PACIFIC ACCESS AND BENEFIT-SHARING (ABS)

IMPLEMENTATION GUIDELINES

An initiative of the African, Caribbean and Pacific Group of States funded by the European Union

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SPREP's vision: *The Pacific environment, sustaining our livelihoods and natural heritage in harmony with our cultures.*

Foreword

I am delighted to share the Pacific Regional Guidelines on the Effective Implementation of the Nagoya Protocol. With financial assistance from the Global Environment Facility (GEF) and implementation by the United Nations Environment Programme (UNEP), the Secretariat of the Pacific Regional Environment Programme (SPREP) is currently executing a Regional Access and Benefit-sharing (ABS) Project in 14 Pacific island countries. The project provides support to countries to ratify the Nagoya Protocol on Access to Genetic Resources and Benefit-sharing of the Convention on Biological Diversity (CBD). Specifically, it is strengthening legal and technical capacity in the countries to implement and operationalise the Protocol at the national level. It also strengthens and improves awareness, communication, and education on access and benefit-sharing issues in the Pacific.

The Nagoya Protocol was adopted in 2010 and came into force in 2014, making it legally binding on State Parties. The ABS project began in 2017 following the regional project inception meeting held in Apia, Samoa. SPREP has consistently engaged with countries from the Pacific region in the development and review of national policy and regulatory frameworks. These frameworks aim to promote the fair and equitable sharing of benefits from utilising genetic resources and associated traditional knowledge. Additionally, they improve and encourage investment, including enhanced national, regional, and international cooperation on academic and commercial research that contributes to conservation and sustainable development of these resources.

These Pacific Regional Guidelines aim to help countries develop domestic-level compliance mechanisms. The capacity building and awareness-raising work of the project has resulted in ten countries becoming Parties to the Nagoya Protocol. However, I note that significant challenges remain in implementing compliance mechanisms under the Protocol.

I wish to acknowledge the financial contribution of the ACP MEAs 3 programme, a partnership between the European Union and the Organisation of ACP States, to the development of these Guidelines.

Thank you to the consultants Dr Evana Wright and Mr. Oliver Rukundo for their commitment to preparing these guidelines in a short time despite many challenges including the global pandemic.

Finally, my sincere gratitude to the ABS Capacity Development Initiative for their technical guidance and support, and to our SPREP Members who provided access to information and participated in the consultation that was instrumental to the development of these guidelines.

Sefanaia Nawadra
SPREP Director General

1 Introduction

1.1 Context

The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* (in these Guidelines referred to as the 'Nagoya Protocol' or NP) is an agreement established under the Convention on Biological Diversity (CBD). The purpose of the Nagoya Protocol is to operationalise the access and benefit-sharing provisions of the CBD.[1] In particular, the Nagoya Protocol supports the third objective of the CBD, that is, the fair and equitable sharing of benefits arising out of the utilisation of genetic resources (GR).[2]

The Nagoya Protocol provides for several obligations that countries must comply with through the adoption of national access and benefit-sharing (ABS) legislative, administrative and policy measures. The obligations stipulated in the Nagoya Protocol cover core elements including access to genetic resources, the fair and equitable sharing of benefits arising out of utilisation, as well as compliance with provisions for prior informed consent (PIC) and mutually agreed terms (MAT). One innovative element in the Nagoya Protocol relates to its compliance measures. To support compliance, Parties are obliged to take measures to monitor the utilisation of genetic resources, including through the designation of checkpoints and reporting requirements. As evidence that genetic resources have been accessed in accordance with PIC and that MAT have been established, a permit or its equivalent must be granted by the provider country at the time of access. Once this permit or its equivalent is made available to the Access and Benefit-sharing Clearing House (ABSCH) of the Protocol, it becomes an "internationally recognised certificate of compliance" which can be used to prove legal access.

Nagoya Protocol Parties also have a set of additional obligations towards indigenous peoples and local communities (IPLCs) regarding IPLC rights over traditional knowledge associated with genetic resources. All countries, including those that have pre-Nagoya Protocol measures in place, need to assess what actions need to be undertaken at the national level to meet the obligations set out in the Nagoya Protocol. This is in keeping with the fact that the Nagoya Protocol contains a series of innovative measures on compliance and in relation to the rights of indigenous peoples and local communities that go beyond the ABS provisions stipulated in Article 15 and Article 8(j) under the Convention on Biological Diversity.

A number of Pacific countries have embarked on the process of developing new or amending existing legislative, administrative and policy measures to meet the obligations in the Nagoya Protocol. However, most countries still face challenges in relation to ratification and implementation of the Protocol. The challenges include:

- Lengthy legal procedures and requirements for ratification, as well as complexity associated with stakeholder consultations, have delayed ratification and accession processes in some countries.
- Lack of inventory of genetic resources and lack of knowledge about their potential economic value.
- Limited capacity to negotiate mutually agreed terms.
- Limited capacity to implement systems for monitoring the utilisation of genetic resources.

[1] See Convention on Biological Diversity, arts 8(j), 15.

[2] Convention on Biological Diversity, art 1.

1.2 Structure and objective of the Guidelines

There are several existing and emerging domestic ABS systems in the Pacific, some of which are under review to ensure their compatibility with the NP.[3] This implies that not every action outlined in these Guidelines will be equally relevant or applicable to all countries. Furthermore, countries do not have to follow the actions as they are presented in the Guidelines, as long as effective domestic measures exist, or are put in place, to deal with each step. The Guidelines are not exhaustive and should be read with primary sources such as the texts of the CBD, NP, International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the Bonn Guidelines.[4] In this context the Guidelines complement other materials on the subject.

[3] See, for example, The ABS Capacity Development Initiative, *ABS Implementation Options: Policy and administrative options for implementing the Nagoya Protocol on Access and Benefit-sharing (ABS) (September 2019) https://www.abs-biotrade.info/fileadmin/Downloads/TOPICS/ABS%20MECHANISM/GLOBAL%20PROCESSES/National%20ABS%20Implementation%20-%20Studies/Collection%20-%20Implementation%20Options%20-%20ABS-I%20-%20201909.pdf*

[4] The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation (Bonn Guidelines) were established in 2002 by the Secretariat of the Convention on Biological Diversity. The Bonn Guidelines provide guidance on the implementation of access and benefit-sharing principles by both provider and user parties including government, institutions, and individuals. See https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

2 How to become a Party to the Nagoya Protocol?

2.1 Rationales and justifications for becoming a Party to the Nagoya Protocol

By becoming a Party to the Nagoya Protocol coupled with sound ABS procedures and processes, monetary and non-monetary opportunities will trickle down to local and national levels, e.g. through access fees, payments of royalties, joint or shared ownership of intellectual property rights etc.; non-monetary benefits can encompass capacity development, improved recognition of traditional knowledge and use practices, or technology transfer. The following considerations may justify a decision towards becoming a Party to the Nagoya Protocol.

- The Protocol, if ratified and effectively implemented, can contribute to **enhancing the economic and social well-being of your country.**
- The Protocol can contribute to **economic development, job creation and poverty alleviation** (i.e. through the re-investment of potential monetary and non-monetary benefits in the national economy).
- Acceding to the Nagoya Protocol ensures that the country's genetic resources and associated traditional knowledge effectively translates into **opportunities for fair and equitable sharing of benefits.**
- The Protocol will strengthen the ability of indigenous peoples and local communities (IPLCs) in your country to **benefit from the use of their knowledge, innovations and practices.**
- By promoting the use of genetic resources and associated traditional knowledge, the Protocol creates opportunities for developing an **economy relying on sustainability** and increased knowledge of the value of natural resources.
- The Protocol **creates incentives f**or preserving genetic diversity and biodiversity in general, while providing the conditions for **continuous research and development on genetic resources.**
- The designation of competent national authorities and national focal points provide an opportunity for countries to **streamline** their ABS procedures and **reduce administrative bottlenecks.**

2.2 Steps towards becoming a Party to the Nagoya Protocol

To become a party to the Nagoya Protocol a State must demonstrate, through a concrete act, its willingness to undertake the legal rights and obligations contained in these two instruments. In other words, it must express its consent to be bound by the Nagoya Protocol.

Under the Nagoya Protocol, States may express their consent to be bound in several ways:

- Ratification (for States)
- Accession (for States and regional integration organisations)
- Formal confirmation (for regional integration organisations)

The primary distinction in becoming a Party

is usually made between ratification and accession. Only those States that *signed* the Protocol when it was open for signature (i.e. between its adoption and the closing date for signature 4 June 2001) can proceed to ratify it. In signing the Protocol, States only indicated general support for its objective and provisions as well as their intention to become Parties in the future and be legally bound by it. However, the act of signing, in itself, did not establish consent to be bound by the Protocol. Therefore, the further act of *ratification* is required before the State becomes a Party. The instrument of ratification is signed by the Head of State, Government or Minister for Foreign Affairs and deposited with the Depositary – the Secretary-General of the United Nations.[5] Once a State has deposited this instrument, the Protocol then enters into force for that State ninety days later.[6] At this point, the State is bound by the provisions of the Protocol and must comply with its obligations.

States that *did not sign* the Protocol during the time when it was open for signature cannot ratify it – they may only accede to it. These States therefore deposit an instrument of *accession* in order to become a Party.[7] (Note: These States have the same rights and obligations as those States that ratified the Protocol.) The formal instrument of accession is signed by the Head of State, Government or Minister for Foreign Affairs. The model instrument of accession provided by the Secretariat of the Convention on Biological Diversity provides the following template language that may be used by countries seeking to accede to the Nagoya Protocol:

> NOW THEREFORE I, [name and title of the Head of State, Head of Government or Minister for Foreign Affairs] declare that the Government of [name of State], having considered the above mentioned [treaty, convention, agreement, etc.], accedes to the same and undertakes faithfully to perform and carry out the stipulations therein contained.[8]

Further information on the process of becoming a party to the Nagoya Protocol, including a model instrument of accession, is available on the website of the Secretariat of the CBD.[9]

It is important to check with relevant country-level Attorney-General's office, Solicitor-General, or other legal officer or advisor on the process of accession or ratification in a specific country.

Finally, ratification at the international level should not be confused with ratification at the national level. At the national level, the State might have to ratify a treaty in accordance with its own constitutional or legal provisions before it expresses consent to be bound internationally. However, ratification at the national level alone is not sufficient to establish a State's intention to be legally bound at the international level. That is why ratification at the international level is still necessary, regardless of national procedures.

[5] Convention on Biological Diversity, *Becoming a Party* https://www.cbd.int/abs/becoming-party/#signature

[6] Nagoya Protocol art 33; Convention on Biological Diversity.

[7] Convention on Biological Diversity, *Becoming a Party* https://www.cbd.int/abs/becoming-party/#signature

[8] Extract from the Treaty Handbook, *Annex III – Model Instrument of Accession* https://www.cbd.int/abs/doc/protocol/treaty-handbook-annexes.pdf

[9] Convention on Biological Diversity, *Becoming a Party* https://www.cbd.int/abs/becoming-party/#signature

3 Scope and application of the Nagoya Protocol

3.1 What is regulated under the Nagoya Protocol?

The Nagoya Protocol applies to genetic resources (GR) that are covered by the CBD, and to the benefits arising from their utilisation. It also covers traditional knowledge (TK) associated with genetic resources that are covered by the CBD and the benefits arising from its utilisation.

The Protocol covers genetic resources when these are "utilised" within the definition of Article 2(c) of the Protocol, meaning "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology". Countries can opt to define the scope of their national measures in line with the provisions of the Protocol but can go beyond by extending the scope of application.

The value of a genetic resource is no longer limited to its biology. The extent and speed with which information about organisms is collected can generate future uses and revenues, regardless of the organism from which the genetic material was originally obtained. The use of data, including data obtained from digital or genomic sequencing of GRs, can create value for GR, other than that resulting from the ownership, use, or management of these resources, while providing assistance and products to those who own, use, and manage GR.

3.2 Recognising sovereign rights of states and rights over indigenous peoples and local communities over genetic resources and associated Traditional Knowledge

3.2.1 Background and context

The Nagoya Protocol establishes three categories of right holders: state sovereignty over its genetic resources, the ownership rights of indigenous peoples and local communities over their genetic resources if established through domestic legislation, and the rights over associated TK "held by indigenous peoples and local communities" where it does not specify how these rights are granted.

Consistent with existing principles of international law, including the Charter of the United Nations, the Nagoya Protocol recognises and affirms the sovereign right of States over their genetic resources.

ARTICLE 6.1 OF THE NAGOYA PROTOCOL 'ACCESS TO GENETIC RESOURCES'

In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing 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 Convention, unless otherwise determined by that Party.

The rights of indigenous peoples and local communities to their traditional knowledge are established under relevant customary laws, community protocols and procedures, and are recognised in the United Nations Declaration on the Rights of Indigenous Peoples. The Nagoya Protocol recognises the rights of indigenous peoples and local communities to their traditional knowledge associated with genetic resources including the right to identify the knowledge holders within their communities.[10] Furthermore, the Nagoya Protocol requires parties to take appropriate measures (legislative, administrative or policy) to give effect to these rights consistent with domestic legislation, including the right to share in benefits arising from utilisation of traditional knowledge associated with genetic resources.[11]

While the Nagoya Protocol recognises the rights of States and indigenous peoples and local communities in genetic resources and associated traditional knowledge, these rights should be reflected in domestic legislation or policy to avoid any doubt as to the requirement for users to obtain prior informed consent for access to, and use of, genetic resources and traditional knowledge. The ABS Clearing House should also be updated to reflect the requirements of such domestic legislation or policy (cross reference section on ABSCH).[12]

For Pacific countries who are not Parties to the Nagoya Protocol, the access and benefit-sharing provisions of the Convention on Biological Diversity may provide a measure of protection and control over the use of genetic resources and associated traditional knowledge. Under the Convention on Biological Diversity, parties have 'the sovereign right to exploit their own resources' and may require prior informed consent for access to and use of genetic resources and associated traditional knowledge.[13] However, Pacific countries seeking to take this route should be aware that the Convention on Biological Diversity provides a less comprehensive suite of protections when compared to the detailed protections set out in the Nagoya Protocol.

3.2.2 The principle of prior informed consent

The practical manifestation of sovereignty is embedded in the concept of Prior Informed Consent (PIC) which is based on the principle that providers have the authority to grant access to their resources and that they need certain information to make informed decisions on whether or not to grant access.

This requires the access seeker to provide information in advance, in local language(s) and in detail about the planned access activity, such as:

- the genetic resources and/or associated traditional knowledge to which access is sought including quantities and locations,
- the purposes for which the genetic resources and/or associated traditional knowledge would be used,
- the potential benefits that may arise out of utilisation of genetic resources and/or associated traditional knowledge.
- the proposed beneficiaries of such arrangement including indigenous and local communities where relevant,
- the impact and potential implications of the planned access activity,

in order for the provider to make an informed decision on whether to allow access.

The following elements must be considered when defining requirements for prior informed consent to access and use of genetic resources and associated traditional knowledge:

[10] Preamble

[11] The rights of indigenous peoples and local communities in traditional knowledge associated with genetic resources are recognised in the following provisions of the Nagoya Protocol: arts 5.2, 5.5, 6.2, 7, 11.2, 12 and 16

[12] Nagoya Protocol arts 6, 13.4.

[13] CBD arts 3, 15.

- What scope of activities trigger access requirements?
- Who has the right to grant PIC? What is the role of government and IPLCs in granting PIC?
- What are the rules and procedures for obtaining PIC and negotiating MAT? Are there existing obligations or requirements in relation to PIC (e.g. existing requirements to obtain PIC from government for a research permit)?

Once these basic questions are defined, it is important to define in the legislation the types of information that the access seeker will need to provide to allow the Competent National Authority to make an informed decision and provide prior informed consent (for further information on the Competent National Authority see section 5 'Institutional Arrangements' below). The following technical and procedural questions could be defined in the legislation:

- Who is accessing, when, where and what genetic resource and/or traditional knowledge?
- What would be the impact of access on conservation and sustainable use?
- What is the intended use, purpose, expected results and budget?
- Who else is involved, e.g. are local bodies collaborating or third parties involved?
- What are the types of potential benefits, and any benefit-sharing terms agreed and who are the beneficiaries of any benefit-sharing? How will the need for confidentiality of information be addressed?

3.2.3 Defining different rules for different types and intent of access

Different PIC procedures may be set out according to the intended use of the genetic resource or traditional knowledge (e.g. commercial, non-commercial, for research promoting conservation and sustainable use, domestic research etc.) Any change in use may require a new application for PIC. Measures should clearly outline permitted uses and any requirements in the case of changes in use. The following questions could be considered:

- Are separate regimes needed for different types and uses of genetic resources?
- How to achieve mutually supportive implementation with other related ABS systems?
- How to address special cases of access – e.g. emergency situations and considering the importance of genetic resources to food and agriculture?

3.2.4 How should PIC and MAT be linked?

Parties can decide whether to require that PIC and MAT be negotiated at the same time or allow for negotiation of MAT including benefit-sharing at a later stage.

Some countries have chosen to require establishment of MAT as a condition of access, with both outlined prior to access and in the same legal agreement. Linking PIC and MAT at early stages can promote greater legal certainty and coherency in ABS agreements. Such an approach also reflects that access can trigger benefit-sharing rather than waiting for commercialisation outcomes.

Other countries separate PIC and MAT into different processes and legal instruments. For instance, PIC can be formalised in a permit and MAT established in an agreement or contract at another time. This approach provides flexibility for users and providers to negotiate MAT at later stages when more is known about potential benefits and separates MAT from the government permitting process.

4 Stakeholder identification and engagement

4.1 Who should be engaged as stakeholders in ABS implementation?

The nature of ABS implies that extensive coordination between various stakeholders must take place, to the extent possible. These stakeholders may include government (including state and local government), indigenous and local communities, researchers and academia, and the private sector. Information sharing and networking are critical to ensuring the efficiency and stability of any approach, allowing for anticipating and managing conflicts, and enhancing collaboration. This requires an enabling legal and institutional framework, which facilitates effective participation, coordination and collaboration across jurisdictional boundaries, departments, institutions, disciplines, and users.

4.2 Biocultural Community Protocol (BCP) tools for the effective engagement of indigenous peoples and local communities

4.2.1 Background

Article 12 of the Nagoya Protocol provides that "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. The Protocol thus places an obligation on its Parties to support the development of community protocol in relation to access to traditional knowledge associated with genetic resources." This has been the basis upon which biocultural community protocols (BCPs) have been developed. BCPs are now recognised as effective tools that can link customary, national and international law in fulfillment of the interests and aspirations of indigenous people and local communities in relation to ABS. The following section provides a brief introduction to BCPs as well as resources for a country or community wishing to develop such a tool to address TK or community-related issues.

4.2.2 What are Biocultural Community Protocols (BCPs)?

Biocultural Community Protocols (BCPs) are instruments that set out clear terms and conditions for governments and the private, research, and non-profit sectors for engaging with indigenous peoples and local communities (IPLCs) and accessing their local resources and knowledge. In the context of ABS, BCPs are relatively new instruments that record community agreements on how the genetic resources and associated traditional knowledge of the community are to be managed and accessed.

The "Draft glossary of relevant key terms and concepts to be used within the context of Article 8(j) and related provisions" (UNEP/CBD/WG8J/9/2/Add.1) defines community protocols as:

> "Community protocols cover a broad array of documents generated by communities to set out how they expect other stakeholders to engage with them. They may reference customary as well as national or international laws to affirm their rights to be approached

according to a certain set of standards".[14]

According to Natural Justice:

> "Biocultural community protocols (BCPs) articulate community-determined values, procedures and priorities. They set out rights and responsibilities under customary, state and international law as the basis for engaging with external actors such as governments, companies, academics and NGOs. They can be used as catalysts for constructive and proactive responses to threats and opportunities posed by land and resource development, conservation, research, and other legal and policy frameworks"[15]

4.2.3 What are the key elements of a BCP?

Every BCP is distinct due to the unique biological and cultural diversity of the people and the communities that develop them. This means that BCPs must be carefully designed to accord with the specific situations, interests and aspirations of a given community as well as any recognition of customary rights to land, marine and terrestrial resources. That being said, Natural Justice has, through their extensive experience in the area, established that BCPs tend to include the following:

1. Definition of the community and governance structure.
2. Values related to the ecosystem and use of resources.
3. Spatial description of resource use (participatory mapping, GPS, etc.).
4. Problems faced by community.
5. Aspirations of community (can be very targeted).
6. Obligations regarding use of biodiversity – often related to customary practices.
7. Relevant rights in national and international law.
8. Particular elements – PIC, Benefit-sharing, Ownership entitlements, etc.
9. Contact details of identified point persons or committees.

The key feature of a BCP is that it is a community-led instrument which can be used to engage government and other stakeholders to secure the rights of IPLCs over their genetic resources or associated traditional knowledge.[16]

4.2.4 How are BCPs developed?

In the context of ABS, BCPs should ideally be developed in response to an opportunity or identified challenge in relation to access and use of a specific genetic resource or associated traditional knowledge of a community.[17] According to Natural Justice, a BCP could be specifically developed to address multiple issues e.g. how to deal with a new application for access by a user, the desire to improve an existing ABS value chain, or the defense against a specific threat of

[14] (UNEP/CBD/WG8J/9/2/Add.1) available at https://www.cbd.int/kb/record/meetingDocument/105434?FreeText=glossary

[15] http://naturaljustice.org/publication/biocultural-community-protocols/

[16] For examples of Biocultural Community Protocols see the following protocols development in Samoa: Aopo Biocultural Community Protocol regarding Traditional Knowledge associated with Genetic Resources, and Faleaseela Biocultural Community Protocol on Access and Benefit-sharing related to Traditional Knowledge associated with Genetic Resources.

[17] Experiences and Lessons Learned from the Development and Implementation of Community Protocols and Procedures: Contribution to the first Assessment and Review

of the Effectiveness of the Nagoya Protocol available at http://naturaljustice.org/submission-community-protocols-procedures-review-effectiveness-nagoya-protocol/

misappropriation of a community's resource.[18] According to Natural Justice, while it may be useful to have community protocols in place before a user applies for access, it is "difficult to trigger and sustain a community-led process if there is no concrete aspiration or threat on the horizon."[19]

Developing a BCP can involve quite a lot of effort and expense. Going through the process of reflection and discussion that is required to reach an agreement can help communities to better understand their collective rights over their genetic resources and associated traditional knowledge. This process should ideally be facilitated by individuals or organisations that are trained and have the requisite expertise in BCP development. In this regard, Natural Justice has proven expertise in working with local and grassroots organisations in the development of BCPs.

4.2.5 Resources and reference materials on BCPs

Natural Justice has developed materials to guide the development of BCPs. The tools and materials are listed below with links to where they can be accessed:

- Community Protocols Toolbox: the Toolbox is a collection of methods and instruments that helps communities to develop their community protocol. It is divided into seven sections: an Introduction, five Booklets, and a Leaflet of additional resources. Download here: https://www.boell.de/sites/default/files/uploads/2016/06/toolbox_intro.pdf?dimension1=division_iup
- Natural Justice's Portal on Community Protocols: This portal contains various publications on Community Protocols and other work and projects by Natural Justice in this area. The portal is at: http://naturaljustice.org/community-protocols/
- Biocultural Community Protocols: Articulating stewardship, asserting rights, affirming responsibilities: A publication highlighting the key features and functions of Biocultural Community Protocols. Download here: http://naturaljustice.org/publication/biocultural-community-protocols/

[18] *Ibid*

[19] *Ibid*

5 Institutional arrangements

5.1 Background

The Nagoya Protocol does not require countries to establish a prescribed type of institutional arrangement. Rather, it sets out core and recommended functions and allows flexibility for Parties to decide which entities carry these functions. The right choice for ABS institutional arrangements will vary among countries depending on national laws, institutional capacities and ABS policy objectives.

The Nagoya Protocol outlines a core set of institutions or entities that Parties must establish or assign to support a functional and effective ABS system, including:

National Focal Point (NFP)	A **National Focal Point (NFP)** must be designated to make information available and liaise with the CBD Secretariat.
Competent National Authorities (CNA)	One or more **Competent National Authorities (CNA)** are needed to administer the ABS system.
Checkpoints	One or more **Checkpoints** must be established to support monitoring the utilisation of genetic resources.
Publishing Authority	Parties must assign institutions, normally a **publishing** authority, to directly notify the CBD Executive Secretariat and register information on domestic measures in the ABS Clearing House.

Countries must establish the necessary institutional arrangements to support the implementation of the NP by designating the NFPs and CNAs including focal points and/or competent authorities of IPLCs, and such other entities as appropriate and provide the relevant details to the ABS Clearing House. These institutional obligations are intended inter alia to provide legal certainty for applicants seeking access to GRs and TK.

Other issues that may be considered include:

- Countries 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.
- Countries may establish procedures for NFPs (and CNAs, if appropriate) to share information with counterparts.

Further to addressing these questions, it is important to reflect on existing institutional structures and arrangements and whether they are suitable to support the implementation of the NP. The idea is to assess if the mandates and functions of existing institutional arrangements and structures can be either redesigned or reinforced to meet the requirements set out in the Nagoya Protocol or if new institutions must be established in light of the specific obligations and functions envisaged under the Nagoya Protocol.

5.2 Focusing on the functions and responsibilities of the Competent National Authority (or Authorities)

The Competent National Authority (or Authorities) plays a key role in developing ABS policies and implementing ABS systems – requiring an institution with both technical expertise and administrative experience. Parties can identify which institutions would be most suitable and strategic to take on the CNA functions by developing a clear understanding of national policy priorities and matching these to the institutions with the relevant experience and expertise.

5.2.1 What does the Protocol require?

Parties to the Nagoya Protocol are required to designate one or more competent national authorities on access and benefit-sharing and notify the ABS Clearing House of their details. Article 13(2) outlines the core functions of Competent National Authorities, in accordance with applicable national legislation or policy, as:

- granting access or issuing written evidence that access requirements have been met, and
- advising on applicable procedures for obtaining PIC and establishing MAT.

The Competent National Authority may be in place or new. Where a party designates more than one Competent National Authority, the party must provide information to the CBD Secretariat as to the responsibilities of each CNA including the genetic resources each is responsible for.

Some questions to consider:

- Should the CNA be designated to an existing or new institution?
- Why choose a centralised, single-institution approach?
- Why choose a decentralised, multiple institution approach?

5.2.2 Policy options

Using existing or creating new institutions: Parties may choose to adapt existing institutions or create new ones to fulfil the institutional functions required under the Protocol. When making this choice, Parties should consider whether relevant experience is present in existing institutions, such as knowledge, skills, and available human resources, or whether capacity development will be needed. Budget implications will be relevant in deciding whether to adapt existing institutions or create new ones.

Centralised single institution approach or decentralised multiple institution approach: Parties may choose to take a centralised approach, with one ministry or institution charged with the functions of the CNA. The ministry responsible for environment and natural resources is a common choice, however others have also been selected.

- Advantages: Designating a single authority offers advantages in delineating a clear lead agency on ABS implementation which can avoid roadblocks caused by conflicting institutional interests.
- Disadvantages: Potential that ABS issues may be siloed into one sector, potentially with limited political influence. This choice may fail to recognise the cross-cutting implications of ABS – which requires collaboration of multiple ministries for ABS policymaking and access to broad expertise on to a range of research and development activities in different academic and commercial sectors to inform decisions on access applications. Where multiple CNA are appointed, procedures should be in place to ensure coordination between different institutions and clarity as to respective roles and responsibilities in the ABS process.

5.3 Focusing on the functions and responsibilities of the National Focal Points

Parties to the Nagoya Protocol are required to designate one national focal point and notify the ABS Clearing House as to their details.[20] The primary function of the national focal point is to provide a central source of information for the country on the following:[21]

- Procedures for obtaining prior informed consent and establishing mutually agreed terms in relation to accessing genetic resources.
- Procedures for obtaining prior informed consent (or approval and involvement) of indigenous peoples and local communities and establishing mutually agreed terms in relation to access to traditional knowledge associated with genetic resources.
- Information on competent national authorities, relevant indigenous peoples and local communities, and relevant stakeholders.

The national focal point can be a pre-existing or new institution. To date, Pacific countries have nominated various ministries or government departments as their national focal point with the most common approach being to use representatives from ministries for the environment.

The national focal point is responsible for liaising with the CBD Secretariat including providing relevant information to the ABS Clearing House.

5.4 Designation of checkpoints

Article 17 of the Nagoya Protocol sets out the essential requirements for monitoring of utilisation of genetic resources including information on prior informed consent, the source of genetic resources and the existence of mutually agreed terms.

Under Article 17 of the Nagoya Protocol, parties must:

- Designate one or more checkpoints to collect or receive information regarding the procurement of PIC, the source of genetic resources, the existence of MAT and the use of genetic resources.
- Ask users to provide information at the checkpoint.
- Take action to address non-compliance with this requirement.
- Provide this information, including the Internationally Recognised Certificate of Compliance (IRCC), if available, to the national authorities, the vendor and the ABS Clearing House.

Checkpoints should be established at locations along the value chain (from research to commercialisation) that interact with users in the process of utilising genetic resources in a country. Their role is to *collect or receive information from users related to the utilisation of genetic resources* as described in Article 17 of the Protocol.

The information collected or received by the checkpoints is intended to inform and alert the National Competent Authorities, and especially the provider country authorities, about how their genetic resources are being used. The information collected or received at checkpoints is made available as a file to the ABS Clearing House in a format called a common checkpoint.

[20] Details of the National Focal Point should also be submitted to the Executive Secretary via email or fax. See https://www.cbd.int/abs/keysteps.shtml

[21] Nagoya Protocol art 13.1.

Some possible examples of checkpoints are where a user should go and provide relevant information when undertaking research and development on a genetic resource, when claiming a right in relation to the innovation made from that research and development, or when commercialising any resulting product.

POSSIBLE EXAMPLES OF CHECKPOINTS

- Patent offices
- Financing institutions
- Publications and publishers
- Market authorities such as export regulators
- Regional organisations
- Research institutions

5.4.1 Checkpoint communiqué

After publication in the ABS Clearing House, the checkpoint communiqué (CPC) becomes available to the public and is automatically sent to the following entities, as applicable:

- Designated national authorities as determined in the common format on checkpoints.
- The National Focal Point (NFC) and the National Competent Authority (NCA) of the country providing the genetic resource.
- The person or entity to whom prior informed consent was given, if such information is not confidential.

While each entity receiving the CPC may take steps to determine whether the utilisation that takes place is in accordance with the original permit (or its equivalent) and the provider country's national ABS requirements, the provider country is in the best position, and ultimately responsible, to evaluate the information received in the CPC and to determine whether access to the genetic resource has been properly obtained and utilised and whether this has been done in accordance with mutually agreed terms.

The ultimate purpose of the CPC is to provide usage information to the provider country. Where the CPC contains a reference to an IRCC or national permit (or its equivalent) and information on how the genetic resource is being used, the provider country will be able to search and consult the original national permit (or its equivalent) containing any confidential information and compare this with the information provided in the release and decide whether to take appropriate action or contact the user in case of any doubt or inconsistency.

THE ULTIMATE GOAL OF THE CPC

The ABS Clearing House provides a tool called a checkpoint communiqué to facilitate the transmission of information to all actors involved.

The checkpoint communiqué is a standard form that collects the information on the IRCC or, if not available, the information on the PIC, MAT, or the source of the GR.

It also allows for the collection of information at the point of control regarding the purposes of utilisation of genetic resources at any stage of the ABS value chain (research, development, innovation, and commercialisation).

WHO RECEIVES THE CHECKPOINT COMMUNIQUÉ?

The ABS Clearing House sends a courtesy copy of the checkpoint release, once it has been issued, to the following actors:

- the user of the genetic resources
- the NCA that issued the permit or equivalent document
- the CNA of the supplier country, and
- the authorities of the country in which the control point is located, and which have been designated to receive the information produced by the control point.

6 The ABSCH and cost-effective tools for Monitoring and Reporting

6.1 The functions and functioning of the ABSCH as an exchange platform

The Access and Benefit-sharing Clearing House (ABS Clearing House, ABSCH) is a platform for exchanging information on access and benefit-sharing established by Article 14 of the Nagoya Protocol, as part of the clearing house mechanism of the Convention. The ABS Clearing House facilitates the implementation of the Nagoya Protocol by enhancing legal certainty, clarity and transparency on procedures for access and for monitoring the utilisation of genetic resources along the value chain.

In practical terms, the sharing of information is done through an online platform (https://absch.cbd.int/) designed to enable, primarily Parties, but also non-Parties indigenous peoples and local communities (IPLCs), international and non-governmental organisations, research institutions and businesses to make information available and access information related to access and benefit-sharing.

The main function of the ABS Clearing House is to allow countries to share information on procedures for accessing genetic resources and monitor the utilisation of the resources along the value chain, and therefore contributes to enhancing the legal certainty and transparency that both providers and users of genetic resources and associated traditional knowledge, are looking for.

6.1.1 What does the Protocol require?

To ensure that the ABSCH fulfils its role in adding clarity and transparency in access and benefit-sharing, Parties to the CBD agreed in Article 14 of the Protocol, to make it mandatory for Parties to share certain types of information through the ABS Clearing House, namely:

a. Legislative, administrative and policy measures on access and benefit-sharing;

b. Information on the national focal point and competent national authority or authorities (CNA), and

c. Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent (PIC) and of the establishment of mutually agreed terms (MAT).

In addition to this essential information, the Protocol also identifies other priority types of information to make available through the ABSCH.

a. Measures to inform potential users of traditional knowledge associated with genetic resources about their obligations for access to and fair and equitable sharing of benefits arising from the utilisation of such knowledge (Article 12, paragraph 2);

b. Information provided to designated checkpoints that 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 utilisation of genetic resources, including from internationally recognised certificates of compliance (IRCC), where they are available (Article 17, paragraph 1 (a) (iii)), and

c. Information on capacity building and development initiatives at national, regional and international levels that should be shared through the ABS Clearing House with a view to promoting synergy and coordination on capacity building and development for access and benefit-sharing (Article 22, paragraph 6).

Additional information specified in the Protocol (Article 14, paragraph 3) that Parties can submit to the ABS Clearing House includes:

a. Relevant competent authorities of indigenous peoples and local communities (IPLCs), and information as so decided;

b. Model contractual clauses;

c. Methods and tools developed to monitor genetic resources, and

d. Codes of conduct and best practices.

6.1.2 Application to national context

At the national level Parties are required to make mandatory information available to the ABS Clearing House. There is no obligation for Parties to develop national ABS Clearing Houses. The categories of information in the ABS Clearing House are divided into three major clusters:

6.1.2.1 NATIONAL RECORDS PUBLISHED BY PARTIES AND NON-PARTIES

This category includes national information relevant for the implementation of the Protocol, as well as information that Parties must provide in accordance with their obligations under the Protocol.

The ABS Clearing House currently hosts the following national records:

a. National Focal Point (NFP): Information on the NFP needs to be officially communicated to the Secretariat who will incorporate this information in the ABS Clearing House.

b. Competent National Authority (CNA).

c. Checkpoint (CP).

d. Legislative, administrative or policy measures on access and benefit-sharing (MSR).

e. Information on the permits or its equivalent for constituting an internationally recognised certificate of compliance (IRCC).

f. Interim national report on the implementation of the Nagoya Protocol (INR).

g. Information for the checkpoint communiqué (CPC).

h. ABS national websites and database (NDB).

The submission forms under the national records category allow governments to publish relevant national information for the implementation of the Protocol in a standardised manner for all countries.

More information on the submission of information on permits or their equivalent for constituting an internationally recognised certificate of compliance (IRCC) and information for the checkpoint communiqué (CPC) can be found on the ABSCH website.[22]

To ensure that records are complete, up-to-date and contain no confidential data (Article 14, 6(3)(e) and provide for legal certainty, there are precise procedures in place for publishing these records. Countries are required to designate a single person responsible for publishing all national records in the ABS Clearing House. This function is referred to as publishing authority (PA). The publishing authority can prepare draft records and publish them directly or can designate one or more national authorized users (NAUs) to assist them in preparing draft records for their publication in the ABS Clearing House.

[22] Access and Benefit-sharing Clearing House, *The flow of information through the ABS Clearing House to support monitoring the utilisation of genetic resources,* https://absch.cbd.int/en/kb/tags/monitoring/The-flow-of-information-through-the-ABS-Clearing House-to-support-monitoring-the-utilisation-of-genetic-resources/5be4876871ac250001aadc45

6.1.2.2 REFERENCE RECORDS

This category includes other ABS relevant information but that can be made available by any user with a CBD account (e.g. Governments, representatives of indigenous peoples and local communities, academia, non-governmental organisations, research institutions, private sector, members of civil society, etc.)

The ABS Clearing House currently hosts the following types of reference records:

a. Community protocols and procedures and customary laws.

b. Model contractual clauses, voluntary codes of conduct, guidelines and best practices and/or standards.

c. Capacity building initiatives (projects/ programmes/activities).

d. Virtual library, including capacity building resources.

Examples of resources included in the Virtual Library are:

- Books, articles and publications.
- Awareness-raising and capacity building materials, such as PowerPoints, brochures, videos, guides, toolkits, booklets, etc.
- Case studies.
- ABS agreements, and
- Literature about ABS measures.

Though reference records can be prepared by any user with a CBD account, the Secretariat is responsible for validating all reference records before final publication in the ABS Clearing House.

6.1.2.3 CBD SECRETARIAT MANAGED RECORDS

These records include official notifications, information on meetings, press releases and statements, and news stories.

6.2 Monitoring utilisation: the role of the Internationally Recognised Certificate of Compliance

Article 6(3)(e) requires Parties to issue a permit or its equivalent as evidence of PIC and MAT. This information is to be made available to the ABS Clearing House. Under Article 17(2) such a permit or its equivalent issued and made available to the ABS Clearing House shall constitute an internationally recognised certificate of compliance (IRCC).

The IRCC is a major innovation of the Protocol designed to support monitoring of the utilisation of genetic resources.

6.2.1 What is the importance of IRCCs?

Compliance measures under the Protocol are aimed to address the challenges that arise once genetic resources have left the country where the genetic resources or associated traditional knowledge were accessed (provider country). The IRCC is designed to be a globally authoritative certificate that provides evidence that domestic ABS requirements have been met. It is a tool that can offer proof of legality and create legal certainty.

It should be noted however that there are limitations to IRCCs. While the IRCC provides evidence that domestic ABS requirements have been met, they do not ensure that utilisation of genetic resources and/or associated traditional knowledge is in accordance with the PIC and MAT between the parties.

6.2.2 How are IRCCs established?

Parties are required to make information on permits or their equivalent issued at the national level available to the ABS Clearing House, in order to constitute an IRCC. Parties need to use the IRCC form on the ABS Clearing House to publish information on their permit or equivalent. Once published, an IRCC is issued, with courtesy copies sent electronically to the NFP and CNA of the country responsible for issuing the permits or equivalent, the provider (if not confidential) and the person or entity to whom prior informed consent was granted (if not confidential).

7 Multilateral Benefit-sharing and Transboundary cooperation

The implementation of ABS may raise specific issues in transboundary situations. In the case of Pacific countries, genetic resources and associated traditional knowledge are often not endemic to a particular country or held by a single local community or indigenous people (IPLC). Indeed, genetic resources are often found in more than one country. Similarly, traditional knowledge is often held by different local communities and indigenous peoples and may be in different countries. In this light, a coordinated approach to ABS implementation is appropriate to minimise competition between different countries or IPLCs sharing the same genetic resources, or the same traditional knowledge associated with those resources. Regional coordination and collaboration may be appropriate to develop regional measures or guidelines on transboundary genetic resources and associated traditional knowledge. Such measures or guidelines may set out principles regarding transboundary cooperation and multilateral benefit-sharing. Guidance may be drawn on Material Transfer Agreements used to govern access to the Multilateral System under the International Treaty on Plant Genetic Resources for Food and Agriculture.

ANNEX 1. Depositary Guidelines

These Depositary Guidelines are published by the United Nations.
A copy of the Depositary Guidelines can be accessed at:
https://treaties.un.org/doc/source/publications/NV/2008/Depositary_Guidelines-2008.pdf

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The Legal Counsel presents his compliments to the Permanent Representatives to the United Nations and has the honour to communicate the following in relation to the Secretary-General's requirements applicable to instruments of ratification, acceptance, approval, accession and related instruments to be deposited with him as depositary of multilateral treaties.

With a view to assisting States in increasing participation in the multilateral treaty framework, the Treaty Section of the Office of Legal Affairs, which discharges the functions of the Secretary-General in his capacity as depositary, has prepared the attached *Guidelines.* These *Guidelines address* (i) the Secretary-General's requirements, consistent with treaty law and his practice, applicable to instruments of ratification, acceptance, approval, accession and related instruments, and (ii) the delivery of such instruments to the Secretary-General. **It would be greatly appreciated if Member States could use these *Guidelines* as a reference to ensure the completeness of their submissions.** It is noted that if any instrument does not satisfy the requirements, it may not be accepted in deposit.

To facilitate prompt processing of actions, States are urged to provide **courtesy translations** in English and/or French of instruments submitted for deposit with the Secretary-General in other languages. In this regard, the attention of the Member States is drawn to General Assembly resolutions A/RES/482 (V) of 12 December 1950 and A/RES/54/28 of 17 November 1999 addressing the question of translations.

Additional information on the deposit of binding instruments may be obtained from the *Summary of Practice of the Secretary-General as Depositary of Multilateral Treaties (ST/LEG/7/Rev.1)* and the *Treaty Handbook published* by the Treaty Section. Both publications are available in the United Nations Treaty Collection at the following address: http://untreaty.un.org. The *Treaty Handbook also* contains model instruments.

Also available in the United Nations Treaty Collection are electronic versions of the certified true copies of most of the multilateral treaties for which the Secretary-General is depositary. States are encouraged to make use of these versions.

The Legal Counsel of the United Nations avails himself of this opportunity to renew to the Permanent Representatives to the United Nations the assurances of his highest consideration.

8 February 2008

DEPOSITARY GUIDELINES

Requirements for the deposit of instruments of ratification, acceptance, approval, accession and related instruments

The instrument must contain the following:

The title of the treaty concerned and the type of action clearly identified, consistent with the provisions of the treaty, *i.e., ratification, acceptance, approval, accession, consent to be bound, etc.;*

1. An unambiguous expression of the will of the Government, acting on behalf of the State, to recognise itself as being bound by the treaty concerned and to undertake faithfully to observe and implement its provisions (a simple reference to a domestic statutory provision will be inadequate);
2. If required, the scope of application identified in conformity with the provisions of the relevant treaty.
3. If required, all mandatory declarations and notifications in accordance with the provisions of the relevant treaty.
4. The date and place where the instrument was issued;
5. The signature of the Head of State, Head of Government or Minister for Foreign Affairs or a person acting, *ad interim*, as one of the above authorities;
6. The title of the signatory. In the case of a person acting, *ad interim,* as the Head of State, Head of Government or Minister for Foreign Affairs, the title must indicate that the person is exercising such powers *ad interim*. In this respect, the depositary accepts the following formulations: Acting President, Acting Prime Minister, Acting Minister for Foreign Affairs, President *ad interim*, Prime Minister *ad interim* and Minister for Foreign Affairs *ad interim*;
7. Official seal. This is optional and cannot replace the signature of one of the authorities of State; and
8. Where reservations are intended, such reservations must be signed by the Head of State, Head of Government or Minister for Foreign Affairs or a person acting, *ad interim*, as one of the above authorities. Reservations may either be included in the instrument or, if not, separately signed by one of the authorities of State.

DELIVERY OF INSTRUMENTS TO THE SECRETARY-GENERAL

- The instrument of ratification, acceptance, approval or accession becomes effective only when it is deposited with the Secretary-General of the United Nations at United Nations Headquarters in New York.
- Delivery of such instruments to the Treaty Section directly ensures prompt processing of the action (Secretariat Building Room S-3200).
- Copies of signed instruments may be faxed to the Treaty Section, provided that the original promptly follows (Fax: +1 (212) 963-3693). The depositary will also accept a scanned copy of a signed document transmitted by electronic mail (Email: TreatyRegistration@un.org).

ANNEX 2. Skeleton: elements to consider in developing ABS legislation

IMPORTANT DISCLAIMER: This skeleton is provided for illustration purposes only. The intent is not to provide a template for the law to be developed. This is to provide the national team an indicative idea of issues that may be included in the law. It is not suggested that the list of issues provided is exhaustive, fixed or that the content is pre-determined for use as a template. The national team is expected to use this document as a reference and adapt its content to national circumstances and legislative rules and procedures in place.

CHAPTER 1
GENERAL PROVISION

- General Introduction: the general aim of the law
- Purposes of the law: what the law seeks to regulate
- Scope of application of the law
  - Scope: the law can apply to genetic resources and biological resources and traditional knowledge associated with genetic resources- it is also important to consider broadening the law to also include use of dematerialized information associated with genetic resources to take care of issues related to the use of digital sequence information (DSI).
  - Exemptions: define possible exemptions such as human genetic resources used outside of utilisation prescribed by the law, use of commodities as traded goods as long as they are not used for purposes of the law
- Use of terms and definitions: define key terms such as access, utilisation, National Competent authority etc.

CHAPTER 2
ACCESS REQUIREMENTS

- PIC procedures (information to be provided by the applicant seeking access- might be good to have a form as an annex)
- MAT requirements
- Procedure for obtaining a permit
- Sequence between Permit & MAT (which comes first)

CHAPTER 3
INSTITUTIONAL ARRANGMENTS

- Designated National Competent Authority
- Institutional and administrative arrangements (general)
- Inter-ministerial coordination (this can be done through a circular providing administrative instruction clarifying works and affairs of the ministries who may play a role in the application of the law (permitting agencies, etc.)
- Designation of checkpoint(s) (compliance under art.17 of the Nagoya Protocol)

CHAPTER 4
BENEFIT-SHARING MODALITIES AND PROCEDURE

- How does the law define benefit-sharing?
- Types of benefits (monetary, non-monetary)
- Benefit-sharing agreements/Material Transfer agreement

Several options possible:

- Including a general obligation in the legislation
- Listing of potential benefits and guidance for the negotiation of MAT
- Defining benefits based on national priorities and goals (conservation, community empowerment, rights of indigenous peoples and local communities, etc.).

CHAPTER 5
OFFENCES, PENALTIES, SANCTIONS AND FORFEITURE

CHAPTER 6
FINAL PROVISIONS

ANNEX 3. Elements to consider to be included as part of implementations rules and regulations

Since regulations are directly applicable and are binding in their entirety, their provisions should be drafted in such a way that the addressees have no doubts as to the rights and obligations resulting from them. In the ABS context, the overall objective of the regulation is that users of genetic resources and associated traditional knowledge are aware of applicable access procedures and requirements in relation to benefit-sharing.

PART I PRELIMINARY

I. Title

II. Object of the Regulations

In this section, the purpose of the regulations should be spelled out. This part should make reference to the sections of the primary legislation that need to be regulated.

III. Application of the regulations

This section must specify the scope of application of the Regulations. The following is an example of what could be included in the scope of the regulations.

- Genetic resources and information and data on genetic resources
- Traditional knowledge associated with genetic resources
- Information and data associated with genetic resources

IV. Definitions

In the Regulations, use of terms and definitions must be consistent with those contained in the primary legislation. A possible formulation: 'In these Regulations, unless the context otherwise indicates, a word or expression defined in the Act has the same meaning.'

PART II ACCESS REQUIREMENTS AND MODALITIES

I. Prior informed consent requirements (Step 1 before the granting of a permit)

Regulations must provide clear information on how to apply for PIC stating that prior informed consent is needed before a permit may be granted.

1. **Obligation for applicants to disclose information:** Applicant must disclose all material information relating to the access sought to the relevant stakeholders and on the basis of that disclosure, has obtained prior consent of the stakeholder to use any of the stakeholder's knowledge of or discoveries about traditional knowledge
2. **Obligation to sign a benefit-sharing agreement:** Further, the applicant and stakeholder involved must negotiate and conclude a benefit-sharing agreement.

II. Modalities in relation to permits (Step 2)

Regulations must specify procedures and requirements for obtaining a permit from the issuing authority (Competent National Authority). The following issues could be addressed in this regard:

- How and where to submit notifications or permit applications
- Cross reference to Application forms
- Assistance by the permit issuing authority
- Consultation between issuing authority and relevant stakeholders

- Issuing authority right to access to information
- Criteria for evaluating permit applications
- Circumstances for refusal of permits
- Communication of decision on permit application by the issuing authority.

In summary, permits may generally be issued if the following conditions have been met:

- The relevant providers have been identified and consulted;
- There has been disclosure of relevant information to all the providers that have been identified;
- The applicant has obtained the prior informed consent of any person, including any Government body, providing or giving access to the genetic resources or associated traditional knowledge to which the application relates, and mutually agreed terms have been entered into with such providers.

The regulations must also contain information on what will happen after permit application. As just an example, after having reached a decision on an application for a permit an issuing authority must undertake the following

a. notify the applicant of the decision in writing within XXX working days after making the decision;

b. if the application was approved, issue the permit, amend the permit, or renew the permit, as the case may be, within XXX working days after making the decision;

c. if the application was refused -

   i. notify the applicant of the decision in writing within XXX working days after making the decision;

   ii. give reasons for the refusal; and

   iii. inform the applicant's right to appeal against the decision

The Competent National Authority must monitor all permit holders to ensure compliance with permit conditions.

PART III INSTITUTIONAL ARRANGEMENTS

- Generally the primary legislation will have made provision for the designation of the Competent National Authority(ies)
- The regulations must set out the powers, functions and responsibilities of the designated Competent National Authority(ies)

PART IV BENEFIT-SHARING REQUIREMENTS

- Minimum requirements for mutually agreed terms: the minimum requirements for mutually agreed terms must be set out in the Regulations.
- The Benefit-sharing Agreement format outlines the minimum terms that should be agreed upon by parties entering into an agreement. This requirement includes the following key areas amongst others: XXX
- Sharing of benefits and the types of benefits to be shared can also be specified (without being too prescriptive (ex. payments of benefits (when, where, how and if monetary how much will be paid))

PART V GENERAL

I. Offences

- This part of the regulations could spell out what would happen in case of breach of the Act or Regulations. The following are examples of situations that could lead to the application of offences:
  1. Undertaking bioprospecting activities without a permit
  2. Export of genetic resources without authorisations
  3. Using traditional knowledge without the consent of rights holder
  4. Etc.

II. Penalties

This should set out applicable penalties

III. Transitional measures

- The transitional measures are intended to ensure a smooth transition towards the full requirements of the new regulations.
- The measures aim to avoid disruption potentially associated with the move to a new regulatory regime.

IV. Short title and commencement

ANNEX 4. Key Terms in Access and Benefit-sharing Arrangements

Introduction

Prior informed consent and mutually agreed terms are key concepts under the Nagoya Protocol. The terms and conditions in any access and benefit-sharing agreement should be developed on a case by case basis to ensure that they are appropriate to, and reflect, the arrangement between the user and provider party. While there is no 'one-size-fits-all' template agreement, a number of resources may be of use when developing access and benefit-sharing agreements. These include resources developed by the ABS Capacity Development Initiative, the World Intellectual Property Organisation, and samples collected and shared on the ABSCH and WIPO databases.

- *The ABS Contract Tool: Version 2.0* (The ABS Capacity Development Initiative) https://absch.cbd.int/api/v2013/documents/B1C6A46D-5EC6-E5BA-45A2-2F3E406DCB49/attachments/ABS_Contract-Tool_EN_ANSICHT.pdf
- WIPO, *A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements* https://www.wipo.int/publications/en/details.jsp?id=4329
- WIPO database of sample and actual ABS contracts https://www.wipo.int/tk/en/databases/contracts/list.html
- ABSCH Model Contracts resources https://absch.cbd.int/search/referenceRecords?schema=modelContractualClause

Specific terms and conditions should be incorporated or considered in every access and benefit-sharing agreement and adapted appropriately. This section outlines some key terms and important considerations to take into account when developing an access and benefit-sharing agreement to reflect prior informed consent and mutually agreed terms.

Disclaimer

The following is provided for general information purposes only and does not constitute legal advice. You should seek advice from a legal practitioner or advisor before entering into any negotiations or contract setting out mutually agreed terms of access to GRs and benefit-sharing.

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. The content set out in this Annex 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.

Parties to the Agreement

When entering into an access and benefit-sharing arrangement, it is important to be clear about who you are contracting with. Is the user party an individual, a company, or a public institution, or is more than one user party involved? Identifying the user party involved will influence the types of terms and conditions you may have in your access and benefit-sharing agreement.

Consider researching the user party further. What is their business? For example, you may have more questions for the user party if they tell you they want to carry out research activities, but they regularly engage in commercial activities. Identify who has ultimate ownership of the business or organisation as you may be dealing with a subsidiary of a much larger company. Consider also whether the proposed user company has a relationship with other organisations. This may influence your decision on whether you want to continue to engage with them. You may also wish to search the user party on company registers or even search whether the user party has patents by searching a patent register such as PATENTSCOPE,[23] Patent Lens,[24] or Google Patents.[25] You might find that the user party is active in patenting in the relevant field (e.g. pharmaceutical development), which may influence your decisions in agreeing on access or benefit-sharing.

When it comes time to sign the access and benefit-sharing agreement, make sure that the party you are dealing with has the power to enter into a contract and sign on behalf of the user party.

[23] https://www.wipo.int/patentscope/en/

[24] https://www.lens.org/

[25] https://patents.google.com/

Subject Matter

Your access and benefit-sharing agreement should clearly define the subject matter of the agreement. Will the user party simply be accessing and taking samples of genetic resources? Or will they be learning about processing genetic resources or traditional knowledge associated with the genetic resources? Will the agreement cover derivatives or synthetic versions of the genetic resources in question?

Scope of Agreement

The scope of your access and benefit-sharing agreement should also be clearly defined. Consider the following important details:

Term of the Agreement: Will the agreement cover initial sampling only, or will it cover a more extended period? Specify when the agreement commences and when it will end.

Activity Covered: What kind of activity is covered by the access and benefit-sharing arrangement? Is it for research or non-commercial purposes only? Is commercial activity allowed? Are there different terms and conditions applicable for different types of activities? Consider also what will happen if the anticipated activity changes. For example, you may initially intend for the agreement to only cover research or non-commercial activity, but this may change if research demonstrates commercial potential. Should the user party be required to obtain new written consent to engage in commercial (or other non-anticipated) activity? Will the user party need to negotiate new mutually agreed terms to cover commercial activity?

Exclusive Rights: Sometimes, a user party will ask for exclusive rights. This means that they will obtain rights to engage in activity to the exclusion of all others. Consider whether this is appropriate in your circumstances. You may have a number of user parties you want to engage with. Traditional or customary use of genetic resources and associated traditional knowledge should remain unrestricted.

Access

The agreement should specify what genetic resources and associated traditional knowledge (if any) can be accessed and under what conditions. Topics to consider include:

- What specific genetic resources and/or traditional knowledge can be accessed? Consider identifying by common and scientific name.
- What locations can be accessed by the user party?
- How much can the user party take? Consider appropriate limits on the number of samples or volume.
- Will the user party be required to report on samples taken? How often should they report? What should those reports contain?
- Consider whether the user party should be required to provide samples to a national depository or institution.
- Are there any limits on the purpose of access? Is it purely access for scientific research? Does the access right extend to harvesting resources for commercial purposes?
- Will the user party be able to export collected samples?
- What will be the consequences if the user party damages the environment? Will they be required to remediate the damage? Pay damages? Could the agreement be terminated in those circumstances?

Benefit-sharing

The access and benefit-sharing agreement should clearly set out the benefits to be shared, including details on the types of benefits, the triggers for benefit-sharing, the beneficiaries, and the reporting requirements.

The Annex to the Nagoya Protocol identifies the following types of monetary and non-monetary benefits:

1. MONETARY BENEFITS may include, but not be limited to:

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 commercialisation;
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.

2. NON-MONETARY BENEFITS may include, but not be limited to:

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 Party providing genetic resources;
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;
h Institutional capacity-building;
i Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
j Training relating to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
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 the Party providing genetic resources;
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 intellectual property rights.

Monetary Benefits

Royalties are a common form of benefit-sharing where it is anticipated that the use of the genetic resource may result in a commercial outcome such as in pharmaceutical development. However, commercialisation outcomes may be uncertain, and the timeframes for product development are long, particularly in the pharmaceutical industry. This may mean that royalty payments are delayed or may not eventuate if product development is unsuccessful. You may want to consider balancing royalties with other upfront or milestone payments to ensure that some monetary benefits are payable earlier and can be realised by the community.

Generally speaking, for monetary benefits, you will need to be specific as to:

- How the benefits will be calculated. Is there a specific formula or schedule of payments? What records will the user party need to keep to demonstrate how the benefits have been calculated? For example, royalties can be calculated as a percentage of sales. What records of sales will the user party need to show?
- When the benefits will be payable. Are there to be regular payments (quarterly, annually)? Will you need to issue an invoice to the user party for them to make payment?
- How the benefits will be paid. Will they be paid into a particular bank account?
- Who will receive the benefits. Will the benefits be paid directly to the government or to a local community?

Non-monetary

Non-monetary benefits are also valuable and may be helpful to address critical areas of development or need. Again, the key is to be specific as to the details. If the user party is to support technology transfer, what exactly will they be required to provide and when? Is it limited to research results or something further? If equipment is to be provided as part of the benefit-sharing, be specific as to the details, including what will be delivered (model, number, size etc.) and the dates it will be delivered. If funding for students is to be provided, be specific as to the number of students, the type of study, and who will be responsible for arranging the logistics.

Intellectual Property

Access and benefit-sharing arrangements may result in inventions or other outcomes that could be subject to intellectual property rights. The access and benefit-sharing agreement should be clear about how such rights will be managed. The agreement should be clear as to whether the user party can apply for intellectual property rights arising out of utilisation of the genetic resources and associated traditional knowledge.

Rights in research results: The terms of the access and benefit-sharing agreement should cover who owns the intellectual property rights in the research results. This includes the right to publish the research results.

Rights in inventions: The access and benefit-sharing agreement should also cover who may apply for intellectual property rights in relation to an invention arising out of the use of the genetic resources and/or associated traditional knowledge and who will own the intellectual property rights in any inventions. Consider whether the user party may apply for intellectual property rights in any resulting invention and any conditions that may be imposed on such applications. Consideration should be given to the different ownership models that may

be appropriate. Co-ownership of intellectual property rights may be an option, or one party may own the intellectual property rights and provide a licence to the other party for specific purposes.

The access and benefit-sharing agreement should detail the following:

- Who will own the intellectual property rights? Will the parties be co-owners? Will any relevant Indigenous or local community members be named as co-inventor?
- Who will be responsible for the costs of applying for intellectual property rights, including application fees, renewal fees, and legal fees?
- Who will be responsible for making decisions regarding intellectual property protection, such as where applications for protection should be filed?
- Can the intellectual property rights owner assign or licence their rights to a third party? If so, are there any restrictions on their rights to do so?

Joint intellectual property rights: Caution should be taken in agreeing to joint intellectual property rights. While this may be a good option, the terms of the access and benefit-sharing agreement should be clear as to who has the right to exploit the intellectual property rights, the terms on which they may be exploited and whether they can be licensed or assigned and on what terms. Many commercialisation experts caution against joint ownership of intellectual property.[26]

[26] See, e.g., the views of patent specialists expressed in John Hagedoorn, 'Sharing intellectual property rights – an exploratory study of joint patenting amongst companies' (2003) 12(5) *Industrial and Corporate Change 1035, 1045-1046.* See also D. L. Marchese 'Joint ownership of intellectual property' (1999) 21(7) European Intellectual Property Review 364. The Model Contract provided by IP Australia as part of the IP Toolkit states that joint ownership 'should only be selected if the Parties are willing to manage the Project IP together for the long term and accept the risk that this may result in additional resourcing and expense and increase the potential for disputes to arise. IP Australia, Australian IP Toolkit for Collaboration: Model Contract (Web Page, September 2015) [Part 3, Contract Details, cl 14.1] https://www.ipaustralia.gov.au/sites/default/files/ip_toolkit_model_contract_0_0.pdf.

For example, the legislation dealing with co-ownership of patents are not consistent across jurisdictions. This means that joint owners of a patent may be subject to different requirements depending on where the patent is granted, an issue that is further complicated where patents are obtained in multiple jurisdictions. While many jurisdictions allow co-owners to exploit the patent without accounting to other co-owners, some jurisdictions allow a co-owner to assign their interest or even, in some cases, grant an exclusive licence without the consent of the other co-owners.[27]

Confidentiality

The protection of confidential information should be considered before entering into any discussions with a third party. Non-disclosure agreements may be used to protect any information you disclose to a potential user party in pre-contract discussions and negotiations.

Important issues to consider include whether either party will have the right to publish details in academic journals or other formats? Universities and other research institutions often have obligations to make research information publicly available. The access and benefit-sharing agreement should set out the conditions on any publication, including whether a party has the right to review and/or approve any potential publication. Consider whether any publication should acknowledge the involvement and rights of the government or Indigenous peoples or local community. It may be useful to request that copies of any publication should be provided free of charge to a national depository.

It is important to note that publication may impact the potential grant of intellectual property rights, especially patents. This is

[27] For example, Canada, France, Germany, Malaysia, and the United States of America allow a joint owner to assign their interest in the patent without the consent of the other joint owner(s). See Philip Mendes, 'The Economic and Bargaining Implications of Joint Ownership of Patents' (2015) *The Licensing Journal 1, 2.*

because patents must be 'novel' to be eligible for protection and a disclosure in a publication can impact the assessment of 'novelty'. Therefore it is important to ensure that any publication plans do not limit the ability to apply for patent protection in future.

Change of Control

Change of control or ownership of the user party is a major risk that should be considered and dealt with in any access and benefit-sharing agreement. The objectives of a new owner may be different from that of the original user party. It may be appropriate to include provisions in any access and benefit-sharing agreement that restrict the ability of a party to assign the agreement to a new owner. For example, it may be possible to include a contract term that requires the prior informed consent of the provider party before any change in control of the user party or to provide a right to terminate the agreement in the event that the party undergoes a change in control or ownership. The trigger for such provision (requiring prior informed consent or allowing for termination) may be where the user party undergoes a substantial change in management or shareholding that results in a change in control of the user party.

Third Party Transfer

Similarly, transfer of samples, research results or intellectual property rights to a third party other than the user party poses a significant risk. The new third party may have different objectives, and they are not subject to the terms of the original access and benefit-sharing agreement. This risk may be addressed by incorporating provisions into the access and benefit-sharing agreement that deal with the transfer of samples, research results and intellectual property rights. For example, is a notice of such transfer required? Is the user party required to obtain prior informed consent from the provider party before such third party transfer? Is there any restriction on rights or use by the third party? Is the third party required to agree to terms and conditions similar to those agreed to by the user party?

It is important to note that the process of tracking and managing the transfer of samples, research rights and intellectual property rights may facilitate compliance with the terms of the Nagoya Protocol.

Breach

It is essential that the access and benefit-sharing agreement clearly identify the circumstances that will be considered a breach of the agreement. This should be set out in the agreement with clear timelines or trigger points. For example, would taking samples outside of those permitted within the agreement be considered a breach? What about a failure to pay benefits? Would the user party be in breach if they were late in paying benefits by one day, or will there be a period of time available to correct the failure to pay?

Termination

Similarly, the provisions dealing with termination should be very clearly set out, including triggers for terminating the agreement and the relevant time frames. For example, some agreements provide a period of time for the parties to attempt to remedy a breach before allowing for termination (such as 30 days). Other breaches of an agreement may be grounds for immediate termination; however, these are usually restricted to serious circumstances or where the breach cannot be remedied, such as where the party becomes insolvent or is bankrupt or wound up.

Dispute Resolution

Consider how any disputes arising out of the access and benefit-sharing agreement should be resolved. Are the parties allowed to go to court in the event of a dispute immediately, or should they be required to engage in some form of alternative dispute resolution such as mediation or arbitration? If there are alternative dispute resolution proceedings, what rules will apply? How will the arbitrator/mediator be appointed? Where will it be conducted? Who will pay? Will alternative dispute resolution be binding, or will the parties still be able to go to court after if they are unsatisfied?

Enforcement

What law will govern the access and benefit-sharing agreement? This could be the law of the provider country or the law applicable in the jurisdiction where a dispute arises. Consider that there may be difficulties in enforcing an agreement against a party not present in your jurisdiction. It is important to investigate what laws (if any) are in force in the user country that can uphold access and benefit-sharing requirements.


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