues of recognition of foreign judgments and access to justice.

C. National Focal Points and Competent National Authorities (NFPs and CNAs)

All governments must establish national focal points and provide information about ABS policies, terms of access, and contact points to the CBD Secretariat. They must establish competent national authorities (CNAs) on ABS which are responsible for providing information on requirements for obtaining PIC and MATs and for granting access or providing written evidence that access requirements have been met.

Governments must decide whether to require prior informed consent (PIC) for access and use of their genetic resources and of any traditional knowledge associated with genetic resources. If so, they must establish measures to provide for PIC and the establishment of MATs administered by competent national authorities (CNAs). This may also include CNA(s) of indigenous and local communities where the use of traditional knowledge associated with genetic resources requires PIC and MATs.

Domestic ABS systems must create legal certainty through fair and transparent rules with criteria established for the granting of PIC by CNAs and the establishment of MATs. Access permits (or their equivalent) issued by CNAs are to be provided to the CBD ABS Clearing-House to allow creation of internationally recognized certificates of compliance, as appropriate.

More broadly, governments are to create conditions to support research for biodiversity conservation and sustainable use including through simplified access to genetic resources for non-commercial use.

They are also to give due regard to speedy access to genetic resources and speedy benefit-sharing in light of emergencies threatening human, animal, or plant health. They must also consider the importance of genetic resources for food, agriculture, and food security.

Governments must make efforts to cooperate together where genetic resources and traditional knowledge associated with genetic resources are shared across their boundaries with other countries, when implementing the Protocol.

D. Obligations Arising from Subsequent Utilization of Genetic Resources

If a user of genetic resources wishes to undertake research and development for any use not covered under the terms on which PIC or MATs have been granted, the user must seek the approval of the provider of the resources involved. Subject to the domestic laws of the providing country and to the domestic laws of the country in which the resources are being utilized, failure to do so may involve civil or criminal penalties and, in some circumstances, may affect the validity or use of intellectual property created.

Similarly, where access to genetic resources has been granted through simplified measures for non-commercial use, any change in intended use different from the approved non-commercial purpose requires the user to obtain the approval of the provider.

This may require the establishment of MATs.

2.0: BENEFIT-SHARING

All governments are to take action using a range of measures to ensure that benefits arising from the utilization of genetic resources (GRs) and any traditional knowledge associated with GRs are shared through MATs in a fair and equitable way with the providing country and, in the case of traditional knowledge, with the indigenous and local community holding the knowledge. Governments should encourage that benefits be used for the conservation and sustainable use of biodiversity.

The Protocol at Article 5(4) anticipates a flexible and wide range of possible benefits. These possible benefits, including monetary and non-monetary benefits are set out in the Annex to the Nagoya Protocol but are not confined to that list. Experience to date suggests that the range of non-financial benefits is suited to supporting technical transfer and capacity-building

Negotiations on benefit-sharing may include the creation of intellectual property (IP), its ownership, the granting of exclusive or non-exclusive licences, the disposition of benefits flowing from income, or other benefits generated by IP and any associated licences granted. The user commonly owns the IP they create but, in some cases, it may suit the parties to the agreement to share ownership. The IP owner may also agree to grant a licence for the other party as part of agreed benefit-sharing.

3.0: COMPLIANCE

A. Compliance Measures

Compliance means meeting the requirements and obligations of national (domestic) ABS legislative, administrative, or policy measures on access and benefit-sharing to genetic resources and traditional knowledge associated with genetic resources in the country in which genetic resources are provided. Similarly, compliance means meeting the requirements of national (domestic) laws and administrative or policy measures of the country in which genetic resources and associated traditional knowledge are utilized. In both cases, compliance also means meeting the requirements and obligations documented in MATs.

The Protocol establishes compliance and monitoring obligations on the part of all countries in which genetic resources are used, together with measures to support the effectiveness of MATs including, opportunities to seek legal recourse in the event of disputes, access to justice, and mutual recognition of foreign judgments.

Compliance with ABS requirements in the Nagoya Protocol and in practice, is addressed at two different levels: compliance with MATs (a contract), and second, compliance with national legislation, policy, or administrative measures on access and benefit-sharing.

In addition, monitoring the utilization of genetic resources is included in the Protocol to support compliance and to enhance transparency on GR utilization. The Protocol provisions on this issue establish obligations to be fulfilled mostly by governments using their public powers (legislative, policy, or administrative measures) but also via communication to the ABS Clearing-House. Compliance with national ABS legislation and measures is a cross-cutting obligation included in all the relevant standards of the Management Tool. These standards are applicable to the providers and users of GRs and tradtional knowledge associated with GRs.

Parties to the Protocol have general obligations to take action to support compliance with the ABS requirements of providers of genetic resources.[25] This also includes the establishment of one or more checkpoints to monitor or enhance transparency in the use of genetic resources.[26]

Also supporting compliance is the development and adoption of codes of conduct, guidelines, and best practice standards. Parties are required to encourage their development. Provision is made in the Protocol for the Meeting of Parties to the Protocol to take stock of their use and to consider the adoption of specific codes of conduct, guidelines, and best practices and/or standards. Certificates of Compliance have key role in such codes and standards.

[25] Articles 5, 16, and 18 of the Nagoya Protocol.
[26] Article 17(1) of the Nagoya Protocol.

Note: Pursuant to Article 30, the Parties to the Protocol will, at their first meeting, consider and approve mechanisms to promote compliance and address cases of non-compliance. Any such mechanism will also include provisions to offer advice or assistance.

B. Internationally Recognized Certificates of Compliance

The internationally recognized certificate of compliance serves as evidence that the genetic resource that it covers has been accessed in accordance with PIC, and that MATs have been established, as required by the domestic access and benefit-sharing legislation, policy, or administrative requirements of the country providing the genetic resource.

The establishment of *Internationally Recognized Certificates of Compliance*[27] under the Nagoya Protocol is the primary mechanism for monitoring the authorized utilization of genetic resources.

Countries regulating access are obliged to report the granting of access by providing permits granted (or their equivalents) to an ABS Clearing-House located within the CBD Secretariat, where they become Internationally Recognized Certificates of Compliance. This instrument could also be used where traditional knowledge associated with genetic resoucres has been utilized. However, the Protocol does not require a Certificate for the utilization of traditional knowledge.

The establishment of Certificates of Compliance creates a tool to support due diligence enquiry. As such, they provide a source of confidence to the competent national authority of the source country, and the country in which they are being used, and to non-commercial and commercial users of genetic resources.

[27] Article 17 of the Nagoya Protocol.

4.0: TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

The Protocol calls on countries to take measures, in accordance with domestic law, aimed at ensuring that traditional knowledge (TK) associated with genetic resources held by indigenous and local communities is accessed with PIC or prior approval and involvement of indigenous and local communities, and, that MATs are established. The Protocol also puts an obligation upon countries to establish mechanisms to inform potential users of TK associated with genetic resources about their obligations and to take into consideration and support customary laws and protocols.

The procedures to be established by governments (consistent with their domestic law) also include:

- Taking measures with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities are shared in a fair equitable way with the communities concerned, based on MATs, in accordance with the established rights of these communities over their genetic resources.
- Taking measures in order that benefits from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with them upon MATs.
- Taking measures with the aim of ensuring that traditional knowledge associated with genetic resources held is accessed with the PIC or approval and involvement of the communities and that MATs are established.
- Taking measures with the aim of ensuring that the PIC or approval and involvement of indigenous and local communities is obtained for access to the genetic resources where they have the established right to grant access to such resources.
- Taking into consideration indigenous and local communities' customary laws, community protocols, and procedures relating to traditional knowledge.
- Informing users of traditional knowledge about their obligations, in consultation with and with participation of indigenous and local communities.
- Supporting development of:
  - Community protocols;
  - Minimum requirements for MATs; and
  - Model contractual clauses.
- As much as possible, not restricting customary use and exchange of genetic resources.[28]

[28] Refers to Article 12 of the Nagoya Protocol.

In addition to this guidance, **Appendix A** includes a table that presents the most relevant provisions of the Nagoya Protocol, a brief explanation of the implications for national implementation including information required to address the different issues/obligations and sustainable development law principles that can be used as a guide in the ABS national system drafting process.[29,30]

[29] See Cabrera Medaglia Jorge et al, Crafting Biodiversity Visionary Laws; CISDL and WFC, Montreal, 2011.

[30] IUCN is currently developing a document titled the *Explanatory Guide to the Nagoya Protocol on ABS*. This document will provide a neutral explanation of the articles presented in the Nagoya Protocol and will be made available on the IUCN website once finalized. See http://cms.iucn.org/

4 MANAGEMENT PROCESSES GUIDANCE ON IMPLEMENTATION

This section provides basic orientation to assist users of the ABS-MT to put in place management procedures, or to improve their existing management systems, to implement ABS activities.

4.1 Integration with Management Systems

All organizations have some form of procedures or "management" systems, whether they are formal or simply based on commonly used or traditional practices. The ABS-MT is designed to help any type of organization understand and improve the practices it follows to comply with CBD and the implementation of the Nagoya Protocol requirements on ABS in accessing – or providing access to – genetic resources.

Organizations such as small and medium-sized enterprises or research institutions can use the ABS-MT to help set their own internal objectives or standards and procedures to follow when requesting access to genetic resources, collecting such resources once PIC has been given, for negotiating MATs and providing benefit-sharing, using the standards presented in Part I, Section 2. Where it is appropriate, the ABS-MT can also help user organizations carry out the right activities to help ensure that traditional knowledge is appropriately respected and acknowledged, and the conservation and sustainable use of the genetic resource is maintained.

Larger organizations can use the ABS-MT to integrate the Best Practice Standards (from Part 1, Section 2) into their existing management systems and to strengthen their procedures by drawing on the Good Practice Guidelines (from Volume II Part 1 below) and drawing on the Management Process advice provided below.

4.2 Participation of Local and Indigenous Communities

Successful ABS relationships are built on trust. An essential factor in building and maintaining trust – and avoiding negative outcomes such as failure to reach an agreement on access, or claims of biopiracy – lies in providing sufficient and appropriate procedures for the participation of Indigenous and local communities that are the holders, owners, managers, or custodians of genetic resources(and associated traditional knowledge), and, as such, could be impacted (negatively or which stand to gain benefits) in the ABS negotation. A key factor in participation of indigenous and local communities in ABS activities – whether initiated by the community itself or by an outside interest wishing to access genetic resources – is providing adequate time for consultations, engagement, and capacity-building.

As practices and requirements vary from country to country in accordance with national legislation, it is important to consult with the competent national authorities when seeking the participation of indigenous and local communities. These may be national bodies or the

authorized bodies of indigenous and local communities – depending on local ABS law and administrative arrangements.

Suggested procedures for ensuring adequate and appropriate participation of Indigenous and local communities in ABS activities include:

- Maintaining effective communication and dialogue with indigenous and local communities and relevant stakeholders, including their involvement in obtaining PIC and negotiation of benefits;
- Responding to the specific concerns and interests of stakeholders, including local communities and indigenous peoples, through information and commitment to address their concerns or providing a rationale for why action is not taken; and
- Involving indigenous and local communities that are holders, owners, managers, or custodians of genetic resources, in decision-making on access and in sharing of benefits derived from collection and use of genetic resources.

Possible management steps which can be taken are:

- At the outset, clarifying, in writing, the roles, rights, and responsibilities of the intended users (collecting institutions, individual researchers, sponsoring organizations, commercial entities, and government agencies) and the providers of the genetic resource (governments, and interested stakeholders including local and indigenous communities);
- Consulting with other stakeholders that may be (directly or indirectly) affected by genetic resource collection;
- Working with governments to provide indigenous and local communities that are prospective providers of genetic resources with the means and access to expertise to provide them with the scientific and legal capacity or advice to decide on access and to negotiate an ABS agreement; and
- Documenting the processes used for consultation with and involvement of local communities and indigenous peoples in seeking access with PIC in negotiating MATs and in implementing benefit-sharing arrangements.

4.3 Reporting

Reporting between parties to an ABS agreement, and/or appropriate public reporting, improves transparency and builds confidence in ABS activities. Including reporting requirements and milestones in ABS contracts will allow stakeholders to monitor the access and use of genetic resources. Publication of genetic resource transactions on the ABS Clearing-House is a key step in reporting and Parties and users of genetic resources may wish to consider whether it is in their best interests to update the information on the ABS Clearing-House when MATs milestones are reached or when PIC conditions are met, for example, the taxonomic identification of organisms collected.

Voluntary public reporting of genetic resource activities by users, including research institutions and companies, provides transparency of activities and helps share information. This transparency can mitigate public or stakeholder concerns about inappropriate practices.

Maintaining appropriate documents that record discussions, agreements reached, and ABS transactions is important for managaing a consistent ABS process. However, documentation requirements can be difficult for small companies or communities to meet if they are too detailed or onerous.

Suggested procedures for ensuring adequate and appropriate documentation and sharing of information include:

- Sharing information, including intended uses, in a transparent manner between potential providers and potential users of genetic resources and in a manner appropriate to each stage of negotiation and agreement process;
- Providing sufficient information to enable the genetic resource provider and the intended user to make informed judgments and decisions, and undertake actions to implement agreements;
- Maintaining the confidentiality needs of commercial stakeholders and the holders of traditional knowledge while working to the spirit of transparency in the relationship; and
- Where traditional and local knowledge associated with a genetic resource is involved, protecting the traditional and local knowledge in the process of access and not making such knowledge available without the consent of local or indigenous communities.

Possible management steps that can be taken are:

- Maintaining records of ABS collection and use, and making them available to the providers and users of the genetic resource, and to the government regulator whenever the provider is a private party;
- Communicating clearly the objectives and likely outcomes of collection activities, including intended uses of the genetic resources;
- Establishing procedures to ensure that all relevant information can be communicated clearly in a language and manner understandable to all relevant stakeholders and in a timely fashion;

- Addressing unrealistic expectations; and
- Enssuring that sample/material suppliers are aware of, and comply with, the terms of collection and sharing of benefits.

Appendix A:

Nagoya Protocol Provisions and National Implementation

APPENDIX A: NAGOYA PROTOCOL PROVISIONS AND NATIONAL IMPLEMENTATION

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 1: Objective	No specific legal actions to be taken. Any legal, administrative, or policy measure must consider the general objective of the instrument. Fair and equitable benefit-sharing must guide any legal, administrative, and policy measures to be adopted by Parties in their national legislation.		• Equity. • Conservation and sustainable use of natural resources. • Notice that the ABS objective is now clearly linked to the other two objectives of the CBD.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 2: Use of Terms	No specific actions. Legal instruments usually incorporate the new definitions: "derivatives" and "utilization," as happens in the past with the CBD-relevant definitions included in ABS legislation (e.g., genetic resources, etc). Definition of utilization of GRs is a new innovation. Seeks to capture and resolve "derivatives issue." Some lack of clarity as to whether all the derivatives are included or not in the Protocol (e.g., derivates accessed without simultaneously having access to the genetic resources). National legislation can provide some clarity on how to understand, from a practical point of view, the issues of utilization and derivatives and expand the glossary of terms. Drafting of legislation should take into consideration the Protocol's objectives.	Relevance and value of the derivatives in the national context.	• Conservation and sustainable use. • Good governance.
Article 3: Scope	No specific legal actions to be taken. Some of the contentious issues arising out in the negotiations are not included explicitly in the text of the scope. National legislation may provide greater clarity about the scope by defining a list of exceptions or a "positive" list of issues covered by the legislation.		• Equity. • Conservation and sustainable use of natural resources.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 4: Relationship with International Agreements and Instruments	No specific legal actions for countries, except the recognition at the national level of any specialized ABS systems. National level actions must create a synergistic implementation between the international obligations, especially those related to the specialized ABS systems. Room should be available for new and emerging ABS sectoral regulations.	Identify relevant legal instruments, processes and actions for the purpose of drafting the legislation, including WTO, WIPO, WHO, FAO, and UNGA, among others.	• Conservation of natural resources. • Interrelationship of economic, social, and human rights.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 5: Fair and Equitable Benefit-Sharing	Direct obligations to "adopt" measures (paragraphs 2, 3, and 4). Three types of situations are addressed here: 1. Fair and equitable sharing arising out of utilization of genetic resources; 2. Fair and equitable sharing arising out of utilization of GRs in possession of indigenous and local communities' lands; and 3. Fair and equitable sharing arising out of utilization of associated TK. Countries should begin to implement this provision immediately in light of the Protocol's objectives.	Identify national legal framework and established rights for indigenous and local communities over their genetic resources.	• Equity. • Conservation of natural resources. • Public participation and access to justice.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 6: Access to Genetic Resources	Obligation to design legal, administrative, or policy frameworks considering the general principles outline in article 6.3. Conditional obligation in the situation of article 6.2 ("in accordance to domestic law" and "as appropriate"). There are no specific legal measures to be put in place, but any measure must follow the characteristics of this article.	Analysis of the basic conditions in the legal regimen for processing and granting permits, including contractual and administrative law where relevant. Information about rights of indigenous and local communities over the genetic resources that are in their possession, including any relevant international obligations.	• Equity. • Public Participation. • Good governance.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 7: Access to Traditional Knowledge Associated with Genetic Resources	Obligation to adopt or take measures qualified for the terms "in accordance to domestic legislation "and "as appropriate." When enacting national measures, articles 7 and 12 could be considered jointly. Equity and public participation should guide any actions regarding the implementation of this article.	Identify the domestic (including international) legislation in place regarding this issue.	• Equity. • Public participation. • Conservation and sustainable use of natural resources. • Language is more progressive than the language of the CBD in relation to TK.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 8: Special Considerations	Mix of different levels of actions required (shall): • "Create" conditions to promote, including through simplified access for research. • "Pay due regard" to… • "Consider" • "Address change of intent" National measures should be put in place to implement these general obligations, including the simplified procedures for non-commercial research, taking into consideration the practical difficulties to draw the line between commercial and non-commercial research. Some examples found in comparative legislation. Implement measures to expedite procedures and secure benefit-sharing in cases of national or international emergencies, fulfilling cooperation duties. These obligations should be considered in the broader process of the development of national ABS measures, including legislation.	Identity needs of the national basic research community, including taxonomic research. Revise patterns of utilization of GRs for the non-commercial sector in the country and identify needs. Identify relevance of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) for the country. Revise legal framework regarding health emergencies in place, including international obligations.	• Good governance. • Conservation of natural resources. • Precautionary approach to human health, natural resources, and ecosystems.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 9: Contribution to Conservation and Sustainable Use	Obligation to "encourage" users and providers. Measures should be pursued with the aim of supporting conservation as an environmental objective. Linking conservation and ABS should be a goal for the entire ABS legislation and should be reflected and integrated in the entire ABS measure.	Identify potential impact of benefit-sharing arising from utilization on conservation activities and ways to strengthen the impact.	• Conservation and sustainable use of natural resources.
Article 10: Global Multilateral Benefit-Sharing Mechanism	Parties may first consider this possibility as an option in the second meeting of the Intergovernmental Committee for the Nagoya Protocol (ICNP). Collective action to be taken first by the Meeting of the Parties (MOP). Had there been extraterritorial and temporal application of the NP, then the function of this provision would have been clearer. Reference to existing or future multilateral mechanisms, in cases where PIC cannot be granted or obtained, could be considered for their inclusion in any ABS legislation.		• Common but differentiated responsibilities. • Equity. • Conservation of natural resources. • Good governance.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 11: Transboundary Cooperation	Obligation upon Parties with shared GRs or associated TK to "endeavour" to cooperate. National legislation should consider concrete mechanisms to implement this general provision, including examples found in comparative legislation.	Identity possible cases and importance of transboundary or shared GRs and associated TK.	• Equity. • Good governance. • Shared species may have different genetic make-up
Article 12: Traditional Knowledge Associated with Genetic Resources	Language conditional "in accordance with domestic laws"; "take into consideration" (12.1). Direct obligation to "establish" (12.2). Obligation to "endeavour to support" (12.3). Concrete measures should be put in place to create more equity and legal certainty in the negotiations, particularly by improving indigenous peoples' and local communities' opportunities, and to empower them.	Identify current legal framework due to the qualified language in the provision. Analyze the situation of customary law and the role and value of community protocols.	• Equity. • Public participation.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 13: National Focal Points and Competent National Authorities	Short-term obligation to designate these authorities and establish the functions described in this article. Legal or administrative measures should allow authorities to develop this function properly.	Identify possible options for competent national authorities, the starting point is clarity on the institutional design to be established (e.g., one central CNA; several CNAs, a decentralized system). Careful assessment of different options and consideration of the weakness and strengths of any potential bodies (agriculture, environment, fisheries, etc.).	• Good governance.
Article 14: The Access and Benefit-Sharing Clearing-House and Information-Sharing	Obligation to submit/make available information to the ABS Clearing-House.	This is a core measure.	• Good governance.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 15: Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-Sharing	Measures to be determined at national level with the guidance of the Parties (15.1 and 15.2). Conditional obligation to: "as far as possible and as appropriate" cooperate (15.3). At the national level, countries can immediately begin to create appropriate measures to secure compliance with other countries legislation and provide measures for cooperation in cases of breaches of national law. A set of options is available. Countries have the opportunity to demonstrate good faith by describing the steps they will undertake to secure compliance and create a functional system to support other countries.	Relevant information on options and legal and administrative measures to support other countries' national legislation. The CBD Secretariat documents produced during the International Regimen negotiations and the results of the Technical and Legal Expert Groups on compliance and the certificate may provide relevant input.	• Good governance. • Common but differentiated responsibilities. • Public participation and access to justice.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 16: Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-Sharing for Traditional Knowledge Associated with Genetic Resources	Same explanation as article 15.	Same.	• Same.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 17: Monitoring the Utilization of Genetic Resources	Direct obligation to "take measures." Measures will include at least checkpoints to be determined and sanctions to be determined. Other measures are qualified as " to encourage." Permit (or equivalent) will become the international certificate (mandatory content in article 17.4). It is possible for countries to immediately exercise this option and create appropriate measures to secure mandatory disclosure of information at appropriate checkpoints and sanctions in cases of non-compliance by the users. This could require legally binding measures depending on the country's legal system (fees, etc.). Set of options/checkpoints available. Countries have the opportunity to demonstrate good faith by beginning a quick implementation of this provision. National legislation should also encourage systems to be adopted by users to support the monitoring of GRs and associated TK.	Identify possible checkpoints in accordance to the description presented in this article, and the best options available for an appropriate implementation in the light of the Protocol's objectives.	• Same.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 18: Compliance with Mutually Agreed Terms	Obligation to "encourage" users and providers (18.1). Stronger obligations to "ensure" (18.2) and take measures (18.3).	Relevant understanding of existing mechanisms found in the legal system regarding access to justice and recognition of foreign sentences and awards.	• Equity. • Good governance.
Article 19: Model Contractual Clauses	National obligation to "encourage." CoP/MoP shall "take stock of model clauses."	Compilation of existing codes and model clauses. Review of national initiatives on this matter. WIPO has developed useful sources of information, including online resources.	• Good governance. • Conservation and sustainable use.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 20: Codes of Conduct, Guidelines and Best Practices and/or Standards	National obligation "to encourage." National recognition of best practices and special treatment for the adherence to Codes of Conduct could be considered given the need to promote compliance and certainty. CoP/MoP shall consider adoption of Codes of Conduct, Guidelines and Best Practices, and/or Standards.	The CBD Secretariat has developed useful sources of information, including online resources. Review of national initiatives.	• Good governance. • Conservation and sustainable use.
Article 21: Awareness-Raising	Direct obligation to take measures to increase awareness. Indicative list provided. National legislation should provide guidance on effective awareness-raising, for example with the research community.		• Good governance. • Conservation and sustainable use of natural resources.

Nagoya Protocol	National Level Actions Required	Useful Baseline Information	ISDL Principles/ General Comments
Article 22: Capacity	At the national level, countries "should" facilitate participation… and "should" identify their needs and priorities. This requires basically a policy measure to allow or facilitate participation consistent with basic principles of sustainable development. Obliges Parties to cooperate in capacity building.		• Equity. • Public participation. • International cooperation
Article 23: Technology Transfer, Collaboration and Cooperation	Obligations for the "Parties." National legislation should address technology transfer, including concrete incentives for promotion. Obliges Parties to cooperate and collaborate.	Different analysis exists on the issue of TT in the field of the biodiversity/genetic resources, including CBD Secretariat documents and papers as well other organizations' (UNCTAD, UNEP, etc.) relevant studies on practical ways to achieved TT.	• Common but differentiated responsibilities • International cooperation

VOLUME II

HANDBOOK FOR IMPLEMENTING GENETIC RESOURCE ACCESS AND BENEFIT-SHARING ACTIVITIES

PART I:
Good Practice Guidance

1 GOOD PRACTICE GUIDANCE

This set of Good Practice Guidance for each of the ABS Standards is presented in checklist form for ease of use. The standards are intended to be applied **flexibly** according to the needs and circumstances of each case. Thus, not all the elements mentioned here need to be included or considered in the negotiations and the ABS relationship. These elements should be adapted to your specific ABS case, in cooperation with the provider of the genetic resources, and consistent with national ABS legislation or regulatory requirements in relevant jurisdictions.

STANDARD 1.0: ACCESS		
1A. Prior Informed Consent (PIC)	**For Provider**	**For User**
• Obtain and comply with all the applicable laws and regulations in force in the country regarding PIC. Meet the identified requirements to comply with PIC obligations. Identify: (a) the competent national authority(ies) to which you should submit an application for PIC or to which you make inquiries on PIC; (b) the neccesary format of the application and specific items of information required; and (c) any other requirements or conditions for obtaining PIC.		X
• If there are no PIC laws or regulations, base the discussions on appropriate information, including the information listed in Part III, 6 (information requirements for PIC).		X
• Identify the competent national authority, indigenous and local communities, and other relevant stakeholders and, wherever possible, determine ownership of the genetic resources and/or associated traditional knowledge. In accordance with national legislation PIC, may be required from different levels of government.		X
• Establish a consultation process and information exchange with interested parties that clarifies their concerns and/or doubts and responds to their requests for information or documentation. • Ensure that all relevant information can be communicated clearly in a language and manner understandable to all relevant stakeholders and in a timely fashion. • Clearly communicate to the providers the risks (e.g., time, money, and uncertainty of finding material with commercial value) that users are faced with undertaking research and developing genetic resources.		X
• Ensure that genetic resources are used only for the purposes outlined in the PIC negotiation, and ensure that new PIC is given for any use that differs in type or scope from those originally outlined. Ensure that new PIC is given in cases of transfer of genetic resources to third parties.		X

STANDARD 1.0: ACCESS		
1A. Prior Informed Consent (PIC)	**For Provider**	**For User**
• To the extent possible, ensure compliance with domestic laws and local traditions or processes related to the application for and approval of access, including community protocols and customary law. Conclude an agreement with the provider that reflects the terms and conditions of PIC including, *inter alia,* terms and conditions regarding benefit-sharing.		X
• After PIC has been obtained, conduct the research and development activities in a manner that complies with the terms and conditions specified in the contract.		X
• Respect restrictions on the use of genetic resources and associated traditional knowledge covered by the PIC agreement.		X
• For *ex situ collections*, obtain PIC from the competent national authority (CNA) and/or the organization governing the *ex-situ* collection concerned. In the case of access to *ex situ* resources, examine the PIC documentation from the provider to determine *whether the material provided was collected legitimately with all required PIC and* if it is adequate to cover the transaction and intended use. If PIC does not exist, or does not cover the transaction and intended use, obtain further PIC from the competent national authority and/or the organization governing the *ex situ* collection concerned. This PIC may come from come the CNA or the *ex situ* collection depending on the time and origins of the sample held.		X
• In the case of genetic resources provided by an intermediary, require proof that the organization supplying genetic resources has the right to transfer the materials and that it is authorized to supply them for product discovery and development. • In the cases that require special considerations according to national and international law, providers and uses need to pay due regard to these special considerations to the extent fesible (See article 8 of the Nagoya Protocol).	X	X

STANDARD 1.0: ACCESS		
1A. Prior Informed Consent (PIC)	**For Provider**	**For User**
How to address difficulties in identifying from whom prior informed consent should be sought? • A diagram presenting the steps taken and duration of process of obtaining PIC in past experiences is useful. A schematic diagram may be helpful in visualizing how to operationalize PIC in practice. • Other factors should be considered in determining relevant stakeholders from whom PIC should be sought: the ownership of land where collection takes place; the role granted to the different levels of government by legislation, customary law, and practices. • When the ABS Clearning House is operational, check if there is information on community protocols and customary law, and how to obtain PIC from indigenous peoples and local communities in the country where access is to take place. • Examples of prior informed consent-related procedures, legislation, guidelines, and agreements: ▸ A diagram operationalizing PIC in, *Perrault. Anne: Prior informed consent and access and benefit-sharing: recognition and implementation, IUCN, March 2006*. ▸ Section III, *Biodiversity and Traditional Knowledge: equitable partnerships in practice,* Laird, Sara (ed.), Earthscan, 2002. ▸ International Cooperative Biodiversity Groups' website (www.fic.nih.gov/programs), which contains useful information on the process of negotiating ABS contracts and securing PIC in real situations).	X	X
How to address the transboundary nature of genetic resources which makes it difficult to identify from whom PIC should be sought or traditional knowledge, which can be shared by more than one community/indigenous peoples. • There is no simple solution. To the extent possible, it is useful to take into account the interests of non-participants in the negotiations. If possible, consider providing benefit-sharing to them (e.g., using a trust fund or other mechanisms, or be clear at the outset that the responsibility for sharing benefits needs to be determined in accordance with traditional practices and customs. It may not be appropriate for the user to determine benefit-sharing on behalf of all stakeholders. ▸ A percentage of the payments could be directed to this mechanism to compensate/assist non-participants in the negotiations. Some ABS laws (e.g., in Peru) address this issue by requesting the user, in the case of shared traditional knowledge, to provide some compensation to non-	X	X

STANDARD 1.0: ACCESS		
1A. Prior Informed Consent (PIC)	**For Provider**	**For User**
participants using a fund created by the law. ▸ When and if operational, a ABS Multilateral Mechanism which is to be created by the Nagoya Protocol, could be useful to implement and deal with transboundary GRs and associated TK. ▸ It is also possible that your obligations and responsbilities will be determined by the provsions set out in national law. If this is the case, then your primary obligation is to follow that law.		
Other useful tips • In addition to PIC and MATs, verify that you have all other the necessary permits (e.g., export permits, CITES, etc.). In cases involving intermediaries, check whether the intermediary has obtained the genetic resources in compliance with the laws and regulations of the country providing the genetic resources and whether the intermediary has been authorized to transfer the resources to a third party. • Include a clause in the contract stating that the intermediary assures that it has obtained the genetic resources in compliance with the laws of the providing country. If you have doubts, check with the government of the Country of Origin about the legality of the transfer or the title of the intermediary. A quick check with the ABS Clearing-House may resolve any doubt if the materail is covered by the Nagoya Protocol. • If a genetic resource is to collected from private land or from local people or landowners from whom PIC is to be obtained, it is advisable to also inform responsible government officials.	X	X X X

STANDARD 1.0: ACCESS		
1B. Mutually Agreed Terms (MATs)	**For Provider**	**For User**
• Comply with all the applicable laws and regulations regarding benefit-sharing in the country. Recognize that legal and policy arrangements differ by country/jurisdiction. • If they exist, take into account any model clauses develop specially for indigenous peoples and local communities. • Negotiate MATs in good faith. Make an effort to ensure that all organizations take into account and consider the other's interests, ideas, and suggestions.	X	X
• Recognize that MATs are the result of a negotiation process that involves give and take with the intent that the user and provider are satisfied with the outcomes.	X	X

STANDARD 1.0: ACCESS		
1B. Mutually Agreed Terms (MATs)	**For Provider**	**For User**
• Be sure that your counterpart has access to independent legal advice to ensure adequate legal guidance in the negotiation of MATs.	X	X
• Set out MATs in a written agreement.		X
• Include in MATs conditions, obligations, procedures, types, timing, and mechanisms of benefit to be shared. These will vary depending on what is regarded as fair and equitable in the light of the particular circumstances. • Include in the MATs, as appropiate, provisions related to dispute resolution, including jurisdiction, applicable law, and options for alternative dispute resolution such as mediation and arbitration.		X
• Seek to ensure that the commercialization and any other use of genetic resources does not prevent the traditional uses of genetic resources.		X
• Include in MATs, if feasible, the source of the material – country of origin and the provider of genetic resources and associated traditional knowledge.		X
• When supplying genetic resources to third parties, ensure that the transactions and intended use are covered by existing MATs and PIC, and honour all terms and conditions regarding the acquired material. Provide to this third party relevant, non-confidential data on their acquisition. Do not transfer genetic resources to third parties unless such transfer is consistent with the terms and conditions of the PIC.		X
• To the extent possible, include in the the agreement provision for internal and/or external audits to report progress on its implementation to both the user and provider of the genetic resource. The involvement of relevant stakeholders, and indigenous and local communities in the various stages of development and implementation of access and benefit-sharing arrangements can play a role in facilitating monitoring and compliance.		X
• Resolve disputes arising in the access agreement in accordance with the relevant contractual arrangements and the applicable laws and practices, taking into account the needs and constraints of, and the resources needed by, the provider and user organizations to secure access to justice.		X
Key challenges/tips:		
What should be done if the parties to the negotiations do not have experience with or clear and appropriate understanding of terms and conditions for MATs? • Some countries' national laws may contain specific stipulations regarding the content of the MATs.	X	X

STANDARD 1.0: ACCESS		
1B. Mutually Agreed Terms (MATs)	**For Provider**	**For User**
• If this is not the case, use the supporting tools in the ABS-MT (Part II, 4 – Generic MTAs, and 5 – Generic ABS Contract outline).		
How to ensure timely negotiations that do not hold up progress. • There is no simple solution. Clear rules for when, for how long and how the negotiations will take place should be jointly agreed. Provider and users should be committed to working towards the succesful conclusion of the negotiation. Both should take responsibility for negotiating and implementing benefit-sharing arrangements to ensure timely negotiations.	X	X
How to ensure sufficient bargaining power for the provider government or community. • Bargaining power and access to legal advice and mechanisms may be different, particularly for local communities or research organizations. See recommendations for addressing the Key Challenges for PIC.		X
Other useful tips: • An MTA is a contract. Its content should be determined by the parties involved. But in some countries national laws may contain specific stipulations regarding the content of the MTA. Therefore is advisable to study the laws and administrative measures of the country in question. • Enquire about the existence of standarized agreements such as standard MTAs. • Settlement of disputes may be costly, and access to legal remedies differs from country to country. Legal mechanisms for dispute resolution are expensive; agreements can make clear who will cover the cost. A specific contribution to the payment of the cost of the dispute mechanism may be considered. Additional mechanisms such as insurance provisions in case of disputes may be explored along with alternative dispute mechanisms involving options for mediation, conciliation or arbitration. • Be sure of the existing mechanisms regarding access to justice and the mutual recognition of foreign judgements and awards in the countries involved in the ABS transaction.	X X	X X X X

STANDARD 2.0: BENEFIT-SHARING	For Provider	For User
• Comply with all the applicable laws and regulations regarding benefit-sharing in force in the provider country. • Take into account the expressed desires and needs of the other organization/community and its capacities when negotiating benefit-sharing provisions, in a fair and constructive manner so as to not put them at a disadvantage.		X
• Use comprehensive and open list/menu to chose from possible monetary and non-monetary benefits to begin the process of negotiating benefits, to apply flexibly for the different cases and situations (list of potential benefits provided in Part II). • Pay due regard to the List of Monetary and Non-Monetary Benefits included in the Annex to the Nagoya Protocol.		X
• Consider short-term, medium-term, and long-term benefits. The time-frame of benefit-sharing should be stipulated. Furthermore, the balance among near-, medium-, and long-term benefits should be considered on a case-by-case basis.		X
• Determine the benefit-sharing mechanisms jointly between the user and provider organizations, depending upon the type of benefits and the specific conditions. • To the extent possible and considering the specific circumstances of the negotiations, seek to direct benefits towards the conservation and sustainable use of biological diversity.	X	X
• Promote the benefits that directly reach the providers (owners/manager/custodians) of the genetic resource, including local and indigenous communities. Training, capacity-building, and technology transfer could be especially considered.		X
• To the extent possible, provide appropriate monetary benefits including financial contributions for research and conservation, royalties, etc.		X
• Carry out the use of genetic resources in and with the participation of the provider country and other providers (owners, users, custodians), including local and indigenous communities, unless it is not feasible.		X
• Identify opportunities in the source country and location of collection for participation in commercialization and value-adding activities.		X
• Seek the original provider of the genetic resource for re-supplying further material when needed, unless this is not feasible.		X

STANDARD 2.0: BENEFIT-SHARING	For Provider	For User
• Establish appropriate monitoring mechanisms in the legal arrangements. • Consider the transboundary nature of GRs and associated TK when establishing ABS agreements. • Provide all the relevant information required by the national checkpoints, considering the confidentiality provisions of the MATs. • Where feasible and appropriate, including through the national focal points and competent national authority(ies), share information on current practices and examples of benefit-sharing to improve the information on this matter.	X	X
Key challenges/tips:		
How to address unrealistic expectations on the magnitude and kind of benefits to be shared. • Sharing information honestly about the potential and real benefits to be received is advisable. It is essential to ensure that your counterpart accurately understands that a (possible) future process of R&D and commercialization takes considerable time before any benefits may be actually generated and that profits do not arise quickly. • Explain that the probability of a product ultimately being placed on the market is generally low. Therefore, only in a limited number of cases it will be possible to share benefits arising from commercialization. • If you are interested in negotiating an ABS agreement in a specific field (e.g., horticulture, crop protection, pharmaceuticals, etc.) it is convenient to review journals and other sources of information about the commercial practices in each field. • Consult general sources of information: ▸ ten Kate, K. & Laird, S. (1999). The Commercial Use of Biodiversity. London: Earthscan.; and, UNEP/CBD/WG-ABS/4/INF/5 ▸ Laird, Sara. The Commercial Use of Biodiversity: An Update on Current Trends in Demand for Access to Genetic Resources and Benefit-sharing, and Industry Perspectives on ABS Policy and Implementation ▸ Kamau, E. & Winter, G. (Eds.) (2009). Genetic Resources, Traditional Knowledge and the LAW – Solutions for Access & Benefit Sharing. London: Earthscan.		X
Royalty and milestone payments are kept confidential in most ABS agreements. A number of factors commonly influence the magnitude of royalty payments and these vary from company to company. Some issues to consider in a royalty structure are: a) relative contribution of partners to invention and development;	X	X

STANDARD 2.0: BENEFIT-SHARING	For Provider	For User
b) information provided with samples; c) novelty or rarity of sample organisms; d) degree of derivation of the final product from the genetic resources supplied; and e) likely market share of the final product.		
How to monitor and track that benefits are being implemented as agreed in the MATs. • It is important to understand that there is no fixed amount or simple guideline for determining the monetary value of benefits. Each case is different and can be influenced by a wide range of factors. • An important starting point is good documentation of the negotiations and outcomes of the MATs – including a clear understanding of the means for implementation and the terms and conditions outlined in the MATs/contract. • Considering the nature of the research and development of genetic resources, establishing appropriate monitoring/tracking and reporting mechanisms in the legal arrangements is advisable but sometimes difficult to enforce. • Legal provisions allowing independent auditing, identifier codes for each sample, etc., should be explored. For instance it may be worthwile to include some mechanisms to: ▸ Label all material with a barcode and identification number; ▸ Establish a requirement for assigning identification numbers to resources the resulting materials; ▸ Ensure that users are obligated to maintain complete accurate internal written records and reporting systems for their research and/or development activities; and ▸ Allow the provider to audit and/or inspect records and reporting systems and make recommendations for improving reporting procedures. • Provider may have access to lab notes.	X	X

STANDARD 3.0: COMPLIANCE	For Provider	For User
• Facilitate information regarding legal mechanisms existent on access to justice, cooperation between the providing country and the country in which the material is utilized, recognition and enforcement of foreign awards, and of legal remedies available in cases of non-compliance with the contract in countries where the genetic resources will be sent upon request of the provider. • Ensure the user of the material has an Internationally Recognized Certificate of Compliance.		X
• Disclose relevant information on prior informed consent, mutually agreed terms, utilization of genetic resources and associated traditional knowledge, and compliance with national ABS measures in the country where the resources were accessed to the checkpoints established in the country where the material is utilized – where these exist.		X
• If checkpoints do not exist, provide relevant information, where appropriate, on the above matters to institutions such as IPR offices, product register, journals, and funding institutions, others on a case-by-case basis.		X
• Prepare and disseminate public reports including information regarding compliance with PIC procedures, MATs, national ABS legislation, and the Nagoya Protocol, taking into account any confidential obligation that may exist. This reporting could be part of the user organization's policies or sustainability reporting practices.		X
• Communicate in a timely manner to the provider any codes of conduct/guidelines on ABS to which the user is subscribed or is a member, including any relevant contact point.		X
• In the process of granting access, take into consideration the membership of the potential user in any relevant codes of conduct, guidelines, etc. on ABS.	X	
• Put in place monitoring and tracking mechanisms on the genetic resources accessed and utilized, and share the existence of these mechanisms with your counterpart and other relevant stakeholders in order to build trust. To the extent feasible on case-by-case basis, include appropriate contractual provisions reflecting these practices.	X	X

STANDARD 3.0: COMPLIANCE	For Provider	For User
Useful tips • Implementation of the national compliance measures in the light of the Nagolya Protocol will begin in the coming years, when countries will enact new compliance measures. Users must be aware of these potential changes, the new regulatory environment, and other factors, by looking at the ABS Clearing-House and other sources of relevant information. Compliance mechanisms may be established at three different levels: a) compliance with the national ABS legislation/measures; b) compliance with MATs/contracts; and c) compliance with the Nagoya Protocol.	X	X

STANDARD 4.0: TRADITIONAL KNOWLEDGE	For Provider	For User
• Put in place a process during the PIC phase to obtain TK and promote participation of indigenous peoples and local communities. • Identify all holders of TK, competent local authorities, and other groups that provide approval.		X
• Apply all applicable requirements of PIC to obtaining TK, especially respecting indigenous peoples' and local communities' decision-making processes.	X	X
• Consider proper benefit-sharing mechanisms for the TK holders not participating in the access negotiations where the use of TK is separate to accessing the genetic resources. • Respect and follow the community protocols in relation to access to traditional knowledge associated to genetic resources. • Respect and follow the minimum requirements for mutually agreed terms and any model contractual clauses for benefit-sharing that may exist, and provide any justification if it is not possible to strictly follow them in specific cases or situations.	X	X
• Suspend collection if TK holders decide that the research is not acceptable. If required, and in accordance with the contract, the use of the TK should be stopped until open discussions are in place to understand the concerns of TK holders.	X	X
Demonstrate respect for and understanding of the TK of indigenous communities by appying the following principles: **Integrity** • Ensure that the research activities and collection do not violate customary laws and practices. • Respect the sacred values and places of TK holders. • Ensure any collection or use of genetic resources does not impede traditional uses of TK. • Ensure that no intellectual property rights are sought, or any form of commercialization is undertaken in a way that affects TK use, unless expressly permitted by the holders of the TK. • Ensure that the information not otherwise publicly available on traditional knowledge associated with the genetic resources accessed or used is not disclosed without the prior informed consent of the TK holders. • Negotiate and provide fair compensation for genuine grievances related to collection of genetic resources that have damaged resources used for livelihoods of local and indigenous communities or people. • Respond to government, stakeholder, local and indigenous community concerns related to proposed or ongoing collection of genetic resources.		X

STANDARD 4.0: TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES	For Provider	For User
Protection and preservation • Report to the TK holders all relevant non-confidential information to support maintenance and improvement of TK. • Support the documentation and registration requirements requested by TK holders. • Properly acknowledge in all the publications and IPR applications the TK holders' contributions. **Compensation/benefit-sharing** • Establish appropriate contractual mechanisms that take into account the freely expressed desires of TK holders, their needs, and particular situations. • Undertake collection and research, and provide compensation to avoid social and cultural disruption. • Consider a broad spectrum of monetary and non-monetary benefits. • Consider appropriate mechanisms for administering monetary benefits, including trust funds.		X
Key challenges/tips		
How to deal with the existence of different cultures and languages and the varying geographic locations of the same communities. • Engaging local people as advisors during the negotiations may be useful.		X
How to address the situation where TK is shared among several traditional communities some of which are non-participants in the agreement(s) for PIC and benefit-sharing. • Both the community concerned or local authorities must be consulted on what should be done in these circumstances, particularly in benefit-sharing implementation. See suggestions presented under PIC. • Consider allowing indigenous peoples or local communities to resolve the benefit-sharing agreement in accordance with their traditions and customs.	X	X
• How to address the different bargaining powers, legal skills, access to justice, and monitoring and reporting capabilities often exist between traditional communities and intended users of genetic resources. • Suggestions for addressing these problems are provided in Part II Guidance sections on MATs (2) and Benefit-Sharing (3).	X	X

STANDARD 5.0: CONSERVATION AND SUSTAINABLE USE	For Provider	For User
• Assess current conservation status of the species and population to be sampled/collected, according to the IUCN Red List categories and criteria prior to granting of PIC, if collection is to exceed simple single sampling.		X
• Assess the current habitat status and any critical environmental concerns, including other uses/pressures on the resource.		X
• Use a combination of scientific methods and local/traditional knowledge for assessment of conservation status and decision-making on sustainable use.	X	X
• Work with local and indigenous communities to respect and incorporate customary practices with regards to conservation and sustainable use.	X	X
• Assess genetic diversity of species of interest for domestication and cultivation.		X
• Develop and implement a collection/harvest management plan and collection protocols that specifically address conservation and sustainable use criteria for the resource being accessed.	X	X
• Deposit taxonomic vouchers of every species or sub-species collected to a museum or other appropriate repository in the source country.		X
• Maximize the involvement of local research institutions, and indigenous and local communities, in collection for conservation research and other conservation activities related to ABS.		X
• For ongoing collection/wild harvesting, monitor the status of the resource to ensure harvest does not exceed the agreed sustainable yield.	X	X
• Consider the contribution to conservation that the non-monetery benefit listed in the Annex to the Protocol may make. Offer these on a high-conservation and sustainable value to the provider or manager of the area.		
• Include funding and other resources for conservation purposes in benefit-sharing arrangements, including under MATs.		X

STANDARD 6.0: TECHNOLOGY AND KNOWLEDGE TRANSFER	For Provider	For User
• Clearly communicate the technology transfer needs, constraints, limitations, etc.	X	X
• Based on knowledge of the range of available technologies, assess priority technology needs through consultation with the provider of genetic resources and associated traditional knowledge considering the local and national capacities within the country. • Design and implement appropriate mechanisms relevant to the transfer and application of technology that are conducive to the transfer of technology. • Technology transfer may include (free of charge or under concessional or preferential terms and licences): transfer of know-how, protocols, state-of-the-art technologies, equipment and infrastructure, integration of local researchers and collaborative research, among others, to create a long-term basis for the research and development on genetic resources and associated traditional knowledge. • To the extent that it is possible, access to and transfer of the latest scientific and technological advances should be considered. • Specific activities can be distinguished according to whether they focus on fostering the provision of technologies or on the reception, adaptation, and diffusion of technologies. • In the process of negotiating technology transfer, provide information on available technologies, including on projected costs, risks, benefits, and constraints; necessary infrastructure, personnel, and capacity; sustainability, etc. • Pre-assess the adaptability of prospective technologies to be transferred. Recognize, and act on, any capacity-building needs of providers and ensure sustainability of the transferred technology. • Be aware of, and comply with, relevant regulations of the provider country.		X
• Encourage the development of cooperative partnerships and/or networks involving, where appropriate, relevant stakeholders.	X	X

STANDARD 6.0: TECHNOLOGY AND KNOWLEDGE TRANSFER	For Provider	For User
Useful tips • The process leading to technology transfer will necessarily differ in accordance with the largely varying socio-economic and cultural conditions as well as the type of technologies transferred. Hence, this process needs to be flexible, participatory, and demand-driven. • Technology transfer, particularly in the context of the third objective of the Convention and the Nagoya Protocol, will not be effective as an one-off and one-way activity, but needs to the result of participatory decision-making processes and then integrated into long-term scientific and technological cooperation. • It would be advisable to review existing technology transfer agreements or technology transfer provisions/clauses in other agreements. This analysis could also include existing templates for standard technology transfer agreements/provisions/clauses and good/best practice on the application of technology transfer agreements/provisions/clauses.	X	X

PART II:
Supporting Tools

This section includes a serues of tools that can assist ABS users and providers with negotiating ABS agreements. These tools are intended to provide additional guidance and information for users of the ABS-MT.

1 ROAD MAP OF INTERACTION BETWEEN NATIONAL LEGAL FRAMEWORKS AND THE ABS-MT

This map is intended to provide some suggestions for determining the applicable legal framework and to improve legal certainty before entering into ABS negotiations. Below is a list of indicative steps to be taken to identify the relevant legal provision on ABS in the country in which access is sought. This may be complemented with the relevant sources of information provided in Part II Section 8.

Step 1

Check whether the research is subject to access and benefit-sharing requirements for genetic resources or is related to the access and use of biological resources more broadly. Depending on the legal requirements of the country, you may not need to use the ABS-MT or apply for ABS-specific approvals. Other approvals or collection permits may be required.

Step 2

Check if the genetic resources to be accessed are covered by the International Treaty on Plant Genetic Resources for Food and Agriculture (the Multilateral System on ABS of the ITPGRFA) and if the country where access is going to take place has ratified the Treaty. If this is the case, you don't need to use the ABS-MT or negotiate an ABS agreement under the CBD. However, the Material Transfer Agreement of the Treaty must be negotiated and signed. Remember that the ITPGRFA does not apply to industrial and pharmaceutical use. Such usage would bring the Nagoya Protocol into play.

Step 3

If the resources are not covered by the ITPGRFA or the country is not member of the Treaty, check to determine if the host country has ratified the CBD.

Step 4

Identify national laws related to the Convention on Biological Diversity, the Nagoya Protocol, and to Access and Benefit-Sharing. Check if there is a national focal point or competent national authority for the CBD or ABS. Check the CBD database on ABS measures for information on official communications from countries on ABS legislation. Seek information on the ABS Clearing-House Mechanism.

Step 5

Check with the national focal point or the competent national authority for a specific national legal framework, including any administrative and policy measures on ABS. If the relevant national legislation does not yet exist, access permits may be issued on a case-by-case basis, based on general principles of law and or similar procedures and rules. Check also if the country has decided not to develop legislation requiring PIC and if there are special considerations for specific uses or genetic resources in certain areas.

Step 6

Determine issues of interest such as ownership of genetic resources, land rights, rights of indigenous and local communities in the country, and locally, as well as administrative competencies, permitting systems for the use of natural resources, and related commercial and contract law, etc. The ABS procedure may be combined with other licences (e.g., research, export, collections, CITES, etc).

Step 7

Contact the national focal point who will direct you to the competent national authority for information on:

a) prior informed consent;
b) mutually agreed terms;
c) benefit-sharing provisions; and
d) other relevant information.

This kind of information may include information on: procedures for obtaining prior informed consent or approval and involvement of indigenous peoples and local communities; competent authorities of indigenous peoples and local communities; model contractual clauses and code of conduct and best practices; and on obligations of the potential user with regard the utilization of TK associated to genetic resources, among others.

Step 8

Obtain information from relevant local sources (e.g., partner institutions) and legal experts.

Step 9

Obtain information from other colleagues and users about their experiences and the legal framework in the country.

2 ABS AGREEMENTS

ABS agreements are contractual arrangements between users and providers of genetic resources that govern their respective rights and obligations, including terms of access to genetic resources, and the benefits to be provided related to access.

A number of different types of ABS agreements that are commonly used are listed below.[31] Many actual agreements are, in fact, a combination of several of these types, depending upon the individual circumstances of the genetic resources in question and the relationships between user and provider.

A. Types of ABS Agreements

Letters of Intent or Heads of Agreement:

Recording preliminary agreement on the overall framework of a proposed collaboration, including any commercial arrangements that may apply, and to ensure that the future negotiations on the details of a contract or licence have a solid basis of understanding;

Confidentiality or Non-Disclosure Agreements:

Requiring the recipient of information to keep it confidential, such as information concerning source of genetic resources, associated TK or know-how, which may be used in gaining access to genetic resources for evaluation purposes, developing a research collaboration, or as a condition of employment; such agreements frequently limit the purposes for which such information can be used – depending on the circumstances, this may include limiting its use to evaluation, research, or non-commercial purposes, or limiting it to certain agreed purposes;

Research Agreements or Research and Development Agreements:

Agreements that define various inputs to research and development, including financial, material (including genetic resources), and intellectual contributions, specify various responsibilities in relation to the conduct of research and development of new products or processes, and set out how the monetary and non-monetary benefits from this research and development should be managed and shared;

Material Transfer Agreements (MTAs)[32]:

Common tools in commercial and academic research partnerships involving the transfer of biological materials, such as germplasm, micro-organisms and cell cultures. In most MTAs, a provider agrees to give identified physical material to a recipient, and the recipient agrees to restrict the uses that may be made of that material, and often of any improvements or derivatives;

[31] Some of the information provided here is based on the document prepared by World Intellectual Property Organization (WIPO), WIPO/GRTKF/IC/7/9 July 2004. Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing (document prepared by the Secretariat).

[32] Additional information on MTAs and an examples of the how MTAs are applied to ABS negotiations is provided in Part III, Section 4.

Licensing Agreements:
Agreements setting out certain permitted use of materials or rights that the provider is entitled to grant, such as agreements to license the use of genetic resources as research tools, or to license the use of associated TK or other IP rights.

Examples of two types of agreements, Material Transfer Agreements and ABS contracts, are provided below.

In addition, links to relevant sources of information and MTAs or contracts are provided in section 8 below, including the WIPO database on MTAs and contracts (which incorporates National Cancer Institute MTA, CGIAR Centre, etc. (see www.wipo.int/tk/en/databases/contracts/).

B. Factors Affecting the Content of an ABS Agreement

A range of factors will affect the basic elements and content of an ABS agreement. Some of these factors are listed below.

Applicable Legislation:	The elements of an MTA or ABS contract are affected for the relevant international, regional, or national legislation. The diversity of national law – both related to ABS/genetic resources and to contract law – and of the practical interests of providers and recipients is likely to lead to a wide range of options when actual provisions are negotiated and drafted. Prior to entering into any legally binding contractual arrangement setting out mutually agreed terms of access to genetic resources and benefit-sharing, all contracting parties should seek expert legal advice.
Genetic Resources:	This may embrace a wide range of genetic materials, of plant, animal, or microbial origin. Genetic material may have clear actual value; its potential value may be high; its value may be untested or uncertain; or it may have unforeseen, surprising, or unpredictable uses and values in different sectors.

Providers and Users:	These may include the government sector (e.g., government ministries, government agencies (national, regional or local), including those responsible for administration of national parks and government land); commerce or industry (e.g., pharmaceutical, food and agriculture, horticulture, and cosmetics enterprises); research institutions (e.g., universities, gene banks, botanic gardens, microbial collections); custodians of genetic resources and TK holders (e.g., associations of healers, indigenous peoples or local communities, peoples' organizations, traditional farming communities); and others (e.g., private land owner(s), conservation group(s), etc.)
Nature of Relationship:	In any particular transaction and collaboration, the nature and terms of a contract can be tailored to fit the needs of the two partners to create an optimal partnership. Negotiators are normally advised to think first about the practical arrangement or partnership that they want to enter into, and then to think about how that arrangement should be expressed in legal terms. This is often more effective than limiting the range of cooperation and sharing of benefits to a pre-existing model. Earlier agreements and precedents can be used as guidance on the options, without pre-determining the actual choices made by the provider and recipient in any scenario. All parties should normally seek expert advice, with experience in the relevant national legal system (or systems), which can[33]: a) Confirm that the agreement properly reflects the underlying access project or research relationship; and, b) Clarify whether the rights and obligations are reasonable, fair and legal, and whether and how obligations under the agreement can be enforced if necessary. Such individual advice cannot be obtained from a consideration of the model or actual agreements of other institutions or organizations; the more that the specific relationship under development is taken as the starting point for contractual negotiations (rather than other agreements developed in other contexts), the more likely that the resulting agreement will be workable and mutually beneficial.

[33] WIPO, op cit.

3 MATERIAL TRANSFER AGREEMENTS (MTAS)

The purpose of an MTA is to govern the transfer of genetic resources for research or commercialization and to regulate the rights and obligations for both the provider and the user, including possible benefits arising from commercialization. An example of the type of instrument used in ABS negotiations is provided below. It is designed to be adapted to the particular conditions of each case. It does not necessarily address or solve all the needs of the different participants in the ABS negotiations. Therefore this instrument presents potential elements to be taken into account in the drafting of an MTA.

Appendix 1 in the Bonn Guidelines presents suggested elements for a Material Transfer Agreement. The elements of an MTA provided below is consistent with the Bonn Guidelines MTA, and at the same time, provides further orientation and content.

Elements of a Material Transfer Agreement

This Agreement rules the transfer of Material(s), described in Annex 1, from (Provider Name) to the Recipient (User Name) for the purpose of **scientific and non-commercial investigations**/OR for the purpose of **commercial research.**

WHEREAS, (Provider Name) will provide (Recipient Name) with certain materials as described below and hereinafter referred to as “Material”;

WHEREAS, Recipient desires to evaluate the Material in its research; and

WHEREAS…. (other relevant considerations)

NOW THEREFORE, in consideration of the mutual promises and covenants herein contained, the Parties mutually agree to the following terms:

TERMS AND CONDITIONS OF THIS AGREEMENT

“Material(s)” mean(s) any biological or chemical material(s) provided by from biological resources available in …… (Country’s name) biodiversity including any living or dead organisms, extract(s), fraction(s), isolated natural compound(s) like proteins, enzymes, lipids, carbohydrates, nucleic acids, primary and secondary metabolites, and others; isolated micro-organism(s), genetic information, cloned gene(s), amplified nucleic acids, or progeny derived from material(s) by either Party; or any transformed biological material.[i] Annex 1 describes the specific Material(s) of concern for this Agreement. *Description of Materials to be transferred.*[34]
“The Recipient” is…….

[34] A Material Transfer Agreement does not apply to the transfer of human genetic materials which lie outside of the scope of the Convention on Biological Diversity.

“The Provider” is…….

“Party” means Provider and/or Recipient.

“Parties” means the Provider and the Recipient.

“Third Party” means any party other than Provider and Recipient.

Provider agrees to transfer the Material(s), specified in Annex 1, to:……

No rights under any intellectual property of (Name of the Country) or rights in any other material or confidential information provided by (Provider Name) to (Recipient Name) under this Agreement is granted or implied as a result of providing this Material to (the Recipient), other than as expressly set forth herein.

(Recipient Name) will use the Material(s) only for the following **non-commercial and scientific investigations**:…. *Description of the research activities to be performed on the Materials.*

If the Recipient desires to use the Materials for commercial purposes, the Recipient agrees, in advance of such use, to negotiate in good faith with the Provider to establish the terms of a commercial licence. Details of the benefit-sharing will be ruled by a separate agreement, which will be negotiated by the Parties in good faith.

The Recipient may transfer the Material(s), obtained under this Agreement, only with prior written authorization from the Provider and only for scientific and non-commercial purposes. All terms and conditions of this Agreement shall apply equally to these Third Parties. The Recipient shall be responsible for ensuring compliance by these Third Parties. A letter with the word “This material has been received under a Material Transfer Agreement which includes terms and conditions for the use by Third Parties” will accompany all transfers. The reproduction or multiplication of the Material(s) is also forbidden, except with prior written permit of …..*Options to allow transfer only with prior notification or without restrictions.*

The Parties recognize each other's right to present or publish information in connection with the Materials. Any such publication of information in scientific journals will be subject to the other Party's consent, such consent not to be unreasonably withheld and to be notified to the Party requiring to publish within 30 days of the date of the request from the Party requiring to publish. Furthermore, Parties agree to delete any confidential information owned by Provider in the proposed publication at the written request to Provider. Should the proposed publication contain information requiring patent protection, Parties agree to delay publication for up to sixty (60) days from the receipt of such proposed publication to allow time to file a patent application.

The Recipient will acknowledge this Agreement and the contribution of Provider´s researchers in all and any publications or presentations involving use of the received Material(s).

The Recipient agrees to provide with a report of the evaluations, analyses and/or research of the Material in the form of a summary in writing of all the results of experiments and data generated using the Material (the "Reports"). The Recipient agrees to provide with said report within thirty (30) days after the conclusion of either (i) its investigations, or (ii) this Agreement, whichever is earlier. The content of such Reports shall be confidential.

Material(s) is (are) understood to be experimental in nature. The Provider extends no warranties of any kind, expressed or implied. The Provider will take no responsibility whatsoever for any damages, resulting from material(s), e.g., by misuse or neglectful handling. The Recipient will indemnify and keep the Provider harmless from any claim, action, damage, or cost, deriving from or in connection with the Recipient's use of the received material(s).

Modifications to this Agreement must be approved in writing by all Parties to this Agreement.

This Agreement, and rights and obligations hereunder, shall not be assigned or transferred, directly or indirectly, in whole or in part, by either Party, without the prior written consent of both Parties, which may be given or withheld at each Party's sole and absolute discretion;

This Agreement and the Parties' rights and duties outlined above shall be interpreted under the laws of …….

The Parties represent and warrant that each has the authority to undertake the obligations set forth in this Agreement without breaching or violating any contractual or statutory obligation owed to another.

This Agreement constitutes the entire agreement and understanding between the Parties concerning the subject matter hereof. It merges with and supersedes all previous agreements and understandings between the Parties.

Upon the expiration or termination of this Agreement and upon the request by the Provider, the Recipient agrees to (i) destroy any remaining Material, and (ii) return all documents and other tangible items containing or representing confidential information provided by the Provider, and all copies thereof. The Recipient may keep a copy of such materials and documents for its own records.

Under this Agreement, the Recipient may retain Material(s) to be used in …… for a period of twelve (12) months from the date of receipt of Material(s). Obligations shall terminate after that period. However, obligations under **Articles 7, 8, 9, 10, 11, 12, 13, 14, 15, and 16 of this Agreement shall survive**.

4 GUIDANCE ON NEGOTIATING STRATEGIES/METHODS

Tips for users and providers for conducting ABS negotiations are provided below.

Some suggestions for users are:

- **Begin the negotiations using the appropriate legal mechanisms** for your protection like a non-disclosure agreement. Be sure to have adequate legal advice and information about your potential partner. Visualize the other party as a potential (reliable) partner.
- **Maintain good communication with your potential partner.** Hold conferences calls and face-to-face meetings, if possible, to exchange all the relevant information needed for the development of a potential ABS relationship. If the ABS project includes joint research, be sure to have a well-defined research plan for your work.
- **Once general information has been shared** and if there is a potential for a collaboration/provision of samples, begin drafting an agreement. Using past examples, model contracts, or the supporting tools of the MT. However, the ABS negotiations are unique.
- **Once you have enough agreement/understanding about most of the terms** of the agreement, including the financial terms, rights and obligations of each party, etc., send the draft to your partner and begin the negotiations on the difficult issues on which there is no agreement or pending details that need to be agreed. Continue permanent communication once you have sent/received the agreement. Take your time to study the implications and proposals carefully, but try to not unnecessarily delay the responses. Avoid ambiguities and lack of clarity in the clauses.
- **Pay attention to: definitions; activities to be carried out by each party** (be sure that you are capable and legally entitled to carry out the research or provision of samples); benefit-sharing provisions (when, how much, and for how long); IPR; reporting obligations; transfer to third parties of the samples and research results; term; and survival obligations. If you have any doubts, make the appropriate consultations.
- **Experience has shown that it is useful to agree in principle** to the major and/or more difficult sections of a contract before agreeing to terms on minor issues. For example, a record can be kept in a “terms sheet” addressing such terms as specific resources to be accessed, or transferred, which is agreed upon in principle. These terms can then be written into a draft contract which also addresses less controversial terms to be agreed, for example, the duration of the contract.

Some suggestions for providers[35]:

- **There must be a clear institutional policy** for the criteria demanded in prospecting contract negotiations. This policy will lead to the stipulation of minimum requirements for initiating negotiations. The institutional policy provides greater transparency and certainty for future negotiations.
- **Existence of national scientific capabilities** and, consequently, the possibilities of adding value to biodiversity elements, increase the negotiating strengths and benefit-sharing which are to be stipulated in contract agreements. They need to add value to material, extracts, etc. This is crucial if they wish to be more that just a simple genetic resource provider.
- **Knowledge of changes and transformations** taking place in the business sector, and of the scientific and technological processes that underlie these transformations helps in defining access and benefit-sharing mechanisms. It is essential to possess knowledge of how different markets operate and of the access and benefit-sharing practices that already exist in these markets. Since they vary from sector to sector, the economic dynamics of the markets in the nutraceuticals, ornamental plants, crop protection, cosmetics, and pharmaceuticals are complex and different. This knowledge is needed to correctly negotiate royalties and other payment terms.
- **Internal capacity for negotiations**, which includes adequate legal and counselling skills relating to the main commercial and environmental law aspects. Possibly, one of the key facts understood is that negotiations involve a *scientific* aspect (of crucial importance to define key areas of interest such as a product, etc.); a *commercial* aspect; a *negotiation* aspect; and the respective *legal* aspects. The latter comprise not only the national trade law, but also international environmental law, conflict resolution, and intellectual property. For these reasons, the creation of interdisciplinary teams is crucial.
- **Innovation and creativity capabilities** for obtaining compensation. An ample spectrum of potential benefits exists. The contractual path fortunately permits parties to adapt themselves to the situation in each concrete case and, from there, proceed to stipulate new clauses and dispositions.
- **Understanding in key subjects such as:** intellectual property rights; importance of warranties on legality; clauses on ways to estimate benefits (net, gross, etc.); requirements and restrictions on third-party transference of the material (including subsidiaries, etc.) and the obligations of such parties; precision of the key definitions provided they condition and outline other important obligations (products, extracts, material, chemical entities, etc.); precision of the property and ownership (IPR and others) of the research results and joint relationships, etc.; confidentiality clauses in the agreements and how to balance the same in relation to the need for transparency in the terms of the agreement; termination of the obligations and the definition of the survivor of some obligations and rights (e.g., royalty, confidentiality, etc.); and conflict resolution.

[35] These suggestions are mostly targeted to providers with some scientific and technical capacities that are able to add value to the genetic resources.

- **Proactive focus according to institutional policies.** There is no need to remain inactive while waiting for companies to knock on the door seeking negotiation. An active approach to negotiations, according to the institution's own outlined policy, could result in important benefits.
- **Understanding of national and local needs** in terms of technology, training, and joint research. There is need for striking international strategic alliances. Even when an institution or community could possess adequate resources to face a concrete demand, knowing the national situation and the strategic needs will permit them to reach better agreements and fulfill a mission which transcends the mere satisfaction of the institution's interests. It will permit the prospecting to work in benefit of society as a whole and demonstrate that it is possible to improve the life quality of the same.
- **Look for inmediate, certain benefits** that are high value to the provider and low cost to the user.
- One key to an equitable and enduring partnership is a shared understanding of the value of the contributions that are made by each party – on the one hand, the value of genetic resources and associated TK that are being provided, and on the other hand, the value of research, development, risk management, and investment that is involved in the use of the resource. Each party may need to understand the limitations of their contributions to the potential arrangement as well as the valuable attributes of their contributions. It will be helpful, for instance, for both parties to recognize the different expectations and perceptions of value that each brings to the discussions.[36]
- Before engaging in negotiations on access and benefit-sharing, a provider of a genetic resource and associated TK may need to identify and review systematically the assets it can potentially offer. This assessment may result in an inventory, which could separately account for physical resources and knowledge resources. It may also identify what the provider does not want to give access to, or what resources could be held in reserve for possible later access, if the partnership develops successfully. This creates an opportunity for the access provider to identify and achieve broader[37]
- A provider of genetic resources will also benefit in negotiations from **recognizing and understanding the way a potential recipient may evaluate the resources and associated TK**. The factors that may be used include[38]:

  alternative source factor – what alternative sources exist for the material of interest and what are the costs and conditions of access through those alternative sources?

  proximity to market factor – the cost, in time, money, and scientific or personnel resources, of R&D investments need to fashion a product that might be saleable.

  risk of technical failure factor – what are the prospects for arriving at a revenue-producing product from a scientific standpoint?

[36] WIPO, op cit.
[37] WIPO, op cit.
[38] WIPO, op cit.

risk of regulatory preclusion factor – what are the prospects for and costs of obtaining regulatory approval to market a final product?

alternative investment opportunity factor – do other investment opportunities exist that offer greater returns or fewer risks?

authority to consent factor – is the provider in a position to give prior informed consent, and is consent also required from other parties or government authorities?

5 INFORMATION REQUIREMENTS FOR PIC

Below are indicative suggestions that could be adapted to national circumstances; they are not to be viewed as requirements.

- Legal entity and affiliation of the applicant and/or collector and contact person when the applicant is an institution.
- Type and quantity of genetic resources to which access is sought.
- Starting date and duration of the activity.
- Geographical prospecting area.
- Evaluation of how the access activity may impact on conservation and sustainable use of biodiversity, to determine the relative costs and benefits of granting access.
- Evaluation of how the activities may support conservation and sustainable use of biological resources.
- Accurate information regarding intended use (e.g., taxonomy, collection, research, and commercialization).
- Identification of where the research and development will take place.
- Information on how the research and development is to be carried out.
- Identification of local bodies for collaboration in research and development.
- Possible third-party involvement.
- Purpose of the collection, research, and expected results.
- Kinds/types of benefits that could come from obtaining access to the resource, including benefits from derivatives and products arising from the commercial and other utilization of the genetic resource.
- Indication of benefit-sharing arrangements.
- Monitoring mechanism to be designed and applied.
- Budget.
- Treatment of confidential information.

6 LIST OF POTENTIAL BENEFITS

Below is a list of short-, medium-, and long-term benefits as described in Appendix II of the Bonn Guidelines and in the Annex to the Nagoya Protocol.

SHORT TERM

- access fees/fee per sample collected or otherwise acquired;
- up-front payments;
- special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
- salaries and preferential terms where mutually agreed;
- collaboration, cooperation and contribution in education and training; (Short-, Medium-, or Long-Term)
- admittance to *ex situ* facilities of genetic resources and to databases;
- transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity; (Short-, Medium-, or Long-Term)
- training related to genetic resources with the full participation of providing parties, and where possible, in such parties; (Short- or Medium-Term)
- access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies; (Short- or Medium-Term)
- research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in provider countries;
- institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities; (Short- or Medium-Term)

SHORT TERM Continued

- collaboration, cooperation, and contribution in scientific research and development programs, particularly biotechnological research activities, where possible in the provider country; (Short- or Medium-Term)
- access fees/fee per sample collected or otherwise acquired;
- up-front payments;
- special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
- salaries and preferential terms where mutually agreed;
- collaboration, cooperation, and contribution in scientific research and development programs, particularly biotechnological research activities, where possible in the provider country; (Short-, Medium- or Long-Term)
- collaboration, cooperation, and contribution in education and training; (Short-, Medium- or Long-Term)
- admittance to *ex situ* facilities of genetic resources and to databases;
- transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity; (Short-, Medium-, or Long-Term)
- training related to genetic resources with the full participation of providing parties, and where possible, in such parties; (Short- or Medium-Term)
- access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies; (Short- or Medium-Term)
- research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in provider countries;
- institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities; (Short- or Medium-Term)

MEDIUM TERM

- research funding; (Medium- or Long-Term)
- milestone payments; (Medium- or Long-Term)
- licence fees in case of commercialization; (Medium- or Long-Term)
- sharing of research and development results; (Medium- or Long-Term)
- human and material resources to strengthen the capacities for the administration and enforcement of access regulations; (Medium- or Long-Term)
- participation in product development; (Medium- or Long-Term)
- joint ownership of relevant intellectual property rights; (Medium- or Long-Term)
- milestone payments; (Medium- or Long-Term)
- licence fees in case of commercialization; (Medium- or Long-Term)
- research funding; (Medium- or Long-Term)
- joint ownership of relevant intellectual property rights; (Medium- or Long-Term)
- sharing of research and development results; (Medium- or Long-Term)
- participation in product development; (Medium- or Long-Term)
- strengthening capacities for technology transfer to user developing-country parties and to parties that are countries with economies in transition and technology development in the country of origin that provides genetic resources. Also, to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources; (Medium- or Long-Term)
- human and material resources to strengthen the capacities for the administration and enforcement of access regulations; (Medium- or Long-Term)
- joint ownership of relevant intellectual property rights. (Medium- or Long-Term)

LONG TERM

- payment of royalties;
- institutional capacity-building;
- contributions to the local economy;
- food and livelihood security benefits;
- social recognition;
- payment of royalties;
- joint ventures;
- institutional capacity-building;
- contributions to the local economy;
- food and livelihood security benefits;
- social recognition.

7 LINKS TO SPECIFIC GUIDELINES

Non-Commercial Sector

Codes of conduct within disciplines, e.g., Principles on Access to Genetic Resources and Benefit-Sharing (http://www.bgci.org/resources/abs/); International Society of Ethnobiology (http://ethnobiology.net/code-of-ethics/).

EMBRAPA standards for approaching indigenous and local communities (www.embrapa.br/english); Brazilian Guidelines to Indigenous Peoples, Local Communities and Family Farmers for Cultural, Natural and Spiritual Patrimony Protection (http://www.inbrapi.org.br/).

Professional standards for integrity and openness of scientific research e.g., NIH Office of Research Integrity (www.ori.dhhs.gov/policies/).

Standard procedures for handling material, especially type specimens, and for scientific conduct e.g., the *International Code of Zoological Nomenclature* (http://www.nhm.ac.uk/hosted-sites/iczn/code/)*;* the *International Code of Botanic Nomenclature* (www.ibot.sav.sk/icbn/main.htm)*;* FAO standards for plant collecting (http://www.fao.org/nr/cgrfa/cgrfa-global/cgrfa-codes/en/).

Data standards for managing collections and tracking transactions and compliance e.g., IPEN exchange system, (http://www.bgci.org/resources/ipen/), Taxonomic Database Working Group (http://www.tdwg.org/); FAO plant accession data standard (http://www.fao.org/nr/cgrfa/cgrfa-global/cgrfa-codes/en/).

Guidelines for good ABS practices e.g., the Swiss Academy Good Practices for Academic Research on Genetic Resources (http://abs.scnat.ch/), the German Research Foundation (DFG) ABS Guidelines (www.dfg.de/forschungsfoerderung/formulare/download/1_021e.rtf)

Standard institutional ABS policies and agreements have been developed by many institutions (for instance, Royal Botanic Gardens, Kew (www.kew.org/conservation), South African National Biodiversity Institute (SANBI) (http://www.sanbi.org/), National Herbarium of Ethiopia (http://www.ibc.gov.et/); NIH (www.ori.hhs.gov/policies/), Rio Botanic Gardens (http://www.jbrj.gov.br/); MOSAICC http://bccm.belspo.be/projects/mosaicc/); World Federation for Culture Collections (www.wdcm.nig.ac.jp/wfcc/) and many others

Pharmaceutical and Biotechnology

- Association of University Technology Managers (AUTM) Uniform Biological Material Transfer Agreement (MTA)
- Michigan State University Material Transfer Agreement (MTA) (and other universities)
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) ABS Guidelines
- EuropaBio Guidelines
- Biotechnology Industry Organization (BIO) Guidelines for Members Engaging in Bioprospecting
- National Institutes of Health (NIH) Letter of Collection
- U.S. National Park Service General Conditions for Scientific Research and Collecting Permit NO.
- Japan Bioindustry Association (JBA) and Ministry of Economy, Trade and Industry (METI) Guidelines on use of genetic resources
- Company-specific policies (see examples on following page)

International Guidelines

Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization/ CBD Decision V/26

FAO. (1993). *The International Code of Conduct for Plant Germplasm Collecting and Transfer.* Available at http://www.fao.org/nr/cgrfa/cgrfa-global/cgrfa-codes/en/

FAO. (2001). *International Treaty on Plant Genetic Resources for Food and Agriculture.* Commission on Genetic Resources for Food and Agriculture. Available at http://www.planttreaty.org/

Belgian Federal Science Policy Office. (2001). *MOSAICC: Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct*. Available at http://bccm.belspo.be/projects/mosaicc/index.php .

Medicinal Plants: *International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (Version 1.0 2007)* BfN, Medicinal Plants Specialist Group/Species Survival Commission/IUCN – International Union for Conservation of Nature.

Sector Codes

Botanic Garden of Irkutsk State University. (2000). *Common Policy Guidelines for Participating Institutions: Principles on Access to Genetic Resources and Benefit-Sharing*. Available at www.isu.ru/insts/botsad/cbd/principles2000_e.htm.

Latorre García, F., Williams, C., ten Kate, K. & Cheyne, P. (2001). *"Principles on Access to Genetic Resources and Benefit-Sharing for Participating Institutions."* Results Of The Pilot Project For Botanic Gardens - Principles On Access To Genetic Resources And Benefit-Sharing, Common Policy Guidelines To Assist With Their Implementation And Explanatory Text. Royal Botanic Gardens, Kew. Available at http://www.bgci.org/worldwide/article/0007/

Society for Economic Botany. (1995). *Guidelines of Professional Ethics: A Brief History of the Society for Economic Botany's Guidelines of Professional Ethics*. Available at http://www.econbot.org/_about_/index.php?sm=03

Queensland Government. (2001). *Ethical Practice for Biotechnology in Queensland: Advancement through Safe and Ethical Practice.* Department of Innovation and Information Economy. Available at http://www.sd.qld.gov.au/dsdweb/v3/documents/objdirctrled/nonsecure/pdf/4130.pdf

WIPO. (2002). *Model Biodiscovery Benefit Sharing Agreement.* WIPO Traditional Knowledge and Cultural Expressions Contracts Database. Available at: http://www.wipo.int/tk/en/databases/contracts/texts/queensland.html

Corporate Policies and Codes

Novozymes

NovoNordisk. (1998). *Environmental Report 1999: Biodiversity*. Available at www.novonordisk.com

NovoNordisk. (1999). *Environmental Report 1998: Summary of external bioethics review.* Available at www.novonordisk.com

NovoNordisk. (1999a). *Environmental Report 1998: Working with the Convention on Biological Diversity.* Available at www.novonordisk.com

Novozymes. (2000). *Environment and Bioethics Policy*. Available at www.novozymes.com

Novozymes. (2000a). *Social Responsibility Policy*. Available at www.novozymes.com

GlaxoSmithKline

GlaxoSmithKline. (2002). *Environment, Health and Safety Report 2001*. Available at www.gsk.com/ser/2001/ehs01/rep-37.html

GlaxoSmithKline. (2003). *Sustainability in Environment, Health and Safety Report 2002*. Available at www.gsk.com/financial/reps02/EHS02/GSKehs-32.htm

Customary Programs

Castillo, G. (2001). *Bringing the Community Around*. *Kuna Ecological Association and Ecological and Management Program for Kuna Yala Wildlands*.
www.itto.int/direct/topics/topics_pdf_download/topics_id=1330000&no=1

National Cancer Institute: Letter of Collection

Cragg, G.M. & Newman, D.J. (2003). The U.S. National Cancer Institute (NCI) Natural Products Drug Discovery and Development Program. Presentation to an International Conference, Medicinal Plants: Access, Use and Benefit Sharing in light of the CBD. Organized by The Centre for Development and the Environment (SUM), University of Oslo, Norway. 3–5 April 2003.

WIPO. (1999). *Natural Products Repository Material Transfer Agreement.* National Cancer Institute, National Institutes of Health. Available at
http://www.wipo.int/tk/en/databases/contracts/texts/ncimta.html

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World Business Council for Sustainable Development. (2002). *Intellectual Property Rights in Biotechnology and Health Care: Results of a Stakeholder Dialogue*.Available at
http://www.wbcsd.org/pages/edocument/edocumentdetails.aspx?id=89&nosearchcontextkey=true

8 OTHER USEFUL LINKS AND RESOURCES

Legal Information

Several organizations have developed studies on ABS laws or maintain databases on legal, institutional and administrative ABS measures: These studies could be a useful source of information.

Cabrera Medaglia, J. (2004). *An Analysis of the Implementation of Access And Benefit-sharing Regulations in Selected Countries*. ABS Project. Bonn; IUCN.

Carrizosa, S., Brush, S.B., Wright, B.D. & McGuire, P.E. (Eds.) (2004). *Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity*, IUCN Environmental Policy and Law Paper No. 54, Gland, Cambridge and Bonn, 2004.

Dross, M. & Wolff, F. (2005). *New Elements of the International Regime on Access to Genetic Resources and Benefit Sharing – The Role of Certificates of Origin*. Bonn: BfN.

Garforth, K., Lopez Noriega, I., Cabrera Medaglia, J., Nnadozie, K. & Nemoga, G.R. (2005). *Overview of the National and Regional Implementation Measures on Access to Genetic Resources and Benefit Sharing.* Centre For International Sustainable Development Law, Montreal, Third Edition. *(This study was updated in 2011 to analyze how ABS measures are integrating the Nagoya Protocol by Cabrera Medaglia et al.).*

Kamau, E. & Winter, G. (Eds.) (2009). *Genetic Resources, Traditional Knowledge and the LAW – Solutions for Access & Benefit Sharing.* London: Earthscan.

Nnadozie, K., Lettington, R., Bruch, C. & Bass, S. (Eds.) (2003). *African Perspective on Genetic Resources*. Washington: Environmental Law Institute.

Other sources include:

- CBD Clearing-House Mechanism (http://www.cbd.int/CHM/)
- Centre for International Sustainable Development Law (www.cisdl.org)
- Environmental Law Centre, IUCN (www.iucn.org)
- Genetic Resources Action International (www.grain.org)
- WIPO data base on legislative text on the protection of TK, traditional cultural expressions and legislative text relevant to genetic resources (www.wipo.int/tk/en/laws/index.html)
- Focal points'/competent national authorities' websites (http://www.cbd.int/doc/lists/nfp-cbd.pdf).

Other Information

CBD case studies, including a comprehensive report dated 2008 available at: http://www.cbd.int/abs/casestudies/

UNU/IAS Reports on Bioprospecting available at: http://www.ias.unu.edu/

IPGRI: Case Studies on access and benefit-sharing: http://www.bioversityinternational.org/

Fridtjof Nansen Institute: Farmers' Rights in Ethiopia: www.fni.no/doc&pdf/FNI-R0706.pdf

Relevant studies from Genbenefit: www.uclan.ac.uk

There are also a number of other useful sources of information on ABS arrangements and/or case studies:

WIPO Contracts Database (http://www.wipo.int/tk/en/databases/contracts/):
An on-line, searchable database of biodiversity-related access and benefit-sharing Agreements is available on the WIPO website, with a particular emphasis on the intellectual property aspects of such agreements.

UNU/IAS Bioprospecting Information Resource (http://www.ias.unu.edu/):
This information resource is being developed and maintained by the United Nations University – Institute of Advanced Studies and covers the following regions: Antarctic, Pacific, Marine, and Arctic. It provides access to a web-based database to assist in assessing and documenting the extent of bioprospecting in those areas.

The ABS Capacity Development Initiative for Africa (www.abs-africa.info):
The Initiative provides on their website short summaries of a number of bioprospecting cases in different African countries.

IP Handbook
The handbook contains a number of contract and MTA samples, case studies on IP issues, licence agreements; techniques and methodologies relevant for negotiations; ABS agreements, etc. www.ipHandbook.org

For ABS contracts or bioprospecting contracts:

Cabrera Medaglia, J. (2004). *Elementos básicos para la negociación de contratos de bioprospección*. Available at http://cmsdata.iucn.org/downloads/cel10_medaglia_2.pdf

Downes, D., Laird, S., Klein, C. & Kramer Carney, B. (1993). Biodiversity Prospecting Contract. In W.V. Reid et al. (Eds.) *Biodiversity Prospecting. Sustainable Use of Genetic Resources, 1st Edition*. San José; World Resources Institute.

Gollin, M. (2002). Elements of commercial biodiversity prospecting contracts. In S. Laird (Ed.) *Biodiversity and Traditional Knowledge. Equitable partnerships in practice*. UK and USA: Earthscan.

Rosenthal, J. (2003). Equitable Sharing of Biodiversity Benefits: agreements on genetic resources, in International Cooperative Biodiversity Groups (ICBG) Workshop Developing Research Access and Benefit Sharing Agreements, Bethesda, Maryland: Fogarty International Center. Available at http://icbg.org/pub/documents/oecdub.pdf

Sampath, P.G. (2005). *Regulating Bioprospecting: institutions for drug research, access and benefit sharing*. The Netherlands: UNU.

International Cooperative Biodiversity Groups experiences
www.Fic.nih.gov/programs/ICBGresources.html

For commercial uses of biodiversity:

Laird, S. *Sectoral Approaches on ABS:* Background Study prepared by the CBD Secretariat. Available at http://www.cbd.int/doc/publications/cbd-ts-38-en.pdf

ten Kate, K. & Laird, S. (1999). *The Commercial Use of Biodiversity*. London: Earthscan.