ABS-Management Tool

Best Practice Standard and Handbook for Implementing Genetic Resource Access and Benefit-sharing Activities

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Volume 1

The ABS Best Practice Standard

Volume 2

Handbook for Implementing Genetic Resource Access and Benefit-sharing Activities

Volume 1

The ABS Best Practice Standard

1.0 Getting Started

1.1 What is ABS and Why is it Important?

The Convention on Biological Diversity (CBD), under the United Nations, has three objectives: 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. The third objective has been developed into a field of practice—and legal requirements—known as "access to genetic resources and benefit-sharing," or "ABS." Parties (i.e., governments) to the CBD have formalized ABS through certain Articles of the Convention, and through 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 are directed to Parties, governments, users, providers and other stakeholders.

Specific requirements under the Bonn Guidelines address:

- Prior Informed Consent for access to genetic resources;
- Mutually Agreed Terms for access and the use of genetic resources; and
- Benefit-sharing from the utilization of genetic resources.

While the Bonn Guidelines provide overall guidance on ABS requirements under the CBD, and in particular to the Parties to the Convention, individual organizations—whether research organizations, companies or communities—have a need for clear guidance and tools to help them comply with and implement the Bonn Guidelines in their access and benefit-sharing activities.

Genetic resources provide substantial existing and potential opportunities for uses that benefit people around the world—including opportunities for scientific research and for the development and commercialization of pharmaceutical, agricultural, horticultural, herbal, industrial and other products. There are many well-known medicines, foods and other products that have been developed from genetic resources. For example, between the years 1981 and 2006, 78 per cent of anti-cancer drugs were either natural products or based on natural products.[1]

There have been, at the same time, actual and claimed cases of inappropriate collection or use of genetic resources (i.e., biopiracy). This has raised questions about what constitutes legal and appropriate collection practices to protect the interests of both those who own the genetic resources (e.g., governments and/or local and indigenous communities) and the interests of those who use the genetic resources (e.g., researchers or companies).

However, beyond the benefit of academic research, the commercial development of genetic resources can be a "risky business." It can be time consuming and costly. It can require many steps in negotiation between the prospective user and the provider of the genetic resource and ongoing reporting by the user on its activities. At the same time, the commercial development of genetic resources can negatively affect the interests of governments or local and indigenous communities that are the "providers" of genetic resources if they are not able to make well-informed decisions about the genetic resources they own.

[1] Newman, David J. and Gordon M. Cragg, 2007, "Natural Products as Sources of New Drugs Over the Last 25 Years," *Journal of Natural Products*. Vol. 70:461–77.

1.2 Purpose of the ABS-Management Tool

The ABS-Management Tool (ABS-MT) is a best practice standard and a handbook which provides voluntary guidance and tools on ABS practice to help companies, researchers, local and indigenous communities and governments ensure compliance with the Bonn Guidelines and ABS requirements under the CBD. It provides users and providers of genetic resources with a structured process, and fair and equitable means of participating in—and making decisions about—ABS negotiations and the implementation of ABS agreements for access to and agreed use of genetic resources.

A key aspect of successful ABS activities is the building of confidence and trust between the genetic resource provider and the genetic resource user. The ABS-MT is designed to inform and guide both users and providers of genetic resources in a neutral way to help them establish 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 a genetic resource through, for example, poorly informed decisions on access, or insufficient sharing of appropriate benefits with a 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.

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

- prior to access;
- access (collection and discovery);
- academic research;[2]
- research and development for commercial purpose; and
- commercialization.

1.3 Who Can Use the ABS-Management Tool?

The ABS-MT is intended for use by providers and users of genetic resources, particularly:

- companies/private enterprises (large and small) involved in, for example:
  - pharmaceuticals,
  - botanicals,
  - crop protection,
  - nutraceuticals,
  - biotechnology, including microbial sources of industrial products, and
  - horticulture, including ornamentals;
- local communities;
- indigenous peoples;

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

- public and private research institutions, including universities;
- holders of *ex situ* collections; and
- intermediaries—commercial and public.

It is structured to be particularly helpful to companies, communities and research institutions that do not have procedures in place to ensure compliance with the provisions of the CBD, and the Bonn Guidelines on ABS. It is also useful to more experienced companies and organizations as a source of guidance for ensuring they are meeting best practice in ABS; and, for governments as a guide to ABS process.

For Users of Genetic Resources

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

- **voluntarily adopt an ABS standard** of practice which facilitates access to genetic resources by ensuring compliance with the CBD and the Bonn Guidelines,[3] including compliance with existing ABS laws, regulations and country policies; and
- **adopt good practices** in accessing genetic resources and providing fair and equitable benefits from their use.

For Providers of Genetic Resources

The ABS-MT is also targeted to genetic resource provider organizations (e.g., national or state/provincial government authorities, indigenous and local communities, research institutions and intermediaries, etc.) to:

- help them make decisions about access by increasing their understanding of the requirements of the Bonn Guidelines and responsible practices; and
- determine expectations and requirements in negotiating agreements for access to and use of genetic resources.

For Government Authorities

Beyond assisting governments in their role as providers of genetic resources, the ABS-MT can:

- help inform government authorities of important steps and practices necessary in ABS transactions; and
- serve as a capacity building guide.

1.4 Development Process of the ABS-MT

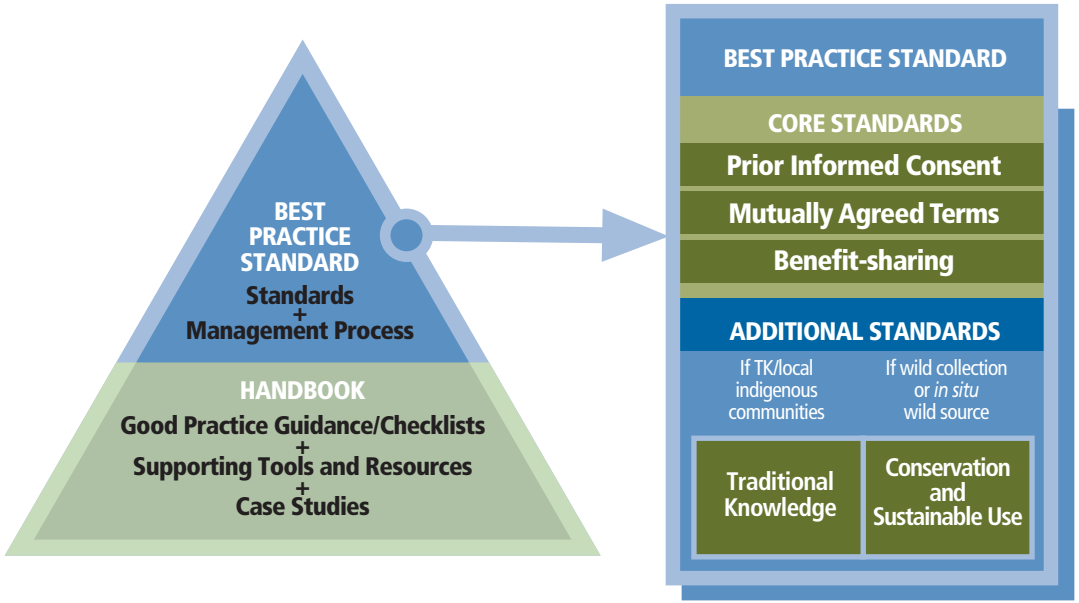
The ABS-MT has been developed through a process of:

- background research and analysis of ABS policies and practices, and broader biological resource management standards and initiatives for responsible practices;
- outreach and dialogue with a wide range of ABS stakeholders and practitioners, including stakeholder-specific meetings, participation in ABS workshops and meetings and side events on the margins of CBD meetings;
- analysis of results from field testing of the ABS-MT;
- review by an international workshop of ABS practitioners from different regions and a range of interests including industry, governments, indigenous peoples, researchers and NGOs; and
- review by the ABS-MT International Advisory Committee of experts.

[3] The ABS-MT is intended to be applied to genetic resources as they are defined in the Convention on Biological Diversity.

1.5 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.



Definitions

Some key definitions to be considered include:

Element	Definition
Provider	Any government/organization/group of people that is/are the source of the genetic resource and/or owner, manager or custodian of these genetic resources.
User	Any organization/group of people that acquires/s and/or use/s genetic resources.
Best Practice Standard	A set of commitments to be followed by the genetic resource acquirer/user organization and provider of genetic resources to achieve an outcome that meets the requirements of the ABS provisions of the CBD and Bonn Guidelines (and represents the current state of best practice).
Good Practice Guidance	Steps or activities to help user/acquirer and provider/source organizations carry out good ABS management practices in support of the ABS Best Practice Standard.
Challenge Tips	Potential solutions and advice on addressing challenges and uncertainties that arise in the process of ABS negotiations and the implementation of ABS agreements.
Owners, Managers or Custodians	Organizations or individuals that have a right over genetic resources (possession, property, etc.), in accordance with a country's legal system or customary law, and are in possession of the biological material that contains the genetic resources, *in situ* or *ex situ*, and have the right to transfer it to a third party.
Traditional Knowledge, Innovations and Practices of Indigenous Peoples and Local Communities	The term "traditional knowledge" refers to the content or substance 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. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.[4]

[4] WIPO Revised Draft Provisions for the Protection of Traditional Knowledge, Article 3.

1.6 Basic Conditions for the Use of the ABS-MT

1.6.1 Willingness to Participate in ABS Negotiations

Both the provider and prospective user of a genetic resource must have the willingness to participate in good faith in ABS negotiations. If there is a lack of trust between potential parties involved in an ABS 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. Negotiations on access, as well as benefit-sharing arrangements, therefore, must be established and implemented in a manner that advances the participation of all relevant stakeholders, allows effective dialogue among these stakeholders and promotes mutual accountability.

1.6.2 Capacity for Negotiating and Decision-making

ABS negotiations are complex. For many governmental authorities, communities and indigenous peoples and other stakeholders, ABS is an unknown legal and administrative area. The Project Team has found that lack of capacity, and a lack of trust in one's own capacities, prevents potential providers from being engaged in ABS negotiations. This fear of making mistakes and the risk of responsibility/liability for possible improper activities, limits the willingness of providers to participate in ABS negotiations. For that reason, a minimum capacity for and knowledge of ABS issues/negotiations is necessary to use the ABS-MT. At the same time, the ABS-MT can be used as a capacity-building instrument by addressing relevant ABS issues to a prospective user; and providing a roadmap for ABS negotiations and discussing best practice.

Among the many lessons learned from use and testing of the draft ABS-MT is that sources providing practical guidance on ABS are few and far between and that the ABS capacity of all stakeholder groups need to be substantially increased to enable compliance with the Bonn Guidelines. This lack of capacity also prevents stakeholders from distinguishing between the practices and processes that comply with the CBD and Bonn Guidelines, and those that do not.

1.6.3 Minimum Legal Framework in Place

Between 20 and 25 countries have adopted specific ABS laws. Some of these countries have developed specific regulations and administrative procedures for implementing their laws, while the majority of countries only have enabling laws. This lack of substantive ABS-specific regulatory and administrative measures creates legal uncertainty. This 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, communities and indigenous peoples) to engage in ABS negotiations.

The country's national legislation should provide for:

(a) a regulatory framework that enables access to genetic resources (i.e., there is no *de facto* moratorium or prohibition on access);

(b) a process for the formal recognition and approval of requests for access and use, either through a permitting system or customary process; and

(c) a legal framework that effectively governs the negotiation and implementation of contracts, including dispute resolution.

Volume 2, Part 2, Section 1.0 provides a simplified roadmap of how the ABS-MT interacts with national legal frameworks. Links to useful databases or legal studies on ABS measures are provided in Volume 2, Part 2, Section 10.0.

1.7 ABS Decision-making and Use of 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. While the ABS-MT is most readily used by larger-scale commercial genetic resource research efforts, it provides a straightforward set of standards to help both large and small entities meet the requirements of the CBD. It also provides guidance for smaller-scale companies and researchers to consider which management processes are appropriate to their situation and more detailed guidance, and for larger companies on how to work to best practice.

For Non-commercial Research: The ABS-MT also provides an ABS best practice standard and guidance for individuals and institutions involved in the research of genetic resources for non-commercial (academic) purposes. However, there is no internationally-agreed distinction between academic and commercial research, and academic research on genetic resources may lead to the identification of commercial potential. As such, academic researchers may decide to use the ABS-MT if it is appropriate for the nature, scale and type of research involved (e.g., when traditional knowledge is involved or conservation and the sustainable use of the resource to be collected needs to be considered).

Since the ABS-MT standard could be difficult to use for individual academic researchers, there are instruments that are more appropriate for these cases, such as the Swiss Academy of Sciences' *Access and Benefit Sharing – Good Practice for Academic Research on Genetic Resources*.

The figures on pages 8–11 provide a decision-making path to the ABS-MT for prospective users and providers of genetic resources.

1.8 Architecture of the ABS-MT

This document is divided into the ABS Best Practice Standard, and a Handbook for Implementing Genetic Resource Access and Benefit-sharing Activities.

ABS Best Practice Standard (Volume 1)

ABS Best Practice Standard – provides an overview of ABS and the relevance of the ABS-MT as well as additional context for users and providers of genetic resources. It also includes a detailed description of the standard and key management processes to support its implementation.

Handbook (Volume 2)

1 – Good Practice Guidance – provides a summary of good practice guidance for applying the ABS-MT standards;

2 – Supporting Tools – provides several supporting tools and examples for applying specific aspects of the ABS-MT; and

3 – Case Studies – specific case studies are included to provide additional guidance on applying the ABS-MT and highlight lessons learned from field tests and other ABS negotiations.

A Decision-making Path to the ABS-MT

Pre-Access

Is the material collected a biological resource or genetic resource?

If biological resource

9.0

If genetic resource and academic research*

1.1 9.0

OR

If genetic resource and commercial research (bioprospecting)

GR identified

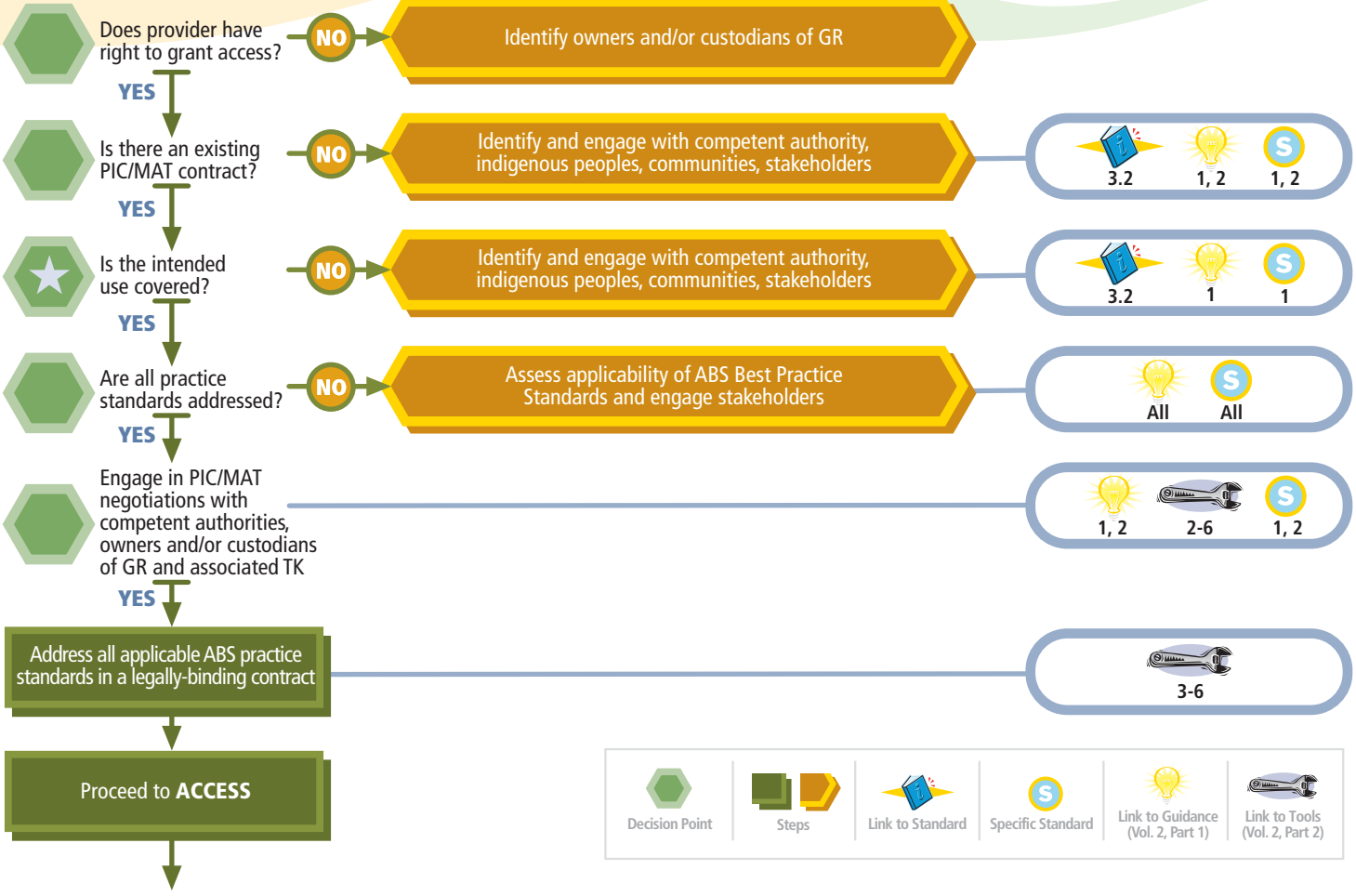
YES

Provider identified

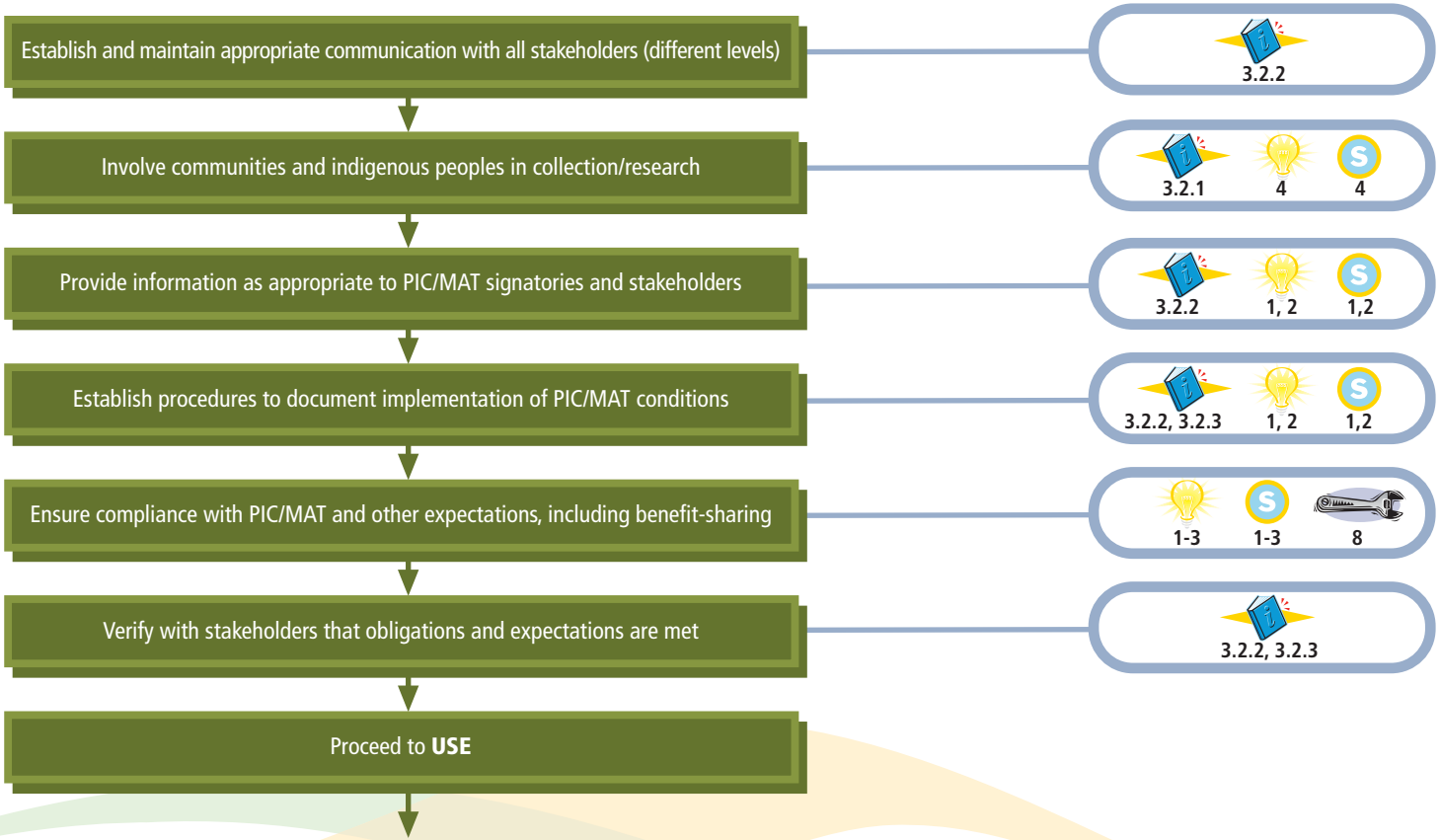
Applicable laws identified

1.6.3 1.0

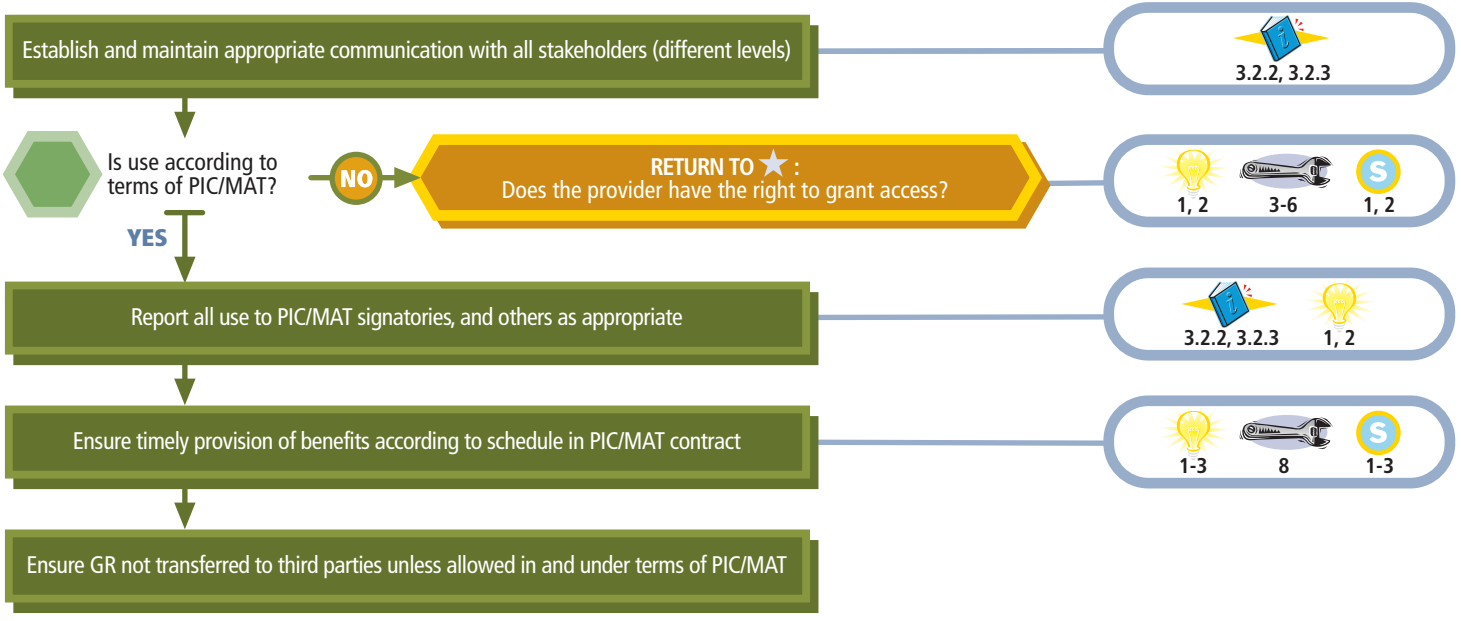
* Since academic research on genetic resources may lead to the identification of commercial potential, academic researchers may decide to use the ABS-MT if it is appropriate.


Does provider have right to grant access?
NO
Identify owners and/or custodians of GR
YES
Is there an existing PIC/MAT contract?
NO
Identify and engage with competent authority, indigenous peoples, communities, stakeholders
3.2
1, 2
S
1, 2
YES
Is the intended use covered?
NO
Identify and engage with competent authority, indigenous peoples, communities, stakeholders
3.2
1
S
1
YES
Are all practice standards addressed?
NO
Assess applicability of ABS Best Practice Standards and engage stakeholders
All
S
All
YES
Engage in PIC/MAT negotiations with competent authorities, owners and/or custodians of GR and associated TK
1, 2
2-6
S
1, 2
YES
Address all applicable ABS practice standards in a legally-binding contract
3-6
Proceed to ACCESS
Decision Point
Steps
Link to Standard
Specific Standard
Link to Guidance (Vol. 2, Part 1)
Link to Tools (Vol. 2, Part 2)

Access


Establish and maintain appropriate communication with all stakeholders (different levels)
3.2.2
Involve communities and indigenous peoples in collection/research
3.2.1
4
4
Provide information as appropriate to PIC/MAT signatories and stakeholders
3.2.2
1, 2
1,2
Establish procedures to document implementation of PIC/MAT conditions
3.2.2, 3.2.3
1, 2
1,2
Ensure compliance with PIC/MAT and other expectations, including benefit-sharing
1-3
1-3
8
Verify with stakeholders that obligations and expectations are met
3.2.2, 3.2.3
Proceed to **USE**

Indicative Guide to ABS Decision-making



2.0 ABS Best Practice Standard

Core Standards

Best Practice Standard

1. Prior Informed Consent (PIC)

Prior Informed Consent is consent obtained by the user 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.

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

1.2 PIC is obtained in writing from the competent government authority, and from the relevant stakeholders, including local communities and indigenous peoples who are the 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. Genetic resources are used only for the purposes expressly outlined at the time of PIC negotiation, and a new Prior Informed Consent is given for any use that differs in type or scope from that originally outlined. An agreement is concluded with the provider that reflects the terms and conditions of PIC including, *inter alia*, terms and conditions regarding benefit-sharing.

1.4 Where access 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 as to why this is not feasible.

2. Mutually Agreed Terms (MAT)

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

2.1 MAT are negotiated in a manner that builds confidence and a relationship of trust between owners, managers or custodians of genetic resources who are the providers, and the users of genetic resources, and that establishes the basis for a long-term, transparent and respectful relationship and communication between them.

2.2 MAT are negotiated in good faith by both users and providers, respecting the terms and understanding of Prior Informed Consent, allowing benefits to flow to the owners, managers or custodians of the genetic resource, and facilitating access.

2.3 MAT 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 user organizations, to allow fair processes of negotiation and equitable outcomes in the benefits to be shared.

3. 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.

3.1 A fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge is provided in order to support compliance with the three objectives of the Convention on Biological Diversity.

3.2 Benefits are provided according to the specific stages of use set out in the PIC agreement (discovery, research, development and commercialization), and are renegotiated when the type of use is expected to change beyond the agreed PIC. Benefit-sharing considers and provides short-, medium- and long-term benefits.

3.3 Benefits are shared fairly and equitably with all those who have been identified as having contributed to the resource management, scientific or commercial process. This may include governments at different levels, and/or indigenous and local communities, and relevant stakeholders who are the owners, managers or custodians of the genetic resource.

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

3.5 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 in the Mutually Agreed Terms.

3.6 Benefit-sharing provisions are negotiated and implemented in a manner that contributes to the conservation of biological diversity.

Additional Standards

If access involves traditional knowledge associated with genetic resources and local or indigenous communities, apply standard 4.

4. Traditional Knowledge

Traditional knowledge (TK) refers to the content or substance 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 TK varies from country to country in accordance with national legislation, policy and practices, it is important to consult with the competent national authorities when applying this standard.

4.1 The integrity of TK 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 undertaken so as not to affect the integrity, sense and value of TK; so as to not denigrate it.

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

4.3 Adequate compensation and sharing of benefits are provided, including a recognition of the community that holds the specific traditional knowledge associated with the genetic resource being accessed and used.

If access involves wild collection or *in situ* wild sources of genetic resources, apply standard 5.[5]

5. Conservation + Sustainable Use

Conservation and sustainable use are practices that ensure or contribute to the maintenance of the diversity of genetic resources accessed.

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 the cultivation/captive breeding of genetic resources are conducted in a manner that maintains the genetic variation of the population or diversity of the gene pool.

5.3 Species listed in Appendix I 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 World Conservation Union (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.

[5] The International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP Version 1.0 2007) provides a more complete standard to ensure the conservation and sustainable use of biological resources including genetic resources.

3.0 Management Processes

This section provides a basic orientation to the ABS-MT's management procedures, guiding users on how to put such procedures into practice, or improve their existing management systems. It is not intended to prescribe the steps a user (e.g., company) or provider (e.g., community) must follow to comply with the Bonn Guidelines.

3.1 Use in an Organization's Management System/Procedures

All organizations have some form of procedures or "management" systems, whether they are formal or based on commonly used or traditional practices. The ABS-MT is designed to help any type of organization understand and improve compliance with the Bonn Guidelines on ABS in accessing—or providing access to—genetic resources.

Using the standards presented in Volume 1, Section 2.0, 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 Prior Informed Consent has been given; negotiating Mutually Agreed Terms; and providing benefit-sharing. Where it is appropriate, the ABS-MT can also help companies 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 Volume 1, Section 2.0 into their existing management systems; draw on the management process advice provided in Volume 1, Section 3.2 below; and strengthen their procedures by drawing on the Good Practice Guidance from Volume 2, Part 1 below.

A case study of how an organization can use the ABS-MT to integrate ABS best practice guidance into its procedures is provided by the Australian Institute of Marine Science (AIMS). This case study can be found in Volume 2, Part 3.

3.2 Other Management Considerations

Once an organization has determined how it will address/use the ABS-MT Best Practice Standards, there are other important management considerations for proceeding with ABS access requests and negotiating ABS agreements. These considerations include:

- the participation of indigenous and local communities;
- documentation and information management and sharing;
- reporting; and
- emerging practices on certificate of origin/compliance with national law.

3.2.1 The Participation of Indigenous and Local 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 (the local owners, managers or custodians of genetic resources and associated traditional knowledge), who could be impacted (negatively or positively) in the ABS negotiation. A key factor in the 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.

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 the negotiation of benefits;
- responding to the specific concerns and interests of stakeholders, including local communities and indigenous peoples, through information sharing and a commitment to address their concerns (or providing a rationale for why action is not taken); and
- involving indigenous and local communities that are owners, managers or custodians of genetic resources in decision-making on access and in the sharing of benefits derived from the collection and use of genetic resources.

Possible management steps that can be taken include:

- 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 who may be (directly or indirectly) impacted by genetic resource collection;
- working with governments to provide indigenous and local communities that are prospective providers of genetic resources with the means to access expertise on scientific and legal questions, or advice from experts to help them arrive at decisions on access and to help them negotiate their ABS agreement; and
- documenting the processes used by local communities and indigenous peoples to consult with stakeholders, seek access with Prior Informed Consent, negotiate Mutually Agreed Terms and implement benefit-sharing arrangements.

3.2.2 Documentation and Information Management

Maintaining appropriate documents which record discussions, agreements reached and ABS transactions is important for managing 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 information sharing include:

- sharing information, including intended uses, in a transparent manner between potential providers and potential users of genetic resources 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 towards the spirit of a transparent relationship; and
- where traditional and local knowledge associated with a genetic resource is involved, protecting 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 may be 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
- ensuring that sample suppliers are aware of and comply with the terms of collection, and benefit-sharing.

3.2.3 Reporting

Reporting between parties to an ABS agreement, and appropriate public reporting can improve transparency and build confidence in ABS activities. Including reporting requirements and milestones in ABS contracts will allow stakeholders to monitor the access and use of genetic resources.

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

3.2.4 Emerging Practices on Certificate of Origin/Compliance with National Law

International discussions on certificates of origin/compliance and their relationship with national law are being held under the CBD. The ABS-MT will be updated to reflect good practice related to these certificates as the discussions proceed.

Notes:

Notes:

Notes:

Handbook for Implementing Genetic Resource Access and Benefit-sharing Activities

Volume 2

Part 1: Good Practice Guidance

This set of Good Practice Guidance for each of the access and benefit-sharing standards is presented in checklist form for ease of use. It is intended to be applied **flexibly** according to the needs and circumstances of each case. Thus, not all of the elements mentioned here need to be included or considered in the negotiations and ABS relationship. These elements should be adapted to your specific ABS situation, in cooperation with the user and the provider of the genetic resources.

1. 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 to which you should submit an application for PIC or to which you make enquiries on PIC; b) identify the necessary 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 Volume 2, Part 2, Section 7.0 (Information Requirements for PIC).		X
• Identify the national competent authority, indigenous and local communities, relevant stakeholders and, wherever possible, determine ownership of the genetic resources and/or associated traditional knowledge (TK). 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 in 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 the transfer of genetic resources to third parties.		X

1. Prior Informed Consent (continued)	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. 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 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 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.		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.		X
Key Challenges/Tips: • *What to do if the provider/authority does not have the legal or scientific capacity to negotiate an ABS agreement?* In some cases there will be a need to have independent legal, financial and scientific advice available to the provider of genetic resources in order to level the playing field with users during the negotiation. Be sure that your counterpart has independent legal advice. Monetary contributions from users to providers may be necessary to enable providers to obtain independent legal advice. *Pro bono* networks of ABS legal experts are emerging.		X
• You may find some assistance, for instance, from the Public Interest Intellectual Property Association. See http://www.piipa.org	X	X
• All relevant parties to grant PIC should designate, according to their own internal rules and practices, a representative with the authorization, legal right and capacity to negotiate and make decisions.	X	X
• The development of an independent capacity for genetic resource providers to be able to negotiate effectively is needed.	X	X

How to address difficulties in identifying from whom Prior Informed Consent should be sought. • A diagram presenting past experiences in obtaining PIC (i.e., the steps taken and the duration of the process) 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 shall be sought: the ownership of land where collection takes place; and the role granted to the different levels of government by legislation, customary law and practices. • Examples of PIC-related procedures, legislation, guidelines and agreements: – a diagram operationalizing PIC in, Perrault, Anne, 2006, *Prior Informed Consent and Access and Benefit Sharing: Recognition and Implementation*. IUCN. – Laird, Sara (ed.), 2002, "Section III," *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice.* Earthscan. – International Cooperative Biodiversity Groups Web site (http://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 both genetic resources and traditional knowledge. Both make it difficult to identify who should be sought to achieve PIC (genetic resources could straddle multiple communities and traditional knowledge could be shared by more than one community/indigenous peoples). • There is no simple solution. To whatever 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-participants using a Fund created by the law.	X	X

1. Prior Informed Consent (continued)	For Provider	For User
Other Useful Tips: • In addition to PIC and Mutually Agreed Terms (MAT), verify that you have all other 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.		X
• Include a clause in the contract stating that the intermediary assures that they have 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.	X	X
• If a genetic resource is to be 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

2. Mutually Agreed Terms (MAT)	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. • Negotiate MAT 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 MAT 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
• Be sure that your counterpart has access to independent legal advice to ensure adequate legal guidance in the negotiation of MAT.	X	X
• Set out MAT in a written agreement.		X
• Include in MAT 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 light of particular circumstances.		X
• Seek to ensure that the commercialization of the genetic resources and any other use of the genetic resources enables the continued traditional use of those resources.		X
• Include, if feasible, in MAT: the source of 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 uses are covered by existing MAT 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 a transfer is consistent with the terms and conditions of the PIC.		X
• If possible, include in the agreement provision for internal and/or external audits to report progress on its implementation to both the user and provider of the genetic resources. The involvement of relevant stakeholders, and indigenous and local communities in the various stages of the development and implementation of access and benefit-sharing arrangements can play a role in facilitating monitoring and compliance.		X

2. Mutually Agreed Terms (continued)	For Provider	For User
• Resolve disputes arising in the access agreement in accordance with the relevant contractual arrangements and 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 to do if the parties to the negotiations do not have experience with or a clear and appropriate understanding of terms and conditions for MAT?* • Some countries' national laws may contain specific stipulations regarding the content of the MAT. • If this is not the case, use the supporting tools in the ABS-MT, Volume 2, Part 2, Generic Material Transfer Agreements (MTA) (Section 4.0) and generic ABS Model Contract Outline (Section 5.0).	X	X
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. Providers and users should be committed to working towards the successful conclusion of the negotiations. 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: • MTA constitute 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 MTA. Therefore it is advisable to study the laws and administrative measures of the country in question.	X	X
• Enquire about the existence of standardized agreements such as standard MTA.	X	X
• Settlement of disputes may be costly, and access to legal remedies differ 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 cases of disputes may be explored.		X

3. Benefit-sharing		
• 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 not to put them at a disadvantage.		X
• Use a 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 Volume 2, Part 2, Section 8.0).		X
• Consider short-term, medium-term and long-term benefits. The time frame of benefit-sharing should be definitely stipulated. Furthermore, the balance among short-, 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.	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 should be especially considered.		X

3. Benefit-sharing (continued)	For Provider	For User
• To whatever 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 collection location for participation in the commercialization process and value-adding activities.		X
• Seek the original provider of the genetic resource for re-supplying material, if additional material is needed for research and development or the commercialization of a product.		X
• Establish appropriate monitoring/tracking and reporting mechanisms in the legal arrangements.	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 assure that your counterpart accurately understands that a (possible) future process of R&D and commercialization take considerable time before any benefits may be actually generated and that profits do not arise quickly.		X
• Explain that the probability of a product ultimately being placed on the market is generally low. Therefore only in a limited number of cases will it be possible to share benefits arising from commercialization.		X
• If you are interested in negotiating an ABS agreement in a specific field (e.g., horticulture, crop protection, pharmaceutical, etc.), it is convenient to review journals and other sources of information about the commercial practices in each field.	X	X

• Consult general sources of information: – Ten Kate, Kerry and Sara Laird, 1999, *The Commercial Use of Biodiversity*. Earthscan, London; and, UNEP/CBD/WG-ABS/4/INF/5. – Laird, Sara, 2005 *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.* CBD Secretariat, Montreal.	X	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 royalty structure are: (a) relative contribution of partners to invention and development; (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. Ten Kate and Laird (1999) present the following figures: • raw materials or early research: 0.5–2.0 per cent (raw material, e.g., dried plants, soil samples and basic extracts); • value-added data: 1–4 per cent (ethnobotanical information; material supplied with some screening results; identified bio-active compound); and • clinical data: 2–5 per cent (animal model data supplied with identified bio-active compound; clinical data supplied with identified bio-active compound).	X	X

3. Benefit-sharing (continued)	For Provider	For User
How to monitor and track that benefits are being implemented as agreed in the MAT? • 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 MAT—including a clear understanding of the means for implementation and the terms and conditions outlined in the MAT/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 worthwhile to include some mechanisms to: – label all material with a barcode and identification number; – establish a requirement for assigning identification numbers to resources; – 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

4. Traditional Knowledge (TK)	For Provider	For User
• Put in place a process during the PIC phase to obtain TK and promote the participation of indigenous peoples and local communities. • Identify all holders of TK, local competent 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 TK holders not participating in the access negotiations.	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 applying the following principles: *Integrity* – Ensure that research activities and collection do not violate customary law 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 (IPR) 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 information not otherwise publicly available on TK associated with genetic resources accessed or used is not disclosed without the PIC of the TK holders. – Negotiate and provide fair compensation for genuine grievances related to the collection of genetic resources that have damaged resources used for the livelihoods of local and indigenous communities or peoples. – Respond to the government and stakeholder/local and indigenous community concerns related to the proposed or ongoing collection of genetic resources.		X

4. Traditional Knowledge (continued)	For Provider	For User
Protection and preservation – Report to the TK holders all relevant non-confidential information to support the maintenance and improvement of TK. – Support the documentation and registration requirements requested by TK holders. – Properly acknowledge TK-holder contributions in all the publications and IPR applications. *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.* • Use of local people as advisors during the negotiations may be useful.		X
How to address when TK is shared among several traditional communities, some of which are non-participants in the agreement(s) for PIC and benefit-sharing. • Both the relevant communities and local authorities must be consulted on what should be done in these circumstances, particularly in benefit-sharing implementation. See suggestions presented in 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 that often exist between traditional communities and intended users of genetic resources. • Suggestions for addressing these problems are provided in Volume 2, Part 1, Tables 2 and 3.	X	X

5. Conservation and Sustainable Use		
• Assess the current conservation status of the species and the population to be sampled/collected, according to the IUCN Red List categories and criteria prior to granting 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 resources.		X
• Use a combination of scientific methods and local/traditional knowledge for the 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
• For every species or sub-species collected, deposit taxonomic vouchers 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 that the harvest does not exceed the agreed sustainable yield.	X	X
• Include funding and other resources for conservation purposes in benefit-sharing arrangements, including under MAT.		X

5. Conservation and Sustainable Use (continued)	For Provider	For User
Key Challenges/Tips: *The ecological information needed for determining sustainable yields and sustainable harvest methods is often not available.* • Contact government authorities and local universities/research institutions to identify existing ecological data on species targeted for collection. • If data/field study results are not available, work with the appropriate government to convene a national/local expert science group to do a rapid assessment of species status using such techniques as the IUCN Conservation and Assessment Monitoring Plan (CAMP) process. • Indigenous and local community representatives to obtain traditional knowledge about the status of targeted species and their habitats. • ABS arrangements can end up not protecting the resources accessed, regardless of broad commitments to do so. • Build incentives into local collection activities to help ensure that species are not collected beyond sustainable levels (e.g., benefits that extend beyond payment for collection). • Put in place field monitoring activities to assess the status of collected species on a periodic basis.	X	X

Part 2: Supporting Tools

This section includes 10 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.

1.0 Road Map of Interaction between National Legal Frameworks and ABS-MT

This map is intended to provide some suggestions for determining the applicable legal framework and improving 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 Volume 2, Part 2, Section 10.0.

Step	Action
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.
2	Check if the genetic resources to be accessed are covered by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) (Annex I). If this is the case you don't need to use the ABS-MT or negotiate an ABS agreement under the Convention on Biological Diversity (CBD). However, the Material Transfer Agreement of the Treaty must be negotiated and signed.
3	If the resources are not covered by the ITPGRFA, check to determine if the host country has ratified the CBD.
4	Identify national laws related to the CBD and to access and benefit-sharing. Check if there is a National Focal Point or National Competent Authority for the CBD or ABS. Check the CBD database on ABS measures for information on official communications from countries with ABS legislation.
5	Check with the National Focal Point or the National Competent 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.

Step	Action
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.).
7	Contact the national focal point who will direct you to the National Competent Authority for information on: a) Prior Informed Consent, b) Mutually Agreed Terms; c) benefit-sharing provisions; and d) other relevant information.
8	Obtain information from relevant local sources (e.g., partner institutions) and legal experts.
9	Obtain information from other colleagues and users about their experiences and the legal framework of the country.

Photo courtesy of Bioresources Development and Conservation Programme Cameroon.

2.0 ABS Agreement Matrix – For Users

The following matrix provides a checklist for organizations preparing to make a request for access to genetic resources, or preparing to enter into negotiations for access and the sharing of benefits. It provides for the ready display of compliance and guidance standards required to be included in the MAT developed with each provider.

List all providers	Issues/Components of Negotiation/Contract				MAT	Comments
	PIC/Access	Benefit-sharing	Traditional Knowledge	Conservation/ Sustainable Use	Requirements: Law and Regulation Customary Law/ Traditional Practices	
National ABS/CBD Focal Point						
National/State/ Provincial Authority to Grant Access						
Local Community Owner, Manager, Custodian of the Resource						
Indigenous Owner, Manager, Custodian of the Resource and Associated TK						
Ex situ Holder/ Owner of GR						
Intermediary/ Transferor of GR						

Use of the Matrix

List all the potential providers of access, material, or permission that may have a stake in the ABS deal in the first column, and head each of the other columns with the compliance standards and guidance standards.

MAT will need to be developed with each provider, to deliver the application of the compliance standards and guidance standards that are relevant to each provider. In some cases, MAT will actually mean a contract or some sort of legally-binding agreement.

Not all compliance and guidance standards will be applicable to every provider.

Example Applied to Australian Institute of Marine Sciences

Description of Access/Collection Activity

The Australian Institute of Marine Science (AIMS), a government science organization, wants to make a marine collection from the central Great Barrier Reef for biodiscovery research. It will involve going into the Palm Islands, which are the traditional lands of the Manbarra people. They do not legally control access to the area but they are the holders of native title rights. As a courtesy, AIMS wishes to acknowledge their traditional ownership, seek consent for the collections, and offer a bunk on the field trip for Manbarra participation. TK will not be collected. The marine areas are in the Great Barrier Reef Marine Park, which includes both Queensland waters (3nm from the coast) and Commonwealth waters (the rest out to 200nm). Both Queensland and the Commonwealth of Australia have new laws for biodiscovery that procedurally separate access from benefit-sharing.

Description of Prospective Users' Understanding of Legal or Customary Law Requirements

Permits will be required to make the collection from the Great Barrier Reef Marine Park Authority (GBRMPS), a Commonwealth agency. AIMS already has an umbrella permit that will cover this proposed collection. Under the Queensland Biodiscovery Act, samples taken from Queensland waters to be used for biodiscovery research need a Biodiscovery Collection Authority (BCA) from the Queensland Environment Protection Agency, as well as a benefit-sharing agreement from the Queensland Department of State Development. AIMS already has the latter but not the former. For material collected from the Commonwealth areas to be used for biodiscovery purposes, the GBRMPA permit is sufficient for the Commonwealth regulations regarding access, but a benefit-sharing agreement needs to be entered into with the Department of Environment and Heritage.

Provider	Issues/Components of Negotiation or Contract				MAT Comments
	PIC/Access	Benefit-sharing	Conservation/ Sustainable Use	Indigenous Participation	
GBRMPA	X		X		MAT required, existing permit covers required PIC and conservation/sustainable use.
EPA	X		X		MAT can be obtained by obtaining a Biodiscovery Collection Authority—the BCA will be the MAT.
QDSD		X	X		No new MAT required, existing benefit-sharing agreement covers required activity, and recognizes the conservation benefits of AIMS activities.
DEH		X	X		Need a benefit-sharing contract to stipulate MAT, and highlight conservation benefits of biodiversity knowledge to be obtained.
Manbarra TO's	X			X	Informal agreement seeking permission and participation.

3.0 ABS Agreements

ABS agreements are contractual arrangements between users and providers of genetic resources which 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.[6] 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.

3.1 Types of ABS Agreements

1. *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.
2. *Confidentiality or Non-disclosure Agreements:* requiring the recipient of information to keep it confidential, such as information concerning the 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.
3. *Research Agreements or Research and Development Agreements:* agreements that: define various inputs into 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.
4. *Material Transfer Agreements (MTA):*[7] common tools in commercial and academic research partnerships involving the transfer of biological materials, such as germplasm, micro-organisms and cell cultures. In most MTA, 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.
5. *Licensing Agreements:* agreements setting out certain permitted uses 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 intellectual property (IP) rights.

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

[7] Additional information on MTA and an examples of how MTA are applied to ABS negotiations is provided in Volume 2, Part 2, Section 4.0.

Examples of two types of agreements, MTA and ABS contracts, are provided below.

In addition, links to relevant sources of information and MTA or contracts are provided in Section 8 below, including the World Intellectual Property Organization (WIPO) database on MTA and contracts (which incorporate National Cancer Institute MTA, Consultative Group on International Agriculture Research (CGIAR) Centre, etc., http://www.wipo.int/tk/en/databases/contracts).

3.2 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.

1. **Applicable Legislation:** The elements of MTA or ABS contracts can be affected by 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 are 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.
2. **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.
3. **Providers and Users:** These may include: the government sector (e.g., government ministries, government agencies—national, regional or local—including those responsible for the administration of national parks and government land); commerce or industry (e.g., pharmaceuticals, 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 and traditional farming communities); and others (e.g., private land owner(s), conservation group(s), etc.).
4. **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 benefit-sharing to a pre-existing model. Earlier agreements and precedents can be used as a guide 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:[8]

   (a) confirm that the agreement properly reflects the underlying access project or research relationship; and

[8] WIPO, *op cit.*

(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 the resulting agreement will be workable and mutually beneficial.

4.0 Material Transfer Agreements (MTA)

The purpose of 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 MTA.

Appendix 1 in the Bonn Guidelines presents suggested elements for MTA. The elements provided below are consistent with the Bonn Guidelines on MTA, and at the same time, provide further orientation and content.

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

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 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

1. "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 microorganism(s); genetic information; cloned gene(s); amplified nucleic acids or progeny derived from material(s) by either Party or any transformed biological material. Annex 1 describes the specific Material(s) of concern for this Agreement. **Description of Materials to be transferred**[9]
2. Recipient: is……. Provider is….
3. "Party" means Provider and/or Recipient.

4. "Parties" means Provider and the Recipient.
5. "Third Party" means any party other than Provider and Recipient.
6. Provider agrees to transfer the Material(s), specified in Annex I, to:……
7. No rights under any intellectual property of (Name of the Country) or rights in any other material or Confidential Information provided by ….. to the Recipient under this Agreement is granted or implied as a result of providing this Material to the Recipient, other than as expressly set forth herein.
8. The Recipient 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.)
9. 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.
10. 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 the compliance of these Third Parties. A letter with the words: "This material has been received under an MTA which includes terms and conditions for its 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.**
11. 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. Party consent should be obtained within 30 days of the initial request. Furthermore, Parties agree to delete any confidential information owned by the Provider in the proposed publication at the written request of the Provider. Should the proposed publication contain information requiring patent protection, Parties agree to delay publication for up to 60 days from the receipt of such a proposed publication to allow time to file a patent application.
12. The Recipient will acknowledge this Agreement and the contributions of the Provider´s researchers in all and any publications or presentations involving the use of the received Material(s).
13. The Recipient agrees to provide a report of the evaluations, analyses and/or research of the Material(s) in the form of a summary in writing of all the results of experiments and data generated. The Recipient agrees to provide said report within 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.
14. Material(s) is(are) understood to be experimental in nature. **Provider** extends no warranties of any kind, expressed or implied. **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 **Provider** harmless from any claim, action, damage or cost, deriving from or in connection with the recipient's use of the received materials(s).

15. Modifications to this Agreement must be approved in writing by all Parties to this Agreement.
16. This Agreement, and the 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 according to each Party's sole and absolute discretion;
17. This Agreement and the Parties' rights and duties outlined above shall be interpreted under the laws of …….
18. 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.
19. 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.
20. Upon the expiration or termination of this Agreement and upon the request of the Provider, the Recipient agrees to: (i) destroy any remaining Material(s); 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 the Recipient's own records.
21. Under this Agreement, the Recipient may retain Material(s) to be used in …… for a period of 12 months from the date of receipt of the 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**.

5.0 Model Contract Outline

In general, there is lack of readily available information with respect to contracts due to the confidentially aspect of most contracts. An outline of the issues and types of provisions to consider in a biodiversity-prospecting contract are provided below, reflecting current best practice.[10, 11]

1 Parties
- 1.1 Source and collector
- 1.2 Collector and transferee
- 1.3 Source, collector and transferee

2 Framework (e.g., recitals or whereas clauses)
- 2.1 Benefits for collectors and source countries
- 2.2 Expertise in collecting
- 2.3 Valuable indigenous knowledge

[10] Gollin, Michael, and Sara Laird, 2002, "Elements of Commercial Biodiversity Prospecting Agreements, *Biodiversity and Traditional Knowledge. Equitable Partnership in Practice.* London: Earthscan.
[11] Note that some of the categories are redundant. Others are mutually exclusive. Therefore, no agreement will have an outline that is the same as this one (Gollin 2002).

3 Access to material and indigenous knowledge

- 3.1 Identify plant material to be collected or transferred (1 – Definition of "Material")
  - 3.1.1 Actual plant (1 – Definition of "Material")
  - 3.1.2 Plant extract (1 – Definition of "Extracts")
  - 3.1.3 Methods of determining what to collect
- 3.2 Responsibility for collecting
  - 3.2.1 Collector
  - 3.2.2 Subcontracting
  - 3.2.3 Country/agency
- 3.3 Access to indigenous knowledge
  - 3.3.1 Uses
  - 3.3.2 Right to license
- 3.4 Certifications
  - 3.4.1 Plant material identity, i.e., correct plant
    - 3.4.1.1 Expert botanist
    - 3.4.1.2 Chemical/forensic evidence
  - 3.4.2 Plant material source, i.e., country/location
  - 3.4.3 Collected according to the local, regional and national laws of source country and international law
    - 3.4.3.1 Proper affiliation
    - 3.4.3.2 Visas
    - 3.4.3.3 Customs clearances
    - 3.4.3.4 Export controls
    - 3.4.3.5 Environmental issues or standards
      - 3.4.3.5.1 Environmental laws
      - 3.4.3.5.2 Environmental assessment (1 – Definition of "Environmental Assessment")
      - 3.4.3.5.3 Obligation to minimize environmental impact while collecting
  - 3.4.4 Collected according to specified standards of conservation, resource and ecology management
  - 3.4.5 Collected according to professional standards of conduct
  - 3.4.6 Collected in accordance with wishes of indigenous peoples
  - 3.4.7 Collected in accordance with the customs of the source region or country
  - 3.4.8 Collected in accordance with the requirements of private landowners
- 3.5 Notice prior to access
- 3.6 Documentation of collection
  - 3.6.1 Collector's name, date, location of collection, sample code number, habitat, taxonomic identification
  - 3.6.2 Procedures
  - 3.6.3 Preservation
  - 3.6.4 Photographs
  - 3.6.5 Matters to be certified (see above)
- 3.7 Source review of specimens
  - 3.7.1 Deposit
  - 3.7.2 Testing

4 Amount to be delivered

- 4.1 On time
- 4.2 Upon request
- 4.3 Recurring or resupply
- 4.4 Minimum amount
  - 4.4.1 Plant material
  - 4.4.2 Extracts

5 Cost of material/fees/compensation

- 5.1 Per sample
- 5.2 Collecting fee
  - 5.2.1 By collector
  - 5.2.2 By source
- 5.3 Handling fee
- 5.4 Fixed fee
  - 5.4.1 One-time
  - 5.4.2 Recurring
  - 5.4.3 Staged (different fees for different periods)
- 5.5 Revenue sharing/royalty
  - 5.5.1 Percentage of revenue from testing activities
  - 5.5.2 Percentage of revenue of middleman from supply activities
  - 5.5.3 Percentage of net sales (as defined) of covered products (as defined)

6 Other compensation

- 6.1 Fund and facilitate education programs and other expertise and technology-transfer initiatives
  - 6.1.1 Build schools
  - 6.1.2 Exchange programs for scientists
  - 6.1.3 Educate source country personnel
    - 6.1.3.1 Provide instructors
    - 6.1.3.2 Collecting techniques
    - 6.1.3.3 Bioassays
    - 6.1.3.4 Chemical screening
  - 6.1.4 Land-use programs
  - 6.1.5 Drug development and research efforts
  - 6.1.6 Joint ventures with third party institutions to develop and commercialize natural compounds or synthesized chemicals
- 6.2 Fund conservation programs
- 6.3 Fund cultural programs
- 6.4 Fund and/or educate source's own drug development and research efforts
- 6.5 Fund infrastructure projects
- 6.6 Provide equipment
- 6.7 Per use (see below for uses)
- 6.8 Provide funds or personnel for services
- 6.9 Trust Fund
- 6.10 Offset or deductions from amounts owed
  - 6.10.1 Royalties to third parties
  - 6.10.2 Failure to provide samples in prior periods
  - 6.10.3 Recouping of out-of-pocket expenses
    - 6.10.3.1 Costs of licensing
    - 6.10.3.2 Costs of obtaining industrial (including patent) protection
  - 6.10.4 Costs of suing or defending against suits for intellectual property infringement
  - 6.10.5 Costs of collection or subcontractors

7 Uses of material

- 7.1 Non-commercial or non-profit use
  - 7.1.1 Evaluation or testing
  - 7.1.2 Research
- 7.2 Commercial use
  - 7.2.1 Use of indigenous knowledge
  - 7.2.2 Evaluation or testing
    - 7.2.2.1 For any commercial uses
    - 7.2.2.2 For uses specific to source country
  - 7.2.3 Research
  - 7.2.4 Products
  - 7.2.5 Sale
- 7.3 Documentation of uses
  - 7.3.1 Periodic reports
    - 7.3.1.1 Language (native and English)
    - 7.3.1.2 Accounting
      - 7.3.1.2.1 Uses
      - 7.3.1.2.2 Quantities
      - 7.3.1.2.3 Payments
      - 7.3.1.2.4 Maintain records for a period of time
    - 7.3.1.3 Source agency to receive reports
  - 7.3.2 Tests taken or to be taken on specimens
    - 7.3.2.1 Reasons for tests
    - 7.3.2.2 Summary of tests and test results/data
    - 7.3.2.3 New chemicals
    - 7.3.2.4 Problems
    - 7.3.2.5 Prospects
      - 7.3.2.5.1 Collection
      - 7.3.2.5.2 Analysis
      - 7.3.2.5.3 Uses
- 7.4 Documentation by source and source agencies/groups regarding project, compensation, uses of compensation, suggestions to facilitate and improve relationship between collector and source

8 Intellectual property rights allocated between source, collector and transferee

- 8.1 Right to distribute to third parties
- 8.2 Rights to use (see above)
- 8.3 Data (1 – definition of "data")
- 8.4 Publication
  - 8.4.1 Each side free to do as it wishes subject to protecting IP rights
  - 8.4.2 One party given all rights
  - 8.4.3 Each party makes own publication, but waits to release simultaneously
  - 8.4.4 Collaboration
  - 8.4.5 Source has veto right over publications by transferee
- 8.5 Patent
  - 8.5.1 Collector gets all rights
  - 8.5.2 Source retains all rights
  - 8.5.3 Transferee gets all rights
  - 8.5.4 Joint ownership
  - 8.5.5 Collector gets all rights except that source retains licence

8.5.6 Allocate rights according to contribution
8.5.6.1 Whoever creates invention gets patent
8.5.6.2 Other
8.5.7 Right to license to third parties
8.5.8 Option to purchase exclusive licence
8.5.9 Obligation to disclose patentable inventions
8.5.10 Right to file patent application
8.5.11 Reporting inventions to other parties
8.6 Trade secrets
8.7 Copyright
8.8 Trademark and publicity
8.8.1 No endorsement/use of name
8.9 Revenue
8.10 Exclusivity
8.10.1 Source outgoing (supply only to transferee)
8.10.2 Supply (obtain only from source/collector)
8.10.3 Use
8.11 Licence
8.11.1 Parties retain non-exclusive licence to IPR
8.11.2 Reasonable efforts to license
8.12 Right to negotiate commercial terms with third parties
8.12.1 If extract is of interest, then additional supply
8.13 Absence of IPR protection
8.14 Obligation to sue infringers of IPR

9 Termination
9.1 Term or indefinite
9.2 Termination at will upon notice
9.3 Unresolved good faith dispute
9.4 Failure to pay minimum revenue threshold
9.5 Breach of agreement
9.6 Bankruptcy of collector
9.7 Embargo or other action against source country by country of collector's domicile

10 Confidentiality
10.1 Existence of agreement
10.2 Terms of agreement
10.3 Activities
10.4 Other

11 Warranties
11.1 None given
11.2 Authority to enter into agreement

12 Liability/Limitation of liability
12.1 For breach
12.2 For breach by third parties
12.3 Illness, injuries, damages from collection, testing, development of samples or products
12.4 No liability

13 Indemnification
- 13.1 By source
- 13.2 By collector
- 13.3 By transferee

14 Assignment

15 Governing law

16 Conflict resolution
- 16.1 Jurisdiction
- 16.2 Dispute resolution
  - 16.2.1 Meeting of the parties
  - 16.2.2 Dispute regarding ownership of invention
  - 16.2.3 Courts
  - 16.2.4 Mediation
  - 16.2.5 Arbitration
- 16.3 Costs
- 16.4 Right to sue transferees
  - 16.4.1 Source retains absolute and sole right
  - 16.4.2 Collector has first right and source can sue only if collector fails to sue
  - 16.4.3 Collector has sole right to sue

17 Miscellaneous
- 17.1 Independent contractors
- 17.2 Survival of terms
- 17.3 Access to documents filed with the U.S. Food and Drug Administration
- 17.4 Severability
- 17.5 Notice
- 17.6 Force Majeure
- 17.7 Entire agreement (integration)

Outline of possible clauses included in biodiversity prospecting contracts
- Recitals
- Definitions
- Source and Amounts
- Uses
- Licences
- Price/Benefits
- Right to Patent/Protection of Intellectual Property Rights
- Exclusivity
- Copyrights
- Trademarks
- Trade Secrets
- Contractual Protection
- Dispute Resolution
- No Liability
- No Warranty
- Authorization
- Confidential Information
- Publications
- Indemnification
- Standards of Conduct
- Accounting and Records

6.0 Guidance on Negotiating Strategies/Methods

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

- 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 conference 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 ABS-MT. However, the ABS negotiations are unique.
- Once you have enough of an agreement or 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 communications once you have sent/received the agreement. Take your time to study the implications and proposals carefully, but try not to 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); intellectual property rights (IPRs); reporting obligations; the transfer to third parties of the samples/research results; and 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 the terms of minor issues. For example, a record can be kept in a "terms sheet" addressing such terms as specific resources to be accessed, or transfered, which are agreed upon in principle. These terms can then be written into a draft contract which also addresses less controversial terms to be agreed (e.g., duration of contract).

Some suggestions for providers noted below.[12]

- **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.

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

- **Existence of national scientific capabilities**, and consequently, the possibilities of adding value to biodiversity elements, increasing the negotiating strengths and benefit-sharing that are to be stipulated in contract agreements. The need to add value to material, extracts, etc., 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 progress that underlie these transformations help to define 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 counseling skills relating to the main commercial and environmental law aspects of the negotiations. 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 respective legal aspects. The latter comprise not only national trade law, but also international environment 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 exist. 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:** rights on intellectual property; 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, materials, 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; the termination of the obligations and the definitions of the survivor of some obligations and rights (e.g., royalty, confidentiality, etc.); conflict resolution.
- **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 a need to strike 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 permits them to reach better agreements and fulfill a mission that transcends the mere satisfaction of the institution's interests. It permits bioprospecting to work to benefit society as a whole and demonstrate that it is possible to improve quality of life at the same time.

- **Look for immediate, 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 bring to the discussions.[13]
- Before engaging in negotiations on access and benefit-sharing, a provider of genetic resources 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.[14]
- A provider of genetic resources will also benefit from **recognizing and understanding the way a potential recipient may evaluate the resources and associated TK**. The factors that may be used include:[15]
  a) *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?
  b) *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;
  c) *risk of technical failure factor*—what are the prospects for arriving at a revenue-producing product from a scientific standpoint?
  d) *risk of regulatory preclusion factor*—what are the prospects for and costs of obtaining regulatory approval to market a final product?
  e) *alternative investment opportunity factor*—do other investment opportunities exist that offer greater returns or fewer risks?
  f) *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?

[13] WIPO, op cit.
[14] WIPO, op cit.
[15] WIPO, op cit.

7.0 Information Requirements for PIC

Below are indicative suggestions that should 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 the sustainable use of biodiversity, to determine the relative costs and benefits of granting access.
- 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 use of the resource or other utilizations of the genetic resource.
- Indication of benefit-sharing arrangements.
- Budget.
- Treatment of confidential information.

Photo courtesy of Australian Institute of Marine Science.

8.0 List of Potential Benefits

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

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;
- 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);
- collaboration, cooperation and contribution in scientific research and development programs, particularly biotechnological research activities, where possible in the provider country (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); and
- strengthening capacities for technology transfer to user developing country parties and to parties that are countries with economies in transition. Also to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources (medium- or long-term).

Long-term:

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

9.0 Links to Specific Guidelines

Sector-specific

- Non-commercial research: *Good Practice for Academic Research on Genetic Resources*, Swiss Academy of Sciences.
- Botanic Gardens: *Principles and Common Policy Guidelines on Access to Genetic Resources and Benefit Sharing Arrangements for Participating Institutions* (Botanic Gardens).
- 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 – The World Conservation Union.
- Micro-organisms: *Micro-Organisms Sustainable Use and Access Regulation (MOSAICC) International Code of Conduct.*
- Society for Economic Botany, *Guidelines of Professional Ethics.*

Region-specific

- *Guidelines on Access to Genetic Resources for Users in Japan.* METI/Japan Bioindustry Association.
- *Code of Ethical Practice for Biotechnology in Queensland.* Australia.

Industry

- *Guidelines for BIO Members Engaging in Bioprospecting.*

Biological resources

- *Practical Guidelines for Equitable Sharing of Benefits of Biological Resources in BioTrade activities.*
- Forest Stewardship Council.
- IFOAM (International Federation of Organic Agriculture Movements).
- Marine Aquarium Council.

Other

- FAO: *International Code of Conduct for Plant Germplasm Collecting and Transfer.*

10.0 Other Useful Links and Resources

Legal Information

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

Cabrera Medaglia, Jorge, 2004, "An Analysis of the Implementation of Access and Benefit-sharing Regulations in Selected Countries," ABS Project, IUCN, Bonn.

Carrizosa, Santiago *et al.* (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.

Dross, Miriam and Francisca Wolff, 2005, *New Elements of the International Regime on Access to Genetic Resources and Benefit Sharing – The Role of Certificates of Origin.* BfN, Bonn.

Gatforth, Kathryn *et al.*, 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. Nov 2005. (This study has been regularly updated).

Nnadozie, Kent *et al.* (eds.), 2003, *African Perspective on Genetic Resources.* Washington: Environmental Law Institute.

Other sources include:

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

Other Information

Databases:

ABS measures database of the CBD (http://www.biodiv.org).

Genetic Resources Action (GRAIN) unofficial database on ABS Measures. (http://www.grain.org).

UICN-FAO Ecolex database (http://www.ecolex.org/index.php).

For ABS contracts or bioprospecting contracts:

Cabrera, Medaglia, Jorge, 2004, "Elementos básicos para la negociación de contratos de bioprospección," unpublished paper.

Convention on Biological Diversity, 1998, "Case Studies on Benefit-sharing Arrangements," distributed to the Fourth Conference of the Parties, Bratislava, Slovakia, May 4-15, 1998.

Downes, David, *et al.*, 1994, "A Biodiversity Prospecting Contract," in Walter Reid *et al.* (eds.), *Biodiversity Prospecting: Sustainable Use of Genetic Resources.* 1 ed. San José: World Resources Institute.

Gollin, Michael, 2002, "Elements of Commercial Biodiversity Prospecting Contracts," in Sara Laird (ed.), *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice.* U.K. and U.S.: Earthscan.

International Cooperative Biodiversity Groups experiences: (http://www.Fic.nih.gov/programs/ICBGresources.html).

Laird, Sara, 1994, "Biodiversity Prospecting Contracts," in Walter Reid *et al.* (eds.), *Biodiversity Prospecting: Sustainable Use of Genetic Resources.* 1 ed. San José: World Resources Institute.

Rosenthal, Joshua, 2003, "Equitable Sharing of Biodiversity Benefits: Agreements on Genetic Resources," in International Cooperative Biodiversity Groups (ICBG) Workshop: Developing Research Access and Benefit-sharing Agreements. Fogarty International Center, Bethesda, Maryland.

Sampath, Padmashree, 2005, *Regulating Bioprospecting: Institutions for Drug Research, Access and Benefit-sharing.* The Netherlands: UNU.

For commercial uses of biodiversity:

Ten Kate, Kerry and Sara Laird, 1999, *The Commercial Use of Biodiversity.* London: Earthscan.

Part 3: Case Studies

The following case studies illustrate how the ABS-MT can be applied to negotiating ABS agreements. They also highlight some of the challenges that can be experienced when negotiating ABS agreements. Over time, additional case studies will be made available to provide more information on the ABS-MT's reach and applicability. Similarly, addition information will be provided on new and emerging issues faced by ABS practitioners.

The three case studies are:

1. Tanzania Field Test of the ABS-Management Tool: Preliminary Impacts and Lessons Learned from the Use of the MT in an ABS Case I Tanzania (Cabrera, J. 2006);[16]
2. Australian Institute of Marine Sciences Framework for Developing Agreements Involving Access to the AIMS Biodiscovery Collection and Benefit-sharing (Evans-Illidge, L., 2007); and
3. Case study on *Hoodia gordonii* and the San People of Africa (Humphreys, G., 2007).

[16] The project team gratefully acknowledges Preston Scott's contribution to the development of this case study.

1.0 Tanzania Field Test of the ABS-Management Tool: Preliminary Impacts and Lessons Learned from the Use of the MT

Introduction/Background

A U.S.-based biotechnology start-up company wanting to undertake research in Tanzania was interested in applying the ABS-MT to its bioprospecting plans in that country. An earlier discussion in late 2004 with a third-party, the World Forum for Environment and Development (WFED), put the ABS-Management Tool project team in touch with this U.S. company and the Tanzanian authorities responsible for ABS.

Based on the U.S.-based company's commitment to test the ABS-MT, including agreement on a Memorandum of Understanding with the ABS-MT project team, and a letter of interest signed by an official of the Government of Tanzania agreeing to test the ABS-MT, two project team members visited Tanzania in June 2005. The team met with the company's president, the WFED executive director, as well as with all of the relevant Tanzanian government authorities. A formal presentation of the MT was given to three departments of the Government of Tanzania, including the Ministry of Environment (the competent authority for the issuance of the research permits and the signature of an ABS agreement).

While Tanzania had recently enacted legislation including provisions on access and benefit-sharing, and government authorities expressed a general appreciation for the opportunity to use and learn from the ABS-MT. They noted that they had not yet enacted the relevant ABS implementing regulations and so were hesitant to both engage in an actual ABS negotiation with the U.S.-based company, and to use the ABS-MT in a formal manner. However, the government expressed an initial interest in exploring how the MT could help them in the drafting of the ABS regulations and related capacity-building activities.

Following the meetings in Tanzania, the company involved informed the ABS-MT project team that they had decided not to continue with the research in Tanzania, and would therefore not be proceeding with the negotiation of an ABS agreement with the Government of Tanzania. Three reasons were given for this decision:

1. after analysis of local environmental conditions, the company had decided that the genetic resources (found in extreme environments) did not hold as much commercial potential as originally hoped;
2. the Tanzanian government was not showing enough willingness to move forward either on the drafting of its ABS regulations or on initiating negotiations toward the signature of an ABS agreement with the company; and
3. a relative lack of initiative and commitment on the part of the Tanzanian research partners.

This indicated a major loss of confidence by the potential user in the opportunities for their specific bioprospecting in Tanzania. Further, the potential procedural benefits associated with the intended use of the ABS-MT did not appear to have been enough to off-set these other major project-development concerns. In this case, the potential user might have been willing to invest in the process longer if there had been clearer signals from the Government of Tanzania to proceed with an ABS agreement.

Despite the fact that the ABS-MT was not fully applied to an ABS negotiation, the Tanzanian case study has provided some useful feedback and lessons learned about the use of the MT.

Reasons for Using the MT

The stakeholders involved agreed that the reasons for using the MT included the potential advantages for building legitimacy and confidence between the intended user, and the prospective provider of genetic resources that the Tool could facilitate, especially for the prospective user of the genetic resources.

The following benefits and reasons were stated by the intended user of genetic resources for using the MT:

1. it provides an objective, procedural, step-by-step framework that could assist the parties to identify and jointly work through the substantive issues involved in an ABS negotiation;
2. use of the MT would hopefully insulate the process against unfounded allegations of unfair negotiations, etc.; and

3. others benefits for using the Tool included the potential of pioneering a model of good practice in the region and realistic attempts to implement ABS provisions of the CBD.

The main advantages associated with the use of the MT were seen as follows:

- especially for parties who are not "schooled" in ABS issues, the MT provides a useful step-by-step roadmap;
- it definitely can help point negotiations in the right direction and help the parties (user and provider) more clearly understand the issues that they must negotiate;
- it provides a clear checklist and structure within which to start and end the process for mutual benefit;
- if flexible in its application, it could be used more widely; and
- it is a very promising tool and it requires a commitment of sufficient understanding, resources and capacity in order to prepare the genetic-resource provider and user to apply the MT.

User Expectations for Using the MT

In addition to building legitimacy and confidence, the user suggested that they had hoped that use of the MT would generate greater interest and thereby initiative on the part of all of the responsible government authorities. Other expectations identified were:

- establishing a framework of practice for ABS-related negotiations;
- formalizing the practice of ABS; and
- establishing a best-practice case for other Sub-Saharan African countries.

Provider Reaction to the Potential Use of the MT

With relation to the Government of Tanzania, the preliminary interest for using the MT appeared to be its timeliness, in as much as Tanzania had just enacted its biodiversity law that included general ABS provisions, and the MT could have been used as a way to help government officials understand issues and processes to aid the implementation of the law's provisions. However, in order to use the ABS-MT, they wanted more information and understanding of the MT before being confident that it would be helpful. They were concerned about the type of user association in the absence of a formal agreement, the implications of MT and the country's participation in the international CBD processes and the implication of MT relative to such processes.

In summary, the ABS-MT was seen to be both a procedural driver to gain momentum in the decision-making processes on ABS for both user and providers; and as source of substantive guidance, presenting an overall framework for decision-making. It could also serve as a confidence-building tool for all stakeholders.

Feasibility and Usefulness of the MT

For the future use of the MT, understanding the circumstances under which the MT would be most useful plays a key role in the improvement of the Tool and for conducting a field test. However, the biggest challenge appears in making the MT genuinely attractive to users and providers preparing for an ABS negotiation; and, this does not appear to happen without a serious commitment of time, and where necessary, training. Means to address these may be:

- a series of discussions and presentations to demonstrate the benefits of the MT and to provide guidance on its use; and
- resources to help organizations have the capacity needed to understand its application.

Considering that a "one-size-fits-all" approach does not apply in the case of any ABS activity and negotiation, where different countries and their cultures, legal provisions and realities exist, there is a need for options for its use. The MT could prove successful if it provides flexibility in its implementation for country-specific providers and users needs, taking account of intended use of the genetic resource and sector of activity.

Implications of Lessons Learned

Despite the early termination of the ABS project in Tanzania, due to reasons outside the control of the project team, a number of useful lessons can be learned from this partial field test, for the improvement of the ABS-MT:

- ABS is a risky business subject in many circumstances which can prevent—or change—an ABS activity.
- The ABS-MT can build trust between users and providers, but there are additional factors which may impede building a successful ABS relationship. Identifying these factors (and adding them to a growing understanding of the key challenges involved in ABS transactions), can help both users and providers to implement successful ABS relationships. Some of these factors are outside the control of the provider (e.g., the scientific assessment of the samples and its value for a company), or the user (the willingness and capacity to enter into an ABS agreement).
- The MT, if sufficiently clear and simple, can be a useful instrument to provide process steps and clear expectations for ABS negotiations which address the relevant questions and issues involved in good ABS practice.
- For making the decision to use the MT, some incentives must exist: gaining legitimacy for the MT among stakeholders and gaining support from NGOs or communities to avoid or reduce biopiracy claims against prospective genetic resources users; and, clarifying the steps that will lead to a successful negotiation.
- The feasibility of using the ABS-MT may depend on some prior conditions being met—for instance, the existence of a minimum capacity and knowledge on ABS issues and practice by the prospective genetic resource provider and the responsible government authority, and legal/regulatory clarity. At the same time, the MT can help to build this capacity. This suggests that the MT can be used for capacity-building activities, prior to the start of an ABS negotiation between a provider (community or government) and a user.
- This test of the MT suggests that, in some provider countries at least, there may be a low level of political commitment to facilitating access to genetic resources. In addition, there is a lack of sufficient information (and sometimes capacity) on how to carry out ABS negotiations which turns into a lack of willingness to initiate an ABS process. Given the competing demands on time and resources and political sensitivity surrounding genetic resource-related issues, this may be understandable. But no amount of commitment on behalf of the research or commercial interests can compensate for the absence of political commitment.

- The ABS-MT can help complement or support the development of a clear legal framework by providing a set of good practices. However, it cannot make up for the lack of regulations and clear procedures on the part of the provider government.

The goal to build trust and confidence between provider and user is one of the characteristics of the ABS-MT. This case strongly supports the importance of this objective. The lack of confidence and certainty felt by the company, and the lack of confidence in its own skills and capacities from the Government of Tanzania, were among the main reasons behind the failure of this initiative to move forward. If the MT can provide some assurances to the provider and user about how to reach a fair and equitable agreement, it can facilitate the building of an ABS relationship.

2.0 Australian Institute of Marine Science Framework for Developing Agreements Involving Access to the AIMS Biodiscovery Collection and Benefit-sharing

General Information about the Field Test and Field Test Participants

The Australian Institute for Marine Science (AIMS) is a governmental research institution specialized in marine resources. AIMS carries out basic and strategic research and has a Department (Program) for biodiscovery (bioprospecting) providing, collecting and receiving genetic and biochemical resources.

Notwithstanding Australia being a developed country, and the Management Tool being targeted for use in developing countries, four reasons convinced the Project Team to initiate a field test in Australia: Australia is a mega-diverse country and acts as a provider and user of genetic resources; Australia has been very active in the process of discussing, drafting and implementing laws (at the federal and state Level), and/or policies on Access and Benefit-sharing (ABS); marine genetic resources are one of the main fields of interest for biodiscovery today and this could increase in the future; and a member of the AIMS staff working in biodiscovery is also a member of the Advisory Committee on the project and has a strong commitment and interest in the project.

AIMS is both a "user" and "provider" of biological resources (including genetic resources) for biodiscovery research. As a "user," AIMS undertakes collections of marine organisms from around Australia and curates the collection in a perpetual library of material for biodiscovery effort. As a "provider," AIMS enters into collaborative research agreements with other parties to create synergistic and strategic partnerships, maximizing the biodiscovery effort. AIMS seeks to comply with the CBD, and understands that a clear demonstration of its compliance is necessary to create legal certainty and attract the necessary funding investment in biodiscovery R&D for the benefit of Australia.

The Northern Territory (NT) is a state in Australia and rich in biological resources. The government has developed the Policy for Access to and Use of Genetic Resources in the NT and more recently an ABS Law was approved. The legal framework in place allows the signature of general agreements between the NT Government and Users (AIMS in this case). It was agreed that the ABS-MT would be used in the negotiations between NT and AIMS. AIMS also used the ABS-MT to develop its own ABS negotiating framework.

A MoU was signed between AIMS and the International Institute for Sustainable Development (manager of the ABS-MT project) outlining the role and responsibilities of the Parties in the process of using the MT in Australia, including reporting and confidentiality aspects. A project team member (Jorge Cabrera) visited Australia on September 2006 and spoke and interviewed representatives of AIMS and the NT.

Use of the MT in the Field Test: The AIMS Framework for ABS

AIMS has used the MT in two ways. First, as the basis for the preparation of the AIMS-ABS Framework (*a framework for developing agreements involving access to the AIMS biodiscovery collection and benefit-sharing*). The Framework will be used in future ABS negotiations. Secondly, in the negotiations of a General Agreement with the NT (using the framework and the MT itself).

Use of the Tool in the Preparation of the ABS Framework

AIMS is committed to applying the practice standards identified in the MT.[17]

AIMS did not incorporate in the AIMS Framework all the Core Commitments or the full detailed Guidance found in the ABS-MT. However, the Framework: uses the seven standards found in the MT; extensively draws on the Core Commitments and the Guidance found in the MT for Prior Informed Consent and Mutually Agreed Terms; and demonstrates that the purpose of creating the Framework is similar to the purpose of the ABS-MT, to create trust, predictability and demonstrate best practice.

Example of Use in the AIMS Framework of the Prior Informed Consent Standards of the MT

ACTION (term used by AIMS in its framework): Agree on terms that comprehensively describe the detail of proposed activities with defined samples; ensure that this is within the scope of the collection PIC; and ensure that terms commit parties to formally amend the PIC prior to undertaking any activities outside its scope, including activities by other parties.

AIMS supports the core commitment that PIC be prior, informed and consented to in both intent and practice. There are two levels of PIC: first, between AIMS and the provider of the genetic resource (the jurisdiction(s) of origin); and, second, between AIMS and a third-party to which AIMS may transfer the genetic resource.

The agreements made between AIMS and the original provider of the genetic resource provides an umbrella and basis for the extension of research agreements between AIMS and other parties. The terms of the latter must effectively "reach back" to meet the obligations of the former.

In order to demonstrate PIC at both levels, research agreements between AIMS and an outside party must provide comprehensive detail on the scope of the proposed activities, and an agreed commitment to only act within that scope.

[17] These are: Prior Informed Consent; Mutually Agreed Terms; Benefit-sharing; Conservation and Sustainable Use; Traditional Knowledge; Community and Indigenous Peoples Participation; Information and Transparency.

AIMS undertakes to only offer samples for collaborative research agreements, where the proposed collaboration is covered within the scope of PIC associated with those samples.

Where the proposed use of samples desired for collaboration fall outside the scope of the existing "jurisdiction of origin" PIC for samples, AIMS will seek to broaden the PIC accordingly to negotiation with the competent authority in the jurisdiction of origin, prior to releasing the samples of the collaboration.

Example of the Use of the Mutually Agreed Terms Standard:
AIMS supports the ABS-MT Standard for MAT to be negotiated in a manner which builds confidence and respect between parties. As with PIC, there are two levels of MAT: first, between AIMS and the provider of the genetic resource (the jurisdiction(s) of origin); and, second, between AIMS and a third-party to which AIMS may transfer the genetic resource.

Again, the terms of the latter must effectively "reach back" to meet the obligations of the former.

AIMS will ensure that the MAT of any agreement regarding use of samples in the collection are consistent with the MAT, PIC and benefit-sharing obligations already associated with samples proposed for use in the collaboration.

Example of the Use of the MT Standard in the Framework with a Potential Collaborator (Company):
ACTION: Agree on terms that comprehensively describe the detail of proposed activities with defined samples, ensure that this is within the scope of the collection PIC, and ensure that terms commit parties to formally amending the PIC prior to undertaking any activities outside its scope, including activities by other parties.

Access and Prior Informed Consent: Company X acknowledges that the use of the AIMS Bioresources Library Material is subject to the scope of Prior Informed Consent given to AIMS by Access Providers for the collection and use of such material. Use of the AIMS Bioresources Library Material under the terms of this agreement is consistent with the scope of existing Prior Informed Consent.

"Company X may not use any AIMS Bioresources Library Material except as expressly set out in this agreement or as approved in writing beforehand by AIMS."

"Nothing in this agreement confers any ownership interest in the AIMS Bioresources Library Material to Company X."

AIMS has developed its ABS Framework to guide negotiations of agreements involving AIMS in its "provider" role. This Framework is based on the MT.

AIMS will provide this document to prospective collaborators and invite feedback at the start of negotiations, to facilitate a sound negotiating relationship based on clear understanding and the terms of engagement.

The Framework formally defines organizational policy and commitment. For example: AIMS policy position on ABS; types of deals it will consider (and the application of ABS to it). This framework was signed off by management (CEO). As an internal framework it defines AIMS' role as a provider and defines part of AIMS' role as a user (collaborations with external parties).

The purpose of the Framework is: to provide to potential partners "up front," an agreement specifying PIC, MAT, and benefits; to define "freedom to operate;" and to use the genetic resource under an umbrella agreement" with the different governments in Australia (i.e., Commonwealth or national, and state). This General Agreement will provide for the terms of engagement with downstream players, the terms of downstream agreements and uphold obligations from access, compliance and monitoring through reporting.

AIMS extensively utilized the ABS-MT through applying its AIMS Framework-for these purposes. For instance:

- Queensland Biodiscovery Act (2004)
  AIMS has signed a General or Framework Agreement with Queensland, by acceptance and formal annexure of the Framework to the Biodiscovery Plan presented by AIMS.
- Commonwealth Environmental Protection Regulations (amended 2005 for ABS)
  AIMS Framework to be annexed to the Benefit-sharing Agreement for the signature of a General Agreement.
- Northern Territory Biological Resources Act (2006)
  AIMS Framework to be annexed to AIMS Framework to be annexed to the Benefit-sharing Agreement for the signature of a General Agreement.

Lessons Learned from Use of the ABS-MT by AIMs

The Project Team interviewed individuals in Australia involved in the use of the ABS-MT and also followed the use of the Framework with the NT. In this case both Parties agreed that the MT was useful for the following reasons:

- the MT reflects good practices;
- was prepared by a third party (the project team). It adds credibility and neutrality to the use of the standards found in the MT;
- the MT was understood as a set of options, then allowing for enough flexibility in their application;
- the MT creates trust and predictability from the beginning of the negotiations. Each Party knows the other Party's intentions and expectations; and
- the MT separates Access and Benefit-sharing (treating both aspects separately).

However, the MT was found to be very complex and redundant and not user-friendly.

Conclusions

In conclusion the MT: guided the Framework to define AIMS-ABS policy and practice which helped AIMS define its "freedom to operate," to both access providers and potential collaborators; positioned AIMS as nexus between the *in situ* resource and end-users; was used in one negotiation with an ABS partner and discussions with several others; was not as directly useful in negotiating with access providers (because the NT had in place a new policy and law); and provided a framework that was useful as an annex to ABS agreements to define AIMS "freedom to operate," being used in formal agreement with three jurisdictions.

Lessons Learned for the Improvement of the MT

Based on the Framework prepared by AIMS, the Project Team field visit to Australia and the e-exchange of information with the participants and presentations made by AIMS in different events, the following preliminary lessons are presented:

- MT can easily be used (as a set of options) for the development of an institution's (provider or user) policy or negotiating framework to be put into place for allowing future ABS negotiations/relationships. The MT can be used by the provider (instead of the user) of genetic resources to establish, in advance and from the beginning, the minimum acceptable terms for ABS collaborations, taking into account that each ABS negotiation is unique. This demonstrates that the MT is a useful instrument for both providers and users, and not only for user of genetic resources.
- Research institutions (and not only commercial enterprises) can use the MT for guiding the development of ABS good practices and policies.
- MT was found attractive for both provider and user mainly because it reflects good practices; was developed by a neutral team and creates a sense of trust and predictability between ABS participants.
- PIC, MAT and Benefit-sharing are the most relevant standards in the ABS-MT because they are "new concepts." Conservation and sustainable use and information and transparency are more familiar practices for institutions involved in biological resources transactions and activities.
- MT was useful for strengthening legal certainty and freedom to operate by AIMS (as a genetic resources user).

3.0 Case study on *Hoodia gordonii* and the San People of Africa

1. Overview

This case study illustrates how an indigenous plant (i.e., *Hoodia gordonii*) used by an indigenous community (the San), was patented by a government research body in South Africa and in turn licensed to a large pharmaceutical company, without any consultation with the San community, apparently because they were believed to be "extinct." With the help of their lawyer, the San embarked on an intensive campaign to be acknowledged as the legitimate holders of the indigenous knowledge on which the patent was based. After months of negotiation, they eventually successfully entered into a benefit-sharing agreement with the research institute.

The negotiations between the San and the Council for Scientific and Industrial Research (CSIR) went on for seven months (June 2001 to January 2002) before they signed a memorandum of understanding on February 1, 2002. Thereafter, the parties negotiated for another year, March 2002 to March 2003, until they signed a benefit-sharing agreement on March 24, 2003.

1.1 Stakeholders

The key stakeholders were:

The San people of Southern Africa: *Hoodia gordonii* was discovered and used by the San People, regarded as the First People of Southern Africa, since pre-historic times. They chewed the bitter *Hoodia* to suppress hunger and thirst, during long hunting trips. The San people are spread over Southern Africa, including South Africa, Namibia, Botswana and Angola.

The Council for Scientific and Industrial Research (CSIR): The CSIR is a major government-funded research institution that served the Apartheids government for decades. During 1995/1996, scientists from the CSIR— apparently after many years of research— isolated the hunger-suppressing chemical component in the *Hoodia gordonii*, now known as P57 and patented it. The CSIR holds the patent on P57.

Phytopharm: In 1997, the CSIR licensed the U.K.–based bio-technological company Phytopharm to further develop and commercialize P57. Phytopharm signed a licensing agreement with CSIR that allows it to take P57 through development and initial stages of clinical trials.

Pfizer: During 1998, Phytopharm sub-licensed drug giant Pfizer, to complete the clinical development, obtain regulatory approval and further market and commercialize P57. In July 2003, Pfizer withdrew from commercial development of P57.

Unilever: During 2004, Phytopharm announced its intention to develop P57 as a food supplement and during November 2004 Unilever, a global consumer products company, purchased the licence from Phytopharm to develop and commercialize P57 as a food supplement.

The Working Group on Indigenous Minorities in Southern Africa (WIMSA) is an NGO, which was founded in 1996. WIMSA is an umbrella organization for San peoples with a membership of 24 organizations spread across South Africa, Namibia and Botswana, aiming to organize, mobilize and raise the political consciousness of the San. WIMSA raised money to pay the fees of the lawyer who assisted the San in challenging the CSIR.

The South African San Institute (SASI) is an NGO that was founded in 1996 in collaboration with WIMSA, with the purpose of providing development support to the San communities of South Africa. SASI provided administrative and logistical support to the South African San Council, who did the negotiations on behalf of all the San communities of Southern Africa.

Hoodia gordonii

Hoodia gordonii (Asclepiadaceae) is a succulent plant that looks like an ordinary cactus, with thin thorny fingers. It grows up to one meter tall in the reddish sands of Southern Africa's Kalahari desert. The *Hoodia* plant has been used for generations by the San in times of low food availability as a thirst and appetite suppressant. The CSIR took up the research into the properties of the *Hoodia* and extracted a bio-active compound called P57 that is responsible for its hunger and thirst alleviating properties.

2. Basic Conditions for Negotiating

(a) Were both users and providers willing to participate in good faith in the ABS negotiation?

The user (CSIR) was initially coerced into the ABS negotiation with the San community after the San were accidentally informed about the *Hoodia* negotiations between CSIR, Phytopharm and Phizer. These negotiations occurred without seeking PIC from the San community. Despite these setbacks, good faith between the parties developed as negotiations proceeded.

(b) Was the capacity and level of understanding of ABS issues adequate?

The provider community did not have an adequate understanding of ABS issues at the time of negotiations. Their capacity has improved since then, but there is still plenty of room for improvement. The user's decisions were based on both an inadequate understanding of ABS issues and blatant disregard for the rights of indigenous communities.

(c) Did a national regulatory framework exist? Did it affect the negotiation?

No national regulatory framework existed at the time of the negotiation. The negotiators had to be guided by their own discretion and perspectives of creating a win-win outcome for all parties involved.

3. Process of Negotiation

How did the stakeholders participate in the negotiations?

Negotiations around benefit-sharing were only conducted between the CSIR and the San.

What methods or instruments were used?

Before any agreements between the San and the CSIR could be concluded, the San had to form a legal entity with a constitution. A San council was thus hastily elected and a constitution workshopped. Thereafter a series of roundtable discussions between the San Council and the CSIR took place during which they negotiated the terms of the memorandum of understanding and the benefit-sharing agreement. Some of the meetings were facilitated by an independent facilitator (Chris Spies) and some were observed by representatives of international organizations including Bio Watch. The San also visited the bioprospecting plant of the CSIR to gain an understanding of the scientific research processes that were happening.

4. Elements of the Negotiation

4.1 Prior Informed Consent

Was PIC obtained in writing from all relevant stakeholders?

No. As mentioned previously, CSIR research and the negotiations between the CSIR and the pharmaceutical companies occurred without involving the San or obtaining PIC. PIC happened at a later stage and was applied as an instrument of damage control.

What methods were used to exchange information and address any concerns from affected parties?

The CSIR and the San exchanged information and resolved their differences in a series of meetings.

4.2 Mutually Agreed Terms

Were MAT negotiated by both users and providers?

Yes.

Were mechanisms in place to take into account the differences in capacities and needs of providers and intended users?

Yes and no. CSIR advanced a loan to the San that could be used to fund their transport and accommodation costs to participate in the negotiations. This loan had to be paid back later with money from the milestone payments and was not adequate to cover tele-communication costs as well as expenses that were incurred for the San representatives to consult with the constituencies on whose behalf they negotiated. The San`s lawyer was not paid by the CSIR loan or any of the user partners.

The user entity took cognizance of the lack of negotiation skills and knowledge about relevant legislation and allowed the San to be assisted by a lawyer. The representatives of the CSIR did not have a lawyer present at the meetings with the San, but obtained legal advice from their lawyers before and after meetings.

Was legal and technical advice available to all parties?

Yes.

Were there any measures to ensure that renegotiation would take place if the type of use changes beyond the agreed PIC?

No.

4.3 Benefit-sharing

What types of monetary and non-monetary benefits were agreed/negotiated?

The following financial benefits were negotiated for the San of Southern Africa: eight per cent of "milestone payments" received by CSIR from the Licensee and six per cent of all royalties received by CSIR from the Licensee (Phytopharm in U.K.) would be given to the San and paid into the *Hoodia* trust account.

What benefits have been realized by the providers of the genetic resource and who has benefited (e.g., government authority or agency, related stakeholders that are owners, managers or custodians of the genetic resource)?

Two milestone payment have been received by the San totaling R$560,000 (approximately US$100,000). This money is currently being used in order to strengthen the institutional base of the San Councils in the three countries (South Africa, Namibia and Botswana). It is anticipated that larger amounts of money will flow at a later stage.

There were also three other non-monetary benefits:

(1) The value of traditional knowledge was affirmed, not just for the San, but also for other local communities in South Africa.

(2) The relationship that was built up with the CSIR during the negotiations led to the San and CSIR entering into a joint bioprospecting agreement, in terms of which the CSIR will assist the San to record their traditional and medicinal knowledge in a private database, and the CSIR will use their scientific expertise to research and develop possible products. Any intellectual property in products developed from this information will then be jointly shared between CSIR and San.

(3) The San have realized that they have the moral right to benefit not only from the P57 patent and profits arising there from, but in addition from the legal growing of *Hoodia*. During 2005, the Hoodia Growers Association of South Africa initiated negotiations with the South African San Council to sign an agreement through which the San community would also benefit from the income derived from the cultivation and sales of *Hoodia* crops. The Hoodia Growers also signed a benefit-sharing agreement with the San in February 2002, in which the Hoodia Growers agreed to pay the San a certain amount of money from

Hoodia sales. This initiative however, has been revised as a result of other positive spin-offs in the form of other stakeholders also wanting to make sure that they honour the national and international ABS regulations. The latest initiative includes that South African Hoodia Growers and the Cape Ethno Botanical Growers Association of South Africa, both of which have entered into a partnership under one umbrella body that, with the cooperation of the Department of Environmental Affairs and Tourism, Cape Nature and the Northern Cape Department of Conservation, strives to ensure that the *Hoodia* industry is managed in compliance with relevant legislation. A memorandum of understanding has already been drawn up, making provisions to ensure that the San would receive R24.00 per kg of dry *Hoodia* exported from the country. The formal benefit-sharing agreement was due to be signed on March 16, 2007, after which a comparative case study between the two benefit-sharing deals could perhaps be considered.

What benefits have been realized by the users of the genetic resource?

The exact amount of monies paid over to the user is not known, but it can be anticipated that both the CSIR, the licensee (Phytopharm) and sub-licensee (Unilever) will in the long run gain substantial riches (millions of rands are expected) from this endeavour.

What mechanisms have been used to monitor benefits?

A trust, which meets on a quarterly basis, was established to monitor the implementation of the benefit-sharing agreement and control of monies involved.

4.4 Other Elements

How were other elements of ABS practice addressed in the negotiation of the ABS agreement and in its implementation?

Traditional Knowledge: What objectives were included in the agreement and what measures were carried out to respect customary law and practices and to protect and preserve traditional knowledge?

No explicit agreements were recorded with regards to customary law and practices pertaining to the *Hoodia*. The user entity understands and respects the fact that the plant is still traditionally utilized for dietary and medicinal purposes. The community has not been barred from the continued customary use of the *Hoodia* by laws and regulations in this regard.

Conservation and Sustainable Use: What objectives were included in the agreement and what measures were carried out to ensure conservation and sustainable use of the genetic resource?

No measures were included in the agreement. However, when it became clear that people were plundering the *Hoodia* plant, the relevant government authorities instigated measures to protect the plant. The *Hoodia* has recently been listed as a protected species under the CITES protocol with resultant controls that curb the illegal harvesting, transportation and sale of *Hoodia*.

5. Challenges

(a) What challenges were encountered in the negotiation and implementation of the ABS agreement and how were/are these being addressed?

Trying to reach agreements within the restricted time and financial limits has been a huge challenge. The San had to hastily form a proper legal structure, with whom the user entity could negotiate. The situation was worsened by the fact that the San people, many of whom are illiterate, are spread over a vast rural area, with limited roads and telecommunications infrastructure. A limited number of meetings could be held and only critical information could be communicated amongst/within the provider community.

Communication within the provider community representatives and the broader constituency still remains a problem, especially taking into consideration that the beneficiaries are spread over South Africa, Namibia and Botswana.

The activities of the so-called "free riders" who disregard ABS rules and regulations posed and still pose a huge challenge to the user and provider communities. A growing number of *Hoodia* products have flooded the market over the past few years, each containing an element of ABS non-compliance or illegitimacy including:

- products claiming to be *Hoodia*, but containing no trace of *Hoodia* whatsoever;
- a product claiming to contain far more *Hoodia* then what is actually the case;
- products untruthfully claiming to have a benefit-sharing arrangement with the San; and
- products sold as *Hoodia*, but not disclosing any information on its origin, composition or any benefit-sharing agreement that might or might not exist.

High-level discussions have currently been started between South Africa and some countries where these practices occur to try to address this matter by making sure that those countries who underwrite the CBD enforce their national legislation with regards to ABS, medicinal control regulations and advertising control standards.

6. Lessons Learned

Identify whether the arrangement has been a success or failure.

The agreement can be regarded as a success that has had positive spin-offs.

What best practices were used during the negotiation and implementation of the agreement?

This case study demonstrates that benefits can be spread amongst the entire provider region or community, without the need for separate structures or benefit-sharing agreements for different communities or countries. Although significant communication challenges still exist, the *Hoodia* trust is functioning relatively well to represent the needs of all countries involved in a satisfactory manner.

The acknowledgement/recognition of each other's contributions (traditional knowledge and scientific expertise) and a spirit of eagerness to reach a win-win solution played a crucial role in the signing of the benefit-sharing agreement, the continuation of cooperation and the possibility of future benefit-sharing agreements.

What guidance and support was used for the ABS negotiations? Can you recommend any tools?

The negotiators were generally guided by the broader provisions of the CBD and the Bonn guidelines. No other particular guidelines or support not yet mentioned was utilized.

It cannot be emphasized enough that communities will only benefit from international and national ABS regulations if they organize themselves properly, capacitate themselves on ABS issues and find the means to secure legal and other support to assist them during any ABS negotiations.

7. Use of/Opportunities for the ABS-Management Tool

How could the ABS-Management Tool have improved the negotiation?

In the absence of national legislation, the ABS-MT it could have been used as a guiding instrument to ensure that adequate checks and balances were built into the benefit-sharing agreement that was concluded. A more balanced process and agreement would for instance have ensured that the users contributed financially and adequately towards the negotiation-related expenditures of the San (and not by means of a loan), that provision was made for the revision of the agreement within a certain period of time, that provision would have been made for immediate and better-spaced financial benefits, that a bigger emphasis was placed on the developmental benefits that do not necessarily involve the transfer of money to the trust fund, that conservation issues were addressed in a timely way and adequately and that greater transparency was enforced. The latter would have played a significant role in enhancing mutual trust and ensuring a healthy, well-balanced, well-communicated and well-accepted agreement that could have been embraced and protected by all the negotiating parties as well as the broader constituencies they represented.

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ABS-Management Tool

Best Practice Standard and Handbook for Implementing Genetic Resource Access and Benefit-sharing Activities

The ABS-Management Tool (ABS-MT) is a best practice standard and a handbook that provides guidance and tools on ABS practice to help companies, researchers, local and indigenous communities, and governments ensure compliance with the Bonn Guidelines and ABS requirements under the Convention on Biological Diversity. It provides users and providers of genetic resources with a structured process for participating in—and making decisions about—ABS negotiations and the implementation of ABS agreements for access to, and agreed use of, genetic resources.

V1

Volume 1 provides the reader with an overview of ABS and the relevance of the ABS-MT for users and providers of genetic resources. It includes the Best Practice Standard and advice on key management processes to support its implementation.

V2

Volume 2 provides the reader with good practice guidance for ABS processes, supporting tools to apply specific aspects of the ABS practice, and three case studies to provide additional information on applying the ABS-MT, and highlighting lessons learned from field tests of the ABS-MT and other ABS processes.