



African Union Practical Guidelines

**for the Coordinated Implementation of the
Nagoya Protocol in Africa**

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Acronyms and Abbreviations

ABS	Access and Benefit Sharing
ABS CH	Access and Benefit Sharing Clearing House
aTK	Associated Traditional Knowledge
AMCEN	African Ministerial Conference on the Environment
ARIPO	African Regional Intellectual Property Organisation
AU	African Union
AUC	African Union Commission
BCP	Bio-cultural Community Protocols
BD	Biological Diversity
BR	Biological Resources
CBD	Convention on Biological Diversity
CGRFA	Commission on Genetic Resources for Food and Agriculture (of the FAO)
CNA	Competent National Authority
COP	Conference of the Parties
DHRST	Department of Human Resources, Science and Technology (of the AUC)
EU	European Union
FAO	Food and Agriculture Organisation (of the United Nations)
GMBSM	Global Multilateral Benefit Sharing Mechanism
GR	Genetic Resources
ICNP	Inter-governmental Committee for the Nagoya Protocol
IGC	Inter-governmental Committee (on Genetic Resources, Traditional Knowledge and Folklore, of WIPO)
ILCs	Indigenous and Local Communities
IPR(s)	Intellectual Property Right(s)
IRCC	Internationally Recognised Certificate of Compliance
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	Mutually Agreed Terms
MTA	Material Transfer Agreement
NFP	National Focal Point
NP	Nagoya Protocol
OAPI	Organisation Africaine de la Propriété intellectuelle
PAIPO	Pan-African Intellectual Property Office
PGRFA	Plant Genetic Resources for Food and Agriculture
PIC	Prior Informed Consent
RECs	Regional Economic Communities (of the AU)
R&D	Research and Development
TK	Traditional Knowledge
WIPO	World Intellectual Property Organisation

Background

Context

After more than ten years of negotiations, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity (Nagoya Protocol) was adopted on 29 October 2010 in Nagoya, Japan. The Protocol provides an international framework for implementing the third objective of the Convention on Biological Diversity (CBD), which is “the fair and equitable sharing of benefits arising from the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding”.

The African Group was very active in the Nagoya Protocol (NP) negotiations because access and benefit-sharing (ABS) is a theme of major importance for Africa, a region with a rich heritage of biological diversity, genetic resource (GRs) and associated traditional knowledge (aTK). These assets have often been misappropriated or utilized without fair and equitable sharing of the accruing benefits with the countries of origin or indigenous and local communities (ILCs). Preventing injustices of this nature has been a priority in Africa, partly because the region views itself primarily as a provider of GRs and aTK.

Nevertheless, Africa is increasingly also a user of GRs, both exotic and indigenous. Crop varieties and livestock breeds originating from other parts of the world make major contributions to Africa’s agriculture and food security. Most African countries are Parties to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which is a specialised ABS instrument for a particular subset of GRs. The African Group also participates in on-going negotiations at the FAO Commission on Genetic Resources for Food and Agricultural (CGRFA) on ABS measures for other groups of GR, including animals, aquatic organisms, invertebrates, micro-organisms and forestry resources.

African institutions also form part of international research networks around e.g. taxonomy (requiring access to specimens), health (requiring access to human, animal and plant pathogens) and climate change adaptation (requiring access to GR adapted to changed environmental conditions). Ensuring that Africa benefits fairly from such research raises substantial ABS issues.

With growing scientific and technological capacity, Africa is beginning to turn its GRs and aTK into novel biotechnology and biotrade products, creating new income opportunities for ILCs in the process. ABS if properly implemented – with appropriate training, technology transfer and funding – offers opportunities to increase Africa’s ability to add value to and benefit from its natural and cultural resources (in line with current African Union strategies on scientific and technical capacity, food security, value-adding to raw materials and industrial development). It can also help to alleviate poverty, stimulate community-level economic development and serve as an incentive for sustainable use and conservation of biodiversity.

Given this complex context, the CBD COP decision adopting the NP (*Decision X/1*) recognised that the International Regime on ABS “is constituted of the Convention on Biological Diversity, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity, as well as complementary instruments, including the International Treaty on Plant Genetic Resources for Food and Agriculture and the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation”. It also referenced on-going ABS-related work in international organisations like the WHO, FAO and WIPO.

Process

The adoption of the NP created an opportunity for African ABS stakeholders to adopt a coordinated approach to ABS implementation; this approach needed to be coherent and in synergy with agreed African positions and related regional and international instruments. The provisions of the NP were analysed against the background of *The African Common Position for the Negotiations of the International Regime on Access and Benefit Sharing (IR ABS)* adopted by the Pan-African Conference of Ministers in charge of ABS held March 2010 in Windhoek, Namibia. This further triggered a need for reflection on how Africa could best implement the NP in synergy with relevant regional instruments such as the *2001 African Model Law for the Protection of the Rights of the Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources* ("the African Model Law").

In response to these needs the African Union Commission Department of Human Resources, Science and Technology (AUC DHRST) in 2011, shortly after the adoption of the NP, commissioned a gap analysis of the 2001 African Model Law comparing it with the requirements and prescriptions of the NP, the ITPGRFA and other international instruments and processes of relevance.

The gap analysis considered the option of completely revising the Model Law but concluded (see Annex 1) that:

A second, probably more practical, option is to prepare a complementary guideline document to be used alongside the African Model Law. ... Such an approach would preserve what is best and most useful in the spirit and letter of the African Model Law, while also ensuring that African countries had access to updated guidance on how to turn noble principles and high aspirations into practical, workable policy, laws and regulations.

These conclusions and recommendations were reported to the 6th Pan-African ABS workshop held at Limbe, Cameroon in January 2012, where a wide range of participating African ABS stakeholders subsequently called for the preparation of draft ABS *Guidelines*. A group of African ABS experts was hence commissioned by the AUC DHRST (with financial support from the ABS Capacity Development Initiative) to do the work.

In September 2012, the fourteenth meeting of the African Ministers Conference on the Environment (AMCEN), held in Arusha, Tanzania, resolved "to encourage the African Union Commission to continue its ongoing work in the development of guidelines to support the coordinated implementation of the Nagoya Protocol on access and benefit-sharing in Africa". This decision was included as paragraph 26 in the *Arusha Declaration on Africa's post-Rio+20 strategy for sustainable development* and by doing so AMCEN clearly positioned this work within the wider African sustainable development agenda.

The progress in developing the *Guidelines* was presented at the 7th pan-African ABS workshop held at Phalaborwa, South Africa in February 2013 and a call for further comments made to the participants and other stakeholders.

The outcome of these initial consultative processes and feedback from various stakeholders was a draft instrument with two sections: An ABS Policy section and a Guidelines section for policy implementation. The ABS Policy Section was discussed in detail at a technical expert consultation meeting held in Addis Ababa, Ethiopia in October 2013. The result of this meeting was the development of the *AU Policy Framework for the Coordinated Implementation of the Nagoya Protocol on ABS*.

The technical expert consultation further requested the AUC and the ABS Capacity Development Initiative to continue facilitating the development of the Guidelines Section into a step-by-step implementation guide and submit the consolidated document for further consultation and comments before its technical validation and formal adoption by relevant AU policy organs.

In February 2014 a group of expert peer reviewers met in Addis Ababa and reviewed the draft *Step-by-Step Guide*, as well as certain aspect of the *Policy Framework*. Written comments received after the meeting were incorporated into a revised consolidated draft, re-titled *African Union Policy Framework and Guidelines for the Coordinated Implementation of the Nagoya Protocol in Africa*, which was submitted to a Verification Workshop in Addis Ababa in August 2014, where the draft consolidated document was validated as follows:

African Union Policy Framework for the Coordinated Implementation of the Nagoya Protocol in Africa.

This document was considered by the AMCEN at its XVth meeting held at Cairo, Egypt in 2015 and adopted after being re-titled as the *African Union Strategic Guidelines for the Coordinated Implementation of the Nagoya Protocol in Africa*.

The *African Union Policy Framework [and Guidelines] for the Coordinated Implementation of the Nagoya Protocol in Africa* were considered and adopted by the AU Assembly at its 25th Ordinary Session held at Johannesburg, South Africa in 2015.

The Guidelines for the Coordinated Implementation of the Nagoya Protocol in Africa provides a practical step by step guidance for the implementation of the Protocol and for an ABS system at national and regional levels. This document sets out the Guidelines as adopted and constitutes an appendix of the AU Policy Framework.

Practical Guidelines for the Coordinated Implementation of the Nagoya Protocol in Africa

1 Introduction

The NP is an international Agreement that will need to be implemented at the domestic level for it to work as intended. In order to facilitate coordinated domestic implementation of the NP, the AU Member States adopted a *Strategic Guidelines for the Coordinated Implementation of the Nagoya Protocol in Africa*. These Practical Guidelines are supplementary to that Strategic Guidelines and were developed to operationalise it.

These *Practical Guidelines* (Guidelines) are meant to facilitate ABS implementation in Africa and to facilitate coordination and cooperation between African countries. However, each AU Member State that becomes a Party to the NP must implement it in a way that suits its own national circumstances, priorities, needs and policies. The *Guidelines* are therefore not intended, and do not attempt, to make ABS measure in Africa completely uniform.

The NP allows Parties flexibility to take domestic legislative, administrative or policy measures to implement its various articles. The African Group insisted on having the term “regulatory requirements” included, because it is often easier to put in place such requirements than to pass new legislation. A country may use administrative or policy measures anchored in existing legislation, or amend existing legislation. However, in some countries new legislation may be necessary. It is therefore important for countries to review - in a participatory and transparent manner involving all relevant stakeholders – their current legislative framework with a view to determining whether it provides sufficient provisions for implementation of the NP. In some African countries, existing laws on biodiversity conservation and management, science, technology and innovation and intellectual property rights, backed by National Biodiversity Strategies and Action Plans, may provide sufficient provisions for implementation of national ABS frameworks without necessarily having to enact new laws on ABS immediately. These existing policy spaces could be used, especially in the short and medium term, to implement ABS.

There are a number of existing and emerging domestic ABS systems in Africa, some of which are currently under review to ensure their compatibility with the NP. This implies that not every action outlined in these *Guidelines* will be equally relevant or applicable to all countries. Furthermore, countries do not necessarily have to take all the actions in the same sequence as they are presented in the *Guidelines*, as long as effective domestic measures exist, or are put in place, to deal with the substance of each step.

The *Guidelines* are not exhaustive and should be read with, and interpreted in light of, primary sources such as the texts of the CBD, NP, ITPGRFA and Bonn Guidelines. In this context the *Guidelines* complement other materials already available on the subject, such as IUCN’s *Explanatory Guide to the Nagoya Protocol on Access and Benefit Sharing*, the Swiss-funded *Management Tool and Best Practice Standard* and its accompanying *Handbook for Implementing Genetic Resource Access and Benefit Sharing Activities* and the SANBio *Traditional Knowledge and Plant Genetic Resources Guidelines*.

Objectives of the Guidelines:

- These guidelines are intended to:
- Provide practical guidance to African Union Members States on how national ABS systems can be implemented in a regionally coordinated manner, consistent with the provisions of the NP, so as to preserve key African interests and positions while preventing a “race-to-the-bottom” scenario in which users of GR and aTK play off African Union Member States and/or African ILCs against one another
- Establish a coordinated and cooperative regional approach to preventing misappropriation of African GRs and/or aTK, and to punishing such misappropriation when it occurs
- Encourage utilisation of Africa’s GR and aTK assets in ways that support regional objectives and strategies on human resource development, technology transfer, scientific and technical capacity building, food security and economic growth, while encouraging conservation and sustainable use of natural and human capital, including the rights of ILCs
- Facilitate the establishment of common African ABS standards, particularly for benefit-sharing.

2 Becoming a Party to the Nagoya Protocol

AU Member States are urged to become Party to the Protocol and are encouraged to consult the CBD Secretariat website which offers guidance on the key steps towards becoming Party to the Protocol¹.

3 Asserting sovereign rights of states and ILC rights over GR and aTK

AU Member States should exercise their sovereign rights over their natural resources in the implementation of the NP by establishing in their domestic law that PIC is required for access to and utilisation of their GRs (including those held ILCs) and aTK.

Explanatory notes:

The sovereign rights of States over their GR are derived from the Charter of the United Nations and the principles of international law (cf. CBD Article 3, confirmed in CBD Article 15). These rights are therefore not dependent on the NP, but Article 6.1 of the Protocol provides additional legal clarity by stipulating that “access to GR for their utilisation shall be subject to the PIC of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the GR in accordance with the Convention, unless otherwise determined by that Party”. This refinement will impact on how sovereign rights are exercised in future for and by Parties to the NP.

Similarly, ILCs have fundamental; inalienable rights to their TK (and GR in many cases) derived from their customary laws and *inter alia* the UN Declaration on the Rights of Indigenous Peoples and the AU Model Law. These ILC rights are reaffirmed in Articles 5.2, 5.5, 6.2, 11.2, 7, 12 and 16 of the NP, which generally provides that such rights must be exercised in accordance with domestic law, regulations or policy measures, and conversely requires that Parties take legislative, administrative or policy measures to secure and give effect to these rights.

¹ <http://www.cbd.int/abs/becoming-party/default.shtml#signature>

Some Parties take the view that sovereign and ILC rights over GR and aTK must be pro-actively asserted and exercised through domestic legal provisions before these rights are relevant for ABS purposes, and in particular for triggering user obligations to ensure compliance with the domestic access measures of provider countries and/or community-level procedures of ILCs. Article 6.1 of the NP is ambiguous in this regard, but in view of the legal principle that “everything that is not prohibited is permitted” which prevails in some user jurisdictions, it is clearly sound policy to establish unambiguously that PIC is required for access to and utilisation of all African GR (including those held by ILCs) and aTK.

It is also relevant to recall that the basics of ABS were laid down in the CBD and only refined and clarified in the NP. A Party to the CBD can therefore exercise its sovereign right to require PIC for access to and utilisation of its GR (and the GR and aTK of its ILCs) without becoming a Party to the NP and/or as an interim measure before it joins the Protocol. To do so a Party can notify the Database on ABS measures and the ABS Clearing House maintained by the CBD Secretariat that it has PIC requirements in place, and provides appropriate details.² While this would not trigger the full suite of user measures envisaged in the NP to ensure compliance (and is therefore no substitute for joining the NP) it should nevertheless preclude any misunderstanding by users that PIC is not required for accessing and utilising GR and aTK from the country simply because it has not yet managed to enact a dedicated ABS law.

As soon as the NP enters into force for a Party it must also notify the ABS CH of its domestic ABS requirements and arrangements and put in place appropriate measures for PIC applications (cf. NP Article 6, especially 6.3, and Article 13.4).

4 The scope implications of use of terms

Member states should consistently use the terms as defined in Articles 2 of the CBD and the NP, in order to avoid misinterpretation, enhance legal certainty and increase compatibility of national ABS systems in Africa. This needs to be taken into account in the implementation of the Protocol.

Member states should take note of the definitions of “utilisation of genetic resources” “biotechnology” and “derivatives” in Article 2 of the Nagoya Protocol to ensure that domestic legislative, administrative or policy measures comprehensively cover the full chain of utilization of GRs, in order to trigger an effective benefit sharing mechanism.

Explanatory notes:

A key question facing ABS implementers is which of the many activities involving flows of biological resources and traditional knowledge they should regulate under the scope of ABS? Applying full ABS measures to e.g. agricultural commodities, fishery products, commercial timber and many other examples of biological resources traded internationally would be impractical and unnecessary, provided such materials were not surreptitiously utilised as GR.

To distinguish what is ABS and what is not, Article 2 of the NP defines “utilisation of GR” (i.e. the trigger for benefit sharing according to the third objective of the CBD) as meaning “to conduct research and development on the genetic and/or biochemical composition of GR, including through the application of

² <http://www.cbd.int/abs/measures/>

biotechnology as defined in Article 2 of the Convention". "Biotechnology" is defined in CBD Article 2 as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use". "Derivative" is defined in the NP as meaning "a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity". This sequence of definitions shows a clear intention to include utilisation of derivatives under utilisation of genetic resources and trigger benefit sharing.

However, the CBD defines "genetic resources" as any material of actual or potential value, and of plant, animal, microbial or other origin *containing functional units of heredity*. Whole organisms, raw samples of organisms and natural exudates are all undoubtedly GRs and access to them "for their utilisation" is clearly subject to PIC, according to Article 6.1 of the NP. Expert opinion differs as to whether access to pure derivatives that do not contain functional units of heredity is similarly subject to PIC under the provisions of the NP, but most agree that access to derivatives can be regulated under national law. The ABS Policy Framework therefore recommends in paragraph A.9 that African Union Member States clarify this affirmatively in national measures, for legal certainty.

There is no argument about the legality and utility of using MAT to control how derivatives isolated from accessed GR are subsequently utilised, applied and/or commercialised. NP Article 5.1 is clear: benefits arising from the utilisation of genetic resources, as well as subsequent applications and commercialization shall be shared in a fair and equitable way, upon MAT. "Products" are therefore subject to benefit sharing as agreed in MAT, but not subject to PIC of the provider country. Whether or not derivatives are made subject to national PIC requirements, utilisation of derivatives clearly triggers benefit-sharing obligations. It is also worth noting that all derivatives (as defined) must originally be extracted from GR and that such extraction clearly qualifies as utilisation. It is therefore important for AU Member States to regulate permitted R&D, including on derivatives, in MAT – being specific on uses that are allowed or not allowed. Researchers in possession of pure extracted derivatives can also reasonably be expected to explain where they were originally obtained.

To ensure that the negotiated compromises behind certain terms are maintained, avoid confusion, enhance legal certainty and increase compatibility of national ABS systems in Africa it is therefore imperative to consistently use all terms as they are defined in Articles 2 of the CBD and NP, respectively. This has significant implications for what is regulated under ABS and how.

5 Stakeholder identification and involvement

AU Member States should identify and involve ILCs and all stakeholders in the implementation of the Nagoya Protocol and subsequent domestic legislative, administrative or policy measures on ABS. In this regard, AU Member States may wish to:

- a) Encourage involvement and participation of ILCs and other stakeholders in order to create a sense of ownership
- b) Develop an effective communication strategy to raise awareness and to share information
- c) Consider establishing national stakeholder committees involving ILCs.

Explanatory notes:

ABS involves and potentially affects many different groups of national stakeholders, ranging from private and communal TK holders and/or land owners who have legal rights to provide access to GR, local researchers and business people involved in bio-prospecting either as intermediaries or end users, and various government authorities tasked with regulating specific habitats (e.g. protected areas) or sets of resources (e.g. marine resources) or legal aspects (e.g. IP).

The complexities of stakeholder involvement include the identification of applicable legal, political and administrative mechanisms for such involvement. It is important to be mindful of differences in national systems and the nature of different stakeholder groups. In view of the above, the following guidance is given for stakeholder identification and involvement:

- a) Encourage involvement and participation of ILCs and other stakeholders in order to create a sense of ownership
- b) Develop an effective communication strategy to raise awareness and to share information
- c) Consider establishing national stakeholder committees including ILCs.

6 Institutional arrangements to regulate ABS under the Nagoya Protocol

AU Member States should put in place the necessary institutional arrangements to support the implementation of the NP by designating the NFPs and CNAs including focal points and/or of competent authorities of ILCs, and such other entities as appropriate. These institutional obligations are intended inter alia to provide legal certainty for applicants seeking access to GRs and aTK.

AU Member States may also establish mechanisms such as National Inter-Agency ABS Committees or National Multi-Stakeholder Committees to foster internal coordination, communication and dialogue regarding regulation of ABS at the national level and streamlining institutional/administrative and decision-making arrangements and procedures.

AU Member States may, in order to foster regional coordination, wish to establish procedures for NFPs (and CNAs, if appropriate) to share information with counterparts, especially in neighbouring and other African countries, and with any databases established by the African Union Commission.

Explanatory notes:

Article 13 of the NP requires each Party to designate one National Focal Point (NFP) and one or more Competent National Authorities (CNA). These can be pre-existing national institutions or new ones can be created if necessary. The two roles can also be performed by one entity. The contact information of the NP or CNA must be notified to the CBD Secretariat by the time the Protocol enters into force for a particular Party and thereafter the information shall be kept updated. The CBD Secretariat will make this information available through the ABS CH. These institutional obligations are intended to provide legal certainty to applicants about who has the authority to grant access for utilisation.

Before existing national institutions are designated as NFP and/or CNAs under the NP their structures and functions should be reviewed and modified or reinforced as necessary to ensure they can effectively implement the Protocol's regulatory measures at domestic level.

ABS implementation also requires setting up coordination and information exchange among relevant institutions and stakeholders. This is not prescribed in the NP but left to national discretion. Many African countries have expressed a preference for a combined NFP and CNA, to simplify communication. If the NFP and the CNA are not the same entity effective communication becomes critical. Communication arrangements with designated compliance checkpoints outside the NFP and CNA, e.g. IP offices, might also be needed.

African Union Member States may wish to consider establishing mechanisms such as National Inter-Agency ABS Committees or National Multi-Stakeholder Committees involving representatives from relevant government ministries and other authorities, ILCs and other relevant stakeholders to foster internal coordination, communication and dialogue regarding regulation of ABS at the national level and streamlining institutional/administrative and decision-making arrangements and procedures.

Last but not least, procedures must also be established for NFP (and CNAs, if appropriate) to share information with counterparts, especially in neighbouring and other African countries, and with any databases established by the African Union Commission. This is an obvious and crucial prerequisite for regional coordination.

National Focal Point

The main function of the NFP is to serve as an authoritative source of information on:

- Procedures for obtaining PIC and establishing MAT, including from indigenous and local communities where necessary
- CNA(s) authorised to grant PIC
- Relevant competent authorities of indigenous and local communities
- Relevant stakeholders

The NFP is responsible for national liaison with the CBD Secretariat. This includes communicating with the ABS CH about regulatory requirements, CNAs and their specific responsibilities, arrangements for PIC from ILCs, PIC decisions made by CNA(s), permits issued and their corresponding Internationally Recognised Certificate of Compliance (IRCCs, cf. NP Article 17.4). Access to various level of online functionality within the ABS CH will be controlled through a system of accreditation. Countries decide who will have accredited access and publishing rights, and at what level.

Competent National Authorities

The functions of the CNAs are:

- Granting access permits and other evidence to show that access requirements have been met
- Advising on applicable procedures for obtaining PIC and entering into MATs

Applications for permission to utilise GR and/or aTK can be made directly to the designated CNA, or to an intermediary office that then channels the application to the relevant authority.

Box 1

Of note:

- One (and only one) NFP must be designated in a Party to the NP
- One CNA must be designated, but more than one are allowed in order to accommodate national circumstances related to e.g.:
 - Location of genetic resources (e.g. protected areas, forests, marine areas etc.)
 - Governance and institutional structures in a Party, e.g. provincial or state authorities having authority over specific biodiversity or genetic resources
 - Specialised national institutions like ex situ collections
- If more than one CNA is designated, the responsibilities of each must be clearly specified
- Having one entity functioning as both NFP and CNA may result in a more efficient decision making procedure and reduce transaction costs, but only if a single institution has all the necessary expertise
- The NFP and CNAs may be designated through legislative, administrative or policy procedures

Indigenous Competent Authorities

Article 14 of the NP provides that Parties can provide additional information, if available and as appropriate, on relevant competent authorities of ILCs. Where such authorities have been identified by national law and/or customary or community procedures it is important to make this information available, so that potential users of aTK know whom to approach for PIC or approval and involvement.

7 Valorisation of GR and aTK

AU Member States should develop and implement GR valorization strategies for the productive use of GRs and aTK to promote sustainable economic development, sustainable use and conservation of biodiversity. This strategy should be flexible and responsive to new developments, with provision for regular reviews and evaluation, as necessary. This is important in order to shape a country's overall strategic approach to the implementation of the Nagoya Protocol on ABS.

AU Member States should take measures to develop endogenous human, technical and institutional capacities to add value to their GR and aTK by, *inter alia*, promoting

- collaborative research activities,
- the establishment of regional and subregional research infrastructures, and
- the organization of joint training programs.

Explanatory notes:

In the ABS context "valorisation" is best understood as productive use of resources, and more specifically the use or application of GR and/or aTK so that they generate value, with the connotation that it results in a positive yield.

Valorisation is one aspect of an ABS approach and in the context of the CBD's integrated and holistic triple objectives it is not in conflict with sustainable use and conservation, which can in fact be values or yields generated by a valorisation strategy if the right policy choices are made.

Valorisation is also not strictly monetary – non-monetary yields such as scientific and technological development, livelihoods of ILCs, socio-economic development or spiritual values are all potential outcomes of appropriate valorisation.

A country's valorisation strategy for its GR and aTK helps to shape its overall strategic approach to ABS implementation. An ABS system aimed primarily at "preventing biopiracy" will obviously result in very different outcomes from a valorisation strategy aimed at "optimal use of the nation's existing natural and human capital", or one targeting "commercial partnerships resulting in technology transfer". In reality these policy objectives are not mutually exclusive – it is a matter of priorities and balance.

Box 2

It is neither possible nor appropriate for a document such as these *Guidelines* to prescribe a one-size-fits-all GR and aTK valorisation strategy for all of Africa. Each country and/or sub-region and/or ILC should reflect on this issue, discuss it with relevant stakeholders, and make corresponding policy choices. Among the many factors that can be considered the following are particularly relevant:

- The extent to which the country or group wants to pro-actively promote supplementary economic opportunities based on GR and aTK. Is it even necessary? Is it a development priority? Why, or why not? Are there obvious priority targets for such promotion?
- National and local capacities to valorise GR and aTK. Consider technical capacity, human and institutional capacity, access to technology and funding, market access, skills transfer etc. Which priority activities can help to build which local national capacities? How can existing GR and aTK assets be leveraged to discover and develop new ones? At what point will external partners with additional resources be required, if at all?
- The cost-benefit ratio of ABS activities. How can transaction costs be minimised while optimising benefits? What is the least amount of paperwork that will still deliver acceptable levels of legal certainty at various stages of the discovery and commercialisation process? Which strategic investments by users or development partners?
- The opportunities that are lost forever when R&D action is delayed while biodiversity loss is on-going. Can non-commercial research aimed at supporting sustainable use and conservation also be leveraged for benefit-sharing purposes?
- The policies and measures needed to support ILCs in developing their GR and aTK heritage into supplementary sources of livelihood.
- Other relevant national policies, e.g. on environmental sustainability, science and technology, human resource development, industrial development, rural development, food, agriculture and food security, intellectual property rights, land rights, human rights, traditional medicine or gender equality. Can ABS activities contribute to achieving the objectives of these policies? Or are there areas of uncertainty or even potential conflict between policies that need to be resolved in order to develop a coherent and effective valorisation strategy for GR and aTK?

The need for a valorisation strategy is not simply a restatement of the truism that “benefits must be created before they can be shared” – it goes beyond that to questions about the kind of benefits desired and how a country goes about ensuring, or at least maximising the chances, that ABS implementation delivers the desired development, sustainable use and conservation outcomes.

To be successful in the longer term an ABS valorisation strategy needs to be flexible and responsive to new developments. It is therefore advisable to avoid fixing such a strategy in stone and instead to plan for a regular process of re-evaluation and re-planning as necessary.

8 Establishment of procedures for PIC and MAT

AU Member States should put in place clear, transparent and user-friendly procedures for PIC and MAT and for this purpose they may wish to adapt and use, as appropriate, the sample forms in Annex 2.

Explanatory notes:

To implement an effective national ABS system under the NP it is necessary to have, or put in place, user-friendly paper work, including prescribed forms and procedures to be used when applying for and granting PIC to utilise GR and aTK. Forms and procedures are also needed for concluding MAT on how the GR and aTK may be utilised and how benefits arising from such utilisation shall be shared. The specifics of each of these aspects – such as who has the legal right to be a provider of GR or aTK – are discussed in more detail in separate sections below; the current section deals only with the forms and procedures required for a coordinated approach.

To better understand how the PIC and MAT sequence might work in practice, as well as the various official forms that are required to make it work, it is useful to break the application and permitting process down into the following simplified steps:

- “Prior Informed” comes first: the applicant must reveal all available and relevant information so that the provider and/or CNA³ can make an informed decision about whether or not to allow the proposed utilisation; to do this a detailed application form is needed. **Annex 2** contains a model application form for a permit to utilize GR and/or aTK. A document with the same structure can be used as a notification form, if a national ABS system provides for a notification option. Allowances should be made for information that the applicant cannot reasonably be expected to know at the start of the utilisation (e.g. the identity of species that might be newly discovered in the course of the utilisation, or new uses developed as a result of the research).
- “Mutually Agreed” comes next: the applicant and the provider and/or CNA must agree on the terms and conditions of the transaction, most importantly about permitted and/or restricted forms of utilisation and subsequent benefit sharing arrangements. **Annex 3** contains a basic ABS agreement that can be used at the time of access to safeguard all relevant rights and outline a process for further

³ The CNA can only be the Provider if national law gives the CNA the required authority to be the Provider. In many countries this is not legally possible without amending Constitutional provisions on property rights. If there is no legal basis in a specific national situation for the CNA to be the Provider and/or no such legal basis can be created, the Provider must be an ILC providing GR from communal land, or an institution with legal powers to manage natural resources *in situ* (e.g. a parks and wildlife authority) or *ex situ* (e.g. museum, botanical garden, gene bank or microbial collection), or an individual land owner.

negotiation and agreement of more detailed MAT if and when this is justified. The completed application form in Annex 2 can be attached to this agreement as an integral part of the contract, and in particular as a detailed record of what has been agreed and not agreed in terms of how the GR and aTK may be utilised.

- “Consent” and “Terms” follow: if the CNA consents to the utilisation proposed in the application form, and the applicant accepts the terms in the basic ABS agreement, the parties then sign the agreement contained in Annex 3 (which includes the application in Annex 2 as an integral part) and the CNA issues a permit, which is then also provided to the ABS CH, thus becoming an IRCC (see below).
- Further rounds of PIC and MAT might be required at later stages, e.g. when the research project moves from the discovery phase to commercialisation. Some users might want to apply right from the start for PIC and MAT that also cover commercial use. **Annex 4** contains a commentary on the key elements of a complete ABS agreement that can be used to guide development of commercial MAT contracts, taking into account the actual situation at hand and with legal advice.
- Other requirements under relevant conventions/treaties may need to be taken into account. For instance, genetic resources that fall under the ABS system of the International Treaty on PGRFA would have to be dealt with under the terms and conditions of its multilateral system and the SMTA, which already pre-establish both PIC and MAT for the specific purposes stipulated under the Treaty.

When a permit (or its equivalent) is issued in terms of NP Article 6.3(e) the ABS CH must be notified. Any such permit made available to the ABS CH constitutes an IRCC (NP Article 17.2) and this IRCC serves as evidence that the GR and aTK which it covers have been accessed in accordance with PIC, and that MAT have been established (NP Article 17.3). The IRCC shall contain the minimum information (when it is not confidential) specified in NP Article 17.4:

- a) Issuing authority
- b) Date of issuance
- c) The provider
- d) Unique identifier of the certificate
- e) The person or entity to whom PIC was granted
- f) Subject matter or GR covered by the certificate [note: “subject matter” can also be aTK]
- g) Confirmation that MAT were established
- h) Confirmation that PIC was obtained
- i) Commercial and/or non-commercial use

In addition to these prescribed data fields it is strongly recommended to also include information about whether transfer to third parties is allowed or prohibited.

Eventually most African countries would probably want to prescribe in law the form and content of PIC applications and ABS agreements. It is preferable not to do this in national legislation, which can be difficult to amend, but rather to use ABS laws to create the regulatory or administrative powers needed by e.g. the Minister of Environment to prescribe the necessary official forms through proclamation in the government gazette. Such powers to make subsidiary regulations can also be delegated to the NFP and/or CNA(s), in recognition of their technical expertise on the subject and for the sake of efficiency.

9 Access for utilisation

AU Member States should include in their domestic legislative, administrative or policy measures provisions on access to genetic resources for utilization, as well as access to aTK.

AU Member States should take legislative, administrative or policy measures, as appropriate, to ensure that aTK held by ILCs is accessed with the prior and informed consent or approval and involvement of these ILCs, and that mutually agreed terms have been established. Where ILCs have the established right to grant access to genetic resources under domestic law, their PIC or approval and involvement should also be sought.

AU Member states should, as appropriate,

- take into account the customary laws, community protocols and procedures of ILCs and endeavour to support the development by ILCs of community protocols and procedures with respect to aTK in accordance with Article 12 of the NP
- grant access only on the basis of MAT, usually by way of material transfer agreement (MTA)s between the provider and the user, in accordance with Article 15.4 of the CBD, and in particular recording which forms of utilisation are permitted or prohibited

AU Member States should put in place measures to ensure that PIC and MAT will be required for utilisation even when physical access has already occurred including for ex-situ collections.

In accordance with article 8 of the NP, AU Member States should, as appropriate, include in their domestic legislative, administrative or policy measures provisions that:

- Consider the importance of genetic resources for food and agriculture and their special role for food security
- Promote and encourage research which contributes to the conservation and sustainable use of biological diversity
- Take into account present or imminent emergencies that threaten or damage human, animal or plant health.

AU Member States should, as appropriate, include in their domestic legislative, administrative or policy measures, provisions that encourage and facilitate access for non-commercial research purposes as well as procedures to address change of intent.

Explanatory notes:

Provisions on how genetic resources (including their naturally occurring biochemical compounds) are to be accessed “for their utilisation”, as well as how traditional knowledge associated with genetic resources is to be accessed, are key elements of national ABS frameworks. Article 6 of the NP reiterates that countries have sovereign rights over their natural resources and therefore have the authority to determine whether access to their genetic resources for their utilisation should be subject to PIC or not. Where indigenous and local communities have an established right to grant access to genetic resources under the domestic law of a country, their PIC or approval and involvement must be sought. With regard to traditional knowledge associated with genetic resources, access is subject to the PIC or approval and involvement of indigenous and local communities, in accordance with national law (see Section 9.6 and Section 12 below).

PIC procedures for access to GR must comply with the criteria stipulated in Article 6.3 of the NP (see Section 9.4 below), including procedures for access to GRs held by ILCs where applicable. Article 12 of the NP further obliges Parties to take into account and support customary laws and community protocols and procedures with respect to aTK.

Box 3

What can be accessed?

- Genetic resources for their utilisation, including naturally occurring biochemical derivatives
- Traditional knowledge associated with genetic resources

Access to GR for utilisation

Article 6 of the Nagoya Protocol provides that “subject to domestic ABS legislation or regulatory requirements, access to genetic resources for their utilisation shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the [CBD], unless otherwise determined by that Party”. This PIC requirement also applies to naturally occurring biochemical compounds in the accessed GR.

Accessing genetic resources for purposes other than “utilisation” as defined in NP Article 2 falls outside the scope of the Nagoya Protocol⁴. Such purposes may include:

- Customary use and exchange of genetic resources by indigenous and local communities
- Harvesting resources exclusively for commodity trade or bio-trade (unless aTK is involved)
- Utilisation under a specialized international ABS instrument such as the International Treaty on PGRFA for the purpose of research, breeding and training for food and agriculture.

The African Model Law (Part III) broadly regulates access to biological resources, not just genetic resources for their utilisation. This includes non-commercial research on biological resources. However, with regard to research carried out by academic and public research institutions, it provides that the conditions for access may be different from those set for other users. This is on the assumption that research carried out by academic and public research institutions is non-commercial, something that may not always be true. Considering that academic and non-commercial research can lead to commercial applications, African countries need to frame ABS regulatory requirements for PIC and MAT in a way that recognises and deals with the possibility of change of intent, for example through an initial basic ABS agreement reserving all rights, with the user given an option of applying for new PIC and concluding new MAT when intent changes. Such considerations are becoming more pertinent as a result of African countries and universities increasingly embracing the private commercialisation of public research (which is already the norm in many developed countries).

⁴ It is nevertheless completely within the sovereign rights of States over their natural resources to regulate such access through other measures, such as harvesting quotas, natural resource management rules or export prohibitions.

Box 4

Genetic taxonomy and DNA barcoding

Genetic analysis has become an important tool in modern taxonomy. DNA barcoding, for example, is essentially a taxonomic technique that uses a very small and specific region of the genome to accurately identify species. Such techniques make some use of genetic analysis (when first “reading” the barcode or genome of a species and again when identifying a sample against a database of known barcodes or genomes) and are therefore strictly speaking subject to PIC requirements. Provided that no further or additional utilisation of the GR takes place and the information is made publicly available (as it invariably has to be for these techniques to function) such utilisation should however qualify for the “simplified measures on access for non-commercial research purposes” foreseen in NP Article 8(a).

Article 6.1 of the Nagoya Protocol provides that access to genetic resources for their utilisation shall be regulated by domestic ABS legislation or regulatory requirements. Article 6.2 obliges Parties to “take measures, as appropriate, with the aim of ensuring that the PIC or approval and involvement of ILCs is obtained for access to GR where they have the established right to grant access to such resources”, in accordance with domestic law. Article 6.3 provides that each Party requiring prior informed consent shall take legislative, administrative or policy measures, as appropriate, to put in place PIC procedures meeting certain minimum standards (see Section 9.4 below). While implementation of the legislative option would require enactment or amendment of existing law, the administrative or policy options could possibly be exercised through existing legislation (e.g. a law or regulation that compels researchers to obtain research and export permits for indigenous species). This means that countries have to review their current legislation to determine whether it may provide a legal basis for ABS measures. There is a particular need to reflect on how the rights of ILCs to give PIC for access to GRs, which they legally control can be integrated into the national ABS system in a way that truly involves ILCs without undermining the sovereign rights of the state.

It could be a useful policy option to distinguish in procedures for access between utilisation for commercial purposes and utilisation for non-commercial purposes. If such a distinction is made it must clearly spell out the limits of what is allowed under non-commercial research, as well as procedures for changing PIC and MAT when a non-commercial user later wants to move on to commercial utilisation. This is discussed in more detail in Section 9.5.1 below.

Access to traditional knowledge associated with genetic resources

Article 7 of the NP obliges each Party to take measures, in accordance with national law and as appropriate, with the aim of ensuring that aTK held by ILCs is accessed with the prior and informed consent or approval and involvement of these ILCs, and that MAT have been established.

The concept of utilisation does not apply to aTK in the same way as it applies to GR and has also not been defined internationally (although “benefits arising from the utilisation of aTK” is mentioned in NP Articles 5.5, 16.1 and others). Access to aTK (e.g. through access to a database or through field interviews) must be regulated in accordance with domestic law and it is therefore imperative that countries put in place national laws to regulate such access where no suitable legal basis exists.

The African Model Law (Part III) takes a broader view, seeking to regulate access to “knowledge or technologies of local communities”, not just traditional knowledge associated with genetic resources. The

Model Law recognizes the inalienability of community intellectual rights and treats access to knowledge or technologies of local communities in exactly the same way as access to biological resources. Recognizing that the right to grant access to knowledge or technologies of ILCs rests with the ILCs, it provides that a CNA can grant access only on the basis of evidence that ILCs have provided PIC and that MAT have been established.

Article 8(j) of the CBD takes a wider view when it calls on Parties to respect, preserve and maintain the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation of biological diversity and to promote their wider application with the approval and involvement of knowledge holders and to encourage equitable sharing of benefits arising out of the utilisation of such knowledge, innovations and practices.

While there is clearly general agreement that ILCs should control their own aTK and benefit fairly from its utilisation, determining how access to aTK can and should be regulated in practice remains a difficult issue, though, posing many unresolved questions, for example:

- How to define an ILC?
- Who has the authority to grant PIC on behalf of an ILC?
- How to deal with different communities holding the same aTK?
- How to deal with individuals or smaller groups within an ILC who hold specialized aTK (e.g. traditional healers and their specialised knowledge about medicinal plants)?

Article 12 of the NP provides some guidance on these thorny questions when it calls on Parties to take into consideration ILC's "customary laws, community protocols and procedures" with respect to aTK. Assisting ILCs to develop community protocols on ABS is certainly one option and was strongly supported by the African Group during the NP negotiations, but at the moment there is limited evidence regarding how cost-effective or efficient such support actually is, particularly when it deals only with ABS. A potential alternative approach is to affirm and boost the legal rights of ILCs to their resources, including aTK, and then help them to develop community protocols and procedures that go beyond ABS by also addressing traditional lifestyles and resource management practices. Such an approach has the benefit of still being useful even if no-one ever tries to access the aTK of a particular ILC (which unfortunately is increasingly likely, because so many potential users are deterred by the legal uncertainty surrounding aTK).

National databases of aTK have also been tried in a few countries (e.g. India and South Africa). While these are clearly useful for preventing bad IP grants (e.g. patents that do not meet novelty requirements) they are costly to implement and it is still unclear whether they can increase benefit sharing, rather than just deterring biopiracy. Measures that oblige users to disclose or declare utilisation of aTK have also been suggested, but again there is limited experience of how this approach would work in practice, and limited legal guidance on what would qualify as utilisation of aTK (and hence trigger benefit sharing obligations).

The role of mutually agreed terms in access

The CBD and NP both specify that benefit sharing shall be upon mutually agreed terms (MAT), which are therefore mainly associated with benefit sharing provisions (see Section 10 below). However, MAT also play a very important role in access, in particular recording which forms of utilisation are respectively permitted and prohibited. Access must only be granted on the basis of MAT between the provider and the user, in accordance with CBD Article 15.4 which provides that "access where granted shall be upon MAT".

The African Model Law has limited reference to MAT. Part III, Article 7.2 stipulates that “the access permit shall be through a written agreement between the National Competent Authority and the local community on one hand” and the person seeking access on the other. This idea – that the state has a role in accompanying and safeguarding ILCs in ABS negotiations – has always had strong support in Africa. Depending on national arrangements, NFPs and/or NCAs will be called on to oversee the establishment of MAT between providers and users and to ensure the fairness of the agreement, especially when the provider is an ILC. This implies that NFPs and NCAs will be required to make informed decisions on the terms of MAT. To evaluate and negotiate such agreements, they – and the ILCs they assist – will need legal and technical support and capacity development. At the African level much can be achieved in this regard by sharing information and working together to develop MAT standards.

MAT may include or involve other parties besides the provider and the user, like institutions or communities earmarked to receive benefits, civil society organizations advising indigenous and local communities, government entities involved in the benefit sharing administration process, or institutions monitoring compliance.

Article 8 of Part III of the Model Law prescribes the minimum contents of the agreement without providing guidance on what other terms of access may be agreed. In establishing rules and procedures pertaining to MAT, African countries should take into account the guidance provided by the African Model Law, the main components suggested in Article 6.3.g of the Nagoya Protocol and Articles 41 to 45 of the Bonn Guidelines.

Circumstances around MAT are wide-ranging, depending on the nature of the GR and/or aTK to be accessed, intended use, provider and user involved and political relationships between State actors and categories of stakeholders, especially ILCs. This complexity means it is difficult to legislate or stipulate in specific detail what should be contained in MAT. Minimum MAT may be provided for in prescribed forms (see Annex 3 for an example). This is key to eventually developing national and/or African benefit-sharing standards (see Section 10 below)

It is recommended that providers never transfer any biological or genetic resource, including derivatives, to users without establishing at least very basic MAT, usually in the form of a Material Transfer Agreement (MTA). In addition to information about the GR and its permitted and prohibited uses, the provider(s), ILCs/aTK holders and users involved, the following basic provisions should be included in all non-commercial MTAs:

- i. Prohibition of any commercial activity (IP applications, pre-market and marketing approvals, product development etc.) without first obtaining new PIC and concluding a Benefit-Sharing Agreement
- ii. Undertaking by applicant to act in a manner that supports sustainable utilisation and conservation of biological diversity
- iii. Agreed monetary and non-monetary benefit-sharing measures
- iv. Information sharing/reporting arrangements
- v. Measures to allow traceability of non-commercial research at further stages of utilisation
- vi. Prohibition of or conditions for transfer to 3rd parties (include on permit and register with ABS CH)
- vii. Procedures to follow in the event of change in the prior disclose intent/purpose for obtaining GR.

- viii. Confidentiality provisions
- ix. Dispute settlement clauses – applicable law, measures related to enforcement, dispute settlement, redress, access to justice – jurisdiction, arbitration etc.

The Basic ABS Agreement in Annex 3 can be adapted for this purpose.

Access standards

Article 6.3 of the NP specifies minimum standards for national measures governing access to GR (but not aTK). These access standards were reluctantly accepted by the African Group as necessary for securing legal relief in the courts of a user country when the national PIC provisions of the provider country have been transgressed.

Box 5

Standards to be met by PIC measures, as laid down by Article 6.3 of the Nagoya Protocol:

- Legal certainty, clarity and transparency
- Fair and non-arbitrary rules and procedures
- Information on how to apply
- Clear and transparent written decision by a CNA
- Cost effective process
- Decisions must be made within a reasonable period of time
- Issuance of a permit or its equivalent as evidence of PIC and MAT
- Notification of the issued permit to the ABS CH
- Procedure for obtaining PIC or approval and involvement of indigenous and local communities
- Clear rules and procedures for requiring and establishing MAT in writing, including:
 - Dispute settlement clause
 - Terms of benefit-sharing, including in relation to IPR
 - Terms on subsequent third-party use
 - Terms on changes of intent

Special considerations for specific types of access for utilisation

Article 8 of the NP, entitled Special Considerations, provides guidance to Parties on developing and implementing ABS legislation or regulatory requirements for:

- Research which contributes to the sustainable use and conservation of biodiversity
- Present or imminent emergencies that threaten or damage human, animal or plant health
- Genetic resources for food and agriculture

Each sector is approached differently, as explained below.

Research which contributes to the sustainable use and conservation of biodiversity

The CBD contains many provisions that underscore the importance of research for achieving sustainable use and conservation. Collaborative research on biodiversity is also an important mechanism for capacity development and technology transfer, and hence of great importance to most African countries.

Article 8.a of the NP obliges Parties developing and implementing ABS legislation or regulatory requirements to “create conditions to promote and encourage” such research “particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent [from non-commercial to commercial]”.

One option for “simplified measures on access” is a straightforward notification procedure based on standard MAT which includes a legal undertaking to engage in future negotiations if/when intent changes – which would then require new PIC and MAT. Many non-commercial researchers care more about speedy access than about the conditions imposed, so fast-tracking non-commercial applications within national ABS systems is another option. Many taxonomy networks freely exchange specimens between their members on standard conditions. One can also envisage fast-tracked access for foreign researchers in partnership with local institutions.

For a CNA to determine whether access is for commercial or non-commercial purposes, it is imperative that the applicant discloses at the earliest stage of the application process whether access is intended for commercial or non-commercial purposes. The template application form in Annex 2 could easily be modified (by including a declaratory/undertaking clause in which the applicant undertakes to notify the provider of change of intent and commit to enter into consequential arrangements) to also apply to a notification procedure, if a country elects to use this policy option.

Box 6

African Model Law, Article 11

Conditions Pertaining to Academic and Research Institutions, Public Agencies and Inter-governmental Institutions

1. The National Competent Authority shall subject all applications for access to a biological resource, a community innovation, practice, knowledge or technology to the prior informed consent of the concerned community or communities.
2. The National Competent Authority shall determine the appropriate conditions to be met under the written agreement referred to in Article 8, by academic and research institutions, public agencies and inter-governmental institutions.
3. The application for access for research purposes shall clearly state the objective of the research and the relation of the applicant to industry. Neither the sample nor the associated information shall be transferred without a material transfer agreement reserving the prior rights of the State and/or community or communities.
4. Where the institutions referred to in this Article change their activities to be predominantly the commercialization of a biological resource, the National Competent Authority shall cause the conditions and terms to be varied accordingly.

The African Model Law contains an elaborate provision on access for non-commercial purposes by academic and research institutions, public agencies and intergovernmental institutions (see Box 6). Article 11 of the Model Law is not in contradiction to Article 8.a of the Nagoya Protocol. These two articles should be considered in tandem by African countries when making special provisions for access for non-commercial purposes.

Many universities now have technology transfer offices charged with commercialising academic research results. Academic researchers are often contractually bound into such commercialisation arrangements and should be required to declare this when applying for access, particularly when the ABS agreement is signed with the university rather than the individual. Applicants for non-commercial research access should also be legally obliged to declare any commercial affiliations or partnerships.

A big challenge for ABS regulator is to know when the intent of the user changes from non-commercial to commercial, especially when a resource has left the jurisdiction of the provider country – this should be an integral part of monitoring compliance. One suggested way of dealing with this is to ensure that researchers from the provider country participate actively in the research (as a form of non-monetary benefit sharing); this is not always possible and will only work as a monitoring strategy if the national researcher can detect and will report any change in intent. Another option is for the applicant/user to declare change of intent. A hybrid option that ensures participation of local researchers as well as requiring declaration of change of intent could also be considered.

The risks inherent in change of intent can further be managed by specifically addressing in MAT for non-commercial research the following potentially indicative activities:⁵

- Restrictions on the release of research findings (e.g. non-disclosure agreements or unwillingness to publish results);
- Limitations placed on the involvement of provider country researchers in a project as collaborators and co-authors;
- Publication of results without providing pre-publication access to results by authorities in the provider country;
- Delays in the public release of data resulting from the research;
- Negotiating excessive fees for access to data, technology, or materials resulting from the research;
- Retention of monetary benefits from sale or lease for profit, patenting, or licensing of research results;
- Transfer of material to commercial third parties;
- Terms of agreements that reserve rights to file patents or maintain ownership of Intellectual Property Rights (IPR);
- Intent to investigate commercial applications, contract with a commercial body or entity, or conduct market research;
- Product development or testing of technology or products as part of a wider undisclosed project; and
- Other forms of contractual restrictions on the dissemination and subsequent use of the results.

⁵ Reproduced from the workshop report at <http://barcoding.si.edu/ABSworkshop.html>

Applicants can be requested to make a statutory declaration that none of the above applies to them.

Possible indicators of pre-commercial use (and thus greater potential for third party transfer etc.) could include:

- Statutes, policies or publicity materials of not-for-profit institution that put strong emphasis on the marketability of research results
- High quantities of accessed material, e.g. 100 kg

There is more to this question than the stated intentions of the applicant, however. Some types of non-commercial research that are particularly useful for supporting sustainable use and conservation also carry a relatively low risk of being abused for surreptitious “commercial research via the backdoor”, most notably taxonomy (including DNA barcoding) and ecology. The risk can be further managed by ensuring that abuse of non-commercial access concessions will result in the user and his/her institution being blacklisted by all African countries. This is also an appropriate way of dealing with illegitimate use of taxonomic accessions housed in ex situ collections (see also Section 11 below).

Access in instances of emergencies that threaten or damage human, animal or plant health

The issue of access to pathogens came close to derailing the negotiation of the NP at one stage. By comparison, the language in NP Article 8.b is relatively mild: Parties shall “pay due regard” to health emergencies and “may take into consideration the need for expeditious access” in exchange for expeditious benefit sharing, “including access to affordable treatments by those in need, especially in developing countries”. Given the public interest dimensions of health emergencies it is in the interest of African countries to collaborate fully in this regard.

There is on-going work on ABS in the three main international bodies (the World Health Organisation, WHO, the World Organisation for Animal Health, OIE, and the International Plant Protection Convention, IPPC) and it is important that African ABS authorities fully involve their national counterparts and NFP responsible for these conventions, as well as other relevant national stakeholders, in national ABS discussions as appropriate.

The WHO has established a non-binding framework agreement, the Pandemic Influenza Preparedness Framework (PIPF) with two Standard Material Transfer Agreements: one for regulating ABS between the provider and institutions within WHO’s Global Influenza Surveillance and Response System (SMTA1), and another between WHO and third parties (SMTA2). These SMTAs call for expeditious access and benefit sharing as critical factors in dealing with health emergencies.⁶ The PIPF can be regarded as a specialised international ABS agreement within the meaning of NP Article 4.4, but it applies only to influenza viruses with pandemic potential, not to seasonal flu viruses or any other viruses or other human pathogens. There are currently no other specialised ABS instruments dealing with human, animal or plant pathogens, although codes of conduct and best practice standards do exist in some communities of practice.

⁶ For more information on WHO Influenza Preparedness Framework, see <http://www.who.int/influenza/pip/en/>

Deciding when and which human, animal or plant health situations qualify as emergencies that warrant expeditious access to genetic resources shall be determined nationally, if it has not been determined internationally.

Access to genetic resources for food and agriculture

NP Article 8.c specifies that Parties shall “consider the importance of genetic resources for food and agriculture and their special role for food security”. Particularly relevant considerations include the interdependence of all countries when it comes to GRFA, and the importance of GRFA for safeguarding agricultural production and food security in the face of climate change. It is also prudent to distinguish between plant genetic resources and other genetic resource for food and agriculture, because they are at different stages in the process of developing specialised international ABS instruments (with animal resources ahead of forestry resources, invertebrates and micro-organism somewhere in between, and aquatic resources far behind).

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) – which pre-dates the NP – is recognised as an existing specialized international ABS agreement that is supportive of and does not run counter to the objectives of the CBD and the NP, as provided for in Article 4 of the NP. The Treaty’s objectives, for instance, include the sustainable use of PGRFA and the equitable sharing of benefits for food security and sustainable agriculture, in harmony with the CBD. Although similar to the objectives as the CBD and NP, the Treaty implements its objectives through a multilateral approach. In this regard it is important for parties to be mindful of the following when implementing access measures at the national level:

- The scope of ITPGRFA is not all genetic resources for food and agriculture, but plant genetic resources for food and agriculture, and more specifically PGRFA within the multilateral system as well as those PGRFA brought under the Treaty under special circumstances. In this regard, some countries have, in the exercise of their sovereignty, agreed that those PGRFA are to be governed in accordance with the special terms and conditions stipulated in the standard material transfer agreement (SMTA) adopted by the Treaty’s Governing Body;
- Under the multilateral system governed by the ITPGRFA, facilitated access to PGRFA applies to those PGRFA listed in Annex I of the ITPGRFA when they are used for the purposes set out in the ITPGRFA;
- The scope of the multilateral system does not automatically extend to plant genetic resources not listed in Annex I to the Treaty, but Parties can determine that the rules of the ITPGRFA also applies to non-Annex I species; even then access must be in accordance with the conditions set in the Treaty and its SMTA;
- The multilateral system also includes all PGRFA listed in Annex I and held in the *ex situ* collections of the International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR)⁷ or in other international institutions that have concluded agreements with the Governing Body of the Treaty.⁸The Governing Body has also endorsed the use of the SMTA by the International Agricultural Research Centres for PGRFA other than those listed in *Annex I* of the Treaty and collected before its entry into force.

⁷ Treaty, Article 11.5

⁸ Treaty, Articles 11.5; 15.5; see <http://planttreaty.org/content/agreements-concluded-under-article-15>

- An increasing number of international ex situ collections of PGRFA have voluntarily been placing their accessions (including crop wild relatives) under the multilateral system. Questions arise when such materials are transferred without the PIC of the countries of origin, in particular those that are not parties to the Treaty – the legitimacy of such actions have been contested in international discussions but the issue has not been resolved yet.
- The Treaty’s Governing Body has initiated a negotiation process to enhance the functioning of the Multilateral System by increasing the flow of benefits as well as re-examination of the coverage of Annex I. Proposals to expand Annex I of the ITPGRFA might have implications for NP implementation and vice versa – this issue should be addressed at national and international levels.
- However, both the CBD COP and the Governing Body of the Treaty have repeatedly reiterated the need to ensure mutual supportiveness in the implementation of both instruments. In this regard, a number of initiatives are currently being undertaken by or between the Secretariats and other institutions on ABS, to promote synergies and mutual supportiveness among the ABS instruments at the international and national levels.

Not all African countries are Parties to the ITPGRFA. When a country is a Party to both the Treaty and the NP, it has a choice between using the Treaty only for the limited set of species and circumstances circumscribed by Annex I and the SMTA, or placing all of its PGRFA under the provisions of the Treaty. To resolve this policy choice it is important that NP NFPs engage their national counterparts for the ITPGRFA and agree on a coherent national approach, including which of the approaches best serve stakeholder interests, especially the ILCs. That judgment call has to be consultative and the outcome may be contingent upon each country’s national context. It is, however, crucial that countries ensure that any legislative, administrative or policy measures taken for the implementation of the ITPGRFA, CBD and or NP are consistent and mutually supportive.

Countries should also be aware that under the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA) there is a programme of work on other GRFA, including animals, micro-organisms (also those used in food processing, e.g. yeasts for fermentation), invertebrates, aquatic organisms and forest resources. The outcomes of this work will impact on the implementation of the Nagoya Protocol at the national level, most likely by initially producing international guidance on the implementation of national measures governing ABS in the various GRFA sub-sectors. This again calls for closer collaboration and coordination of activities between national sectoral agencies dealing with these GRFA and national ABS focal points under the NP.

There are many open questions about when special access considerations should apply to GRFA not included in the MLS, and which GRFA should be included or excluded. Rather than embarking on arbitrary and ultimately futile attempts at categorization it might be helpful to focus on how a particular GR is actually being used for food and agriculture.

Accessing GR and aTK held by ILCs

NP Article 6.3(f) requires Parties to set out “where applicable and subject to domestic legislation . . . criteria and processes for obtaining PIC or approval and involvement of ILCs for access to GR”. Article 7 prescribes PIC and MAT measures relevant for aTK. National arrangements for obtaining PIC from and concluding MAT with ILCs need to be agreed with stakeholders at national level (bearing in mind the letter and spirit of the AU Model Law) and published on the ABS CH. Such measures should address the following considerations:

- i. Relevant competent authority(ies) of ILCs (NP Article 14) to grant PIC for utilisation of aTK (and GRs, in situations where ILCs have established rights to grant PIC for GR) – traditional authorities, local government structures, community conservation groups, procedures codified in BCPs, individual knowledge holders (e.g. traditional healers) etc.
- ii. Role of the State in PIC and MAT negotiations – active, facilitating, collaborative, oversight?
- iii. Legal status of agreements concluded – stand-alone contracts or ancillary to main ABS agreements with NFP/CNA?
- iv. Legal aid to ILCs in case of disputes.

There is a very big need for capacity building and governance support in this regard.

Miscellaneous access considerations

- **Other permits:** Users sometimes obtain other permits and try to pass them off as ABS permits. To counter this, national ABS rules should clarify that any other permit(s) a country may issue (e.g. for research, research ethics clearance, export of specimens, export of commodities etc.) do NOT constitute PIC permits for utilisation of GR or aTK – this should be specified through the ABS CH and can also be printed on the other permit forms (when they are next reprinted). This issue is related to clearly identifying the competent authorities (national, or of ILCs) with the authority to grant access, and also to the need for coordinated national approaches.
- **Formal and traditional institutional arrangements of ILCs** related to transboundary GR should be considered in the management of such GR.
- **PIC and MAT are needed for utilisation even when physical access has already occurred:** The NP very clearly governs “access for utilisation” and “sharing of benefits arising from utilisation”. This implies that PIC and MAT are needed for utilisation to be legitimate, even when physical access has already occurred (i. e. also applies to GR and aTK accessed from *ex situ* collections and public sources). PIC should never be granted unless MAT have been concluded (see Section 9. 3 above).
- **Non-arbitrary rules and procedures:** NP Article 6.3.b specifies that access rules and procedures must be “fair and non-arbitrary”. It is completely legitimate to give national users and/or other sub-groups of users preferential ABS treatment, as long as the distinction is based on transparent criteria, preferably documented in a national policy or legal instrument and made available to the ABS CH. For example, South Africa requires that foreign applicants apply jointly with a South African partner (which might not work for countries without SA’s large and sophisticated research capacity). Many countries favour national entities to encourage national research. Denying access to users who are not domiciled in a Party to the NP where adequate user measures are enforced is a policy option advocated in the Policy Framework above.
- **Be specific:** In PIC applications and access permits, be very specific about what utilisation is permitted and what not. Being specific is an important part of legal certainty; this is why it is recommended to attach the application form to the ABS permit as an integral part of the agreement.
- **Exclude incidental microbes:** Plant and animal material usually contains beneficial, commensalistic, or parasitic microorganisms, which might exhibit interesting properties for research. Unless microorganisms are the target of the research and so described in PIC and MAT, always specifically exclude them in MAT and on permits when they are incidentally carried on/in the material. This might

not prevent them from being utilised entirely, but at least it will clearly make such utilisation illegitimate and subsequent commercialisation much more difficult. An undertaking clause can be included to compel a user to take consequential steps before commencing such utilisation outside the prior disclosed intent.

10 Benefit sharing

AU Member States should, as appropriate, include provisions in their domestic legislative, administrative or policy measures to clarify ownership of GR and aTK, in order to provide legal certainty and ensure fair and equitable sharing of benefits arising from their utilization.

When negotiating benefit sharing arrangements, provisions should be made in MATs about how various costs will be covered.

When developing community protocols or procedures, ILCs may wish to reflect on how they will be dealing with sharing of benefits deriving from the utilization of aTK shared by neighbouring or other communities, in the same country and elsewhere.

AU Member States shall support the creation of a GMBSM to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent.

Explanatory notes:

The third objective of the CBD is often shortened to “the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources” but actually it goes on: “. . . including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding”.

CBD Article 15, which is unfortunately and mistakenly titled “Access to Genetic Resources”, expands on the benefit sharing objective when it says in Article 15.6 that “Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties” and continues in Article 15. 7 “Each Contracting Party shall take legislative, administrative or policy measures . . . with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.” The almost automatic pairing of “access” with “benefit sharing” in ABS, as if by necessity, can therefore be rejected as an illegitimate, deliberate and willful distortion of the Convention by those Parties who have an economic interest only in access to genetic resources and have resisted meaningful benefit sharing for more than 20 years.

The history of the NP further illustrates this verbal sleight-of-hand: after the World Summit on Sustainable Development (Johannesburg, September 2002) had called for “the negotiation of an international regime, within the framework of the Convention, to promote and safeguard the fair and equitable sharing of benefits arising from the utilisation of genetic resources” the Convention’s Conference of the Parties responded at its seventh meeting, in 2004, by mandating its Ad Hoc Open-ended Working Group on Access and Benefit-sharing “to elaborate and negotiate an international regime on access to genetic resources and

benefit-sharing in order to effectively implement Articles 15 (Access to Genetic Resources) and 8(j) (Traditional Knowledge) of the Convention and its three objectives” [emphasis added].

From the above it is clear that those stakeholders with an economic interest in benefit sharing, including all African countries and ILCs, will have to act strategically to secure it by negotiating strong benefit-sharing terms when establishing MAT, with advice from competent contract lawyers. For Africa’s future economic development it is especially important to focus on technology transfer as a form of benefit sharing.

Benefit sharing standards

During the negotiation of the Nagoya Protocol the African Group consistently argued for the Protocol to elaborate benefit sharing standards, to no avail. Nevertheless, NP Article 5.1 provides that benefit sharing “shall be on MAT”. CBD Article 15.4 provides that “access, where granted, shall be on MAT”. NP Article 6.3(g)(iii) provides that “each Party requiring PIC” shall “establish clear rules and procedures for requiring and establishing MAT” in writing, which may include “terms on benefit sharing, including in relation to intellectual property rights”. Read together, these provisions create an opportunity for Africa to develop and enforce its own benefit sharing standards through collaboration and a coordinated approach to the implementation of the Nagoya Protocol. It also underscores the crucial importance of MAT in effective ABS implementation (see Sections 9.3 above and 10.7 below).

Benefits arising from subsequent applications and commercialisation

According to NP Article 5 benefits to be shared arise when genetic resources or traditional knowledge associated with genetic resources are utilized. In the case of GR this is in accordance with the definition of “utilisation of genetic resources” contained in Article 2 of the Protocol “as well as subsequent applications and commercialization”. Since “subsequent applications and commercialization” are the major source of monetary benefits, but are not automatically subject to PIC when carried out by subsequent users, they must be made subject to MAT by including them in the original MAT concluded when PIC is granted and specifying appropriate benefit sharing terms (or at least a process to negotiate such benefit sharing terms) for subsequent uses by third parties.⁹

Any use of biological systems (including the use of genetic, biochemical or other information contained in GR) through any kind of technological transformation should be treated as utilisation, and therefore subject to benefit sharing obligations.

Benefit sharing with ILCs

Benefit sharing under Article 5.1 of the Nagoya Protocol must be “in accordance with Article 15, paragraphs 3 and 7 of the CBD”. At international level this means that the country, as the Party to the CBD with sovereign rights over its natural resources, is the direct beneficiary of the benefits shared by users of GR.

The sovereign rights of states over their GR notwithstanding, NP Article 5.2 explicitly provides that where ILCs have established rights over GR according to domestic legislation, each Party shall take measures to

⁹ This may be challenging if the original user is an ingredient manufacturer selling on to larger producers of consumer goods, but even a very small percentage of the larger company’s sales could have a major impact on supporting conservation and sustainable use.

ensure that benefits are shared with these communities on MAT. In the case of aTK, NP Article 5.5 provides that benefits derived from the utilisation of that knowledge should be shared with the communities holding such knowledge.

This creates a dichotomization of GR and aTK, where States have sovereign rights over GRs but do not have clear rights over aTK, while ILC have rights over aTK but the extent of their rights over GR remains contentious in many countries. It is therefore critically important that national ABS measures clarify ownership of GR and aTK, to provide legal certainty and ensure that ILCs receive a fair and equitable share of the benefits.

Monetary versus non-monetary benefits

Article 12 of the African Model Law only makes provision for monetary benefits and not in any specific detail. Article 5.4 of the NP however provides that benefits may be monetary or non-monetary. The Annex to the NP provides a list of monetary and non-monetary benefits. This list is not exhaustive. The decision on how these benefits are to be shared is left to the parties to the agreement to decide, as long as they are shared fairly, equitably and on mutually agreed terms. This freedom to decide also implies freedom to collaborate and coordinate – an important aspect of developing benefit-sharing standards.

Whether parties agree to monetary or non-monetary benefits or a mix of the two depends on a range of factors including:

- whether research is commercial or non-commercial
- the GR and/or aTK being accessed
- purpose of access
- period/ length of access
- nature and cost of R&D on the GR/aTK
- the potential and time-scale within which to commercialize the result of the R&D

Monetary benefits refer to financial payments that a user of GR and/or aTK makes to the provider. Some monetary benefits such as up-front payments may be realized immediately after a benefit sharing agreement is entered into, but will probably only be available from (some) commercial users. Others, like milestone payments, are payable in the medium term upon successful completion of a specific event such as a patent grant or clinical trial. Payment of royalties and establishment of joint ventures are only realized in the long-term, once commercialisation occurs.

Similarly, some forms of non-monetary benefits may be received immediately, including training and capacity building. Other non-monetary benefits such as sharing of research results are only realizable in the longer term. Non-monetary benefits may often be the only benefits available to be shared from non-commercial research. Non-monetary benefits are often more direct, immediately available, have longer-term impacts and are also more suited to contribute to conservation. Some non-monetary benefits such as technology transfer, sharing of knowledge, or duplicate samples for national inventories may also be available at low marginal cost to the GR/aTK user, yet be of high value to the provider.

Receiving monetary benefit is relatively easy but monitoring that they are shared fairly can be more difficult, requiring access to the user's business accounts, which are often confidential. If monetary benefits

are part of an ABS agreement MAT must include provisions granting the provider (or an independent intermediary such as an auditor or chartered accountant) sufficient access to information to effectively exercise its contractual rights in this regard. Distributing monetary benefits also needs careful consideration of mechanisms and modalities, particularly when the money needs to be divided between different providers (e.g. one providing GR and an ILC providing aTK). Some countries have established national trust funds to deal with this issue.

Non-monetary benefit sharing requires appropriate on-the-ground arrangements to receive and effectively use such benefits. African countries must therefore put in place measures to enable non-monetary benefits to be shared. For example, it is useless to stipulate that the user must provide duplicate samples if the provider has nowhere to store them, or to receive technologies that no-one in the country is trained to use.

When considering benefits it is also advisable not to lose sight of costs. MAT should specify clearly who will bear various costs, including how unforeseen expenses will be funded. This is particularly important for technology transfer.

Sharing benefits arising from the utilisation of shared GR and aTK

GRs are often found in ecosystems that traverse national boundaries, and even more so in Africa with its arbitrary colonial borders. Africa therefore has a particular interest in ABS as it relates to GR and aTK found in more than one country.

NP Article 11 (which was originally proposed by the African Group) provides for transboundary cooperation in cases where GR and aTK are shared by more than one Party or more than one ILC in several Parties. This is particularly important when it comes to benefit sharing, to prevent users simply going to more pliable provider nation as a strategy to undermine better regulated NP-compliant jurisdictions, which would clearly not be fair or equitable.

Some regions have established collaborative mechanisms to address such situations. For example, under the Andean Community regime on genetic resources a committee was established and tasked with promoting management, monitoring and control of access authorizations relating to genetic resources and their derivatives that exist in two or more Member Countries (Article 51 of the Andean Decision 391). Countries in the Himalayan region are envisaging establishing a common ABS framework, which would facilitate fair and equitable sharing of benefits from the commonly held biological resources and aTK and create economic opportunities. It would help to increase bargaining power of the countries in the region by enabling them to express their common interests and priorities in a stronger way and avoiding the risk of playing off against each other in negotiations with bioprospectors seeking to access shared resources. The framework would also facilitate cooperation among countries at the technical level and foster exchange of information.

African Union Member States may wish to establish a Regional Committee of Experts to provide advice to Member States that have common GR and aTK being sought by bioprospectors on how to cooperate in negotiating common PIC and MAT and avoid competing against each other. Such a Committee could also help to mediate any disputes between Member States, between a Member State and communities, or between communities regarding access to common GR and aTK.

When developing community protocols or procedures ILCs may also wish to reflect on how they will deal with aTK shared by neighbouring or other communities, in the same country and elsewhere.

Global Multilateral Benefit Sharing Mechanism

The creation of a GMBSM as foreseen in NP Article 10 was a proposal made by the African Group quite late in the process of negotiating the NP to get around some of the difficult issues related to the geographic and temporal scope of the Protocol. The mechanism is envisaged to receive a share of benefits from users of GR and aTK that occur in “transboundary situations or for which it is not possible to grant or obtain PIC”. Such benefits will then be used to support the conservation and sustainable use of biodiversity globally.

Although the GMBSM could also be used voluntarily by Parties to discharge their obligation under NP Article 11, it is really intended to address situations where resources occur in areas beyond national jurisdiction (such as the high seas, deep sea bed and Antarctic Treaty Area) and cases where no-one has the authority to grant PIC (including some resources housed in ex situ collections).

The GMBSM is still subject to negotiations by Parties once the NP enters into force, but as the proponents it is appropriate for the African Group to strongly support its creation and effective implementation. As the custodians of a significant portion of global biodiversity, Africa and especially African ILCs also stand to benefit greatly from the creation of such a mechanism.

Benefit sharing agreements: concluding commercial MAT

The critical importance of MAT to both access for utilisation and benefit sharing has been pointed out in Sections 9.3 and 10.1 above. The key features of non-commercial MAT were also explained in 9.3. This section looks at how to go about concluding commercial MAT, or benefit sharing agreements, which is a much more complicated subject, but crucially important to benefit sharing.

The single best piece of advice available on the topic of commercial MAT is to retain the services of a good commercial lawyer to advise the NFP, CNA, ILC or other provider stakeholders involved. ABS contracts have some unique features, but when it comes to the nuts and bolts they are not very different from more ordinary commercial cooperation contracts, many of which might also be directly relevant in ABS situations (e.g. non-disclosure agreements, material transfer agreements, background IP agreements, joint venture agreements, partnership agreements, heads of agreement on collaborative research or technology development exercises, technology transfer agreements, IP licences, warranties, indemnities, disclaimers, undertakings, fundamental breaches and breaches of fundamental terms, declaratory preambles, even accommodations for arbitration, etc.). If the applicant is a large commercial operator or a university department with commercial research intent it will almost certainly have access to high calibre commercial legal advice of its own, which could put legally inexperienced providers at a significant disadvantage when negotiating and concluding MAT.

It should be noted that, although it is current practice in many countries, private persons should generally not sign ABS agreements. For example, researchers should not access the genetic resource and/or associated traditional knowledge as private individuals, but as authorized representatives on behalf of their institution. This is important in ensuring that the agreement entered into holds the desired degree of accountability and credibility. Furthermore, issuing research permits to individuals may render an ABS agreement ineffective, especially its provisions on IPR and benefit sharing, as usually any rights over the results of the research and the intellectual property developed rest with the institution.

It is essential to build a critical mass of legal officers with the relevant competence in ABS commercial transactions to provide the requisite legal support. Potential alternatives include soliciting law firms for *pro*

bono advice (in many countries the local law society expects its members to contribute a percentage of their time to public interest law), or making use of specialised legal NGOs (which however might not have staff with the required business law experience). Teaching government lawyers to negotiate ABS agreements is another possibility (but relying on commercially inexperienced official legal advisers may lead to expensive mistakes and lost benefits). Furthermore, it is equally important to enhance the capacity of indigenous and local communities to ensure that they can effectively negotiate MATs.

A crucial step towards developing the African benefit sharing standards foreseen in Section 10.1 above is to start developing standard contracts and model clauses for use across the region, in accordance with NP Article 19. Due to the varied nature of ABS collaborations it is very difficult (maybe impossible) to produce a complete one-size-fits-all solution. This stems from the fact that in any particular transaction and collaboration, the nature and terms of a contract can be tailored to fit the needs and interests of the Parties to it to create an optimal and mutually beneficial arrangement. In any event, in any potentially legally binding relationship, all parties should normally seek technical and legal advice. That being said there is ample scope for collaboration, coordination and information sharing, so that best practices can be replicated, in accordance with NP Article 20.

Annex 4 contains a commentary on the key elements of a complete ABS agreement that can be used to guide development of commercial MAT contracts, taking into account the actual situation at hand and with legal advice. In addition to the standard clauses contained in the non-commercial MTA in Section 9.3 above, commercial MAT may also need to include:

- i. A provision obliging users to disclose the source/origin of GR and aTK in IP applications through inclusion in abstract (see Section 11 below)
- ii. Schedule of non-monetary benefits to be shared, corresponding timeframe and conditions (particularly important for capacity development and technology transfer)
- iii. Formulae and timeframes for monetary benefit-sharing (milestone payments, royalty percentages, verification auditing of accounts, . . .)
- iv. Provisions on background IP, formulae for determining ownership of new IP, allocation of responsibility for IP applications, maintenance and defense
- v. Non-disclosure or confidentiality provisions (if any)
- vi. Warranties and indemnities (or exclusion of such)
- vii. Undertaking regarding consequential obligation arising from change of intent and transfer to third party
- viii. Undertaking regarding cooperation and obligation to facilitate monitoring compliance

11 Compliance and monitoring

AU Member States should in their domestic legislative, administrative or policy measures clearly prohibit the utilization of GR without PIC and MAT from the provider country and utilisation of aTK and GRs held by ILCs without their PIC or approval and involvement.

AU Member States should in their domestic legislative, administrative or policy measures clearly provide for compliance with:

- i. PIC and MAT for the utilisation of GRs within their jurisdiction.
- ii. PIC or approval and involvement of ILCs and MAT for access to aTK held by ILCs.

AU Member States should designate one or more checkpoints to collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate.

To support compliance with MAT, AU Member States should encourage the inclusion of provisions in MATs to cover, where appropriate, dispute resolution including the jurisdiction to which any dispute resolution processes will be subjected, the applicable law and alternative dispute resolution mechanisms.

AU Member States should put in place measures for the use of IP systems to monitor and track utilisation of GR and aTK by obliging users in MAT to disclose the origin or source of GR and aTK in the summary of IP applications using or based on such GR and aTK.

AU Member States in their domestic IP legislation should require as appropriate that IP applications related to GR and aTK include information on the origin and evidence that PIC has been obtained and that MAT have been established as applicable.

AU Member States should exempt sustainable customary or traditional use and exchange of GR and aTK within and between ILCs from domestic ABS compliance measures.

AU Member States should put in place appropriate and effective legislative, administrative or policy measures and institutional mechanisms to encourage compliance and to address situations of non-compliance with ABS measures. Such measures should include the establishment of robust internal procedure at national checkpoint and using IRCCs, the CNA or the NFP to regularly follow up on fulfillment of MAT and the utilisation of GR and aTK, and to penalize non-compliance.

AU Member States should co-operate as far as possible and as appropriate by, inter alia, exchanging and sharing information when it is alleged that ABS laws or regulations have been violated.

African Union Member States may consider utilising relevant regional dispute settlement bodies in cases of non-compliance.

AU Member States should include in their domestic measures, as appropriate, provisions regarding access to justice and the utilisation of mechanisms regarding the mutual recognition and enforcement of foreign judgements and arbitral awards on ABS issues.

Explanatory notes:

Compliance, a key cornerstone of the international ABS regime, has three distinct meanings under the Nagoya Protocol. The first two are closely related:

- Compliance with the access regulations and PIC procedures of the provider country, including those dealing with access to aTK held by ILCs in that country; and
- Compliance with the provisions of MAT.

NP Articles 15, 16, 17 and 18 deal with various aspects of compliance with PIC and MAT by users of GR and aTK, in particular by establishing obligations on Parties to ensure that GR and aTK utilized within their

jurisdiction have been accessed in accordance with PIC and that MAT have been established, that the utilisation of GR is monitored through checkpoints and IRCCs, and that MAT can be enforced in courts of law. African Parties to the NP are just as obliged as traditional “user countries” to implement all these compliance measures.

The third meaning of compliance derives from NP Article 30, which addresses the obligations of State Parties to the NP to comply with the provisions of the Protocol, as well as cooperative procedures and institutional mechanisms to encourage such compliance and remedy cases of non-compliance. The details of this “compliance with the Protocol” system will be considered and approved by the first COP-MOP of the NP. Since it is not yet in place and only tangentially relevant to the coordinated implementation of the NP in Africa, it is not discussed further in these *Guidelines*.

In the context of an African approach to ABS regional juridical institutions like the African Court on Human Rights and Justice could potentially play a role in ABS compliance. The court has jurisdiction over all cases and disputes submitted to it concerning the African Charter on Human and People’s Rights and any other relevant human rights instruments ratified by the State Party concerned. It has a mandate to make binding decisions including orders of compensation and reparation¹⁰.

Compliance with domestic ABS measures on GR and aTK

Articles 15 and 16 deal with genetic resources and associated traditional knowledge respectively, but follow a similar three-step pattern:

- a) An obligation on Parties to take appropriate, effective and proportionate legislative, administrative or policy measures to provide that:
 - i. GRs utilized within their jurisdiction have been accessed in accordance with prior informed consent as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.
 - ii. aTK utilized within their jurisdiction has been accessed with PIC or approval and involvement of ILCs as required by the domestic ABS laws or regulations of “the other Party where such ILCs are located” (Article 16); and
 - iii. that MAT have been established (in both cases).
- b) An obligation on Parties to take appropriate, effective and proportionate measures to address situations of non-compliance with their own compliance measures developed under (a) above.
- c) An obligation on Parties to co-operate “as far as possible and as appropriate” when it is alleged that the domestic ABS law or regulations of a Provider country have been violated.

For this system to work it is important that the ABS laws or regulations of the provider country are sufficiently clear and fair to meet the standards of jurisprudence prevailing in the jurisdiction of the country where the utilisation takes place.

¹⁰ In 2008, the AU decided to merge the African Court of Justice with the African Court on Human and Peoples’ Rights into an African Court of Human Rights and Justice. Transition to the new Court will begin after 15 Member States have ratified the Protocol on the Statute of the African Court of Justice and Human Rights. As at 1 September 2013, 29 states had signed the Protocol (most recently South Sudan on 24 January 2013) and five had ratified it (most recently Benin on 28 June 2012)

It is also important to note that the NP, being an international legal agreement, does not prescribe to Parties how to ensure that their own citizens comply with their own ABS measures when accessing and utilizing local GR and aTK within their national jurisdiction. Such “domestic compliance” measures are nevertheless an important part of national ABS systems, because national researchers and intermediaries are often the original culprits when it comes to misappropriation and misuse of national GR and aTK. One way to ensure this is to make ABS measures clearly and equally applicable to both foreign and national users. However, there is a delicate balance between non-arbitrary ABS regimes and the need to support and encourage the use of GR and aTK by citizens, research entities and local businesses of provider countries. If national users are given preferential treatment it must be non-arbitrary and on the basis of a clearly documented national policy.

Articles 15 and 16 of the Nagoya Protocol give countries a high degree of flexibility in determining compliance measures, which could for example be legislation, regulations or policy requiring users of GR and aTK to declare and confirm that PIC and MAT have been established in accordance with the domestic ABS legislation and regulatory requirements of the country providing these resources, backed up by appropriate, proportionate and dissuasive sanctions for making false declarations. Another option could be a “due diligence”¹¹ system such as that developed in the *EU Regulation on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*. Compliance measures are closely linked to measures to monitor utilisation of GR (and possibly aTK – see below) through checkpoints and IRCCs.

Box 7

Article 67.2 and 3, African Model Law

(2) Without prejudice to the exercise of civil and penal actions which may arise from violations of the provisions of this legislation and subsequent regulations, sanctions and penalties to be provided may include:

- i) Written warning;
- ii) Fines;
- iii) Automatic cancellation/revocation of the permission for access;
- iv) Confiscation of collected biological specimens and equipment;
- v) Permanent ban from access to biological resources, community knowledge and technologies in the country

(3) The violation committed shall be publicized in the national and international media and shall be reported by the national Competent Authority to the secretaries of relevant international agreements and regional bodies

¹¹ The EU system requires users to seek and keep information about the origin of GR they utilise, to exercise due diligence that it has been accessed legally, and to declare that they have exercised such due diligence when receiving research funding and at the stage of final development of a product.

<http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2014-0193&language=EN&ring=A7-2013-0263>

Similarly, Parties are given much flexibility on how to address situation of non-compliance. Box 7 below reproduces the provisions of the African Model Law on sanctions and penalties, which may still serve as guidance for national implementation.

Sanctions and penalties usually have to be put in place through legislative means, although measures such as prohibition or suspension of the use of a genetic resource could be executed through regulatory or administrative actions if suitable powers to prohibit or suspend are conferred on an appropriate national authority (e.g. the responsible Minister).

Articles 15.3 and 16.3 of the Nagoya Protocol require Parties to cooperate “as far as possible and as appropriate” in cases of alleged violation of domestic ABS legislation or regulatory requirements. How countries should cooperate is not prescribed, but exchanging and sharing of information is an obvious possibility. Cooperation is not restricted to the providing and user countries and can be extended to third countries. Any number of countries can therefore agree to cooperate by regularly exchanging information on alleged violations in their regions. Further, since cooperation does not require legislative, administrative or policy measures countries are free to use any mechanisms, including informal ones, to cooperate.

Along the pattern of TRIPS-plus bilateralism, there is no reason why African countries could not canvass the idea of including ABS compliance as an integral part of various trade, partnership, development or research collaboration agreements with user countries.

Compliance with MAT

To comply with MAT means to abide by the terms agreed between provider and user, which are usually in the form of a written contract.

To support compliance with MAT, Article 18.1 of the NP obliges each Party to the Protocol to “encourage” providers and users of GR and/or aTK (the parties to the contract) to include dispute resolution clauses in MAT, including the jurisdiction to which any dispute resolution processes will be subjected, the applicable law and/or options for alternative dispute resolution such as mediation or arbitration. Such clauses are standard legal practice in most agreements. For an example see the basic ABS agreement in Annex 3.

Article 18.2 obliges each Party to ensure that an opportunity to seek recourse is available under its legal system, also for foreign plaintiffs but subject to the normal requirements in that legal system, in cases of disputes arising from MAT.

Article 18.3 obliges each Party to “take effective measures, as appropriate” regarding access to justice and the utilisation of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards. The access to justice provision means that citizens and foreigners must have equal opportunities and forums to access the judicial system, challenge decisions and obtain the necessary information to go to court when they have evidence of violation of MAT by the other party. Equal opportunities do not guarantee equal outcomes though, and providers might find it very expensive to pursue justice in foreign courts. One idea that has been mooted is to include provision of financial support for dispute resolution in MAT, but it is doubtful whether many users would agree to such a condition.

An important aspect of monitoring compliance that is not explicitly mentioned in the NP is that of following up on fulfillment of MAT. It is not uncommon for users to obtain PIC and conclude MAT and then simply not comply with e.g. reporting requirements agreed in MAT, leaving providers or national ABS authorities with

the burden of discovery, which can be exceedingly difficult and expensive in the case of foreign users. Parties should therefore establish an internal procedure at the national checkpoint, the CNA or the NFP to regularly follow up on fulfillment of MAT, especially on periodic reports as agreed. This procedure must be robust and capable of surviving several and/or frequent changes in personnel, because it can take ten years or more between GR and aTK being accessed and being commercialised.

If a user fails to comply with agreed reporting obligations the intervention of relevant ABS authorities in the user country should be sought, as a first step, even though the NP provides no obligation on user countries to cooperate when violation of MAT is alleged. Another option is to provide criminal sanctions in national ABS laws or regulatory requirements for failure to report as agreed in MAT, which might help trigger the cooperation procedures provided in Articles 15.3 and 16.3. This consideration reinforces the strategic importance of only granting access to users domiciled in Parties to the NP.

Article 18.4 acknowledges the weak nature of these MAT compliance provisions by providing that “the effectiveness of this article shall be reviewed by the COP-MOP in accordance with Article 31”.

Monitoring the utilisation of GR (and aTK)

Article 17 of the Nagoya Protocol establishes two main systems to monitor compliance with national measures (including the national measures of other countries) on ABS and with MAT: designation of checkpoints and using IRCCs. Note that Article 17 makes no mention of aTK. In the African context, given the widely acknowledged importance of aTK to the region and its ILCs, this deliberate omission can and must be remedied in national laws or regulatory requirements.

Each Party to the NP is required to designate one or more checkpoints to receive relevant information for monitoring compliance and enhancing transparency about the utilisation of GR (and aTK). The choice of checkpoints is very flexible but they must be effective and should have functions relevant to the role of a checkpoint, in particular the collection of relevant information at any stage of research, development, innovation, pre-commercialization or commercialization of GR (and aTK) as set out in article 17.1(a)(iv) of the Nagoya Protocol.

Checkpoints can be designated by way of legislative, administrative or policy measures. Checkpoints collect or receive relevant information related to PIC, the source of the GR (and aTK), the establishment of MAT and/or the utilisation of GR (and aTK), as appropriate. Parties must require users of GR (and aTK) – including national users, at least when they are using GR (and aTK) from another country, but preferably also when using “home-grown” resources – to provide the specified information, including information on the knowledge holders, at a designated checkpoint and take appropriate, effective and proportional measures to address situations of non-compliance.

Information collected at checkpoints, including from IRCCs if they are available, must without prejudice to the protection of confidential information be provided to relevant national authorities, the Party providing PIC and the ABS CH. In the African context such information should also be shared with the AUC database on ABS and with other AU Member States who might have an interest, for example because they are also countries of origin of the same resources or home to ILCs holding the same or similar aTK. Information can also be shared directly with those ILCs who are known to the checkpoint to be relevant knowledge holders, but it would be unrealistic to expect the checkpoint to identify and communicate with all potential knowledge holders.

Before designating checkpoints it is advisable to review candidate institutions, their organisational structures and their current mandates to evaluate whether they can carry out the prescribed functions. Existing legal powers might well support straightforward administrative designation of existing institutions (IP offices, export authorities, customs officers etc.) as checkpoints; in rare cases laws might need amendment to properly embed checkpoint function.

Some considerations to bear in mind when selecting checkpoints include:

- The NFP or CNA should be designated as a super-checkpoint to whom users can submit compliance information at any time for it to be placed on record
- Current institutional interfaces with users (commercial or non-commercial) that could be modified to be checkpoints (e.g. IP offices, research applications, phyto-sanitary and veterinary permit offices, investment centres, . . .)
- Nature or character of GR and/or aTK potentially covered by a checkpoint
- Nature of the information that each checkpoint should receive or collect, from whom, in what format, and pass on, to whom
- Normal and potential information flows through particular checkpoints
- Data management and communication capacities at potential checkpoints – “cost effective communication tools and systems”
- Capacity development, capital and running costs of operating a checkpoint, compared to its potential relevance to ABS

Parties must “encourage” users and providers of GR to include provisions in MAT to share information on the implementation of MAT. Such encouragement can take the form of:

- Legal guidance to providers on agreeing checkpoints, reporting schedules and information exchange protocols in MAT
- Criminal sanctions for deliberate failure to comply with information sharing agreements
- Providing a platform for users and providers to report jointly on progress made with the implementation of MAT.

Article 17.1.(c) encourages “the use of cost-effective communication tools and systems”. This is an important consideration, because the essence of a checkpoint’s function is to collect and share information while protecting confidential information – it must therefore have adequate information management capacities and protocols in a place. If a checkpoint is not also the NFP, workable arrangements for information sharing between checkpoint(s) and the NFP (who is formally responsible for communicating with the ABS CH) must be put in place.

As far as regional cooperation is concerned, African countries should consider designating similar institutions as checkpoints. This will ease horizontal information exchange between counterpart institutions and facilitate the implementation of compliance measures.

Box 8	
Some commentary on institutions that may be designated as checkpoints	
Institution	Commentary
Competent National Authorities	Given that applicants for genetic resources must invariably submit themselves to the CNAs, CNAs are important checkpoints for collecting and receiving information, particularly relating to the source of the genetic resource, purpose of access, and whether PIC and MAT have been established. If only one checkpoint is designated the CNA would be the obvious candidate.
Customs authorities	Customs authorities already request individuals at border points to declare plant, animal and other material in their possession. Extending this to include genetic resources could be considered. Such information may be useful in tracking actual movement of genetic resources between countries and could help users to show legal provenance and legal compliance with ABS measures. Routine custom searches against smuggling of drugs or currency might occasionally reveal GR smuggling, if officers knew how to spot it.
IP offices	Applying for IP, particularly patents, in an important step in commercialisation of GR and aTK. IP offices can serve as useful checkpoints particularly in detecting when commercialisation is intended and checking whether MAT for this purpose have been established. South African legislation requires disclosure of origin, knowledge, PIC and benefit sharing. Regional IP organisations like ARIPO and OAPI could also play an important role in ABS monitoring.
Market/regulatory approval offices	Regulatory approval for market purposes is an important step in commercialisation of genetic resources products. Market approval offices may therefore be able to capture information relating to commercialisation and sources of genetic resources, as well as on establishment of PIC and MAT.
Research funding agencies	As funding is necessary for research on genetic resources, research funding agencies would be important checkpoints, particularly for information on nature of research and the prospective source of genetic resources. Further, given that grantees are usually required to report regularly on research progress, research funding agencies could require that information on whether PIC and MAT have been established be provided as well.
Various permit offices	Research, phytosanitary, veterinary, forestry, fisheries and herbal medicine permit offices could serve as specialized sectoral checkpoints.
Research institutions	Users of GR and aTK often collaborate with national scientific and academic stakeholders e.g. universities, botanical gardens, zoos, national parks, museums etc. Some of these might be suitable as checkpoints, or as subsidiary sources of information to monitor utilisation of GR.

One of the main sources of information that can be checked at checkpoints is the IRCC. This a permit or its equivalent issued by the CNA at the time of access to GR or aTK as evidence of the decision to grant PIC and the establishment of MAT. A national permit becomes an IRCC once it has been made available to the ABS CH (the exact modalities are still under development but should include a function that will allow checkpoints to verify the authenticity of a certificate). An IRCC therefore serves as evidence that the PIC provisions in the domestic ABS laws or regulations of the providing country have been complied with, and that MAT have been established (see also Section 8 above).

Issued at the domestic level as a permit, the IRCC would be a legal document in a prescribed form. This means that it has to be a creature of the law. Some countries may need to pass new legislation or amend existing legislation to create such a permit.

It is also worth noting that Article 17.4 of the Nagoya Protocol only provides for the minimum information to be contained in the certificate. Other information may be included as a country deems appropriate. It is highly recommended that any information pertaining to third party transfers of GR and aTK be included on the IRCC. This flexibility provides additional room for countries to coordinate monitoring compliance.

Use of IP system to monitor and track utilisation

Although the African Group and other developing countries did not succeed in getting mandatory disclosure of origin in IP applications included as a compliance measure in the NP (and have not yet managed to achieve it in on-going negotiations at the WIPO IGC either) the excellent and readily searchable information management capacities embodied in the international IP system remains a potential (and very cost-effective) tool for tracking and monitoring utilisation of GR and aTK.

This capacity can be used even without an internationally agreed disclosure provision, by obliging users in MAT to disclose the origin or source of GR and aTK in the summary (or abstract) of IP applications using or based on such GR and aTK.¹²A provision to this effect can be included in MAT and/or prescribed in law, in line with NP Article 17.1(c).

Exemption of sustainable customary use from ABS compliance measures

In line with its general exemption from ABS measures, the sustainable customary or traditional use and exchange of GR and aTK within and between ILCs should also be excluded from monitoring and compliance measures.

12 Traditional Knowledge associated with Genetic Resources

AU Member States should put in place measures in relation to traditional knowledge associated with genetic resources that;

- take into consideration the customary laws of ILCs, community protocols and community procedures
- establish mechanisms to inform potential users of aTK about their obligations

¹² See <http://www.cbd.int/doc/meetings/cop/cop-10/information/cop-10-inf-44-en.pdf>

- build the transactional and negotiation capacity of ILCs and support further articulation of procedures, protocols and customary laws relevant to ABS.

AU Member States should, where possible facilitate ILCs, including women, to develop instruments and tools such as community protocols and minimum requirements for MAT and model contractual clauses.

Box 9

Additional obligations of Parties when dealing with traditional knowledge associated with genetic resources

- To take into consideration
 - Indigenous and local communities' customary laws
 - Community protocols
 - Community procedures
- To inform potential users of traditional knowledge associated with genetic resources about their obligations
- To support the development of community protocols, minimum requirements for MAT and model contractual clauses

To build the transactional and negotiation capacity of ILCs and support further articulation of procedures, protocols and customary laws relevant to ABS

Explanatory notes:

The Nagoya Protocol treats traditional knowledge associated with genetic resources (aTK) as a crosscutting issue as well as an issue requiring special attention. Thus, in addition to other articles dealing with this issue in the context of access, benefit sharing and compliance, Article 12 addresses aTK exclusively and creates additional obligations for Parties when dealing with aTK. These additional obligations must be in accordance with domestic law. Domestic law therefore takes precedence over these additional obligations.

Indigenous and local communities' customary laws: these are non-written norms that have evolved in indigenous and local communities' societies over time, constantly responding to changes in these societies and the surrounding environment. Non-codification of customary laws is key in enabling them to adapt in response to ever-changing societal interests.

Community Protocols: these are written documents adopted by a community holding aTK after a consultative process to outline the community's core ecological, cultural and spiritual values, and customary laws relating to their traditional knowledge and resources, based on which they provide clear terms and conditions to regulate access to their knowledge and resources. The process of developing community protocols involves reflection about the interconnectedness of various aspects of indigenous and local communities' ways of life and may involve resource mapping, evaluating governance systems, and reviewing community development plans. It also involves legal empowerment so that community members can better understand the international and national legal regimes that regulate various aspects of their lives, such as those linked to ABS. (See Annex 5.)

Community procedures: these are indigenous and local communities' other processes for ABS governance, including informal and/or oral procedures, traditional rituals and social customs.

The NP requires Parties to inform potential aTK users of relevant access procedures and their obligations to knowledge holders. NP Article 13 makes it the responsibility of the NFP to provide this information to the ABS CH, but countries can delegate the function to other institutions, including “relevant competent authorities of ILCs” as long as the NFP takes final responsibility for the accuracy of the information. Finally, countries are obliged to support ILCs to develop a variety of instruments to assist them to better deal with ABS situations.

Box 10

- Instruments to assist indigenous and local communities including women, deal with access to traditional knowledge associated with genetic resources and benefit-sharing
- Community protocols, customary laws and procedures
- Minimum requirements for mutually agreed terms

Model contractual clauses for benefit sharing

Article 12 recognizes the importance of facilitating the ability of ILCs to deal with access requests and ensure benefit-sharing. Countries are tasked where possible to help ILCs, including women, develop instruments such as community protocols. Community protocols are optional internal norms adopted by communities stipulating procedures and terms for granting access. Other instruments serving a similar function are written minimum requirements for MAT and model contractual clauses. If these instruments are put in place prior to access requests, their preparation enables ILCs to internalize ABS issues before they present themselves. Such a process invariably involves building capacity of ILCs, but is challenging to deliver cost-effectively.

Article 12.1 of the Nagoya provides that customary laws, community protocols and procedures regarding aTK should be taken into consideration in accordance with domestic laws. Countries need to review whether current domestic laws support customary laws, community protocols and procedures. Where no domestic law exists one ought to be enacted, while laws that insufficiently support customary laws, protocols and procedures should be amended.

Some African countries are already cooperating in developing guidelines on the management and protection of some aspects of aTK. In the SADC region, the Southern African Network on Biosciences, SANBio has developed guidance on the use of plant genetic resources and aTK, including recommendations relating to their documentation and the steps that should be taken prior to, during and after documentation. Regional approaches need domestic implementation measures.

13 Link between ABS, Sustainable Use and Conservation

AU Member States should make provision, as appropriate, in their domestic measures, to direct benefits arising from the utilisation of genetic resources towards the conservation of biological diversity and the sustainable use of its components in accordance with Article 9 of the NP.

AU Member States may consider potential mechanisms for linking the three objectives of the CBD including:

- a) Developing regional and national scientific capacity and promoting research geared towards conservation or sustainable use
- b) Directing some benefits arising from utilisation of genetic resources to conservation and to enhancement of livelihoods

- c) Developing strategies for conservation and sustainable harvesting of genetic resources
- d) Promoting and supporting traditional lifestyles relevant for the conservation of biodiversity and sustainable use of its components.

Explanatory notes:

During the NP negotiations the African Group consistently emphasized the inter-connectedness of the three objectives of the CBD and stressed the important role of fair and equitable benefit sharing with the custodians of biodiversity, especially ILCs, as an incentive for and support to sustainable use and conservation. This African position is reflected in the objective and Article 9:

“The objective of [the Nagoya] Protocol is the fair and equitable sharing of the benefits arising from the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.” (NP Article 1, emphasis added)

The Parties shall encourage users and providers to direct benefits arising from the utilisation of genetic resources towards the conservation of biological diversity and the sustainable use of its components (NP Article 9).

The additional possibility of capturing benefits that are derived from utilisation of GR and aTK but are currently not shared under bilateral ABS arrangements and then using this income stream to support sustainable use and conservation globally was also an important driver behind Africa’s proposal to create a Global Multilateral Benefit Sharing Mechanism (NP Article 10).

In implementing the NP, African countries should strive to give effect to this link between fair and equitable benefit sharing, “traditional lifestyles relevant for the conservation and sustainable use of biological diversity” (CBD Article 8.j), sustainable use of the components of biodiversity, and the conservation of global biodiversity.

Potential mechanisms for linking the three objectives of ABS, sustainable use and conservation include the following:

- a) Promoting research geared to conservation or sustainable use
- b) Directing some benefits arising from utilisation of genetic resources to conservation
- c) Developing strategies for sustainable harvesting of genetic resources

14 Coordination and stakeholder roles

AU Member States should, at a regional level, coordinate in the implementation of the NP through -

- The establishment and strengthening of institutional frameworks
- Awareness raising and information exchange
- Capacity building and preparedness for negotiations
- Establishment of policy and legal frameworks
- Fostering international cooperation

- Ensuring a sustainability mechanism

The AUC as the central organ is called upon to play the following role:

- Spearhead and coordinate, cooperate and communicate with the regional economic communities (RECs) and relevant sub-regional organizations and the National Focal Points
- Coordinate and harmonize capacity building initiatives (standards, harmony, synergy)
- Organize preparatory meetings prior to major multilateral negotiations of relevance to ABS, to form and harmonize positions
- Engage with all stakeholder departments within and at regional levels and organs of the AU as appropriate on matters of ABS
- Engage with ILCs and other stakeholder groups as appropriate on matters of ABS.

The RECS could undertake the following roles:

- Information dissemination and exchange
- Sub-regional preparatory meetings to harmonize sub-regional interests
- Set standards, guidelines and requirements
- Identify sub-regional priorities for capacity- building and enhance sub-regional cooperation
- Mobilize their members to fulfill regional or international obligations

15 Adaptive and responsive measures

AU Member States should endeavour to update their state of knowledge and information on ABS. ABS related subjects in the region should also constantly be brought up-to-date in accordance with international and regional developments and with regard to specific relevant regional, subregional and national experiences of Member States. Member States should develop adaptable and responsive domestic legislation or regulatory requirements on ABS that accommodate the evolving nature of the subject. To this effect, these guidelines will be reviewed periodically.

Explanatory notes:

The international ABS regime is expected to continue developing for years to come (see for example NP Article 4). It would therefore be prudent to shape any *sui generis* ABS legislation that is being developed at national level into enabling legislation that allows a suitable authority (e.g. the Minister of Environment) to publish new or amended ABS Regulations as the system evolves, to avoid as far as possible the need to go back to Parliament to amend legislation.

At international level it is also critically important that the African Group stays engaged in and coordinate its positions on on-going ABS-related negotiations in international fora like the ICNP, NP COP-MOP, CBD COP, ITPGRFA, FAO CGRFA, UNESCO, WIPO IGC, WHO, WTO TRIPS Council, IPPC and IOE.

In parallel, African countries need to continuously exchange information and coordinate policies and activities on ABS, with a view to learning-by-doing and thereby constantly improving the coordinated implementation of ABS in Africa.

Annexes

Annex1: Extract reproduced from A Gap Analysis Report on the African Model Law on the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources

CONCLUSIONS AND RECOMMENDATIONS

Africa's current approach to dealing with matters related to biological diversity in general and ABS in particular indicates strong commitment on the continent in this regard. In each and every forum where biodiversity issues have been discussed, Africa's voice has been heard. Africa's quest, both at pan-African and sub-regional levels, for home-grown solutions that suit its unique circumstances and level of socio-economic development has not waned.

At continental level these solutions include the Algiers Convention, the successful revision of which provides further evidence of the African Union's ability to adapt to the changing needs of the continent.

At the sub-regional level activities of intellectual property institutions such as ARIPO and OAPI, the emergence of regional economic blocks such as the Economic Community of Central African States (ECCAS), East African Community (EAC), the Economic Community of West African States (ECOWAS), the Common Market for Eastern and Southern Africa (COMESA) and the Southern African Development Community (SADC) attests to Africa's diversity, but also its co-operative approach to seeking solutions.

In marine biodiversity regional instruments such as the Convention for the Protection, Management and Development of the Marine and Coastal Environment of the Eastern Africa Region (the Nairobi Convention) and the Convention for Co-operation in the Protection and Development of the Marine and Coastal Environment of West and Central Africa (the Abidjan Convention) are in place.

Yet Africa's approach to confronting challenges on the biodiversity front still faces several issues. For example, there appears to be a disconnect between some of the activities carried out by regional bodies and those of the African Union. The activities of ARIPO and OAPI aimed at the protection of traditional knowledge, traditional cultural expressions and genetic resources appear to be weakly aligned with Africa's position at the WIPO IGC and other fora. Similarly, efforts by ARIPO and OAPI to establish regional plant breeders' rights protection systems appear to run counter to aspirations expressed by the African Group in negotiations or documents, including the African Model Law.

Another apparent challenge is duplication of efforts. The development of similar instruments for the protection of traditional knowledge and traditional cultural expressions with only linguistic differences attests to this point. Similarly, opening the Swakopmund Protocol for signature to parties beyond members of ARIPO is likely to cause further confusion not only of mandate, but also in national implementation efforts.

The policy developments that have been driven by regional organisations such as OAPI and ARIPO suggest that efforts to co-operate, between these regional institutions themselves and also with the African Union require more optimization. More effective collaboration is therefore necessary. Consideration should be given at the African Union level for greater deployment of personnel to follow and monitor progress in genetic resources and intellectual property policy at other levels. This will enable the creation of synergies and the establishment of conditions for mutual learning between the AU-centered policy making processes and other initiatives. The development, improvement through reviews and/or implementation of the instruments produced by these various organizations is likely to benefit greatly from such increase in synergies.

The African Model Law is very strong and detailed in its approach to the protection of community rights, farmers' rights and plant breeders' rights. It has made the interests of local and indigenous communities into a central concern to be taken into consideration by stakeholders in regulating access to and utilisation of biological resources, as well as in the sharing of benefits derived from such activities

However, the model legislation also clearly contains prominent gaps, especially when seen in the context of the Nagoya Protocol. It is necessary to keep in mind here that one of the core purposes of the African Model Law was to give effect to the third objective of the CBD and its Article 15 in particular. The adoption of the Nagoya Protocol, an instrument that reflects some if not most of the aspirations contained in the African Model Law, is a milestone in the achievement of the objectives of the model legislation. It has therefore become necessary to devise a way to use the positive characteristics of the African Model Law to help African countries meet their international obligations, including implementation of the Nagoya Protocol.

Two potential approaches can be considered in this regard. One is a thorough review and revising of the African Model Law. In this regard it is however useful to recall that the African Model Law is in essence a model – a guide to follow – that was never intended to have the status of a Convention or Treaty in Africa, like the Algiers or Abidjan Conventions. For this reason an overhaul of the African Model Law, leading to a new text document for adoption by the AU Heads of States, may not be the most effective means of bringing the African Model Law up to date.

A second, probably more practical, option is to prepare a complementary guideline document to be used alongside the African Model Law. Such a guide would not only highlight the developments and positions that the African Group subscribes to on each of the issues contained in the African Model Law, but would also offer an opportunity for model clauses to be formulated in response to the numerous obligations that African countries have to fulfill. The guide could also consider sectoral approaches, particularly in areas where Africa's biodiversity is most attractive and valuable. Such an approach would preserve what is best and most useful in the spirit and letter of the African Model Law, while also ensuring that African countries had access to updated guidance on how to turn noble principles and high aspirations into practical, workable policy, laws and regulations.

Annex 2: Sample application form for a permit to utilize GR and/or aTK

C O V E R P A G E

[Header of the competent national authority]

[Serial number of the application]

[Date of application]

Sample Application for Access to and Utilisation
of Genetic Resources¹³ and/or Associated Traditional Knowledge¹⁴
and Export if applicable

KIND OF PERMIT APPLIED FOR (Tick relevant boxes¹⁵)

Permit for

Access to and utilisation of

- Genetic resources
- Traditional Knowledge associated with genetic resources

And export

[Header of the competent national authority]

[Reference number of the application]

[Date of application]

¹³ **Utilisation of genetic resources:** In this context utilisation means to conduct research and/or development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention on Biological Diversity. [...to be defined in national legislation].

¹⁴ **Utilisation of traditional knowledge:** [. . . to be defined in national legislation].

¹⁵ Note that several boxes can be ticked at the same time.

Sample Application for Access to and Utilisation
of Genetic Resources and/or Associated Traditional Knowledge
and Export if applicable

Please note that this application form, if it is approved, will become an integral part of a **Basic ABS Agreement** governing access to and utilisation of the subject matter of the application. Please be as specific and accurate as possible.

Attach additional sheets, clearly numbered, as necessary.

Application Checklist

You will need to provide:

- A Basic ABS Agreement attached to this application¹⁶
- Written permission/s from the access provider/s attached to this application¹⁷
- A signed payment form or receipt attached to this application¹⁸
- Application for an Export Permit, as applicable¹⁹

I APPLICANT

(If applicant is a legal person, please complete 1 – 6 below.)

(If applicant is a natural person, please complete 7 – 9 below.)

¹⁶ The Basic ABS Agreement sets out the basic obligations between the PROVIDER and the RECIPIENT of the genetic resources and associated traditional knowledge for the utilisation described in the application form only. It affirms the purpose and content of the project and includes, among others, commitments with respect to the sharing of non-monetary and monetary benefits (benefit-sharing agreement), as well as expressly prohibits any form of utilisation not described in the basic ABS agreement. Note that, subject to domestic legislation or regulatory requirement, the PROVIDER can be the competent national authority (CNA) or e.g. indigenous and local communities where they have established rights to grant access to such resources and/or traditional knowledge associated with genetic resources held by them. See template for the Basic ABS Agreement. Note also that the application form and the Basic ABS Agreement will form integral parts of the final permit or its equivalent and be attached to it.

¹⁷ Subject to domestic legislation or regulatory requirements, additional written permission from the physical access provider to the genetic resource may be needed (e.g. private landowner, indigenous and local communities where they are managers or custodians of the genetic resources). See section II. 3. 11 of this application form.

¹⁸ An application fee of [amount] for administrative costs is payable and non-refundable.

¹⁹ Applicants planning to export samples need to obtain a permit according to domestic legislation and/or regulatory requirements [Insert link/reference to existing permitting system or refer to template for export permit].

1. NAME OF INSTITUTION OR BODY:

Name:

2. IS THE LEGAL PERSON REGISTERED OR ESTABLISHED IN (insert country)?

Y	N
---	---

3. IF YES, PROVIDE THE (insert country) REGISTRATION NUMBER OR ESTABLISHMENT DETAILS OF THE LEGAL PERSON:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

4. IF NOT, IN WHICH COUNTRY IS THE LEGAL PERSON REGISTERED? PROVIDE THE REFERENCE NUMBER:

Country:																			
Type of registration:																			
Nr:																			

5. CONTACT DETAILS OF THE LEGAL PERSON:

Name:	
Tel No:	
Fax No:	
E-mail:	
PostalAddress:	PhysicalAddress:

6. DETAILS OF CONTACT PERSON IN THE LEGAL PERSON²⁰:

Name of contact person:													
Capacity:													
Identity or Passport No: (Attach a certified copy)													
Tel No:													
Fax No:													
E-mail:													
Postal Address:							Physical Address:						

(If applicant is a natural person, please complete clause 7 – 9 below.)

7. APPLICATION BY A NATURAL PERSON:

Name of applicant:													
Identity or Passport No: (Attach a certified copy)													
Tel No:													
Fax No:													
E-mail:													
Postal Address:							Physical Address:						
Nationality:													

²⁰ Note: If the contact person changes, the Competent National Authority (CNA) and/or the ABS National Focal Point (ABS NFP) shall be notified. See also section ... of Basic ABS Agreement.

8. IS THE APPLICANT AFFILIATED TO A LEGAL PERSON?

Y	N
---	---

9. IF YES, CONTACT DETAILS OF LEGAL PERSON:

Name of juristic body:	
Contact person:	
Tel No:	
Fax No:	
E-mail:	
Postal Address:	Physical Address:

(The following part is to be completed by ALL applicants. If required, please use additional pages.)

10. NAME AND CONTACT DETAILS OF OTHER PARTNERS²¹:

A.

Name:													
Identity or Passport No: (Attach a certified copy)													
Tel No:													
Fax No:													
E-mail:													
Postal Address:							Physical Address:						

²¹ Partners' are persons or institutions who take part in the project with the applicant (e.g. national research institution of [insert country]).

B.

Name:													
Identity or Passport No: (Attach a certified copy)													
Tel No:													
Fax No:													
E-mail:													
PostalAddress:							PhysicalAddress:						

11. NAMES AND CONTACT DETAILS OF INDIVIDUALS who will be involved in the activities for which access authorization is requested:

A.

Name:													
Identity or Passport No: (Attach a certified copy)													
Tel No:													
Fax No:													
E-mail:													
PostalAddress:							PhysicalAddress:						

B.

Name:													
Identity or Passport No: (Attach a certified copy)													

Tel No:	
Fax No:	
E-mail:	
PostalAddress:	PhysicalAddress:

12. Details of the relevant qualifications and experience of INDIVIDUALS WHO will be involved in the activities for which access authorization is requested

Person	Qualifications and Experience

13. ARE THERE FOREIGN PARTNERS²² INVOLVED?

Y	N
---	---

14. IF YES, CONTACT DETAILS OF FOREIGN PARTNERS

Name:	
Contact Person:	
Tel No:	
Fax No:	
E-mail:	
PostalAddress:	PhysicalAddress:

²² Partners institutions or persons which collaborate in the project or support the project financially /in kind, such as funding agencies, foundations etc.

15. ARE THERE (insert country) SPONSORS INVOLVED?²³:

Y	N
---	---

16. IF YES, CONTACT DETAILS OF (insert country) SPONSORS

Name:	
Contact Person:	
Tel No:	
Fax No:	
E-mail:	
PostalAddress:	PhysicalAddress:

I. THE PROJECT

Please note that, if this application is granted, the applicant will be permitted to carry out ONLY the utilisation of GR and/or aTK described here. All other forms of utilisation will be expressly PROHIBITED unless permitted under a new application. Therefore please be very precise and include all relevant details.

1. Title of the PROJECT

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2. Summary of the PROJECT

Provide a summary of **the project**: What? How? With whom? Where? When?

--

²³ See footnote 10.

3. Detailed description of the PROJECT

Please provide a detailed description of the project, including as appropriate information on [3. 1 to 3. 16]. If any of these categories of information is not available, please state “not available” or “not yet known” and provide a brief explanation – further evidence may be requested. If any of the required information is confidential please indicate this AND DO NOT INCLUDE IT IN THIS APPLICATION FORM but state how and on what conditions you would be prepared to disclose it to the Competent National Authority (CNA) [3. 14]. Confidential information will be handled in accordance with the applicable provisions in the Basic ABS Agreement.

3. 1. Objectives: Describe the overall objectives (e.g. context of the project, possible end products)

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3. 2. Intended utilisation of the genetic resources and methods: Describe the research and/or development on the genetic and/or biochemical composition of the genetic resources that you propose, including the methods in more detail (e.g. research methods, use of equipment/technical capacity etc.)

Note: Refer also to applicable codes of conducts, standards, if relevant.

3. 3. Partners and their role: Provide details on the function, type of contribution of the partners

Note: Subject to national law, participation of national partners in the project may be required.

3. 4. Genetic resources: List the genetic resources to which you are seeking access for utilisation, including the quantity of genetic resources to be collected and a collection schedule. If unknown, please provide a description of collection methods and the quantity and type of organisms likely to be collected using those methods.

Common name	Taxon. (to the most specific taxonomic level known)	Amount/number/volume, including schedule (if possible)	Method

3. 5. Location: Provide details of where the genetic resources will be taken, including the latitude and longitude or GIS coordinates of the location area. Please also attach a location map or proposed route of voyages on a separate sheet to your application.

Location/s
Latitude/Longitude
MapAttached

3. 6. Time and Duration of the project: Please provide a timeline indicating the different phases and respective milestones of the project (can be attached as annex to this application form).

From:
To:

3. 7. Possible Benefits for Biodiversity: Identify how the project will benefit conservation and sustainable use of biological diversity. Specify any likely benefits for the access area in particular.

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3. 8. Possible Threats to Biodiversity: Identify and describe possible environmental impacts of the project according to [insert reference to relevant legislation or regulation]

Note: List species, areas etc. which could be threatened according to national legislation/regulation

3. 9. Describe the methods by which you will minimize or avoid the negative/adverse impact on biodiversity

Methods (e.g. harvesting method):

3. 10. Knowledge of indigenous and/or local communities (Traditional knowledge): Identify the use (if any) that is proposed to be made of indigenous and/or local communities knowledge in more detail.

Identification of the community/ies:
Describe the type of knowledge (e.g. to determine the genetic resources to be accessed, and/or the particular areas to be searched, and/or to identify the properties of the genetic resources; and/or the type of application (e.g. crème, tea)):
Describe intended utilisation:

3. 11. Written Permission of Physical Access Provider: List the name of each access provider and provide a copy of his/her written permission to access genetic resources for their utilisation from each access provider²⁴.

Access Provider
Written Permission Attached

3. 12. Basic ABS Agreements with indigenous and/or local communities: Provide further details if the Basic ABS Agreement was made with indigenous and/or local communities in relation to the utilisation of genetic resources where they have established rights to grant access to such resources and /or in relation to the utilisation of traditional knowledge associated with genetic resources that is held by them.

Describe the process of negotiating the Agreement: Include as a minimum what prior information on the project was provided to the indigenous and/or local community while seeking their prior informed consent; describe the nature of the community's governance structure and attach any evidence that reflects that a collective decision was taken regarding the sharing of the TK.

²⁴ Subject to national legislation or regulatory requirements, also an additional written permission from the physical access provider to the genetic resource may be needed (e.g. private landowner, indigenous and local communities where they are managers or custodians of the genetic resources).

3. 13. Other permits: List any other applications for permits or permits and their equivalent issued in relation to the research activity and the planned utilisation of the genetic resources and/ or traditional knowledge associated with the genetic resource. Include applications for permits or permits or their equivalent issued in other countries.

<p>Other Permits: [Include date of application, issuing authority, title of application, permit number & expiry date (if a permit was issued)].</p>
--

3. 14. Are details of this project confidential?

YES	NO
If yes, regarding which subject matter?	
Indicate on what conditions you would be prepared to disclose the confidential information to the Competent National Authority (CNA).	

III. Declarations

I/ We declare that the information contained in this application form is true and correct, and I/We shall be responsible for any wrong/incorrect information.

By signing below and submitting this application form, I/We agree to it being incorporated as an integral part into the separate Basic ABS Agreement that I/We have to sign and submit with this application form for review and approval by the Competent National Authority. The permit will refer to the application form and the Basic ABS Agreement as its integral parts and they will be attached to it.

I/We am/are authorised to make this declaration for and on behalf of [insert LEGAL PERSON] (if applicant is a legal person).

Signature

Receipt stamp

Annex 3: Basic ABS Agreement between PROVIDER and RECIPIENT On Access to Genetic Resources and/or Associated Traditional Knowledge for their utilisation²⁵

This outline Basic ABS Agreement and the guidance provided cannot substitute for specialized legal advice. Prior to entering into any legally binding contractual arrangement setting out mutually agreed terms of access to GRs and benefit sharing, all contracting parties should seek expert legal advice.

The diversity of national laws and of the practical interests of providers and recipients is likely to lead to a wide range of choices when actual provisions are negotiated and drafted. This basic agreement is hence not meant to prescribe one template but is intended to outline the essential features that should be included or considered in an ABS Agreement

In any particular transaction and collaboration, the nature and terms of a contract can be tailored to fit the needs and interests of the Parties to it to create an optimal and mutually beneficial arrangement. In any event, in any potentially legally binding relationship, all parties should normally seek technical and legal advice based on mutual understanding. Such advice cannot be solely obtained or derived from a consideration of models or seemingly similar agreements; the more an agreement is tailored to meet the specific interests and goals of the Parties to it, the more likely that the resulting agreement will be workable and mutually beneficial. ABS relationships are notoriously hard to pin down in detail, in advance. The purpose of a Basic ABS Agreement is to reserve rights, establish certain ground rules and describe principles and procedures that will apply if and when the relationship evolves and new agreements are made. Adapted – with suitable technical and legal advice – from this outline, and with the Application Form attached as an integral part, a Basic ABS Agreement allows the Parties to facilitate for a conducive ABS infrastructure between the Parties.]

This Agreement governs access to genetic resources and/or associated traditional knowledge for their utilisation between [INSERT PROVIDER NAME] and [INSERT RECIPIENT NAME], and is subject to the grant of the permit or its equivalent applied for in [INSERT SERIAL NUMBER OF APPLICATION²⁶] filed with [INSERT NAME OF COMPETENT NATIONAL AUTHORITY]. The application forms an integral part of this agreement {and is attached as an Annex}.

WHEREAS, [INSERT PROVIDER NAME] will provide the [INSERT RECIPIENT NAME] access to the genetic resources described in [INSERT SERIAL NUMBER OF APPLICATION] for their utilisation;

WHEREAS, [INSERT PROVIDER NAME] will provide the [INSERT RECIPIENT NAME] access to traditional knowledge associated with genetic resources and described in [INSERT SERIAL NUMBER OF APPLICATION] for its utilisation; [if applicable]

WHEREAS, [INSERT RECIPIENT NAME] desires to utilize the genetic resources to conduct research and/or development on their genetic and/or biochemical composition including through the application of biotechnology, as described in the application form; and

²⁵ This outline is a Basic ABS Agreement containing standard MAT that can be used as a material transfer agreement covering the discovery phase and reserving all relevant rights of providers

²⁶ Note: The application form includes a serial number when handed out.

WHEREAS, . . .(other relevant considerations in the context of the research activities as described in the application form)

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

DEFINITIONS

[Note: This section contains some standard definitions of the terms generally used in ABS Agreements. The Parties are however encouraged to replace or customize the terms in accordance with their needs and in particular in accordance with the planned research activities/ use of genetic resources and or traditional knowledge to be use. In this regard, Parties may choose between narrow or broader definitions by excluding or including different options.]

“APPLICATION FORM” means the written application for permission to access and utilize genetic resources and/or associated traditional knowledge, completed by the recipient and filed with [INSERT NAME OF COMPETENT NATIONAL AUTHORITY] with [INSERT SERIAL NUMBER OF APPLICATION] dated [ENTER DATE] which is attached to this Agreement and forms an integral part thereof;

“Associated Traditional Knowledge” and “Traditional Knowledge Associated with Genetic Resources” mean the specific knowledge, innovations and practices described in the Application Form;

“Genetic Material” means any material of plant, animal, microbial or other origin containing functional units of heredity;

“Genetic Resources” means genetic material of actual or potential value;

“Biotechnology “means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use”

“Derivative “ means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological and genetic resources, even it does not contain functional units of heredity. ”

“Third Party” means any person or institution other than the Provider, the Recipient and any collaborator under their control or supervision.

“The RECIPIENT” is.....

“The PROVIDER” is.....

“Party” means PROVIDER or RECIPIENT.

“Parties” means the PROVIDER and the RECIPIENT.

[Insert other relevant definitions, as needed . . .]

TERMS AND CONDITIONS

[Note: The following text outlines some of the terms and conditions that are often stipulated in an ABS agreement. Some of the clauses may not be applicable in particular cases. Furthermore additional clauses may need to be introduced to give effect to specific scenarios/ situations. As such, and as each agreement

is different, the Recipient and User must tailor the terms and conditions of an agreement in accordance with their specific needs, interests, goals and mutual understanding.]

Conditions for access to GR and/ or Associated Traditional Knowledge

The provision of access to the Genetic Resources and/or Associated Traditional Knowledge by the PROVIDER to the RECIPIENT described in the Application Form for their utilisation will be subject to the following conditions:

1. The RECIPIENT will access and utilize the Genetic Resources and/or Associated Traditional Knowledge only as stated in the Application Form; any access to and utilisation of the Genetic Resources and/or Associated Traditional Knowledge that is not expressly mentioned in the Application Form shall be deemed as prohibited.
2. Access to and utilisation of micro-organism incidentally carried on or in the Genetic Resources is expressly prohibited.
3. The RECIPIENT undertakes not to utilize the genetic resources and/or associated traditional knowledge otherwise than for uses specified in the application form unless
 - a. [the Provider] OR [the competent national authority and the PROVIDER] has/have been notified in writing, and
 - b. the present Agreement has been revisited and revised, as needed,
 - c. and a new application has been filed and approved.
4. The Genetic Resources and/or Associated Traditional Knowledge remain the property of the PROVIDER;
5. The PARTIES shall abide by all relevant laws at all times and when applicable laws change vary this agreement accordingly. [Mention governing laws as appropriate.]

[Add conditions as appropriate]

Benefit sharing arrangements

6. The benefits arising from the utilisation of the Genetic Resources and/or Associated Traditional Knowledge as well as subsequent applications and commercialisation shall be shared fairly and equitably, in accordance with the provisions of the CBD and the Nagoya Protocol on Access and Benefit-sharing and as detailed in this Agreement, by the RECIPIENT with the USER and [insert third-party beneficiaries if applicable]. Benefits that may be shared may include monetary and non-monetary benefits including but not limited to those listed in the Appendix to this agreement.
7. Specific benefits to be shared are: [Insert specific benefits that have been agreed, timeframe for benefit sharing, recipients – be as specific as possible.]

Third Party Transfer

8. The RECIPIENT undertakes not to transfer²⁷ the Genetic Resources and/or Associated Traditional Knowledge to a Third Party, without the written authorization of the PROVIDER; and then only under a legally binding written agreement with the PROVIDER based on this Agreement.

²⁷ The term 'transfer' includes e.g. to export, sell, give, provide or pass on.

Change of intent of utilisation and new utilisation

9. The Commercialization of the Genetic Resources/ and or associated traditional knowledge is prohibited. Any change in utilisation from non-commercial to commercial shall require a new Prior Informed Consent in writing issued by the Provider. In this case, the terms of such Commercialization shall be subject to a separate agreement (MAT) between the involved parties.

Confidentiality and Non-Disclosure

10. The PARTIES agree to maintain confidentiality on . . . [Define subject matter and see Application Form, Section II, 3.]. [Note: Confidentiality and non-disclosure clauses may be used as means to require the recipient of information to keep it confidential, such as information concerning source of GR associated TK or know how, which may be used in gaining access to GRs for evaluation purposes, developing a research collaboration etc. Such clauses generally limit the purposes for which such information can be used.]
11. Notwithstanding the foregoing, Confidential Information may be disclosed to the extent required by any law or regulation of any governmental authority having jurisdiction over any of the Parties, with appropriate efforts made to maintain confidentiality
12. The RECIPIENT agrees not to publish or otherwise place in the public domain any information about the Genetic Resources and/or Associated Traditional Knowledge without prior written authorization from the PROVIDER.

Intellectual Property Rights

13. The RECIPIENT shall not claim any intellectual property rights (IPR) over the Genetic Resources in the form received or any progeny or derivatives thereof; and/or Associated Traditional Knowledge, without the prior written consent of the PROVIDER.
14. If the RECIPIENT wants to obtain intellectual property rights on research results such act shall be treated as change in utilisation and thus shall be regulated under paragraph 9 of the present Agreement.
15. Any future agreements between the PROVIDER and the RECIPIENT authorizing claims for IPRs will include a provision obliging the RECIPIENT or its successor in title to disclose in the claim the origin of the Genetic Resources and/or Associated Traditional Knowledge utilised in developing the intellectual property claimed.

Reporting requirements

16. The RECIPIENT undertakes to provide a written project report to the PROVIDER in [XXX fill in relevant language] in accordance with [if applicable, insert domestic access and benefit-sharing legislative, administrative, policy or regulatory requirements; otherwise identify basic requirements in this Agreement²⁸].

²⁸ The report will include, but need not be limited to, the following information for the reporting period [list e.g. content, frequency, confidentiality].

17. Reporting shall be done according to the following time schedule: [insert timeline or table] in accordance with [if applicable, insert domestic access and benefit-sharing legislative, administrative, policy or regulatory requirements]

Warranties/ representations

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

Provisions with regards to Non-Compliance

The Parties agree to implement this agreement in good faith. Where there is breach the areas of non-compliance shall be settled in accordance with the dispute settlement mechanisms of this agreement.

Settlement of Disputes

19. In the event of any dispute under this Agreement between RECIPIENT and PROVIDER, the Parties agree to make attempts in good faith to negotiate the resolution of any disputes that may arise under this Agreement. If the Parties are not able to resolve a dispute within a period of [XX] months, such dispute shall be finally settled by an arbitrator. The designation of the arbitrator shall be mutually agreed between the Parties.
20. The RECIPIENT acknowledges that he/she is acting as a duly authorised representative of the institution he/she represents, and that the terms of this Agreement shall be binding on all present and future employees of his/her organisation, for as long as this Agreement remains in force.
21. If the Parties are not able to resolve any dispute within a period of [XX] months, such dispute shall be resolved before the [DISPUTE RESOLUTION BODY/COURT] as the only competent body for resolving disputes arising under this Agreement and in accordance with [XXX]. [Insert applicable Law; Jurisdiction]

Duration and Termination of the Agreement

22. This Agreement, unless terminated as provided herein, shall be effective from the date of execution/signature and is valid for [number of years/months] until [termination date]. [needs to be in line with the permit]
23. Either PARTY may terminate this Agreement with immediate effect by a written notice to the other PARTY if the other PARTY is in breach of any provision of this Agreement and (if it is capable of remedy) the breach has not been remedied within 60 days after receipt of the written notice specifying the breach and requiring its remedy.
24. Upon expiration or termination of the Agreement and upon request of the PROVIDER, the RECIPIENT agrees to (i) return any remaining Genetic Material, and (ii) return all documents and other tangible items containing or representing confidential information provided by the PROVIDER, and all copies thereof.
25. The following paragraphs shall survive termination of this Agreement: [detailed list, which should include e.g. benefit-sharing clauses, confidential information]

General

- 26. This Agreement, and rights and obligations hereunder, shall not be assigned or transferred, directly or indirectly, in whole or in part, by either Party, without the prior written consent of both Parties, which may be given or withheld at each Party's sole and absolute discretion;
- 27. Modification of this Basic ABS Agreement must be approved in writing by the Parties to this Agreement [and notified to the CNA]. [if CNA is not the PROVIDER]
- 28. This Agreement and the Parties' rights and duties outlined above shall be interpreted under the law of [insert country].
- 29. 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.

[INSERT PROVIDER NAME]

[INSERT RECIPIENT NAME]

("Provider")

("Recipient")

Authorized Signature

Authorized Signature

Print Name: _____

Print Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

As witnesses:

As witness:

Signature

Signature

Print Name: _____

Print Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

As witnesses:

As witness

Signature

Signature

Print Name: _____

Print Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

Annex 4: The ABS Agreement: Key Elements and Commentary

What is an ABS Agreement?

An ABS agreement is essentially an agreement between parties regarding the terms of access and utilisation of genetic resources and associated traditional knowledge, including the sharing of benefits arising from utilisation, subsequent applications and commercialization. An ABS agreement while unique to ABS shares some characteristics with ordinary contracts.

An ABS Agreement: Its Distinct Nature

It is important to keep in mind that each access situation has its specificities. Different types of users and sectors use genetic resources and associated traditional knowledge in different ways and for different purposes. While some elements of an ABS agreement may be standardized, others need to be handled flexibly on a case by case basis, in light of the legal and factual context.

The following list aims to highlight and explain the key elements of an ABS agreement. While some of the elements listed below are basic elements generally addressed in a contract or in a legally binding agreement between two Parties, others are unique to ABS agreements and will deserve special consideration in the process of negotiations between a provider and a user of genetic resources.

Finally, it is important to note that these key ABS elements are not meant to answer all questions and challenges in ABS contracts but rather to provide a broad overview of legal issues to be aware of when negotiating an ABS Agreement.

A. The Preamble

Most agreements have a preamble at the beginning that precedes the provisions that detail the terms of a contract. A preamble introduces the parties to the agreement, the subject and nature of the agreement and its broad objectives. There are no rules about what a preamble should contain, except that it should be a simple and straightforward introduction to an agreement and should not be overloaded with details. Where applicable, however, the preamble may outline in a chronological way relevant past events, existing relevant regulations (for example export and research rules), and memorandum of understandings or invoke prior or on-going developments that are relevant to the agreement. In many jurisdictions the preamble is not considered binding as it only provides mere background and premise of the agreement.

B. Terms and Definitions

A good agreement needs to have a section that defines key terms that are used in the body of the agreement. If parties to the agreement do not share a common understanding of the applications of the essential terms of the agreement, they could have different views on what they have agreed to, leading to costly misunderstandings and conflicts that could even cause a break down in the agreement.

It is therefore critical to include a section in the ABS agreement, usually following the preamble, which lists the key terms of the agreement and defines them in a manner that is acceptable to all parties. This section should offer a sufficient level of precision to ensure it can be understood and enforced by the parties' national courts or an arbitrator in the event of a dispute.

However, not every term used in the ABS agreement needs to be defined. Parties could reasonably be assumed to share a common understanding of terms such as disputes, monetary, patent, trade mark, etc. However, other terms such as genetic resources, traditional knowledge, utilisation, third party transfer etc., which have a specific meaning in relation to ABS, could be understood in different ways and would hence need to be defined.

- C. Details of parties to the agreement, including representation authority of signatories, legal and financial ability to undertake contract, authority to determine access to GR and TK etc.

The preamble generally introduces the parties to the agreement. The parties to the agreement on both the provider and user side need to be clearly identified (including relevant contact information). Parties as entities need to have legal authority to sign the agreement (e.g. as representative of a company with authority to bind it, a legitimate representative of an indigenous and local community or national authority).

The provider of the genetic resources and/ or associated traditional knowledge must be the one vested with the legal authority to do so. For example, depending on the specific national legal situation of the country providing the genetic resources, the rights over the genetic resources may be vested with the national government, a landowner or indigenous and local communities or their trustee. In other words, depending on the national ABS legal framework, the ABS agreement can be negotiated with the competent national authority of the provider country or directly with the provider of the resources, which may be a private landowner or a community.

It should be noted that, although it is current practice in many countries, private persons should generally not sign ABS agreements. For example, researchers should not access the genetic resource and/or associated traditional knowledge as private individuals, but as authorized representatives on behalf of their institution. This is important in ensuring that the agreement entered into holds the desired degree of accountability and credibility. Furthermore, issuing research permits to individuals may render an ABS agreement ineffective, especially its provisions on IPR and benefit sharing, as usually any rights over the results of the research and the intellectual property developed rest with the institution.

It is also important that the agreement pre-empts and accommodates future changes in the composition of the parties by including the successors-in-title of the parties to the contract. Corporations, for example may be acquired or may merge and change their names under a new ownership.

Where agreements anticipate this kind of situation, it forecloses the possibility of a non-interested resulting entity from reneging on a pre-existing commitment on the basis of contractual technicalities. Further, involving successive entities as party to an ABS agreement imposes a burden on the Recipient to fully disclose its obligation under the present agreement to stakeholders in future corporate re-arrangements. The same argument can also be made in regard to sovereign states and ILCs.

Finally, a good understanding of the company-structure is important. For example, the benefit-sharing obligations should be placed in the entity where the actual profit is going to be earned.

- D. Details regarding the genetic resources, i. e. collected material

While the section on definitions will define what the parties to the agreement mean by the term genetic resources and their utilisation in general, this does not preclude the need to provide more information on the genetic resource in question in the terms of the agreement. The genetic resources that are being

accessed for utilisation need to be clearly identified. It is recommended that the Parties list each type of genetic resource, specifying its taxonomical determination and common name, the quantity of the material and the parts of the organism, if applicable, to be collected. A collection schedule should also be provided.

E. Details Regarding Traditional Knowledge Associated with the Genetic Resource (as applicable)

As there is no generally accepted definition of “traditional knowledge”, the common understanding of traditional knowledge may vary, as well as its permitted and prohibited uses in light of national circumstances. While the ABS laws of the country from where the traditional knowledge associated with genetic resources is accessed may have a definition or a description of what it means, it is still important to provide details regarding the concrete traditional knowledge being utilized in the definition of terms section of the agreement. This would not only prevent potential misunderstandings between the parties to the agreement, but also allow courts in user countries (when the user belongs or is domiciled) to have a better understanding of the subject matter for compliance and contractual enforcement issues.

F. Purpose and Scope of Utilisation

ABS agreements should, to the extent possible, contain a detailed description of the exact purpose and scope of utilisation of the genetic resources and associated traditional knowledge. Where an exhaustive list of activities that would constitute utilisation of the resource or knowledge is not possible, it should be substituted by a non-exhaustive description of the type of activities that would constitute utilisation for the purposes of the agreement.

Generally, a comprehensive and detailed project description includes all the necessary information and should be an integral part of the agreement (e.g. objective and scope, possible restrictions or exclusions from scope of the exact utilisation of the material, as well as milestones and timeline). This information is critical as it describes in what form and for which purpose the genetic resource/ associated traditional knowledge can be utilized. Any other form and purpose of utilisation would therefore not be within the scope of the agreement and would hence be prohibited.

In the event of a change in utilisation, the agreement should create an obligation on the recipient /user of the genetic resource to disclose any “utilisation” that was not anticipated in the initial agreement. It should also establish an obligation to negotiate a new agreement or to review/ renegotiate the agreement or relevant sections of the initial agreement, as the case may be, to take into account the new situation (As indicated in Section J)

In addition, to make the agreement more robust, it is also recommended to include in agreement concrete clauses outlining consequences/penalties that would be applicable in case of a breach of any of the terms of the agreement. (See section S on Breach of Agreement).

G. Material transfer conditions if part of an ABS Agreement (e.g. export purpose and information needed according to national export provisions)

Many countries already have standard material transfer agreements and conditions for research permits elaborated as part of an integral part of their national export policy, regulations or other related legislation. Conditions of material transfer may be integrated into the agreement or may remain as a standalone separate agreement. However, the standard material transfer agreements that are currently prevailing could have preceded the ABS legal framework in the country and may not elaborate in an ideal manner the ABS objective stipulated in the national law and the ABS agreement. Therefore it will be important to

ensure that any standard agreements that are being used are in line with the ABS laws and regulations of the country.

H. Access rights granted (rights retained, exclusivity or non-exclusivity, further re-supply etc.)

The agreement must clearly identify the access rights and any rights retained (e.g. the provider retains ownership of the material). It may also address the issue of exclusivity/non-exclusivity, i. e. whether the accessing Party may have exclusive rights to access and utilize the genetic resource and/or associated traditional knowledge for a specific purpose or whether the providing Party may give similar rights to other potential users and on what terms or circumstances. Another issue may be further re-supply. Depending on the kind of research and development taking place, a continuous supply of the genetic resources may be required. In this context, it is advisable to identify the providing Party e.g. as the first source of supply, as well as agree on other specific requirements of the supply chain (e.g. sustainable collection methods, quality, time frames etc.).

I. Benefit sharing arrangements

The benefit-sharing arrangements deserve particular attention, as they represent a key component of each ABS agreement. They should address the following elements:

1. Non-monetary benefits

Non-monetary benefits generally arise in the research and development phase of a project in the form of sharing samples, research participation, training and transfer of technology etc. In most cases non-monetary benefits are easy to implement and can help to build in-country capacity in the medium to long term. Non-monetary benefits can play therefore a key role in a country's overall development strategy, building its national capacity in the bio-discovery sector.

2. Monetary benefits

Monetary benefits are generally linked to the commercialization of products based on the utilisation of genetic resources and/or associated traditional knowledge, for example, through royalties, upfront payments, etc. In this context, parties to an agreement need to be aware of the fact that the likelihood of such monetary benefits is generally unknown at the time of access or at the beginning of a research and development project. While it is possible to negotiate monetary benefits at the time of access, it may be advisable to postpone agreement on monetary benefits at the time of commercialization in order to have a more realistic idea of what to negotiate (see also section 3 below).

3. Timeline or phases of benefit sharing scheme

Parties to the agreement should also agree on the timing of the different benefits and identify, for example, different phases of a benefit-sharing scheme. Whereas, for example, during the research phase of a project the focus will be on non-monetary benefits, such as training and sharing research results, the focus will shift as soon as commercialization of those results starts. For example, parties could agree to milestones payments, which are linked to specific accomplishments or identified milestones in the research and development process until commercialization.

4. Distribution and use of benefits: contribution to conservation and sustainable use

While the provider should be free to decide on the distribution and use of benefits according to its national regulatory system, as well as in light of national circumstances and the specific case at hand, the ABS agreement should endeavour to include some commitment on the part of both the provider and recipient to directly deploy parts of the benefits to conservation of biological diversity and the sustainable use of its components (e.g. payments to trust fund supporting biodiversity research, like taxonomy, or to community funds which helps preserving traditional livelihoods etc.).

J. Change of intent of utilisation and new utilisation

It is important to include a clear requirement to apply for a new permit, i. e. a new prior informed consent (PIC) and renegotiate the present agreement or enter into a new separate agreement, when a change of utilisation or intent, which had not been foreseen at the time of access, takes place.

This can include a change from non-commercial to commercial intent, but also present a change in utilisation (i. e. new and different kind of utilisation which had not been agreed on at the time of access). Indications of a change of intent from non-commercial to commercial are, for example, the application for IPR or the transfer of the material to a commercial partner. A change of utilisation could be a new and different commercial use of a genetic resource based on the discovery of unexpected properties.

K. Third party transfer (including transfer of rights)

The agreement must include provisions regarding whether the genetic resources, its derivatives and/or associated traditional knowledge may be transferred to third parties and if so, what conditions should apply. Users will often transfer the resource or sometimes derivatives thereof to other individuals or partners for further research/commercialisation. In this situation, the conditions and terms of the agreement with the initial user are to be transferred to this new user or third party.

The typical situation in ABS is that the party or body accessing the GR or TK *in situ* for research purposes is rarely the same as the one who will eventually commercialise a product based on that resource and/or associated TK. From the time of access until the time of commercialisation (if a product is developed and commercialised), a number of actors may be involved which will be in turn providers and users of genetic resources. Also as research is carried out, the genetic resource may change its form and derivatives of the initial genetic resource accessed may be developed and be passed on to a new user. It is therefore important for the initial ABS contract to cover derivatives in order to avoid that the genetic resource or its derivatives are transferred to a third party without transferring obligations to this third party to obtain a new PIC and MAT from the provider for new utilisations that were not foreseen at the time of access.

L. Intellectual Property Rights (IPRs)

An ABS agreement for the utilisation of genetic resources for non-commercial purposes normally excludes the use of IPRs over any genetic resources or derivatives thereof and should provide for the opportunity to renegotiate commercial use, including IPRs at a later stage (refer to section J on Change of Intent). In the case of utilisation of genetic resources for commercial purposes, a more comprehensive ABS agreement will be needed, which should then address IPRs in more detail. Among others, the kind of intellectual property rights sought, ownership as well as the distribution of the value derived from the IPRs will need to be addressed. The specific circumstances of the case in question (i. e. kind of utilisation, sector specific subsequent application and commercialization) will need to be taken into consideration, as well as other aspects (general IP strategy of the user etc.). Issues that need to be considered in more detail as well as possible options to address these include the following:

- What IPRs could result from the ongoing research and development on the genetic resources that have been accessed?

The type of IPRs sought will depend, on a case-by-case basis, on the nature of the research carried out and on the type of protection sought for a particular product or process developed on the basis of a genetic resource. Potential IPRs may include patents or plant variety rights or other suitable IPRs, including trademarks and origin-based intellectual property such as geographical indications, depending on the type of protection sought and the subject matter of the protection.

- Who should own those IP rights? How should they be exercised, maintained, licensed or transferred?

The parties to an agreement must clarify who will have ownership of those IP rights. Joint ownership is one option, but it needs to be carefully considered, as it does not necessarily represent an ideal benefit-sharing mechanism. Rather, it also comes with costs and responsibilities of maintaining, securing and enforcing the rights in question. In addition, an IP right in itself does not guarantee concrete economic benefit. It needs to be commercially exploited in order to lead to benefits. In light of this, many users of genetic resources often choose not to commercialize IP rights themselves, but elect between numbers of different options to manage those rights so as to get the commercial benefits of their research. A licensing agreement, which allows the IP owner to license an IP right to others to develop or use a product or process commercially, is a common way to do so. The ownership and control of the IP itself remains with the initial IP owner and benefits, e.g. royalties from the commercial development and use, are shared. Therefore, a provider's interests may be better served through sharing of the license fees of the invention in the contract rather than seeking to own a patent or other IPRs.

- How can you achieve the best outcome for the parties and an equitable sharing of benefits?

As mentioned in the previous paragraph, it is important that the provider of the genetic resource retains rights arising from this agreement with respect to the sharing of monetary benefits through, for example, a licensing agreement. At the same time, the provider may also be interested in more immediate benefits, which include broader, non-monetary benefits, such as infrastructural development, provision of incentives, transfer of technologies, training, capacity building, employment guarantee, etc. and which should also be taken into account when negotiating the IP provisions of the agreement.

IPRs issues are complex and this section only gives a first short introduction to some basic questions and issues to be considered when negotiating ABS agreements. Effort must be made to seek specialized legal advice/support given the asymmetry in IPRs competence between users and providers of genetic resources. Well-negotiated IPRs related provisions constitute crucial aspect of the success the ABS agreement. If not formulated in an appropriate manner, ill-considered IPRs clauses may be counterproductive to the ABS process. It may be necessary to provide for periodic review of IPRs in the light of developments and unforeseen aspects of the research and development or utilisations of genetic resources.

M. Confidential information

Confidential information includes privileged commercially valuable information, which may be in the nature of trade secret or restricted information, but is incidental to the information exchange between parties to the ABS agreement. Parties may therefore need to agree on the level of confidentiality needed in a particular case in light of the privileged information, which is being shared. Such a confidentiality obligation

may apply to the ABS agreement as a whole or to specific terms thereof, in particular terms dealing with the genetic resources and the associated traditional knowledge, research results, the intended utilisation or any other technical matters. However, provisions on confidential information should not be designed to undermine the requirement of prior informed consent of the provider party or other reporting requirements that may be mandated pursuant to applicable laws and regulations.

Parties to the agreement should clearly state in the agreement what should be treated as confidential. This can be in the interest of both the provider and the user party. For example, research results may be of great importance for the researcher itself, but also for the provider country if the research results are the basis for a potential commercialization in the long run or if the research results can contribute to building the national capacity of the provider country to utilize its own genetic resources based on an improved understanding of the value of its resources.

N. Publications and ownership of research results

The right to publish is closely linked to the issue of confidentiality of research results. Publishing information on the utilisation of genetic and/or biochemical composition of genetic resources etc., thereby making it publicly available, may influence the market value of that information and may prevent the provider country from future benefits arising from the utilisation of that information. The agreement should therefore include provisions that clarify in detail the extent, timing, and nature of any limits imposed on publishing any information on the genetic resources, traditional knowledge or relevant research results. In this context, also the obligation to acknowledge the provider party as the source country of the material, as well as any other contribution or attributions to the research (e.g. joint authorship or application of IPRs) should be addressed in the agreement.

O. Reporting requirements

Detailed provisions on reporting requirements, including procedures of data-sharing and regular reports regarding activities to be carried out under the contract are of major importance. Reporting requirements represent the basis for monitoring and compliance control for the agreement, as well as an integral aspect of accountability. They are the basis for a transparent and long term relationship based on trust between the provider and the user. It should be noted that translation of reports and interpretation in the case of consultations may be necessary, so that everyone concerned can easily understand the content of the reports or follow the discussions etc. If necessary, the agreement should include clear instructions in this regard (e.g. provide for translation of relevant documents in a native language, the availability of interpretation).

P. Meetings

In some cases there may also be a need to organize periodic face-to-face meetings and consultations amongst the Parties on a regular basis. This could facilitate direct exchange of experiences and, where necessary, also resolve any controversial issues and further build confidence. The agreement should then specify the timing and location, frequency, as well as who should bear what costs for such meetings.

Q. Duration and termination of the Agreement

Any contract agreement includes duration and termination clauses (i. e. termination, expiration, cancellation and impossibility or frustration clauses). In the context of ABS, the agreement, for example, may be effective for the duration of a given research project or an initial testing period. However, the issue

of termination is challenging as an ABS agreement may not be easily cancelled, as for example e.g. the genetic resource and the associated traditional knowledge and related information has already been transferred. In this context, an agreement on provisions that survive termination may prove to be useful (see section R below).

R. Survival clause

Parties to the agreement should also agree that certain provisions of the agreement, i. e. certain rights and responsibilities of the Parties will survive beyond termination. This should, for example, include the provisions on confidentiality, as well as those on publications and ownership over research results and other benefit-sharing. In addition, the agreement should give clarity on what happens to the material transferred e.g. whether any unused samples should be destroyed or returned to the provider, if at all possible.

S. Breach of the Agreement

To be more effective, the agreement should also include provisions specifying the consequences of a breach of the agreement. The agreement could, for example, include a provision that obliges the user to pay a penalty for any material breach of the Agreement. It could also be included, that the provider may terminate the agreement and revoke the relevant permit by a written notice if the user defaults in the performance of any obligations under the agreement. The user should then, however, be notified in writing of such defaults by the provider and have the chance to seek remedy within a certain period of time after the date of notice.

T. Dispute resolution and settlement

Parties to the agreement should finally also agree on how to solve disputes related to the contract. It is recommended to first try to solve any dispute through informal negotiations. Parties may also opt for alternative dispute resolution (ADR) mechanisms, such as mediation and arbitration. ADR has the potential to provide quicker, cheaper and more effective solutions to disagreements among contracting parties than litigation in the courts. In transboundary situations, litigation, including issues related to access to justice and the recognition of foreign judgments can be challenging and costly. For example, when bringing an action before a foreign court, the plaintiff will have to deal with different rules relating to procedural matters etc. If the plaintiff institutes proceedings in his own country, it may be difficult to enforce the judgment against the user in a foreign jurisdiction.

Appendix²⁹: Benefits

Monetary benefits

- a. Access fees/fee per sample collected or otherwise acquired;
- b. Up-front payments;
- c. Milestone payments;
- d. Payment of royalties;
- e. Licence fees in case of commercialization;
- f. Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
- g. Salaries and preferential terms where mutually agreed;
- h. Research funding;
- i. Joint ventures;
- j. Joint ownership of relevant intellectual property rights.

Non-monetary benefits

- a. Sharing of research and development results;
- b. Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the provider country;
- c. Participation in product development;
- d. Collaboration, cooperation and contribution in education and training;
- e. Admittance to *ex situ* facilities of genetic resources and to databases;
- f. 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 utilisation of biological diversity;
- g. Strengthening capacities for technology transfer to user developing country Parties and to Parties that are countries with economies in transition and technology development in the country of origin that provides genetic resources. Also to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources;
- h. Institutional capacity-building;
- i. Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;

²⁹ The list of non-monetary and monetary benefits is taken from the Annexes of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable of the Benefits arising out of their utilisation and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their utilisation to the CBD. This list is not exhaustive and Parties may include other benefits they may see fit.

- j. Training related to genetic resources with the full participation of providing Parties, and where possible, in such Parties;
- k. Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
- l. Contributions to the local economy;
- m. Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in provider countries;
- n. Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
- o. Food and livelihood security benefits;
- p. Social recognition;
- q. Joint ownership of relevant intellectual property rights.

Annex 5: Basic Principles for Community Involvement in Access and Benefit Sharing

In their capacity as traditional knowledge holders, indigenous and local communities (ILCs) are important stakeholders in the Access and Benefits Sharing (ABS) process. But ILCs face many challenges, including social marginalization and exclusion from public processes; their weakness position and vulnerability as providers of the resources in the context of their relationships with users; the weak implementation of prior informed consent, weak benefit sharing mechanism and the legal pluralism and fragmentation of law. This annex summarises and presents to AU member states workable principles for community involvement in ABS processes at domestic level, which should guide the development of community protocols (pursuant to Article 12 of the Nagoya protocol).

- “In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities’ customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources”. (Article 12(1) of the Nagoya Protocol)

Community protocols are a community-based tool to facilitate the interface between communities that want to engage in ABS on the one hand and users of associated traditional knowledge (aTK) on the other. Their development helps communities to evaluate the value of ABS as a means to generate local livelihoods. Community protocols are able to clarify the principles guiding a community’s involvement in ABS as well as highlight the process for accessing or utilizing their genetic resources (GR), where communities have these established rights, and aTK. The core features of community protocols in ABS are summarised below:

1. Predictability and transparency

Community Protocols aim to create predictable conditions for accessing GR and aTK. A Community protocol is an interface document developed by indigenous or local communities through extensive consultations within the community and is designed to clearly present to the government and potential bioprospectors the process of engaging the community and how the community makes decisions.³⁰ A good community protocol process helps ensure that decisions in relation to aTK or GR are made according to a clear community mandated procedure, thus providing the government with verification on the integrity of the community resolution and providing potential bioprospectors with definitive steps to follow when engaging with the indigenous or local community.³¹

Communities are best placed to make informed decision when they fully understand the ABS framework and view any request for access to their aTK within the context of their collective aspirations. As a legal empowerment and capacity development tool, they also help facilitate the understanding of the economic, social and cultural and environmental values of GR.

³⁰South Africa’s Bioprospecting Access and Benefit-Sharing Regulatory Framework: Guidelines for Providers, Users and Regulators.

³¹As above.

2. Clarity and legal certainty

Community protocols provide a helpful interface between customary law and national law. They are able to clarify customary rights to GR and aTK and should be taken into consideration in designing ABS regimes, especially when customary law is not recognized by the formal legal system. Clear rights are a precondition for equitable benefit sharing. There is an increasing appreciation that community protocols provide greater clarity and legal certainty to governments, researchers, and other actors.

Community protocols will assist users of aTK to interact with communities because they articulate the framework that governs a communities' aTK and details other factors such as identifying the community, customary procedures for providing PIC and decision making structures. The process of developing community protocols and the different consultations held at the local level between the providers of GR and users will help both parties to agree on the conditions and use of the resources through the conclusion of MAT.

The process of developing community protocols should include the provision of legal advice to ILCs on prior informed consent (PIC) and mutually agreed terms (MAT), as well as providing further guidance to communities on how to engage with external actors. This enables communities to more effectively negotiate equitable benefit sharing agreements.

3. Prior informed consent

Community protocols, as a legal empowerment tool, bridge the gap between the customary systems of indigenous peoples and local communities and "external" legal and policy frameworks, and that enable informed and equitable engagement between actors. They give clear guidance to communities on the legal systems and procedures for providing PIC. The community protocol allows the community to define or identify itself for the purpose of any ABS agreement. This might be, for example, on the basis of a geographical area, livelihood or shared aTK. It will also provide clarity on customary procedures and decision-making processes, which are crucial for users when obtaining PIC and entering into MAT. Before access to GRs or aTK can commence, the PIC from owners of GRs or aTK holders is required. The party requesting material or information is expected to disclose the intended use of a resource, and the method of collection, in order that the provider of the resource or the knowledge can make an informed decision about whether to provide access.³²

4. Equitable benefit sharing

New legal approaches such as community protocols can serve as a platform for communities to engage with and inform planning processes before decisions are made. They acknowledge that the holders of TK who may have contributed to discoveries should be justly rewarded. The process of community protocol development could thus include training on ABS negotiation skills and facilitate discussion on the use of monetary or non-monetary benefits. Decisions by the community on benefit sharing can then be clearly enunciated to the user of the resource or aTK. Examples of community protocols in ABS have included traditional health practitioners engaging with local cosmetic companies and indigenous peoples with nutraceutical companies. The mutual understanding build through the community protocol process has helped articulate an equitable balance between the rights and interests of those that develop, preserve and sustain TK, and of those who use and benefit from GR and ATK.

³² No 9 above.

5. Dialogue and Negotiation

The bio-prospecting process is regarded as involving very diverse set of stakeholders groups including ILCs, the government, the private and public sector, the multinational corporations, business, and companies. These groups may have sharply conflicting views and interests concerning the use of GR and TK.³³ Community protocols are an effective tool to facilitate community interaction with external stakeholders as they can play an important role as intermediaries. They help clarify expectations for business and government and facilitate dialogues between different interests. Also for government they can provide support with respect to ensuring due diligence. They can define the terms on which outsiders may access the resources and knowledge of ILCs, and how to share the benefits. Community protocols could be used to bring together and engage different stakeholders to develop a community vision for a range of issues. Community protocols support dialogue and constructive collaboration between different rights-holders and duty-bearers.³⁴

The outcomes of a community protocol process are foundations for long term, sustainable relationships, establishment of shared values, and legal certainty. For more information on community protocols please refer to www.community-protocols.org

³³ Laird Sarah (ed), 2002, Biodiversity and traditional knowledge, Equitable partnership in practice, People and plants conservation series, Earthscan.

³⁴ There are two stakeholder groups in the ABS process, the rights holders, or the ILCs who do not experience full rights, and the duty bearers, or the multinational corporations, business companies, and the government who are obligated to respect, protect and fulfill the rights of the rights holders. Community protocols aim at strengthening the capacity of duty bearers and empower the rights holders.

