An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing

Thomas Greiber, Sonia Peña Moreno, Mattias Åhrén, Jimena Nieto Carrasco, Evanson Chege Kamau, Jorge Cabrera Medaglia, Maria Julia Oliva and Frederic Perron-Welch in cooperation with Natasha Ali and China Williams

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Foreword

On 29 October 2010, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity was adopted in Nagoya, Japan. Being a supplementary agreement to the Convention on Biological Diversity it is one of the most important multilateral environmental treaties recently adopted.

The objective of the Nagoya Protocol is to set an international, legally binding framework to promote a transparent and effective implementation of the ABS concept at the regional, national and local level in the future. IUCN considers ABS, the third objective of the Convention, to be a concrete example for valuing biodiversity and its ecosystem services, and for taking proper account of this value as a prerequisite for conservation and sustainable use. Therefore, IUCN welcomes the adoption of the Protocol following six years of negotiations which marks an important step towards the implementation of the Convention on Biological Diversity.

In this publication, the IUCN Environmental Law Centre and the IUCN Global Policy Unit proudly present the results of a one-and-a-half year process of co-operation and consultation during which an Explanatory Guide to the Nagoya Protocol was developed. This ABS Guide is the fourth in a series of IUCN Guides to promote greater understanding of particular international environmental agreements. It is the product of a fruitful, constructive, and harmonious collaboration with ABS experts from different regions and international institutions who engaged with IUCN in the writing and reviewing of this Guide. IUCN hopes to offer through this Guide an adaptable tool for future ABS capacity-building and awareness raising initiatives, as well as an important reference for countries in their efforts to implement the Nagoya Protocol and operationalize ABS in practice.

We are very grateful to the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) for its long-standing support of the IUCN Environmental Law Centre and the provision of financial support for the development of this Guide. Furthermore, we would like to express our gratitude to the Ministry of Foreign Affairs of Denmark (DANIDA) for co-funding the translations of this Guide into French and Spanish.

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The development of the Guide started with an inception and coordination meeting held at the IUCN Environmental Law Centre in Bonn, Germany in May 2011. This event brought together a small team of co-authors and advisors who agreed on the process of collaboration, the objective of the Guide as well as its outline. Initial constructive discussions on how to explain the different provisions of the Nagoya Protocol were held at this occasion among the team members. The results of this inception meeting and the initiative to develop an IUCN Explanatory Guide to the Nagoya Protocol were presented during the first meeting of the Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol which was held from 5 to 10 June 2011 in Montreal, Canada.

The first draft of the Guide was then prepared in the following months. It was presented at a side event during the 15th meeting of the Subsidiary Body on Scientific, Technical and Technological Advice of the Convention on Biological Diversity held from 7 to 11 November 2011 in Montreal. This event was the starting point of an extensive consultation process, producing at each step a refined version. Throughout the process, the drafts were made publicly available in order to support ongoing capacity-building and awareness raising activities, as well as countries' efforts to ratify the Protocol. Furthermore, the wide dissemination of the draft versions triggered additional feedback from readers that helped to further improve this publication.

The cornerstones of the consultation process were two workshops in December 2011 and March 2012, as well as an electronic review held during February 2012. At each step, different draft versions of the Guide were examined in order to identify contentious and unclear issues and to resolve open questions. In particular, the two review workshops provided an opportunity for fruitful discussions among international legal and policy experts on how to address specific comments received from external reviewers, and how to move forward in improving and finalizing the Guide.

The "pre-final" draft was made available at the second meeting of the Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol which was held from 2 to 6 July 2012 in Delhi, India. The final publication was then launched at the 11th meeting of the Conference of the Parties to the Convention on Biological Diversity which took place in Hyderabad, India, from 8 to 19 October 2012.

As a result of this, many people in their personal capacities have assisted in the preparation of the Guide, not only by participating in the review process described above, but also by providing thoughtful verbal or written comments. All of the comments received were carefully considered by the editors and co-authors in the preparation of the final text. We would like to acknowledge all those contributions, and especially thank the following individuals (in alphabetical order) who acted as advisors and main reviewers of the Guide in their personal capacity: Kabir Bavikatte, Françoise Burhenne-Guilmin, Geoff Burton, Juanita

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List of Acronyms

ABNJ	areas beyond national jurisdiction
ABS	access and benefit-sharing
ACP	Africa, the Caribbean, and the Pacific
AHWG	Ad Hoc Open-ended Working Group
ATA	Antarctic Treaty Area
ATS	Antarctic Treaty System
BBNJ	biological diversity beyond areas of national jurisdiction
BCP	bio-cultural community protocol
BMZ	Federal Ministry for Economic Cooperation and Development (Germany)
CBD	Convention on Biological Diversity
CGRFA	Commission on Genetic Resources for Food and Agriculture
CH	Clearing-House
CHM	Clearing-House Mechanism
CIIC	Co-Chairs Informal Inter-regional Consultation
CNA	competent national authority
COP	Conference of the Parties
ECJ	European Court of Justice
EU	European Union
FAO	Food and Agriculture Organization
GEF	Global Environment Facility
GTLE	Group of Technical and Legal Experts on Concepts, Terms, Working Definitions and Sectoral Approaches
GR	genetic resource
ICG	Informal Consultative Group
ICNP	Intergovernmental Committee for the Nagoya Protocol on ABS
IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IHR	International Health Regulations
ILC	indigenous and local community
INBio	National Institute of Biodiversity (Costa Rica)
ING	Interregional Negotiating Group
IPR	intellectual property rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN	International Union for Conservation of Nature
JPOI	Johannesburg Plan of Implementation
MAT	mutually agreed terms
MEA	multilateral environmental agreement
MOP	meeting of the Parties
NBSAP	National Biodiversity Strategy and Action Plan
NFP	national focal point
NPIF	Nagoya Protocol Implementation Fund
PIC	prior informed consent
PIPF	Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits

PGRFA	plant genetic resources for food and agriculture
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice
SMTA	Standard Material Transfer Agreement
TK	traditional knowledge
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCED	United Nations Conference on Environment and Development
UNCLOS	United Nations Convention on the Law of the Sea
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples
UNEP	United Nations Environment Programme
UNGA	United Nations General Assembly
UPOV	International Union for the Protection of New Varieties of Plants
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WSSD	World Summit on Sustainable Development
WTO	World Trade Organization

Structure and Purpose of this Guide

The series of Explanatory Guides developed by the IUCN Environmental Law Centre[1] seeks to address a critical need within international law of conservation and sustainable development – to provide neutral expert analysis of the text of critical international documents. It focuses primarily on new international instruments, providing an explanation of their contents and relationship with other key instruments, policy documents and action plans. The Guides are intended as reference documents for anyone desiring more information on these key instruments and possible steps for their implementation.

The main goal of this Explanatory Guide is to facilitate the understanding of the legal obligations of the Parties under the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity. The target audience of this Guide is broad, including lawyers as well as non-lawyers; policy-makers as well as the private sector and civil society, including everyone who did not sit at the negotiation table and is trying to understand the Nagoya Protocol on ABS. It therefore attempts to investigate and explain the origin and meaning of the provisions of the Protocol in an unbiased and "simple" manner, avoiding too complex scientific, legal and technical jargon.

The Guide begins with an introduction which addresses the subject of ABS. This section provides an overview of the ABS concept, explains the general challenges to the implementation of ABS and recalls the negotiation history. Furthermore, it summarizes the Nagoya Protocol, as well as its relationship with other ABS-related instruments and processes.

The main part of this Guide is the "commentary" to the Protocol's provisions. Here, each Article as well as the Annex of the Protocol is analysed and explained. The sub-section "Background" aims to give a brief introduction to and summary of the Article, including an explanation of the title of the provision, if necessary. In the sub-section "Explanation", the emphasis is on outlining the main obligations and/or commitments; clarifying to whom they are addressed – provider and/or user country – and what exactly is expected from the addressee. This section provides also information on concepts, key terms and their possible understandings. References to the negotiation history of a particular text, concept, or term are only made, if this is perceived to be helpful to improve the understanding. Furthermore, where there are ambiguities or issues which are left unresolved in the text of a provision, some guidance as to possible interpretation is provided. However, this Guide does not purport to provide an authoritative interpretation of the text of the Protocol, and other interpretations are possible. In addition, specific interpretations may be agreed and adopted by the Parties to the Protocol in the future as they consider its provisions further.

The final section of the Guide – "Possible Ways Forward" – aims at providing guidance on what is needed to make the Protocol operational. It explains possible options for developing ABS policies and strategies, key components of ABS legislative, policy or administrative measures, as well as ABS institutions. It is important to note that this section is not intended as a detailed guide on how to implement the Nagoya Protocol on ABS at the regional, national and/or local level but rather aims to provide some guidance into possible ways to move forward towards the implementation of the Protocol once it enters into force.

1 Currently, the series includes Explanatory Guides on the Convention on Biological Diversity, the Cartagena Protocol on Biosafety, and the International Treaty on Plant Genetic Resources for Food and Agriculture.

The Guide concludes with a bibliography which provides a list of selected writings on ABS and the Nagoya Protocol, largely from academic books and journals, as well as a number of important supplementary materials:

- 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity – The provisions of the Protocol are reproduced throughout the Guide, but the full text is provided here for ease of reference.
- 2002 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising from their Utilization – The Guidelines were recognized as a useful first step of an evolutionary process in the implementation of relevant provisions of the Convention on Biological Diversity related to ABS.
- 1992 Convention on Biological Diversity – As explained in the Introduction, the 1992 Convention is the parent Convention of the Protocol and contains a number of provisions which remain directly applicable or relevant to its implementation.
- Decision VII/19 of the Conference of the Parties to the Convention on Biological Diversity – This decision provided the mandate for the negotiation of the Protocol.
- Decision X/1 of the Conference of the Parties to the Convention on Biological Diversity – In this decision the Conference of the Parties to the Convention on Biological Diversity adopted the Nagoya Protocol on ABS. The decision also makes provision for interim arrangements, including preparatory work by the Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol.

Introduction

Introduction

The Convention on Biological Diversity (CBD) was adopted on 22 May 1992 and opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development (UNCED). On 29 December 1993, the CBD entered into force. As of July 2012, the CBD had 193 Contracting Parties,[1] making it an almost universally accepted international agreement.

During the negotiations of the CBD, and since its entry into force, perhaps no other subject has been as controversial as the issue of access and benefit-sharing (ABS). Controversy has stemmed from the implications of ABS for, amongst other topics, State sovereignty, economic development, indigenous and local communities, scientific research, the industries dependent on genetic resources and traditional knowledge associated with genetic resources, and the conservation and sustainable use of biological diversity. Furthermore, lack of awareness regarding ABS, widespread misunderstandings about its scope and legal principles, and gaps in States' policies and legislation have hampered the efficient and effective implementation of ABS in practice.

The aim of this Introduction is to:

- provide an overview of the concept of ABS under the CBD;
- explain the main challenges to its implementation;
- outline the history of the ABS negotiations; and
- give a brief introduction to the Nagoya Protocol as well as its relationship with other international instruments and processes.

A. Overview

The CBD is the first attempt by the international community to address biological diversity as a whole in a global legal instrument. It is based on a broad ecosystem approach rather than the sectoral approach (focusing on specific species, ecosystems, or sites) that is characteristic of other international conservation agreements. Indeed, Article 2 of the CBD defines biological diversity (biodiversity) as the variability among living organisms from all sources, occurring at three levels: diversity within species (genetic diversity),[2] diversity between species, and diversity of ecosystems.

The CBD addresses not only conservation of biodiversity per se but also related socio-economic aspects, which makes it a milestone in the field of environment and development. According to Article 1, the CBD has three main objectives:

- conservation of biological diversity;
- sustainable use of its components; and
- fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

1 For further information, see www.cbd.int/convention/parties/list/.

2 Genetic diversity refers to the frequency and variability of the gene pool within a single species. It includes the variation both within a population and between populations.

The broad CBD objectives are a consequence of the opposing interests of developing and developed countries (the so-called North-South divide) that characterized UNCED and its preparatory meetings. Throughout this process, many States, particularly from "the South", were not willing to accept a CBD that focused only on biodiversity conservation. Instead, the majority of developing countries pushed for the "Rio package deal" – that is, they made their support for conservation obligations conditional on more directly use-oriented provisions, as well as on obligations and measures on three types of access:[3]

- access to genetic resources subject to national authority;
- access to relevant technology, including biotechnology; and
- access for the providing States to benefits ultimately gained from the use of genetic material in the development of biotechnology (Glowka et al., 1994, p.5).

In the end, access to genetic resources and the fair and equitable sharing of the benefits arising out of their utilization – in short, ABS – was introduced as the third objective of the CBD. It was meant to take into account the need to share the costs as well as the benefits of biodiversity conservation between developed and developing countries and to find ways and means of supporting practices and innovations by indigenous and local communities.

The ABS Concept

In order to better comprehend the concept of ABS, it is important to understand the context within which genetic resources are provided and utilized.

Genetic resources – whether from plant, animal, or micro-organisms – may be used for different purposes (e.g., basic research or commercialization of products). Users of genetic resources and/or traditional knowledge associated with genetic resources include research institutes, universities, *ex-situ* collections, and private companies operating in a wide range of sectors, including the pharmaceutical, biotechnology, seed, crop protection, horticulture, cosmetic and personal care, fragrance and flavour, botanicals, and food and beverage industries (Laird and Wynberg, 2008, p. 8).

Providing these users with international access to genetic resources for use in research and development, including commercialization, and sharing the benefits of such utilization has the potential to be beneficial for social and economic development. At the same time, it offers both a concrete example for valuing biodiversity and its ecosystem services in practice and an economic tool to take proper account of this value. This again is considered to be a prerequisite for conservation and sustainable use.

Table 1: Market Sectors and the Importance of Genetic Resources[4]

Sector	Size of total market in 2006	Importance of genetic resources
Pharmaceutical	US$ 640 billion	20–25% derived from genetic resources

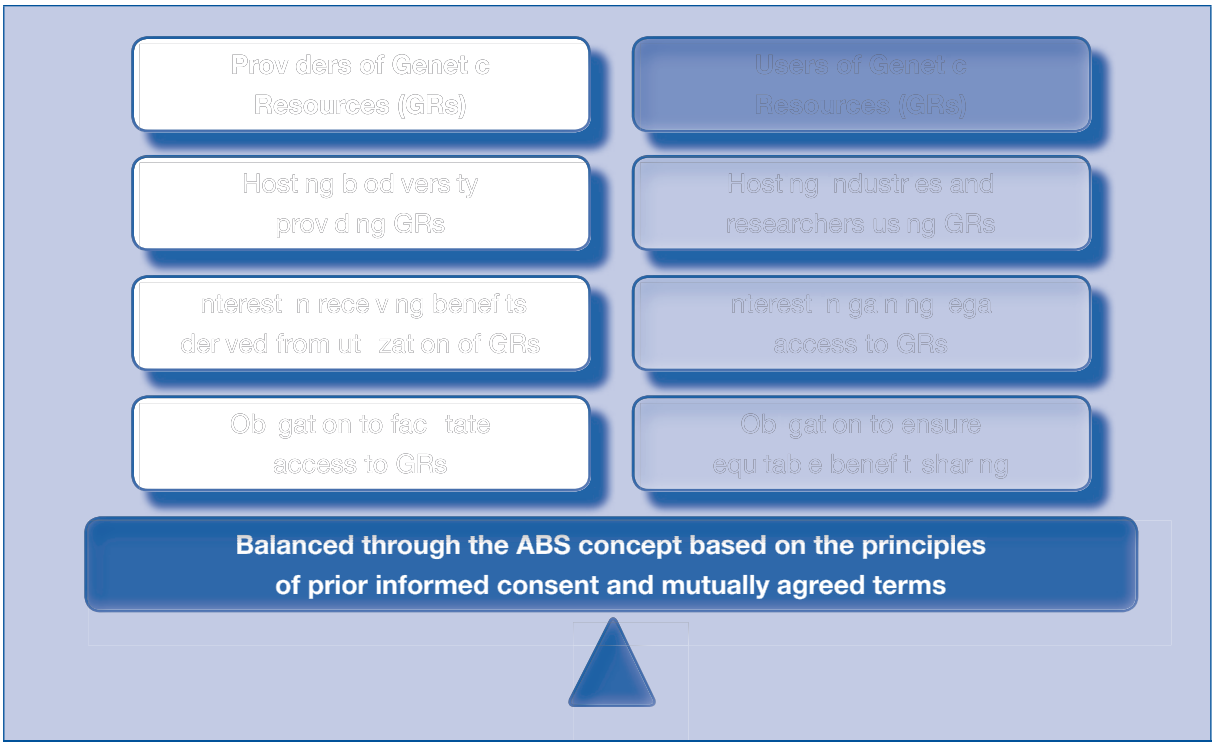
3 Interestingly, at the tenth meeting of the Conference of the Parties to the CBD, developing countries pushed again for a "package deal" by making their agreement to the Strategic Plan for Biodiversity 2011–2020 and the Strategy for Resource Mobilization conditional on the adoption of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.

Sector	Size of total market in 2006	Importance of genetic resources
Biotechnology	US$ 70 billion from public companies alone	Many products derived from genetic resources (enzymes, micro-organisms)
Agricultural seeds	US$ 30 billion	All derived from genetic resources
Personal care, botanical, and food and beverage industries	US$ 22 billion for herbal supplements US$ 12 billion for personal care US$ 31 billion for food products	Some products derived from genetic resources: represents "natural" component of the market

Source: Based on ten Brink, 2011, p. 17.

Often, although not always, innovation based on genetic resources relies on having physical access to genetic material. While many States have historically controlled access to their biological resources through legislation or regulatory requirements, only few have also controlled access to genetic resources (Glowka, 1998, p. 1). It is important to note that there has been a lot of discussion on what is a genetic resource, how to determine when a resource being accessed is genetic or biological, and whether it is the use that determines if a resource is accessed as a genetic resource or a biological resource.

Figure 1: Visualization of the "Simplified" Relationship between ABS Stakeholders



As a consequence, before the CBD entered into force, access to genetic resources, as well as to traditional knowledge associated with genetic resources, was freely available in most parts of the world.

4 Note: The following figures provide "ballpark" estimates for various categories of products derived from genetic resources. It is important to understand that the markets are not entirely based on genetic resources.

This often led to the exploitation, utilization, and/or monopolization of such resources and knowledge without sharing any benefits with the countries providing the resources or the holders of the knowledge. As this situation was perceived to be inequitable, the CBD introduced the ABS concept, with Article 15 containing the main ABS obligations. Article 15 of the CBD tries to balance the interests of the users of genetic resources, who want to have continued access to those resources, with the interests of the providers of such resources, who want to receive an equitable share of the benefits that may be derived from the use of such resources. In short, according to the ABS concept, the provider States shall facilitate access to their genetic resources while user States shall share in a fair and equitable manner the benefits arising from the access to and use of those resources. In effect, with the entry into force of the CBD, a change of paradigm was put in place as the conservation community moved from considering genetic resources as a common heritage to recognizing the sovereign rights of States to those resources and to regulating their use.

However, it is important to note that there is no clear line between providers and users. Indeed, States are often both provider and user country at the same time. Furthermore, the very different circumstances and situations surrounding the use of genetic resources makes it impossible for each State that could provide genetic resources to specify, a priori, what benefits should be shared and the modalities to be employed to facilitate sharing. What will be desired by the State providing access to genetic resources, and what will be acceptable to the party (government institution or private enterprise) seeking access, varies in each case. This can depend on, among other factors:

- the nature of the genetic resources provided (e.g., whether from a collection *(ex-situ)* or its natural habitat *(in-situ));*
- the location where the genetic resources are found (e.g., on State or privately owned lands, protected areas, indigenous and community conserved areas, or areas under no conservation management regime);
- the types of subsequent use proposed (e.g., whether it is used for scientific research, education, and/or commercial development);
- whether genetic resources from multiple providers shall be used to create a particular end-product; and
- whether the final product and/or final user have already been determined.

Finally, it is important to note that in the CBD context, genetic resources are biological resources needed or used for their genetic material and not for their other attributes. This means that, for example, access to a forest for “conventional” timber extraction or hunting would not be covered by the ABS concept of the CBD. On the other hand, if it were the intention to use the genetic material of such timber or prey, ABS obligations would come into play.

Table 2: Complexity of Possible ABS Circumstances

Attributes	Characteristics	
Source of supply	*Ex-situ*	Non-commercial (botanical gardens, gene banks, etc.)
		Commercial (broker companies)
	In-situ	One source country
		Several source countries
Purpose of usage	Commercial	Development of end-products
		Development of intermediate products
	Non-commercial	Basic non-commercial research with option to transfer material to commercial users
		Basic non-commercial research with material kept for conservation
Relationship between genetic resources and product	Closely related	Chemical molecule found in the plant serves as prototype for an active compound in the product (pharmaceutical utilization)
		Extracts (raw material) of the plant are substance of the content in the product (natural medicine, natural cosmetics, dietary supplement) NOTE: no genetic resource according to CBD definition, but different views possible in national ABS laws
	Not closely related	Molecule found in the plant needs to be modified in many steps to be included in the product (derivative in pharmaceutical utilization)
		The function of an organism or its parts serve as a model (e.g., mimics in material research, biotechnology)
	Not related	Genetic resource serves as tool in research and development (e.g., used as catalyst)
Characteristics of material identifiable before utilization	Identifiable	Material obtained from *ex-situ* collections, further information included
	Partly identifiable	Material acquired by bioprospecting activities, type of related knowledge
	Not at all identifiable	Material obtained by wide-scale, random bioprospection; no further information available/acquisition of sample of completely unidentified resources

Source: Based on Täuber, S., Holm-Müller, K. and Feit, U. *An Economic Analysis of New Instruments for Access and Benefit-Sharing under the CBD – Standardisation Options for ABS Transaction, Interim Report* (BfN: Bonn – Bad Godesberg, 2008), p. 7.

Given the ABS complexity, the CBD provides an ABS framework. Within this framework, Article 15 of the CBD, entitled "Access to Genetic Resources", is the core ABS provision. Further ABS-related provisions can be found in Articles 8(j), 10(c), 16, 18, and 19 of the Convention.

ABS-Related Obligations and Commitments under the CBD

This section provides a short overview of ABS-related obligations and commitments under the CBD in order to explain the ABS concept in more detail.

Access

Article 15(1) of the CBD clearly confirms the authority of governments to regulate physical access to genetic resources in areas within its jurisdiction. At the same time, Article 15(1) does not grant the State a property right over these resources (Glowka et al., 1994, p. 76). Ownership of genetic resources is not addressed by the CBD at all but is subject to national and sub-national legislation or law (including common law as well as customary law).

The authority of a government to determine access to genetic resources is qualified by Article 15(2) of the CBD, which requires the Contracting Parties to endeavour to create conditions that:

- facilitate access to their genetic resources for environmentally sound uses by other Contracting Parties and
- do not impose restrictions that run counter to the objectives of the CBD.

Determining when a use is environmentally sound is left to the discretion of the Party providing genetic resources. Furthermore, facilitating access and eliminating or minimizing restrictions implies that potential users of genetic resources should be supported in acquiring access to these resources. This is based on the understanding that the most immediate indirect benefit of facilitating access and minimizing or eliminating restrictions will be to increase the probability that genetic resources within areas under a State's jurisdiction will be used, which again increases the likelihood that benefits will be created and then be shared. In other words, the logic behind Article 15(2) of the CBD is that fair and equitable sharing of benefits can only be realized after access to genetic resources has actually been granted.

Article 15(3) of the CBD limits the genetic resources covered by Article 15 (as well as Articles 16 and 19) to those:

- provided by Parties that are countries of origin ("country of origin" of genetic resources is defined by Article 2 CBD as "the country which possesses those genetic resources in *in-situ* conditions") or
- provided by Parties that have acquired the genetic resources in accordance with the CBD.

Only these two categories of genetic resources entitle a provider to benefits under the CBD.

Prior informed consent and mutually agreed terms

Furthermore, access to genetic resources is made subject to the prior informed consent (PIC) of the Party providing the genetic resources, unless otherwise determined by that Party (Article 15(5) of the CBD). And where access is granted, it is conditional upon reaching mutually agreed terms (MAT) between the Party providing the genetic resources and the potential user (Article 15(4) of the CBD). PIC and MAT are the primary means to:

- authorize access to genetic resources;
- control their subsequent use; and
- establish the fair and equitable sharing of benefits from their subsequent use.

The concept of PIC is based on the principle that prior to potential users getting access to genetic resources, those affected and those authorized to make decisions should be informed about the potential uses in order to be able to make a fully educated decision. In the context of ABS, PIC requires that:

- the provider who makes the genetic resources available gives his/her consent through an affirmative act;
- this decision (affirmative act/consent) is based on information provided by the potential user of the genetic resources; and
- the information is provided prior to the actual decision (affirmative act/consent) that grants access.

However, the exact manner, extent, and procedure in which PIC should be obtained are governed by national access legislation. Here, it is important to note that Article 15(5) of the CBD refers to "unless otherwise determined by that Party". This implies that in exercising their sovereign rights over genetic resources, Parties may decide to require or not to require PIC for access to their genetic resources. This interpretation is also supported by Article 15(1) of the CBD, which states that "the authority to determine access to genetic resources rests with national governments and is subject to national legislation".

At the same time, the exercise of its sovereign rights does not exempt the Contracting Party from providing genetic resources as per its obligations under Article 15(2) of the CBD – that is, to take the necessary steps to establish a procedure in its legal system that will facilitate access Glowka et al., 1994, p. 81).

MAT imply a negotiation between the Party granting access to genetic resources and an entity aiming to use those resources, such as an individual, a company, or an institution. In the case of a successful negotiation, this will lead to an access agreement (sometimes called a material transfer agreement, research agreement, or contract).

Benefits

Article 15(7) of the CBD requires each Contracting Party to take legislative, administrative, or policy measures the goal of which is the fair and equitable sharing of benefits with the Contracting Party providing genetic resources. While the CBD does not give a definition of the term "benefits", it foresees different types of (monetary and non-monetary) benefits to be shared, including:

- research and development results, Article 15(7);
- commercial or other benefits derived from utilizing the genetic resources provided, Article 15(7);
- access to and transfer of technology using the genetic resources, Article 16(3);
- participation in all types of scientific research based on the genetic resources, Article 15(6);
- participation specifically in biotechnological research activities based on the genetic resources, Article 19(1); and
- priority access to the results and benefits arising from biotechnological use of the genetic resources, Article 19(2).

Therefore, benefit-sharing has to be based on MAT (as identified in Articles 15(7), 16(3), and 19(2)) and negotiated for each individual case.

Traditional knowledge

While Article 15 of the CBD does not address the issue of traditional knowledge, Article 8(j) of the CBD requires each Contracting Party, subject to its national legislation, to

- respect, preserve, and maintain knowledge, innovations, and practices of indigenous and local communities (ILCs) embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity;
- promote their wider application with the approval and involvement of the holders of such knowledge, innovations, and practices; and
- encourage equitable sharing of benefits derived from their utilization.

The link between genetic resources and traditional knowledge in the context of ABS is based on the second and third obligations under Article 8(j) of the CBD. Accordingly, the CBD acknowledges the value of traditional knowledge to modern society and recognizes that holders of such knowledge, innovations, and practices are to be involved and provide their approval, subject to national laws, when it gets to the wider application of those knowledge, innovations, and practices. Furthermore, States are encouraged to equitably share the benefits arising out of the utilization of ILCs' knowledge, innovations, and practices.

In this context, it must not be forgotten that traditional knowledge, innovations, and practices on animals, plants, insects, or ecosystems can provide interesting leads to and an initial screen for isolating particular properties of genetic resources found in nature. Consequently, traditional knowledge has guided a number of companies in the development of new products (Laird and Wynberg, 2008, p. 20).

Table 3: Summary of CBD Provisions Relevant to ABS

Provision	Content
Preamble	Notes the desirability of equitably sharing benefits arising from the use of traditional knowledge, innovations, and practices relevant to the conservation of biological diversity and the sustainable use of its components.
Article 1	Lists ABS as one of the three CBD objectives.
Article 2	Defines the terms “genetic resources” and “genetic material”, as well as the terms “country of origin of genetic resources” and “country providing genetic resources”.
Article 8(j)	Requires CBD Parties to respect, preserve, and maintain the knowledge, innovations, and practices of ILCs; promote their wider application with their holders’ approval and involvement; and encourage the equitable sharing of the benefits arising from their utilisation.
Article 15(1)	Clarifies that States have sovereign rights over their natural resources and the authority to regulate access.
Article 15(2)	Requires CBD Parties to facilitate access for environmentally sound purposes and not to impose restrictions that are counter to the CBD.
Article 15(3)	Provides that only the country of origin or a country that has acquired genetic resources in compliance with the CBD may grant access to genetic resources.
Article 15(4)	Provides for access only on MAT.
Article 15(5)	Provides for access subject to PIC.
Article 15(6)	Provides for full participation of the provider in scientific research based on the genetic resources provided.
Article 15(7)	Requires CBD Parties to take legislative, administrative, or policy measures to share benefits from research and development and commercialization equitably and based on MAT.
Article 16(3)	Requires CBD Parties to take legislative, administrative, or policy measures to provide access to and transfer of technology that makes use of genetic resources accessed on MAT and in accordance with international law.
Article 19(1)	Requires parties to the CBD to take legislative, administrative, or policy measures to ensure the effective participation by providers in biotechnological research on the genetic resources.
Article 19(2)	Provides for priority access to the results and benefits from biotechnologies based on genetic resources provided.

B. Challenges to Implementation of ABS

Soon after the adoption and entry into force of the CBD, it became clear that the implementation of ABS in practice, in particular the development of ABS legislation, presented challenges for the international community. This section briefly describes the sometimes difficult relationship between the issues of access, benefit-sharing, and compliance, as well as a number of complexities in regulating ABS, in order to provide a better understanding of the realities within which ABS is applied.

Access, Benefit-sharing, and Compliance: The Pillars of ABS

As explained before, the ABS concept of the CBD is founded on a bilateral relationship between a provider of a genetic resource on the one hand and a user of this resource on the other hand. According to Article 15(3) of the CBD, a provider can be either a country that possesses a genetic resource in *in-situ* conditions or a country that has acquired the genetic resource in accordance with the CBD.

In practice, the role of a provider is not limited to biodiversity-rich countries. Indeed, genetic resources that could be provided (microbes, for example) can be found universally regardless of the level of biodiversity in a country. Furthermore, countries that do not possess a specific genetic resource in *in-situ* conditions may hold the resource in an *ex-situ* collection after acquiring it in accordance with the CBD. At the same time, the role of a user is also not limited to industrialized countries. In practice, every country has the potential to become a user country since it has the possibility to build up the necessary infrastructure and capacity for research and development in relation to genetic resources.

Although every country has the potential to be a provider and a user of genetic resources at the same time, the relationship between providers and users has often been controversial due to (mis) interpretation of the situation as a divide between developing countries and developed countries. Such (mis)interpretation, in combination with alleged cases of misappropriation and/or misuse of genetic resources or traditional knowledge associated with those resources (sometimes referred to as cases of “biopiracy”), led to certain mistrust on both sides and influenced the ABS discussions. While there is no agreed definition of the terms “misappropriation” and “misuse”, the following general distinction can be made:

- Misappropriation is linked to the acquisition of genetic resources in violation of domestic ABS legislation requiring PIC and MAT. In short, it could be understood as unlawful appropriation of genetic resources.
- Misuse arises more out of contractual obligations, as it captures the situations in which genetic resources are used in violation of MAT that were set up between the provider and the user. In short, it could be understood as utilization of genetic resources in a non-agreed way, including without sharing any benefits.

While the issues of misappropriation and misuse are without doubt a great concern for providers as well as users, a serious analysis of its underlying causes needs a differentiated and neutral approach. As noted, one problem with discussions on misappropriation and misuse is the lack of a common definition of these terms.

Furthermore, the sole apprehension of being accused of misappropriation or misuse of genetic resources has already become a serious impediment to research and bioprospecting activities. Researchers as well as private industries fear image problems in case of public outcries. Allegations of “biopiracy” would make it difficult for them to negotiate legitimate ABS agreements with other parties and gain access to potential funding sources, likely causing significant loss of commercial opportunities that

may be available to a competitor.[5] Potential users are also concerned about possible administrative appeals or formal lawsuits that might render their activities unprofitable or at least unpredictable.

The situation becomes even more complicated when taking into account the lack of legal clarity, certainty, and transparency in some domestic ABS legal frameworks. This again discourages many researchers and companies from engaging in bioprospecting activities. Some people even see here the underlying cause of the majority of alleged cases of misappropriation that they consider to be unintentional.

As a consequence, the specific legal framework in which an allegation of misappropriation or misuse may occur has to be taken into account. A differentiated assessment is necessary when:

- the acquisition of genetic resources takes place in a provider country that does not have any ABS legislation or administrative processes in place;
- genetic resources are acquired in a provider country with ABS legislation and processes in place that turn out to be unclear and non-transparent;
- traditional knowledge is accessed and used when it is impossible to clarify which ILCs should have been involved in order to get their approval;
- the material transfer agreement includes loopholes, such as with regard to a possible change in the intended utilization of the acquired resources; or
- a clear case of misappropriation takes place – that is, when genetic resources and/or traditional knowledge associated with genetic resources are acquired either in violation of existing domestic legislation of a provider country that includes clear requirements for PIC and MAT for access to genetic resources or without the appropriate involvement and approval of the holders of the knowledge and without mutually agreed terms.

Finally, when genetic resources/traditional knowledge associated with those resources are transferred from a provider to a user country, neither the provider nor the user State alone can take appropriate measures that ensure an efficient and effective ABS regime. While provider States have sovereign rights over their genetic resources, due to the territoriality principle they are hampered in monitoring and controlling the downstream process of utilization. It is generally not possible to enforce provider countries' ABS legislation in user countries. The enforcement of ABS agreements in user State courts is possible, but very costly. User States again can be obliged to monitor and control the utilization of genetic resources/traditional knowledge associated with those resources within their jurisdiction. However, tracing back to provider countries is a great technical and administrative challenge, leading to high transaction costs.

All this explains the complex relationship between providers and users, as well as the interrelationship among the issues of access, benefit-sharing, and compliance. All three components appear to be essential for making ABS work in practice. They form the "pillars" of ABS, which can be summarized as follows.

On the one hand, users need clear, transparent, predictable, equitable, and efficient legal and administrative frameworks to secure legal clarity and certainty when accessing genetic resources and traditional knowledge associated with those resources. Without such legal certainty, researchers and industries will be less eager to invest in bioprospecting activities. This will lead to less access and as

5 Secretariat of the Convention on Biological Diversity, *Compilation of submissions by Parties on experiences in developing and implementing Article 15 of the Convention at the national level and measures taken to support compliance with prior informed consent and mutually agreed terms.* UNEP/CBD/WG-ABS/5/INF/2/Add.1 (Montreal: 2007), para. 3.

a consequence to less benefit-sharing in the end. Furthermore, lack of legal clarity will make it difficult for users to fully comply with the providers' ABS requirements, leading to controversy and allegations of misappropriation or misuse.

On the other hand, the main interest of providers lies in the fair and equitable sharing of the benefits arising from the utilization of their genetic resources and traditional knowledge associated with those resources. Providers therefore need effective measures to ensure that users in their jurisdiction do not misappropriate or misuse genetic resources and traditional knowledge associated with those resources. Thus, they aim for compliance with their domestic ABS regime in general and with the MAT for benefit-sharing in particular.

Complexities of Implementing ABS in Practice

Apart from finding appropriate ways of regulating these three pillars of ABS, the international community has faced a number of other challenges in order to effectively and efficiently operationalize ABS. These include the following issues amongst others.

Implementation in a wide variety of national contexts

Since the entry into force of the CBD, only a limited number of States, mainly biodiversity-rich countries, have adopted comprehensive ABS regimes at the national level.[6] Many countries, however, still do not provide for any specific ABS laws, regulations or administrative processes.

Countries that developed domestic ABS frameworks have chosen different ways in which to implement the ABS provisions of the CBD at the national level. For example, different ways of understanding biological resources, genetic resources, derivatives, and products exist, which has led to a variety of definitions of scope in ABS legislation. Countries may choose to extend the scope of their ABS regime beyond that of the CBD to cover not only genetic but also biological resources, or they can interpret the scope more narrowly. Furthermore, countries may take a very restrictive approach when regulating access to their genetic resources, or they may provide for free access. Also, each country has its own legal system, national authorities, and stakeholders. ABS procedures will therefore differ from provider country to provider country, with sometimes long, confusing, cumbersome processes requiring permits from several regional and local agencies that administer the same resource.

Consequently, there is a wide variation in the implementation of ABS at the national and sub-national level, which can lead to confusion for both providers and users of genetic resources and/or traditional knowledge associated with such resources.

Institutional arrangements and lack of capacity

Practical experience of the implementation of ABS has further shown that in addition to an appropriate legislative framework, an enabling institutional framework is required. However, many countries face similar difficulties in setting up efficient and effective institutional arrangements that support the operationalization of ABS. One underlying problem seems to be the competition between existing institutions and entities regarding the authority to grant access, and even more so to receive potential benefits. Unclear, overlapping, or simply non-existent institutional competencies have also been highlighted as challenges to implementing ABS effectively.

6 A database including ABS measures undertaken by the CBD Contracting Parties can be found at www.cbd.int/abs/measures/.

Another difficulty relates to the lack of capacity on all sides to deal with the complexities of ABS. ABS implementation involves technical expertise regarding negotiation of ABS agreements, intellectual property rights, biodiversity conservation, business, commerce, economics, biotechnology, national and international law, social and cultural issues, and other issues. Such interdisciplinary expertise has been limited if not absent in many countries (Carrizosa et al., 2004, p. 300).

The resulting legal uncertainties, administrative deficiencies and delays, and high transaction costs may lead to considerable frustration among ABS stakeholders.

Ex-situ collections

Finding an appropriate and fair approach in view of *ex-situ* collections has been another critical stumbling block in the implementation of ABS. *Ex-situ* conservation is defined by Article 2 of the CBD as "the conservation of components of biological diversity outside of their natural habitats". *Ex-situ* collections take the form of collections of genetic resources held in gene banks (seed and in the field), zoos, arboreta, botanical gardens, in vitro storage, pollen storage, and DNA storage, to name a few examples (Maxted et al., 1997). Seed gene banks are the most common storage practice (FAO, 1998, p. 510).

Article 9 of the CBD further clarifies:

- the use of *ex-situ* conservation method to support *in-situ* measures;
- *ex-situ* collections should be kept and researched preferably in the country of origin; and
- those collections should be used for measures for recovery and rehabilitation of threatened species for reintroduction into natural habitats, under appropriate conditions.

Research on *ex-situ* collections can take a wide variety of forms and purposes. Most research is of a non-commercial nature, to improve understanding of genetic diversity and how to best conserve it. There are also examples of applied commercial research on collections, resulting in a commercial product of various forms (see Laird and Wynberg, 2008). Botanical gardens, in particular, have played an important role in medical and taxonomic research, the distribution of useful plants and their genetic resources worldwide, and the conservation of biological diversity (Davis, 2008, p. 6).

Many if not most of the genetic resources collected *ex-situ* were accessed before the entry into force of the CBD, and a large amount of the stored resources historically came from biodiversity-rich developing countries. Regardless of pre- or post-CBD acquisition, developing countries have had high expectations of benefiting from new utilizations of the collected genetic resources. For a combination of ethical and pragmatic reasons, some botanical gardens and herbaria treat all of their collection as falling under the obligations of the CBD. However, in practice the unknown geographical origin of some genetic resources may hamper appropriate benefit-sharing in practice.

Traditional knowledge within CBD and other international fora

As explained earlier, the link between traditional knowledge associated with genetic resources and ABS is based on Article 8(j) of the CBD. However, the implementation of ABS in relation to traditional knowledge associated with genetic resources is a challenge for several reasons.

First of all, Article 8(j) of the CBD does not define the term "traditional knowledge". In fact, it only provides an indication of how the concept of traditional knowledge must be understood in the CBD framework, namely as such "knowledge, innovations and practices" that "embody traditional lifestyles relevant for the conservation and sustainable use of biological diversity". It is developed from experience gained

over centuries and adapted to the local culture and environment, transmitted orally from generation to generation, and collectively owned, and it takes the form of stories, songs, folklore, proverbs, cultural values, beliefs, rituals, community laws, local language, and agricultural practices. Such a broad understanding can sometimes make it difficult to capture what qualifies as traditional knowledge. This again may lead to confusion on both the provider and user sides, as well as to complications for regulation through legal instruments, such as intellectual property rights.

Particular legal and practical problems may arise in cases when ownership of such knowledge is not definable – that is, the holder of the knowledge is unknown or not identifiable – or when such knowledge leaves a community without PIC of the relevant ILC group and enters the "public domain", which means that it is not protected by an intellectual property right and therefore can be appropriated by anyone without liability for infringement.

Traditional knowledge can be dispersed outside of the control of the original ILC in a number of ways, such as:

- when the knowledge about a potential utilization of a genetic resource has spread to people living in the same area as the ILC in question and is since used by non-members of the ILC for that specific purpose; or
- when a scientist, visiting the ILC holding the traditional knowledge, finds out about said knowledge and afterwards publishes an article on the research findings.

ABS related to traditional knowledge associated with genetic resources is linked to ongoing discussions on intellectual property rights–related aspects, particularly in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organization (see section E). This Committee is working on an international legal instrument or instruments that would ensure the effective protection of genetic resources, traditional knowledge, and traditional cultural expressions.

It is also important to underline that the issue of traditional knowledge associated with genetic resources is closely linked to discussions on the general rights of ILCs at the international as well as national level. At the international level, the United Nations Declaration on the Rights of Indigenous Peoples (adopted in 2007)[7] and the International Labour Organization Convention No. 169 on Indigenous and Tribal Peoples (adopted in 1989, entry into force in 1991)[8] are important legal instruments of varying legal strength that aim to protect ILCs' rights and thus should be taken into account in the context of ABS related to traditional knowledge.

Furthermore, local and national structures are needed, which:

- involve ILCs in the development and implementation of ABS policies at the domestic level;
- recognize the rights of ILCs in domestic legal systems, in particular property rights as well as self-determination and indigenous governance procedures, which will also enable effective protection vis-à-vis foreign jurisdictions;
- clearly identify the knowledge holder(s) and owners of genetic resources; and
- define and establish local competent authorities in cases where they do not exist and determine community-level procedures for ABS.

7 For further information, see the UN Permanent Forum on Indigenous Issues, at www.un.org/esa/socdev/unpfii/index.html.

8 For further information, see www.ilo.org/indigenous/Conventions/no169/lang--en/index.htm.

Without such a structure in place, a three-party relationship between ILCs, their "home" countries, and users might be created that lacks sufficient transparency, clarity, and efficiency. Such a situation could in the end hamper the effective implementation of ABS related to traditional knowledge associated with genetic resources in practice.

Varying conditions for commercial and non-commercial research

Another challenge in the implementation of ABS relates to the differentiation between non-commercial and commercial research, as both are characterized by the intent of the research undertaken and not the form. Non-commercial research can be understood as non-profit research to generate new scientific insights on multiple levels, from genetic composition of biological resources to related functions. It is one of the fundamental preconditions for the conservation and sustainable use of biological diversity and the appreciation of the value of the diversity of genetic resources. Furthermore, countries that provide access to their biodiversity for non-commercial research may derive a range of non-monetary benefits, including training or a better understanding of their genetic resources. As a consequence, it makes sense for national access modalities in provider countries to treat non-commercial (non-profit) and commercial research differently.

However, both research types can use the same methods and facilities and be pursued by the same researchers. As a consequence, non-commercial research can be connected with commercial research and may lead to applied research, product development, or further uses of genetic resources. Nevertheless, in many research activities this is not the case. Still, provider countries may be reluctant to differentiate between non-commercial and commercial research based on the following practical concerns:

- changes of intent from non-commercial to commercial research;
- use of sample materials by third parties in ways that were not approved by a provider country in legal agreements; and
- commercial use of research results in the public domain without sharing benefits with the provider country.

Consequently, provider countries are faced with the challenge of recognizing the particular needs of non-commercial research while defining tangible indicators that separate non-commercial from commercial research (e.g., restrictions on dissemination of research results, restrictions on access to reference specimens, and patent applications).

Transboundary situations

The implementation of ABS could become a challenge in transboundary situations. It has to be recalled that genetic resources, as well as traditional knowledge associated with them, are often not endemic to a specific country or held by only one ILC. Indeed, genetic resources are often found in more than one country or even in more than one geographical region; the same traditional knowledge is often held by different ILCs, which might even be located in different countries. In such situations, a bilateral ABS approach may appear to some to be unjust, as it gives a single provider State/ILC the right to receive all of the benefits. Furthermore, the bilateral ABS approach might be considered problematical to address such transboundary situations, as it can lead to competition between the different provider States/ILCs sharing the same genetic resources/traditional knowledge associated with those resources, which will weaken their position in the negotiation of MAT and might lead to a "race to the bottom" regarding ABS

requirements. Therefore, it is sometimes argued that a multilateral benefit-sharing approach could be more appropriate and fair to tackle such transboundary situations.

However, it is important to recall that Article 15 of the CBD clearly envisages applying a bilateral instead of a multilateral ABS approach. Furthermore, it must be noted that polymorphism means the economic value may lie in the internal genetic differences between examples of the same species (local adaptations, for example). Moreover, countries that put ABS systems in place may feel aggrieved if other countries effectively "free ride" and obtain a share in benefits derived on the basis that they happen to have the same species occurring *in-situ*.

C. The Road to Nagoya and Beyond

The challenges just described illustrate the need for specific guidelines and instruments in order to facilitate implementation of ABS in practice. More than 18 years passed between the adoption of the CBD in May 1992 and the adoption of 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 (Nagoya Protocol) in October 2010 in Nagoya, Japan. During this time the CBD Contracting Parties studied, discussed, elaborated, and further negotiated the ABS concept. The way to Nagoya was a long road, with four different phases and important stepping stones to be recognized.[9]

Phase 1: ABS Developments Prior to the Negotiation of an International Regime

The issue of ABS was addressed by the CBD Conference of the Parties (COP) from the beginning. The first COP (1994, Nassau, Bahamas) listed ABS in agenda item 6.6 of the medium-term programme of work of the Conference of the Parties.[10] In subsequent years, CBD COP 2 (1995, Jakarta, Indonesia) and CBD COP 3 (1996, Buenos Aires, Argentina) requested, considered, and analyzed compilations of national, regional, and sectoral legislative, administrative, and policy measures as well as participatory processes and guidelines for activities covered by Article 15, including information on the interpretation of ABS key terms, case studies, and experiences with implementation.[11]

ABS developments accelerated after CBD COP 4 (1998, Bratislava, Slovakia), when a regionally balanced expert panel on ABS was set up and formally initiated the work on ABS under the Convention.[12] Bringing together representatives of the private and public sector as well as ILC representatives, the expert panel met on two occasions (1999 in San José, Costa Rica, and 2001 in Montreal, Canada) and developed a set of recommendations, including ones on PIC and MAT, approaches for stakeholder involvement, and options to address ABS within the CBD framework.

CBD COP 5 (2000, Nairobi, Kenya) further formalized the ongoing ABS process by establishing the Ad Hoc Open-ended Working Group on ABS (AHWG) with a mandate to develop for submission to the COP guidelines and other approaches on PIC and MAT, the participation of stakeholders, benefit-sharing mechanisms, aspects of *ex-situ* and *in-situ* conservation and sustainable use, and the preservation

9 For more detailed information on the ABS history, see the CBD website at www.cbd.int/abs/background/#timeline.

10 See CBD COP 1 decision I/9, *Medium-term programme of work of the Conference of the Parties.*

11 See CBD COP 2 decision II/11, *Access to genetic resources, and COP 3 decision III/15, Access to genetic resources.*

12 See CBD COP 4 decision IV/8, *Access and benefit-sharing.*

of traditional knowledge.[13] At its first meeting (2001 in Bonn, Germany), the AHWG prepared the draft Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization (Bonn Guidelines) (SCBD, 2002), which were later adopted with some changes at CBD COP 6 (2002, The Hague, Netherlands).[14] The Bonn Guidelines were intended to provide guidance by, amongst other aspects:

- identifying steps in the ABS process, with an emphasis on the obligation for users to seek PIC from providers;
- identifying the basic requirements for MAT;
- defining the main roles and responsibilities of users and providers and stressing the importance of the involvement of all stakeholders;
- covering other elements such as incentives, accountability, means for verification, and dispute settlement; and
- suggesting elements for inclusion in material transfer agreements and providing an indicative list of both monetary and non-monetary benefits.

While this was an important first step, the Bonn Guidelines could not be seen as a final decision or sufficient guidance. Indeed, they were planned to be "evolutionary" in nature, meaning that they were intended to provide starting points for national framework development processes and national negotiations that had to be reviewed, accordingly revised, and improved as ABS experience was gained. Furthermore, the Guidelines were relatively contentious, with some Contracting Parties and ABS stakeholders criticizing them as being incomplete, only voluntary, focusing too much on the user side, and not taking enough into account the critical concerns of providers (e.g., compliance with and enforcement of national ABS regimes), as well as conservation and sustainable use issues. Others considered the Bonn Guidelines as too specific and detailed. Nevertheless, they presented best practices for providers and their implementation in domestic ABS laws provided valuable experiences that were fed into the negotiations leading to the Nagoya Protocol.

Phase 2: The Mandate to Negotiate an International Regime on ABS

At the United Nations World Summit on Sustainable Development (WSSD) in 2002 in Johannesburg, South Africa, the "Johannesburg Plan of Implementation" that was adopted included different references to ABS. Amongst others, the international community called for action to negotiate an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources[15] within the framework of the CBD, taking the Bonn Guidelines into account.

CBD COP 7 (2004, Kuala Lumpur, Malaysia) followed this call and mandated the AHWG "with the collaboration of the Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions, ensuring the participation of indigenous and local communities, non-governmental organizations, industry and scientific and academic institutions, as well as intergovernmental organizations, to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention".[16]

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13 See CBD COP 5 decision V/26, *Access to genetic resources.*

14 See CBD COP 6 decision VI/24, *Access and benefit-sharing as related to genetic resources.*

15 Plan of Implementation of the World Summit on Sustainable Development, Chapter IV, Paragraph 44 (o).

16 See CBD COP 7 decision VII/19, *Access and benefit-sharing as related to genetic resources (Article 15),* D. 1.

In doing so, COP 7 interpreted the WSSD call for action in the CBD context and broadened the mandate of the AHWG to focus not only on benefit-sharing but also on the issue of access. Furthermore, CBD COP 7 adopted the terms of reference of the AHWG for the negotiation of the international regime,[17] which had been discussed at the second AHWG meeting (2003, Montreal).

Box 1: Understanding the Scope of the Mandate

According to *Black's Law Dictionary,* the term "international regime" can be defined as a set of norms of behaviour and rules and policies that cover international issues and that facilitate substantive or procedural arrangements among countries.

Mandating the AHWG to negotiate an international regime therefore granted the Contracting Parties the flexibility to explore and negotiate different ABS options and components, including but not limited to the development of:

- one or more instruments;
- composed of policy, legal, and practical measures;
- including a set of entirely new measures or a set of new elements in combination with pre-existing measures;
- being mandatory or voluntary or a mixture of both;
- including binding or non-binding provisions or a combination of both; and
- using diverse ABS approaches and tools.

Phase 3: The Negotiation Process

The actual negotiation process started with the third (2005, Bangkok, Thailand) and fourth (2006, Granada, Spain) meetings of the AHWG, where compilations of a draft text were produced as a basis for future negotiations. At the following CBD COP 8 (2006, Curitiba, Brazil), the AHWG was instructed to continue with the elaboration and negotiation of the international regime. Timothy Hodges from Canada and Fernando Casas from Colombia were appointed as Co-Chairs of the AHWG, and a group of technical experts was established to explore and elaborate on the idea of an internationally recognized certificate of origin, certificate of source, or certificate of legal provenance. Furthermore, the AHWG was asked to complete its work at the earliest possible time before COP 10.[18] Setting a concrete deadline for the finalization of the negotiation process was of strategic importance for several reasons: first, it provided the AHWG with a final goal towards which it was working; second, it increased the pressure on the Contracting Parties to move forward in their negotiations; and third, it was important as the Strategic Plan for the Convention on Biological Diversity (Strategic Plan 2002–2010) was expiring at this point in time.

17 Ibid., Annex.

18 See CBD COP 8 decision VIII/4, *Access and benefit-sharing,* A.

At its fifth (2007, Montreal) and sixth (2008, Geneva, Switzerland) meetings, the AHWG focused on the main components of the international regime on ABS. During the Geneva meeting, a contact group was formed and made progress, thanks to a procedure that separated what delegates agreed should form part of the regime (so-called bricks) and elements that were still pending agreement (so-called bullets). This method helped reassure many delegates that their views were being taken into account, helped to build trust, and allowed the group to move forward with its overall mandate. While key issues like the nature of the regime and its scope were still pending agreement, the sixth meeting of the AHWG was considered an important step forward in the process. The result was a draft decision for CBD COP 9 and a short and concise working document on the international regime. The working document consisted of a compilation of proposals concerning the objective, scope, and nature of the regime, as well as lists of components on the issues of fair and equitable benefit-sharing, access to genetic resources, compliance, traditional knowledge associated with genetic resources, and capacity-building. The components under each item were subsequently split into two further categories: those "to be further elaborated with the aim of incorporating them in the international regime" (the bricks, agreed in principle) and those calling "for further consideration" (the bullets, disagreed about or in need of further clarification).[19]

CBD COP 9 (2008, Bonn) instructed the AHWG "to finalize the international regime and to submit for consideration and adoption by the Conference of the Parties at its tenth meeting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and its three objectives".[20] Furthermore, the so-called Bonn Mandate was adopted, a roadmap from COP 9 to COP 10 that provided for:

- three meetings of the AHWG, preceded by regional and interregional meetings;
- clear instructions on the issues for which operational text was to be developed and negotiated at each AHWG meeting; and
- the establishment of expert groups on a) compliance; b) concepts, terms, working definitions and sectoral approaches; and c) traditional knowledge associated with genetic resources in order to provide legal and technical advice.

According to Decision IX/12, the seventh meeting of the AHWG (2009, Paris, France) was mandated to negotiate operational text on objective, scope, compliance, fair and equitable benefit-sharing, and access. At the end of the meeting, a highly bracketed text, the "Paris Annex", was developed that provided draft language on most items and set out Parties' preferences and points of divergence. The meeting was marked by disputes between several regional negotiating groups, which accused each other of turning bullets into bricks. In the end, these discussions led the AHWG to abolish the bricks and bullets approach.

The eighth meeting of the AHWG (2009, Montreal) addressed the issues of traditional knowledge associated with genetic resources, capacity-building, compliance, fair and equitable benefit-sharing, and access to genetic resources. It was held back-to-back with the sixth meeting of the Working Group on Article 8(j), which adopted and transmitted recommendations on the international regime on ABS. At the end of the eighth meeting of the AHWG, an important step forward in the negotiation process was made with the adoption of the "Montreal Annex". This annex included the first-ever complete draft of the international regime incorporating operational text on all elements. Furthermore, it included a second annex containing open discussion points of the regime for the next AHWG meeting.

19 See Earth Negotiations Bulletin, summary report of AHWG 6, at www.iisd.ca/download/pdf/enb09416e.pdf.

20 See CBD COP 9 decision IX/12, *Access and benefit-sharing,* 3.

Despite the considerable progress made, the Montreal Annex was still heavily bracketed. With less than a year left until CBD COP 10, pressure on the negotiating partners increased. In order to accelerate the negotiation process before the next AHWG meeting, it was decided to convene two informal intersessional meetings: the meeting of the ABS Friends of the Co-Chairs in Montreal in January 2010 and the ABS Co-Chairs Informal Inter-regional Consultation (CIIC) in Cali, Colombia, in March 2010. In addition, regional consultations for Asia, Latin America and Caribbean Countries, Central and Eastern European Countries, the Pacific, and Africa took place in collaboration with the United Nations Environment Programme and the CBD Secretariat.

The ninth meeting of the AHWG started in Cali immediately after the CIIC. For the first time in the process, a draft protocol was tabled by the Co-Chairs and adopted by the AHWG as a basis for further negotiations. With only seven months left until CBD COP 10, this was necessary for procedural reason. According to Article 28(3) of the CBD, any proposed protocol to the Convention has to be communicated to the Contracting Parties by the Secretariat at least six months before a meeting of the Conference of the Parties.

The adoption of this draft text as the future basis for negotiations marked the next critical step on the road to Nagoya, in that an implicit decision was made regarding the form of the international agreement: a protocol under the CBD. Furthermore, the Co-Chairs took the strategic decision to establish an Interregional Negotiating Group (ING), which worked in a roundtable format and consisted of a small number of negotiators and observers: five representatives for each UN region; two representatives each for ILCs, civil society, industry, and public research; and representatives of the current (German) and upcoming (Japanese) COP Presidencies. In format and function, this approach was described as a "modified Vienna setting".[21] At the end of the Cali meeting, further progress was made on benefit-sharing from derivatives as well as on the establishment of an internationally recognized certificate of compliance. However, as the text-based negotiations were not yet finalized, it was decided to suspend the ninth meeting of the AHWG and resume the meeting in July in Montreal.

At the resumed meeting, negotiations continued in the ING format. The outcome of multiple day and night sessions of discussion and negotiation was a further advanced draft protocol with a common understanding on important issues related to compliance, access, and benefit-sharing including derivatives, as well as on the relationship with other international instruments. Still, additional consultations were needed for the development of a draft protocol to be presented at COP 10. This led the AHWG to reconvene the ING in September in Montreal and in October in Nagoya. Two days before the opening of COP 10, the resumed meeting of the ninth meeting of the AHWG adopted a draft protocol that was not yet finalized but was ready to be transmitted to the COP for its consideration.

Negotiations continued throughout the full two weeks of CBD COP 10 in Nagoya. In order to facilitate the ABS negotiations, an Open-ended Informal Consultative Group on ABS (ICG) was established in the first plenary session of COP 10. The ICG was chaired by the Co-Chairs of the AHWG and tasked to finalize the protocol text. Key issues that required compromise included utilization and derivatives, scope, access to genetic resources in emergency situations, relationship with other international instruments, checkpoints, and mandatory disclosure requirements, but also traditional knowledge–related issues. When it became clear that the ICG would fail to agree on a final text, a compromise text was tabled by the Japanese COP Presidency as a basis for Ministerial informal consultations. This "closed doors approach" stood in contrast to the "ownership-based approach" that was taken

21 The term "Vienna setting" goes back to the negotiations of the Cartagena Protocol on Biosafety under the CBD. Here it was introduced to describe the arrangement of a hexagonal negotiating table, seating the Chair and representatives of the five negotiating groups, with other delegations seated behind.

throughout the negotiation process. However, it proved to be successful in the end, so that 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 was adopted by COP 10 Decision X/1 on 29 October 2010.

As the Nagoya Protocol was part of a package deal comprising the Strategic Plan for Biodiversity 2011–2020, including the Aichi Targets[22] and the Strategy for Resource Mobilization,[23] its final adoption was not only an important achievement to facilitate the future implementation of ABS but also a necessary step to safeguard CBD COP 10 and the CBD process in general from failing. Furthermore, the agreement on the Nagoya Protocol sent an important signal to the international community. It proved that despite ongoing failure in other political fora (such as the negotiation process under the United Nations Framework Convention on Climate Change), international multilateralism could still work.

Phase 4: The Way Forward

According to its Article 32, the Nagoya Protocol was open for signature from 2 February 2011 to 1 February 2012, following which a State could become a Party through accession (Article 35(1) of the CBD). Article 33(1) requires 50 instruments of ratification, acceptance, approval, or accession for the Protocol's entry into force. This occurs 90 days after the threshold is reached.

In order to prepare for its entry into force, CBD COP 10 established an Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol on ABS (ICNP). The ICNP is in charge of the preparations necessary for the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, at which time it will cease to exist.[24] The ICNP's work plan is set out in Annex II of the COP Decision adopting the Nagoya Protocol.[25]

The first meeting of the ICNP was to address the following issues:

- modalities of operation of the ABS Clearing-House (CH);
- capacity-building in developing countries;
- awareness raising; and
- the compliance mechanism foreseen under Article 30 of the Nagoya Protocol.

The second meeting of the ICNP was mandated to address:

- programme budget for the biennium following the entry into force of the Protocol;
- guidance for the financial mechanism;
- guidance for resource mobilization for implementation of the Protocol;
- rules of procedure for the COP serving as the meeting of the Parties to the Protocol;
- draft provisional agenda for the first meeting of the COP serving as the meeting of the Parties to the Protocol;

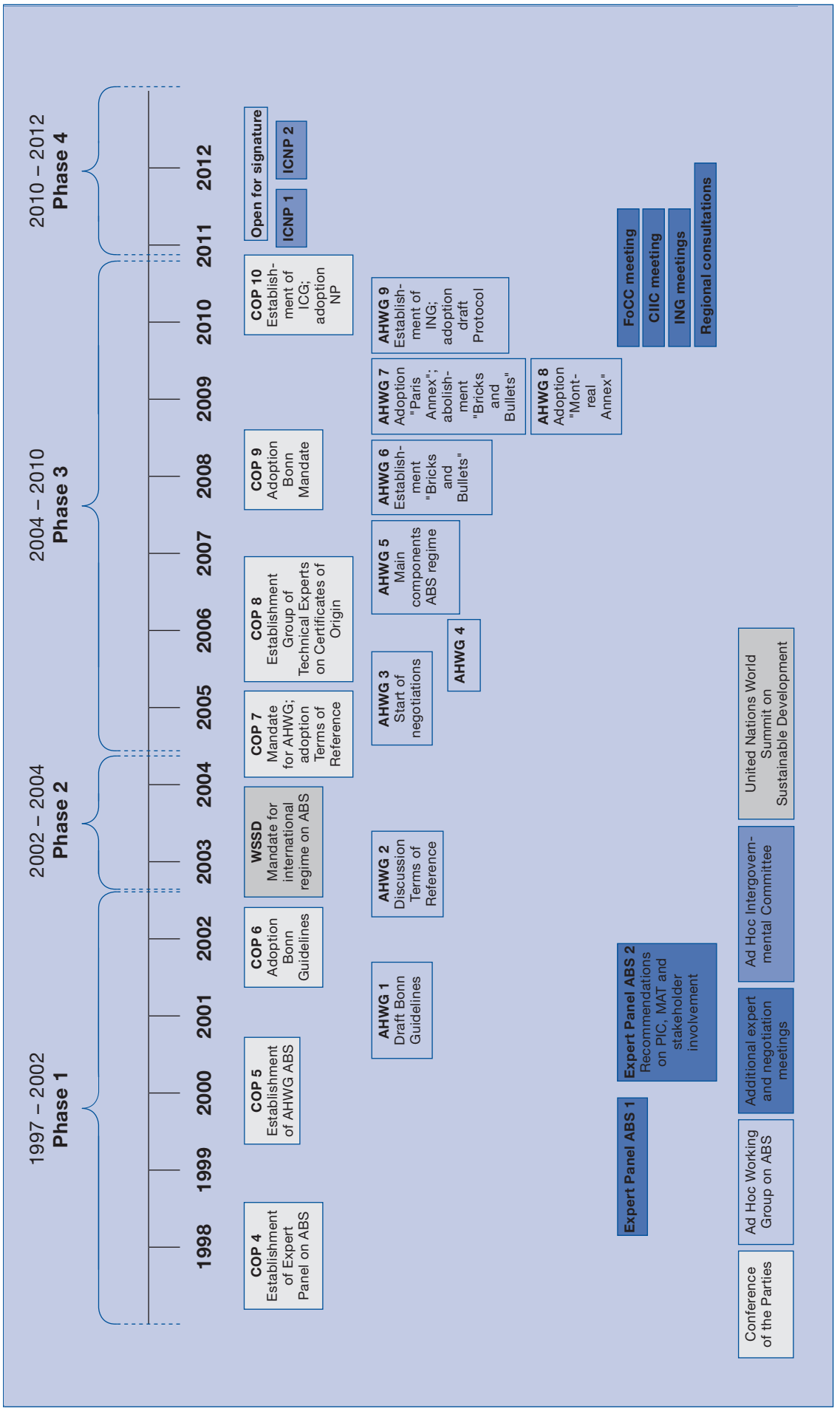
22 See CBD COP 10 Decision X/2, *The Strategic Plan for Biodiversity 2011–2020 and the Aichi Biodiversity Targets.*

23 See CBD COP 9 Decision IX/11, *Review of implementation of Articles 20 and 21, and CBD COP 10 Decision X/3, Strategy for resource mobilization in support of the achievement of the Convention's three objectives.*

24 See CBD COP 10 Decision X/1, *Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization,* 7–8.

25 Ibid., Annex II.

Figure 2: Visualization of the Road to Nagoya and Beyond



- the need for and modalities of a global multilateral benefit-sharing mechanism; and
- continued consideration of items taken up at the first meeting of the ICNP, as needed, such as the compliance mechanism under Article 30 of the Nagoya Protocol.

D. The Nagoya Protocol: An Overview

The Nagoya Protocol is a legally binding, supplementary agreement to the Convention. It aims to further develop the legal ABS framework provided by the CBD. The development of protocols is explicitly foreseen in Article 28 of the CBD. Its legal relationship with the CBD is regulated by Article 32 of the CBD.

The Nagoya Protocol has 27 preambular clauses, 36 articles containing operative provisions, and one annex containing a non-exhaustive list of monetary and non-monetary benefits. It establishes a framework for regulating how users of genetic resources and/or traditional knowledge associated with genetic resources (for example, researchers and commercial companies) may obtain access to such resources and knowledge. It provides for general obligations on sharing the benefits arising from the utilization of such resources and knowledge. And it obliges Parties to ensure that users under their jurisdiction respect the domestic ABS legislation and regulatory requirements of the Parties where the resources or knowledge have been acquired.

This section provides a brief overview of the most important provisions of the Nagoya Protocol. A more detailed analysis is undertaken in the explanatory part of this guide, where each individual article is addressed in depth.

Objective

The objective of the Nagoya Protocol is addressed in Article 1. The text of this provision draws from the third objective of the CBD as stated in its own Article 1, and it refers to “the fair and equitable sharing of the benefits arising from the utilization of genetic resources” as the main goal of the Protocol. Article 1 clarifies that such benefit-sharing includes appropriate access to genetic resources, appropriate transfer of relevant technologies, and appropriate funding. Accordingly, benefit-sharing entails more than sharing a certain percentage of the profits when a product is developed on the basis of a genetic resource. Furthermore, it is re-stated that when sharing benefits, the rights over the accessed resources and to the transferred technologies have to be taken into account. Finally, it is highlighted that the Nagoya Protocol aims at contributing to the conservation of biodiversity and the sustainable use of its components, which connects ABS with the other two objectives of the CBD.

Scope

The scope of the Nagoya Protocol was one of the most controversial issues in the negotiation process. The definition of the substantive, temporal, and geographical scope was perceived as critical to determine applicability and contribute to legal certainty.

The scope of the Nagoya Protocol is addressed in Article 3 and deals with genetic resources for utilization within the definition of Article 2. Article 3 provides neither a positive list of what is included nor a negative list of what is excluded, as was originally proposed during the negotiation process. As no agreement could be achieved on the final content of these lists, their drafts were not included at the end of the negotiations and were replaced by a general provision that refers to “genetic resources within the scope of Article 15 of the Convention” and to “traditional knowledge associated with genetic

resources within the scope of the Convention". As these references do not provide a direct answer to the different scope-related questions, Article 3 has to be read and interpreted in combination with all other provisions of the Nagoya Protocol, and in particular with:

- Article 2: This is of specific importance for the inclusion or exclusion of so-called derivatives in the Protocol. Apart from incorporating the definitions provided under Article 2 of the CBD (such as the terms "genetic resources" or "genetic material"), Article 2 defines the terms "utilization of genetic resources" and "biotechnology" as well as "derivatives". It is important to note that the term derivative is not used outside of Article 2(d) and (e) of the Nagoya Protocol; that is to say, it does not appear in the operative text of the Protocol. However, it is linked to the term utilization, which is used directly (verbatim) or indirectly (adjusted depending on the context in which it appears) in many provisions of the Protocol.
- Article 4: The relationship between the Nagoya Protocol and other ABS-related international instruments and processes (see Section E) was another highly contested issue during the negotiation process. This clause clarifies that the Protocol's provisions shall not affect rights and obligations from existing international agreements; that Parties may develop and implement other specialized ABS agreements in the future; that such specialized ABS agreements prevail if they are in line with the objective of the Nagoya Protocol; and that due regard should be paid to ongoing international processes. For example, ABS in relation to genetic resources for food and agriculture is regulated by the International Treaty on Plant Genetic Resources for Food and Agriculture, which qualifies as a specialized instrument under Article 4.
- Article 10: This creates the legal basis for consideration of a future global multilateral benefit-sharing mechanism. Article 10 was constructed as a "catch-all" provision addressing situations where ABS requirements cannot be met through a bilateral approach. It distinguishes between three situations: where genetic resources are located across national boundaries; where it is not possible to grant PIC for genetic resources; and where it is not possible to obtain PIC. It is important to understand that although Article 10 helped at the final stage of negotiations to defer the definition of fundamental yet controversial topics such as the temporal and geographical scope of the Nagoya Protocol, it provides only an enabling clause, which means the Parties still have to decide upon the actual need for and the modalities of such a mechanism.

Finally, it is important to note that even though the Nagoya Protocol does not apply to pre-Protocol accessions, the ABS regime of the CBD still applies to materials accessed after entry into force of the CBD.

Access

The issue of access to genetic resources and/or traditional knowledge associated with genetic resources forms a core part of the ABS concept. It is addressed in different parts of the Nagoya Protocol.

Article 6(1) reiterates the sovereign rights of States over their natural resources. It clarifies once more that access to genetic resources is subject to PIC granted by the provider country, unless otherwise determined. Article 6(2) regulates access to genetic resources. However, this provision refers to situations where ILCs have established rights over genetic resources. In this particular case, States are required to take measures, in accordance with domestic law and as appropriate, to ensure that PIC or the approval and involvement of ILCs is obtained. Article 6(3) aims at creating more legal certainty by introducing a number of measures that must be taken by all Parties requiring PIC at the domestic level:

- provision for legal certainty, clarity, and transparency of their ABS legislation or regulatory requirements;

- provision for fair and non-arbitrary access rules and procedures;
- provision of information on PIC applications;
- provision for written and cost-effective PIC decisions within a reasonable period of time;
- issuance of a permit or equivalent as evidence of PIC and MAT and notification of the ABS Clearing-House;
- establishment of criteria and/or processes for obtaining PIC or approval and involvement of ILCs; and
- establishment of clear rules and procedures for establishing MAT.

In contrast to Article 6, Article 7 regulates access to traditional knowledge associated with genetic resources. Accordingly, States shall take measures, in accordance with their domestic law and as appropriate, aiming to ensure that such traditional knowledge held by ILCs is accessed either with their PIC or with their approval and involvement. Furthermore, Article 7 clarifies that in such cases MAT have to be established with the ILCs. Article 7 aims at contributing to the implementation of Article 8(j) of the CBD. At the same time, its obligations go beyond those already included there.

Article 8 requires special considerations in national ABS regimes to:

- promote and encourage scientific research that contributes to the conservation and sustainable use of biological diversity;
- pay due regard to cases of present or imminent emergencies that threaten or damage human, animal, or plant health; and
- consider the importance of genetic resources for food and agriculture and their special role for food security.

The implementation of these access provisions is supported by Articles 13 and 14, which provide for the necessary institutional frameworks at the national and international level. Article 13 requires the designation of a national focal point and/or one or more competent national authorities that shall:

- inform about national access requirements;
- grant PIC; and
- enter into MAT.

Article 14 plays an equally important role as it establishes an ABS Clearing-House as part of the clearing-house mechanism under Article 18(3) of the CBD.[26] The ABS CH shall serve as a means for sharing ABS information that is relevant for implementation of the Protocol and made available by each Party. Furthermore, it will improve the connection between providers and users of genetic resources. According to Article 14(2), each Party has the obligation to submit the following information to the ABS CH:

- legislative, administrative, and policy measures on ABS;
- national focal point and competent national authorities; and
- permits or their equivalent as evidence for PIC and MAT.

Article 14(3) provides a list of additional information that may be submitted by the Parties, if available and as appropriate:

- relevant competent authorities of ILCs;

26 Previous experience of a clearing-house mechanism under the CBD already exists through the Biosafety Clearing-House established under the Cartagena Protocol on Biosafety.

- model contractual clauses;
- methods and tools developed to monitor genetic resources; and
- codes of conduct and best practices.

It is important to note that the ABS CH does not only play a critical role in the context of access to genetic resources, but it intends also to facilitate compliance with the ABS regimes of provider countries (see below).

Fair and Equitable Sharing of Benefits

Like the issue of access, fair and equitable benefit-sharing is also addressed in different parts of the Nagoya Protocol. While Article 5 is the main benefit-sharing provision, Articles 9, 10, 19, 20, and 23 and the Annex address particular aspects in this context.

Article 5(1) picks up on the fundamental notions already included in Article 15(3) and 15(7) of the CBD. It clarifies that:

- benefits to be shared shall include those arising from the utilization of genetic resources but also those arising from subsequent applications and commercialization;
- benefits shall be shared only with the Party providing such resources, which is "defined" as the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the CBD; and
- specific benefit-sharing arrangements will be established through MAT between the provider and the user of genetic resources, thus on a contract basis.

Article 5(1) has to be read with Article 5(3), which includes the actual obligation for Parties to take measures, as appropriate, to implement paragraph 1. Article 5(2) again addresses the specific case where ILCs have established rights over genetic resources in accordance with domestic legislation, and it requires Parties to take measures, as appropriate, aiming to ensure that benefits are shared with the ILCs concerned, based on MAT. Article 5(4) repeats that benefits may be monetary as well as non-monetary and refers to the Annex, which includes an indicative and non-exhaustive list of potential monetary and non-monetary benefits to be shared. The concrete benefits (possibly a mix of non-monetary and monetary) will need to be identified by providers and users in MAT, as they are likely to vary between different types of uses and different sectors. The examples provided in the Annex are taken verbatim from Appendix II of the Bonn Guidelines. Finally, Article 5(5) addresses benefit-sharing in relation to traditional knowledge associated with genetic resources. Accordingly, Parties are required to take measures, as appropriate, so that the benefits arising from the utilization of such traditional knowledge are shared fairly and equitably with the ILCs holding the knowledge. Such benefit-sharing shall be upon MAT.

Article 9 suggests the direction in which shared benefits should flow. Parties are obliged to encourage their providers and users to direct the benefits arising from the utilization of genetic resources towards the conservation and sustainable use of biological diversity. This provision reaffirms the linkages between benefit-sharing and the other two objectives of the CBD (conservation and sustainable use).

As mentioned earlier, Article 10 provides the legal basis for consideration of a potential global multilateral benefit-sharing mechanism that could be established in the future in order to address the fair and equitable benefit-sharing in specific cases where bilateral ABS on the basis of PIC and MAT is problematic. While providing only a procedural obligation on the Parties to "consider the need for and

modalities of" such a mechanism, Article 10 clarifies that, if established, it shall direct the benefits in a way that supports the conservation and sustainable use of biological diversity globally.

Articles 19 and 20 include obligations for Parties to encourage the development, update, and use of sectoral and cross-sectoral model contractual clauses for MAT, as well as voluntary codes of conduct, guidelines, and best practices and/or standards in relation to ABS. If properly implemented by the Parties, these instruments will create a supportive environment for providers and users to successfully negotiate, develop, and execute fair and equitable benefit-sharing agreements.

Finally, Article 23 focuses on two specific types of non-monetary benefit-sharing: collaboration and co-operation in technical and scientific research and development programmes, as well as access to and transfer of technology. While there is a clear obligation to collaborate and co-operate in such research programmes (Article 23, sentence 1), the provision includes only a general commitment, not an obligation, regarding the promotion and encouragement of access to technology by developing country Parties and the transfer of technology to them (Article 23, sentence 2).

Compliance

It is fair to say that the compliance regime of the Nagoya Protocol builds the necessary backbone of the instrument. Its aim is to prevent and react to future cases of misappropriation of genetic resources or traditional knowledge associated with genetic resources (Articles 15–17), and to ensure the enforcement of benefit-sharing agreements (Article 18).

Article 15 refers to compliance of users of genetic resources with domestic ABS legislation or regulatory requirements of provider countries:

- According to Article 15(1), all Parties to the Nagoya Protocol are obliged to take measures to provide that genetic resources utilized within their jurisdiction have been accessed in accordance with PIC and that MAT have been established, if such PIC and MAT are required by the domestic ABS legislation or regulatory requirements of the other Party. This provision therefore aims to "defend" the integrity of the PIC and MAT requirements of the provider country (if such requirements exist at the domestic level). In other words, it aims to "promote" compliance by individual users of genetic resources (whether they are natural or legal persons) with domestic ABS legal frameworks of provider countries.

- According to Article 15(2), all Parties of the Nagoya Protocol are obliged to take measures to address situations of non-compliance with the measures taken under Article 15(1). Article 15(2) thus refers to non-compliance with user country measures under Article 15(1), while Article 15(1) refers to compliance with provider country measures. This is an important distinction that may not be apparent in the first instance.

- Article 15(3) obliges all Parties to the Protocol to co-operate in cases of alleged violation of domestic ABS legislation or regulatory requirements of the provider country, which will be important for their detection.

Article 16 "mirrors" the obligations of Parties under Article 15 but with a specific focus on traditional knowledge associated with genetic resources:

- According to Article 16(1), all Parties to the Nagoya Protocol are obliged to take measures to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with PIC or approval and involvement of ILCs and that MAT have been established, as required by the domestic ABS legislation or regulatory

requirements of the Party where such ILCs are located. This provision thus aims to "promote" compliance by individual users of traditional knowledge associated with genetic resources (natural or legal persons) with domestic ABS legal frameworks related to traditional knowledge that exist in the country where such ILCs are located.

- Thus, Article 16(1) refers to compliance with provider country measures related to traditional knowledge associated with genetic resources; Article 16(2) refers to non-compliance with user country measures under Article 16(1); and Article 16(3) obliges all Parties to the Protocol to co-operate in cases of alleged violation of domestic ABS legislation or regulatory requirements related to traditional knowledge of the provider country.

It is important to note that Articles 15 and 16 provide user countries with flexibility in their implementation. They both give the discretion to choose between legislative, administrative, or policy measures. Furthermore, they require Parties only to take those measures that are appropriate and proportionate. However, a certain "performance requirement" is also established, as the measures finally taken have to be effective.

Article 17 will support the implementation of Article 15, but it does not relate to Article 16. Article 17(1) establishes an obligation for all Parties to the Protocol to monitor and enhance transparency surrounding the utilization of genetic resources. Mandatory measures include:

- designating one or more checkpoints (Article 17(1)(a));
- encouraging users and providers of genetic resources to agree on MAT clauses that require information sharing and reporting on the implementation of MAT (Article 17(1)(b)); and
- using cost-effective communication tools and systems (Article 17(1)(c)).

Article 17(1)(a) further explains that:

- the role of a checkpoint is to collect or receive information related to PIC, the source of the genetic resources, the establishment of MAT, and the utilization of genetic resources (active collection);
- each Party shall require users of genetic resources to provide such information at a checkpoint (passive collection);
- such information will be provided to relevant national authorities, to the Party providing PIC, and to the ABS CH (information sharing); and
- checkpoints must be effective in view of the whole chain of utilization.

In contrast to Article 17(1), Article 17(2)–(4) does not contain any obligations but focuses on:

- defining the internationally recognized certificate of compliance that is published through the ABS CH;
- explaining its function – namely, to provide evidence that a particular genetic resource covered by the certificate has been accessed in accordance with PIC requirements of the provider country and that MAT have been established; and
- clarifying the minimum information that has to be contained in such a certificate.

Article 18 refers to a different issue of compliance than Articles 15–17. Its objective is specifically to promote the enforcement of MAT between individual users and providers of genetic resources and/or traditional knowledge associated with genetic resources. In other words, it aims to support compliance with contractual obligations but not with domestic ABS legislation or regulatory requirements. As a consequence, Article 18 obliges each Party to:

- encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to address issues of dispute resolution in their MAT (Article 18(1));
- provide an opportunity to seek recourse under its legal system in cases of disputes over MAT (Article 18(2)); and
- take effective measures, as appropriate, regarding access to justice and the utilization of mechanisms that mutually recognize and enforce foreign judgements and arbitral awards (Article 18(3)).

Traditional Knowledge

Being a cross-cutting issue, traditional knowledge associated with genetic resources is addressed within several articles of the Nagoya Protocol as an integral part (such as in Articles 5(5), 10, 11(2), and 18(1)). However, due to its importance, traditional knowledge is also addressed in stand-alone provisions, such as Articles 7 and 16 (see above) and Article 12. Article 12 includes a number of obligations for Parties when implementing the Protocol, namely the duty:

- to take into consideration, in accordance with domestic law, ILC's customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources;
- to establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations;
- to support the development by ILCs of traditional knowledge–related community protocols, minimum requirements, and model contractual clauses; and
- not to restrict, as far as possible, customary use and exchange of genetic resources and traditional knowledge associated with genetic resources, which is in accordance with the objectives of the CBD, within and amongst ILCs.

Tools and Mechanisms to Support Implementation

In order to effectively implement the Nagoya Protocol at the national level, a variety of tools are established. The role and functions of ABS national focal points and competent national authorities, as well as the importance of the ABS CH, have already been explained. Further tools and mechanisms include:

- model contractual clauses (Article 19);
- codes of conduct, guidelines, and best practices and/or standards (Article 20);[27]
- awareness-raising (Article 21);
- capacity-building (Article 22); and
- financial resources and a financial mechanism, which is provided through the Global Environment Facility (Article 25).

27 Examples of existing tools can be found at CBD, *Existing instruments, guidelines, codes of conduct and tools addressing ABS,* at www.cbd.int/abs/instruments/.

Last but not least, Article 30 provides for the Conference of the Parties serving as the meeting of the Parties to the Protocol at its first meeting to consider and approve cooperative procedures and institutional mechanisms to promote compliance with the Protocol and address cases of non-compliance. This provision addresses the need to develop a mechanism to promote compliance of Parties with their international obligations under the Protocol. Article 30 is an "enabling provision", which means that it does not yet establish a compliance mechanism, but it provides a basis for its future development and establishment by the Conference of the Parties serving as the meeting of the Parties.

Box 2: Understanding the International Compliance Mechanism

Article 30 calls for an international compliance mechanism to promote compliance of individual Parties with all their obligations under the Protocol, including but not limited to those obligations stemming from Articles 15, 16, 17, and 18. This compliance mechanism may identify instances where Parties have not complied with their different obligations under the Protocol and may foresee consequences (which depend upon the type of compliance mechanism finally created). Furthermore, the compliance mechanism will supplement the review of the collective implementation of the Protocol by its Parties, which is to be carried out by the Conference of the Parties serving as the meeting of the Parties according to Articles 26(4), 29, and 31.

The objective of the compliance mechanism to be adopted under Article 30 is therefore to provide procedures and an institutional framework to address questions, whether or not individual Parties have taken sufficient measures to implement their treaty obligations under the Nagoya Protocol. It is not the objective of this provision to address situations of non-compliance of individual users of genetic resources and/or traditional knowledge associated with genetic resources with domestic legal frameworks related to ABS. In other words, the compliance mechanism under Article 30 has to be distinguished from those procedures and institutional measures that Contracting Parties will take in order to implement Articles 15, 16, 17, and 18 of the Protocol, thus to address (or detect) situations of misappropriation or misuse or of non-compliance with provider country measures or to deal with disputes arising from MAT (enforcement of MAT).

Article 30 specifies that the procedures and mechanisms to promote compliance with the Protocol include provisions of advice and assistance and shall be separate from the dispute settlement mechanism established under Article 27 of the CBD.

Institutional Arrangements

Finally, the Protocol includes the following institutional arrangements:

- Article 26 foresees that the Conference of the Parties to the CBD serves as the meeting of the Parties to the Nagoya Protocol.
- Article 28 explains that the CBD Secretariat will serve as the Secretariat of the Protocol.
- Article 29 provides for monitoring and reporting provisions.
- Article 31 states that an evaluation of the effectiveness of the Protocol shall be undertaken four years after its entry into force.

- Article 33 regulates the entry into force of the Protocol, requiring 50 instruments of ratification, acceptance, approval, or accession by States or regional economic integration organizations that are Parties to the CBD.

E. Relationship with Other International Instruments and Processes

As explained in Section C, a contentious issue in the negotiation process was the scope of the international regime on ABS/Nagoya Protocol (see the explanation of Article 3 later in this Guide) and its relationship with other ABS-related international instruments and processes (see the explanation of Article 4). In this section, important ABS-related international instruments and processes are briefly presented in order to explain how they coexist with and relate to the Nagoya Protocol and what this means for the Protocol's application.

ABS-related International Instruments

International Treaty on Plant Genetic Resources for Food and Agriculture

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was adopted in 2001 and entered into force in 2004. According to its Article 1, the objectives of the ITPGRFA are "the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the CBD, for sustainable agriculture and food security". Contrary to the Nagoya Protocol, which relates to genetic resources in general, the ITPGRFA only focuses on plant genetic resources for food and agriculture (PGRFA) (Article 3 of the ITPGRFA).

Most important from the ABS perspective, the ITPGRFA established a Multilateral System for Access and Benefit-sharing under Article 10(2) of the ITPGRFA. This system shall facilitate access to genetic resources of 35 major food crops and 29 forage genera that are listed in Annex I to the ITPGRFA and will ensure the fair and equitable sharing of the benefits arising from the utilization of these resources, in accordance with multilaterally agreed terms and conditions.

Box 3: Interdependence and Food Security

Plant genetic resources are the foundation for modern agriculture, which depends to a large extent on the continued improvement of plant crops. All regions and countries are dependent, to a greater or lesser degree, on PGRFA from other regions or countries – that is, countries are interdependent insofar as PGRFA are concerned. Therefore, continued access to a wide range of plant genetic resources in other regions is essential not only for crop improvement and modern agriculture but also for achieving food security.

The list of crops set out in Annex I to the ITPGRFA, which are included in the Multilateral System of ABS, has been established in accordance with the criteria of food security and interdependence. The crops listed contribute some 80 % of the world's total energy food supply.

Source: G. Moore and W. Tymowski, *Explanatory Guide to the International Treaty on Plant Genetic Resources for Food and Agriculture* (Gland and Cambridge: IUCN, 2005), p. 5.

Scope of the Multilateral System

All the PGRFA of the crops listed in Annex I are not automatically included in the Multilateral System. Only the crops for which PGRFA are under the management and control of the Contracting Parties and are in the public domain are automatically included within the Multilateral System (Article 11(2) of the ITPGRFA). All other holders of PGRFA are encouraged to include them into the system, and Contracting Parties shall take appropriate measures to encourage those inclusions (Article 11(2) and (3) of the ITPGRFA). Furthermore, the Multilateral System includes 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 (Article 11(5) of the ITPGRFA).

Facilitated access

Contracting Parties agreed to facilitate access to the PGRFA included in the Multilateral System for other Contracting Parties and for legal and natural persons under their jurisdiction, according to the conditions set out in Article 12 of the ITPGRFA. In particular, Article 12 provides that:

- such facilitated access will only be provided for the purpose of utilisation and conservation for research, breeding, and training for food and agriculture and not for chemical, pharmaceutical, and other industrial uses beyond food and animal feed (Article 12(3)(a) of the ITPGRFA) – access for other purposes is therefore not covered by the Multilateral System;
- facilitated access shall be pursuant to a standard material transfer agreement (SMTA) that has been developed by the Governing Body (Article 12(4) of the ITPGRFA);[28] and
- recipients of material are required not to claim intellectual property or other rights that limit facilitated access to PGRFA, or to their genetic parts or components, in the form received from the Multilateral System (Article 12(3)(d) of the ITPGRFA).

It is important to note that by being a Contracting Party to the ITPGRFA, a country is effectively agreeing that access to the specific PGRFA does not require Contracting Parties to grant PIC or to negotiate bilaterally MAT for each transaction (Moore and Tymowski, 2005, p. 28). In legal terms, however, it could be said that PIC has already been granted through Article 11 of the ITPGRFA and that MAT have been pre-negotiated and agreed multilaterally by the Contracting Parties, as contained in the SMTA, which a recipient must accept in order to obtain PGRFA from the Multilateral System.

Furthermore, it needs to be recognized that for PGRFA outside of the limited scope of the Multilateral System, Contracting Parties may nevertheless decide to provide facilitated access as foreseen under Article 12(3) and (4) of the ITPGRFA (Moore and Tymowski, 2005, p. 89).

Benefit-sharing

Article 13 of the ITPGRFA sets out the agreed terms for benefit-sharing within the Multilateral System. According to Article 13(1), the Contracting Parties recognize that facilitated access to PGRFA itself constitutes already a major benefit. Furthermore, any benefits arising from the utilization of these resources shall be shared fairly and equitably through a range of mechanisms described in Article 13(2):

- exchange of information;
- access to and transfer of technology;
- capacity-building; and
- sharing of monetary and other benefits of commercialization.

28 The SMTA can be downloaded at ftp://ftp.fao.org/ag/agp/planttreaty/agreements/smta/SMTAe.pdf.

An important innovation of the ITPGRFA in the area of benefit-sharing can be found in Article 13(2)(d)(ii). A provision is included in the SMTA that requires recipients who commercialize products that are PGRFA and that incorporate materials accessed from the Multilateral System to pay an equitable share of the benefits arising from the commercialization of the product into an international fund established by the Governing Body. Such payment is mandatory where restrictions are placed on the availability of the product for further research and breeding. Where no such restrictions are in place, the recipient is not under any obligation to make a payment but is encouraged to do so voluntarily. The benefits arising from the use of PGRFA shall flow directly or indirectly to farmers in all countries who conserve and utilize PGRFA, especially those in developing countries and countries with economies in transition (Article 13(3) of the ITPGRFA) (Moore and Tymowski, 2005, p. 16).

Arguably, the ITPGRFA provides for a specialized international ABS instrument in the sense of Article 4(4) of the Nagoya Protocol and thus prevails over the ABS provisions under the Protocol. Also, the possible expansion of Annex I of the ITPGRFA may qualify as relevant ongoing work or practices under other international instruments, in terms of Article 4(3) of the Nagoya Protocol. This understanding is supported by different provisions in the Preamble of the Nagoya Protocol that specifically recognize and recall the importance of the ITPGRFA and its Multilateral System.

International Convention for the Protection of New Varieties of Plants

The International Convention for the Protection of New Varieties of Plants, adopted in Paris in 1961 (entry into force in 1968),[29] established the International Union for the Protection of New Varieties of Plants (UPOV). The mission of the UPOV is "to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society".

Farmers have practiced seed selection and plant breeding since the beginning of agriculture. The UPOV Convention acknowledges the achievements of breeders of new varieties of plants by providing a *sui generis* form of intellectual property protection that has been specifically adapted for the process of plant breeding and has been developed with the aim of encouraging breeders to develop new varieties of plants. It offers protection to the breeder, in the form of a "breeder's right", if the plant variety meets the following requirements:

- distinct from existing, commonly known varieties;
- sufficiently uniform;
- stable; and
- new in the sense that they must not have been commercialized prior to certain dates established by reference to the date of the application for protection.[30]

According to Article 15(1) of the UPOV Convention, three compulsory exceptions limit the breeder's right that shall not extend to acts done:

- privately and for non-commercial purposes (exemption for subsistence farmers);
- for experimental purposes (the so-called research exemption); or
- for the purpose of breeding other varieties (the so-called breeder's exemption).

29 Since its adoption, the International Convention for the Protection of New Varieties of Plants was revised in 1972, 1978, and 1991.

30 UPOV *Introduction,* at www.upov.int/en/about/introduction.htm.

Furthermore, Article 15(2) contains an optional exception for farm-saved seed, the "farmer's privilege", such that "each Contracting Party may, within reasonable limits and subject to safeguarding of the legitimate interest of the breeder, restrict the breeder's rights in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety".

UPOV considers the system of breeder's rights and exceptions as a specialized form of ABS. This reflects the view of UPOV that plant breeding is a fundamental aspect of the sustainable use and development of genetic resources and that the worldwide community of breeders needs access to all forms of breeding material to sustain the greatest progress in plant breeding and to maximize the use of genetic resources for the benefit of society.[31] It therefore provides for access to genetic resources as a key requirement for sustainable and substantial progress in plant breeding, and it includes benefit-sharing principles in the form of breeder's exemptions and other exceptions to the breeder's right.

United Nations Convention on the Law of the Sea

The United Nations Convention on the Law of the Sea (UNCLOS) was adopted in 1982 and entered into force in 1994. UNCLOS is perceived as the cornerstone of the currently existing international legal framework governing the oceans and seas. It "sets out the legal frameworks within which all activities in the oceans and seas must be carried out and is of strategic importance as the basis for national, regional and global action and cooperation in the marine sector."[32]

UNCLOS foresees different maritime zones within which coastal States can exercise different rights and are expected to fulfil certain obligations:

- In its internal waters and the territorial sea, the coastal State exercises sovereignty over the living and non-living natural resources found in the water column, the seabed, and the subsoil thereof.
- In its contiguous zone, the exclusive economic zone, as well as on the continental shelf up to 200 nautical miles from the baseline, the coastal State enjoys sovereign rights over the exploitation, conservation, and management of living and non-living natural resources found in the water column, the seabed, and the subsoil thereof and exercises jurisdiction over marine scientific research and for the protection of the marine environment.
- On its extended continental shelf (not exceeding 350 nautical miles from the baseline or 100 nautical miles from the 2.500 metre isobaths), the coastal State enjoys sovereign rights over non-living natural resources found in the seabed and the subsoil thereof, as well as over sedentary species – that is, organisms that "either are immobile on or under the seabed or are unable to move except in constant physical contact with the seabed or the subsoil".

ABS for marine genetic resources found in these geographic areas is subject to national legislation and thus falls under the scope of the Nagoya Protocol. In contrast, marine genetic resources found in areas beyond national jurisdiction (ABNJ) – that is to say, the high seas and the so-called Area (that is the deep seabed) – are outside of the scope of the Nagoya Protocol.

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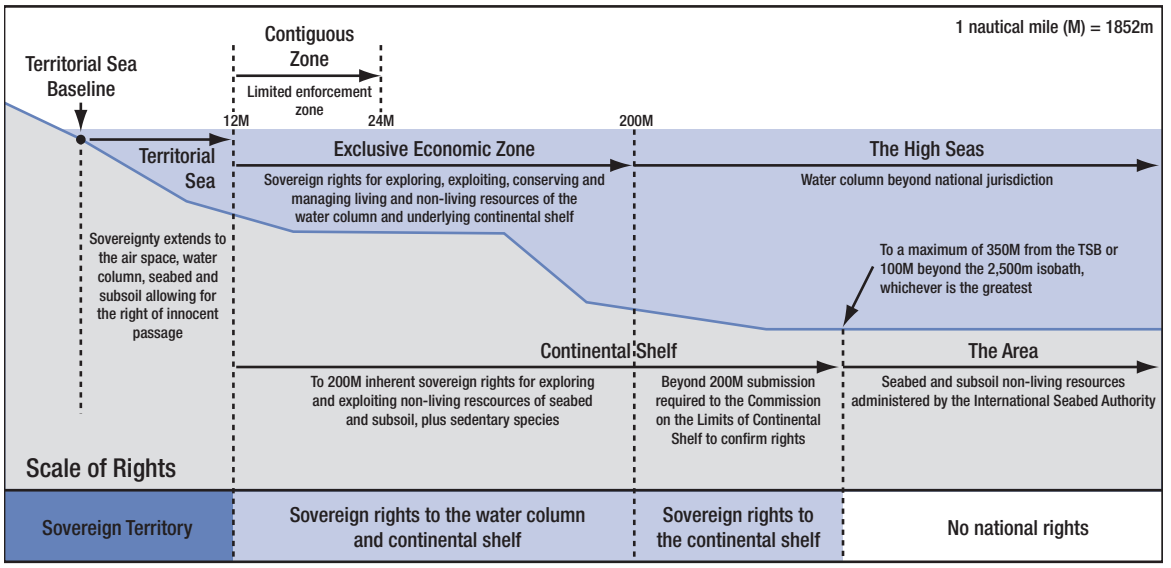
31 UPOV. *Access to Genetic Resources and Benefit-sharing – Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity (CBD)* (Council of UPOV, 37th ordinary session, 2003), p. 2, at www.upov.int/news/en/2003/pdf/cbd_response_oct232003.pdf.

32 UN doc A/RES/65/37, of 7 December 2010, Preambular para 4, at www.un.org/Depts/los/general_assembly/general_assembly_resolutions.htm#2010.

Figure 3: Overview of Different Maritime Zones According to UNCLOS



Source: Arctic Council, *Arctic Marine Shipping Assessment 2009 Report* (Tromsø, Norway: 2009), p. 52, available at www.pame.is/images/stories/PDF_Files/AMSA_2009_Report_2nd_print.pdf .

It is important to note that ABS for marine genetic resources from ABNJ is not specifically addressed by UNCLOS. In fact, the term "marine genetic resources" is neither utilized nor described in the treaty text. Silence on this matter triggers the question as to whether a regulatory gap exists under UNCLOS with regard to ABS for marine genetic resources in ABNJ. This point has led to disagreement between States due to different interpretations of those UNCLOS provisions that could be interpreted to cover the issue of marine genetic resources in ABNJ. Such provisions include mainly the ones related to UNCLOS Part VII on the high seas, UNCLOS Part XI on the Area, and UNCLOS Part XIII on marine scientific research.

However, the issue of ABS for marine genetic resources from ABNJ is being addressed by the United Nations General Assembly (UNGA). Several resolutions on "Oceans and the law of the sea" call upon States to further consider the relevant legal regime in ABNJ.[33] In 2004, an Ad hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction (BBNJ) was established by the UNGA.[34] The BBNJ process could lead to the development of an ABS regime for marine genetic resources in ABNJ. This would be in line with decisions taken by the CBD COP, which repeatedly recognized that the law of the sea (and UNCLOS) provides a legal framework for regulating activities in marine ABNJ.[35] Furthermore,

33 For example, UNGA Resolution 65/37, UN doc A/RES/65/37, of 7 December 2010, at www.un.org/Depts/los/general_assembly/general_assembly_resolutions.htm#2010.

34 UNGA Resolution 59/24, UN doc A/RES/59/24, of 17 November 2004, para 73, at www.un.org/Depts/los/general_assembly/general_assembly_resolutions.htm#2010.

35 CBD COP 7 Decision VII/5, Marine and coastal biological diversity, 31; CBD COP 8 Decision VIII/21, *Marine and coastal biological diversity: conservation and sustainable use of deep seabed genetic resources beyond the limits of national jurisdiction, 6; CBD COP 9 Decision IX/20 Marine and coastal biological diversity.*

the CBD COP invited the UNGA to further coordinate work relating to conservation and sustainable use of genetic resources in ABNJ.[36]

Antarctic Treaty System

The Antarctic Treaty System (ATS), including the 1959 Antarctic Treaty (entry into force in 1961), the 1991 Protocol on Environmental Protection to the Antarctic Treaty (entry into force in 1998), and the 1980 Convention on the Conservation of Antarctic Marine Living Resources (entry into force in 1982), is of further relevance for ABS related to marine and terrestrial genetic resources in "the area south of 60° South Latitude, including all ice shelves" (Article VI of the Antarctic Treaty). The genetic resources found in this geographical area also fall outside of the scope of the Nagoya Protocol. As there is no recognized sovereign State in the Antarctic Treaty area (Article IV of the Antarctic Treaty), its genetic resources are found in areas beyond national jurisdiction. Nevertheless, the ATS establishes a distinct international framework for governing activities in the Antarctic Treaty area for which sharing the benefits of Antarctica is an important aim.

ABS-related International Processes

FAO Commission on Genetic Resources for Food and Agriculture

The Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations (FAO Commission) was established in 1983 under Article VI(1) of the FAO Constitution. Its original mandate to deal with issues related to plant genetic resources was broadened in 1995 to cover all components of biodiversity relevant to food and agriculture.

The Commission has developed codes of conduct, in particular the Code of Conduct for Germplasm Collecting and Transfer, and other non-legally binding policy instruments in the field of genetic resources for food and agriculture. Apart from the ITPGRFA, which was negotiated under the Commission, it has not developed any legally binding ABS instrument. However, part of the FAO Commission's terms of reference under its Multi-Year Programme of Work is "to keep under continuous review all matters relating to the policy, programmes and activities of FAO in the area of genetic resources of relevance to food and agriculture, including their conservation and sustainable use and the fair and equitable sharing of benefits derived from their utilization."[37] Therefore, the FAO Commission may decide to develop further legally binding ABS instruments for specific components of biodiversity for food and agriculture in the future, such as animal genetic resources for food and agriculture, or others. Article 4(2) of the Nagoya Protocol allows the development of such specialized ABS agreements in the future as long as they are supportive of and do not run counter to the objectives of the CBD and its Nagoya Protocol.

36 CBD COP 7 Decision VII/5, *Marine and coastal biological diversity, 55.*

37 Secretariat of the Convention on Biological Diversity, *Study on the Relationship between an International Regime on Access and Benefit-sharing and Other International Instruments and Forums that Govern the Use of Genetic Resources – The International Treaty on Plant Genetic Resources for Food and Agriculture and the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations,* UNEP/CBD/WG-ABS/7/INF/3/Part.1 (Montreal: Secretariat of the Convention on Biological Diversity, 2009), at www.cbd.int/doc/meetings/abs/abswg-09/information/abswg-09-abswg-07-inf-03-part1-en.pdf.

Box 4: The International Code of Conduct for Plant Germplasm Collecting and Transfer

The International Code of Conduct for Plant Germplasm Collecting and Transfer aims to:

- promote the rational collection and sustainable use of genetic resources;
- prevent genetic erosion; and
- protect the interests of both donors and collectors of germplasm.

Recognizing national sovereignty over plant genetic resources, this voluntary code sets out standards and principles to request and/or to issue licences for collecting missions, provides guidelines for collectors, and extends responsibilities and obligations to the sponsors of missions, the curators of genebanks, and the users of genetic material. It calls for the participation of farmers and local institutions in collecting missions and proposes that users of germplasm share the benefits derived from the use of plant genetic resources with the host country and its farmers.

For the International Code of Conduct for Plant Germplasm Collecting and Transfer, see http://www.fao.org/nr/cgrfa/cgrfa-global/cgrfa-codes/en/.

World Trade Organization

Established in 1995, the World Trade Organization (WTO) is an international organization dealing with the rules of trade amongst its Members States through the implementation of trade agreements. One of the WTO agreements, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), raises issues related to the CBD in general and to ABS in particular.

Adopted in 1994 (entry into force in 1995), TRIPS is one of the pillars of the WTO that introduces intellectual property rules into the multilateral trading system. Some TRIPS provisions, in particular Article 27, need to be considered in the implementation of the Nagoya Protocol. Article 27 defines which inventions governments are obligated to make eligible for patenting and what they can exclude from patenting.

A patent is an intellectual property right granted by a State to an applicant (who may but does not have to be the inventor) for a limited period of time in exchange for the public disclosure of the invention. It usually grants the exclusive right to the patent holder to prevent others from making, using, selling, or distributing the patented invention without permission.

According to Article 27(1) of TRIPS, inventions that can be patented include both products and processes and should generally cover all fields of technology. Furthermore, three basic patent requirements need to be fulfilled:

- novelty, meaning the product or process must be new;
- inventive step, meaning the idea must be non-obvious/“new enough”; and
- industrial applicability, meaning it must be useful.

Patenting is a useful instrument for users of genetic resources and traditional knowledge associated with genetic resources to protect the products or processes derived from their research and development; that is to say, patents are important for users to protect their innovations and investments. At the same

time, provider countries are concerned that the principles of PIC, MAT, and fair and equitable benefit-sharing are respected in such patenting processes.

Article 27(3)(b) of TRIPS deals with patentability and non-patentability of plant and animal inventions and the protection of plant varieties. Governments are allowed to exclude some kinds of inventions from patenting – that is, plants, animals, and "essentially" biological processes – but micro-organisms and non-biological and microbiological processes have to be eligible for patents. Plant varieties also have to be eligible for protection either through patent protection or through a system created specifically for the purpose *(sui generis),* or through a combination of these two.

The debate on the relationship between the Nagoya Protocol and the WTO provisions is strongly focused on the disclosure of origin of genetic resources and traditional knowledge associated with genetic resources as well as compliance with the ABS legislation of the country of origin, all of which are currently not considered patent requirements under TRIPS. It is therefore being discussed whether an amendment of TRIPS establishing such patent requirements or alternative approaches could be more effective in ensuring mutual support between TRIPS and the Nagoya Protocol.

Box 5: Options to Achieve Mutual Support between TRIPS and the Nagoya Protocol

Several different options on how to achieve mutual support between TRIPS and the Nagoya Protocol exist.

- Amendment of TRIPS in order to include a mandatory disclosure requirement

In patent applications, the applicants could have the obligation to disclose the country of origin of the genetic resource and the traditional knowledge associated with genetic resources. In case of failure, the application could not be processed.

Source: Submission from Bolivia, Brazil, Colombia, Cuba, Dominican Republic, Ecuador, India, Peru and Thailand (2005). *The relationship between the TRIPS agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge – elements of the obligation to disclose evidence of benefit-sharing under the relevant national regime.* Council for Trade-Related Aspects of Intellectual Property Rights. IP/C/W/442, 18 March 2005.

- Amendment to the Patent Cooperation Treaty of the World Intellectual Property Organization

This could include an obligation for patent applicants to declare the source – that is, the entity of the government that granted access to the genetic resource and to the traditional knowledge associated with a genetic resource and that participates in the sharing of benefits deriving from it. The sanctions used in the Patent Cooperation Treaty could be used in case of non-compliance. ▶

Alternatively, patent applicants could be obligated to disclose the geographic origin of the genetic resources or the traditional knowledge used in the invention. However, this obligation could be separated from the patentability criteria, and the legal consequences in case of non-disclosure could be separated from the patent process.

Source: Submission from Switzerland (2004). *Additional Comments by Switzerland on its Proposal Submitted to WIPO Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications.* Council for Trade-Related Aspects of Intellectual Property Rights. IP/C/W/423, 14 June 2004. Submission from the European Union (2002). *Communication from the European Communities and their Member States.* Council for Trade-Related Aspects of Intellectual Property Rights. IP/C/W/383, 17 October 2002.

- Development of national legislation

Based on an understanding that no real conflict between TRIPS and the CBD exists, the development of national legislation separated from the patent system could be a way to achieve the objectives of the CBD and TRIPS. The sharing of benefits could be achieved through contractual agreements based on such national legislation, which could include disclosure obligations.

Source: Submission from the United States (2004). *Article 27(3)(b), Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore. Communication from the United States.* Council for Trade-Related Aspects of Intellectual Property Rights. IP/C/W/464, 26 November 2004.

World Intellectual Property Organization

The World Intellectual Property Organization (WIPO) is a specialized agency of the United Nations established by the WIPO Convention in 1967. It is dedicated to the promotion of the protection of intellectual property throughout the world. WIPO administers 24 treaties, including the WIPO Convention.

Discussions in different WIPO Committees are relevant for genetic resources and traditional knowledge, particularly those taking place in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). The WIPO IGC was established by the WIPO General Assembly in 2000 as a forum for discussions among Member States and is undertaking text-based negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments) that will ensure the effective protection of traditional knowledge, traditional cultural expressions/folklore, and genetic resources. Furthermore, the WIPO IGC has compiled an on-line, searchable database of biodiversity-related ABS agreements and related information, with a particular emphasis on the intellectual property aspects of such agreements.

World Health Organization

The World Health Organization (WHO) is the UN Specialized Agency providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends.

One instrument developed under the WHO is the International Health Regulations (IHR) that were adopted in 2005. The objective is to facilitate the prevention and response to public health risks that

have the potential to become global problems. The IHR define the rights and obligations of countries to report public health events and establish a number of procedures that the WHO must follow in its work to uphold global public health security.

In addition, parallel to the ABS negotiations under the CBD, negotiations took place within the WHO regarding access to pathogens, in particular influenza viruses, and the distribution of the resulting "advantages" in particular vaccines. This development was accelerated by actions of Indonesia, which in early 2007 stopped sending samples of the H5N1 virus to the WHO on the grounds that it required a more equitable system of access to vaccines for developing countries. As a consequence, the sixtieth World Health Assembly decided to develop a new global mechanism for virus sharing in cases of global pandemic influenza viruses that would be fairer to poorer nations.[38]

In 2011, the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIPF) was adopted by the World Health Assembly.[39] The PIPF is a new framework providing for a multilateral benefit-sharing arrangement. Amongst other goals, it aims for more equitable access to affordable vaccines and, at the same time, guarantees the flow of virus samples into the WHO system so that the critical information and analyses needed to assess public health risks and develop vaccines are available.

According to its Article 3, the PIPF applies only to the sharing of H5N1 and other influenza viruses with human pandemic potential, not to seasonal influenza viruses or other non-influenza pathogens or biological substances that may be contained in clinical specimens. Its objective is to strengthen the protection against pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system. At the same time, the objective of the PIPF is a fair, transparent, and equitable system for sharing H5N1 and other influenza viruses with human pandemic potential and for access to vaccines and the sharing of other benefits.

The PIPF could be considered a specialized instrument under Article 4(4) of the Nagoya Protocol, and cases regulated under its framework would have to be understood under Article 8(b) of the Nagoya Protocol.[40]

In the sections that follow, each individual Article and the Annex of the Nagoya Protocol are analyzed, providing background on the provisions as well as explanations of their obligations and commitments. Afterwards, the implications of the adoption of the Nagoya Protocol as well as ideas on potential options for its implementation are presented. Finally, a bibliography of selected ABS writings, as well as supplementary materials for ease of reference, is provided.

38 World Health Assembly Resolution 60.28, of 23 May 2007, *Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits* (Sixtieth World Health Assembly, 2007), WHA60.28, Agenda item 12.1, at apps.who.int/gb/ebwha/pdf_files/WHASSA_WHA60-Rec1/E/reso-60-en.pdf.

39 World Health Assembly Resolution 64.5, of 24 May 2011, *Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits* (Sixty-fourth World Health Assembly, 2011), WHA64/5, Agenda item 13.1, at apps.who.int/gb/ebwha/pdf_files/WHA64/A64_R5-en.pdf.

40 It is important to note that other practices relevant to the issue of pathogens also exist, namely under the World Organization for Animal Health and the International Plant Protection Convention.

Explanation

Preamble

The Parties to this Protocol,

Being **Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",**

Recalling **that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the Convention, and recognizing that this Protocol pursues the implementation of this objective within the Convention,**

Reaffirming **the sovereign rights of States over their natural resources and according to the provisions of the Convention,**

Recalling further **Article 15 of the Convention,**

Recognizing **the important contribution to sustainable development made by technology transfer and cooperation to build research and innovation capacities for adding value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention,**

Recognizing **that public awareness of the economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components,**

Acknowledging **the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability and thereby contributing to achieving the Millennium Development Goals,**

Acknowledging **the linkage between access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources,**

Recognizing **the importance of providing legal certainty with respect to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization,**

Further recognizing **the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources,**

Recognizing also **the vital role that women play in access and benefit-sharing and affirming the need for the full participation of women at all levels of policy-making and implementation for biodiversity conservation,**

Determined **to further support the effective implementation of the access and benefit-sharing provisions of the Convention,**

▶

Recognizing **that an innovative solution is required 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,**

Recognizing **the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaptation to climate change,**

Recognizing **the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions,**

Recognizing **the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard,**

Mindful **of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes,**

Acknowledging **ongoing work in other international forums relating to access and benefit-sharing,**

Recalling **the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture developed in harmony with the Convention,**

Recognizing **that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention,**

Recalling **the relevance of Article 8(j) of the Convention as it relates to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising from the utilization of such knowledge,**

Noting **the interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities, the importance of the traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities,**

Recognizing **the diversity of circumstances in which traditional knowledge associated with genetic resources is held or owned by indigenous and local communities,**

Mindful **that it is the right of indigenous and local communities to identify the rightful holders of their traditional knowledge associated with genetic resources, within their communities,**

Further recognizing **the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other**

▶

forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity,

Noting **the United Nations Declaration on the Rights of Indigenous Peoples, and**

Affirming **that nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities,**

Have agreed as follows:

A. Background

The Preamble of an international agreement forms an integral part of the agreement. The Vienna Convention on the Law of Treaties (adopted in 1969, entry into force in 1980) gives it the same legal status as the remainder of the text in providing context for the interpretation of a treaty's terms (Article 31(2) of the Vienna Convention).

The legal purpose of a Preamble is therefore to provide assistance in interpreting terms but also in resolving conflicting interpretations of provisions or context for further negotiations. It also gives insight into the issues behind a treaty's negotiation and adoption, as this is where the Parties set out their concerns and motivations and identify the issues addressed and the actual need for an agreement. Furthermore, the Preamble often contains paragraphs that are not completely developed in the operational provisions of the agreement and thus have implications that go beyond the obligations in the substantive articles that follow (Glowka et al., 1994, p. 9). Consequently, it is also important for future implementation of the treaty in practice.

On several occasions as the Nagoya Protocol was being developed, the Preamble served as the vehicle to reach agreement on issues where consensus on operative text was not possible during negotiations (Tsioumani, 2010, p. 289). Furthermore, it should be noted that the Preamble of the Nagoya Protocol often refers to related international agreements considered relevant by Parties. Giving due consideration to the Preamble can thus assist Parties in developing coherent and complementary legislation and policies implementing the concept of access and benefit-sharing (ABS) as it is understood in the Nagoya Protocol. However, it must be recognized that the verbs at the start of each preambular paragraph (e.g., recognizing, recalling, acknowledging, mindful) give different strength and meaning to the text that follows.

B. Explanation

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

The Convention on Biological Diversity (CBD) is the global treaty that comprehensively addresses the subject of biological diversity while giving a significant amount of discretion in the creation of protocols (Articles 23(4)(c) and 28 of the CBD). This opening paragraph indicates that only Parties to the CBD may become Parties to the Nagoya Protocol.

Recalling that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of the three core objectives of the Convention, and recognizing that this Protocol pursues the implementation of this objective within the Convention,

This paragraph links the Nagoya Protocol to the implementation of the third objective of the CBD and situates it clearly within its framework. It foreshadows the objective of the Protocol and eliminates any confusion over the meaning of its terms when read alongside other global treaties with similar purposes.

Reaffirming the sovereign right of States over their natural resources and according to the provisions of the Convention,

The sovereign right of States over their natural resources is a long-standing principle of international law dating to the post-colonial era, overtly recognized in the 1962 United Nations General Assembly Resolution on *Permanent Sovereignty over Natural Resources*[1]. It was articulated in the environmental context in Principle 21 of the Stockholm Declaration on the Human Environment of the United Nations Conference on the Human Environment (adopted in 1972) and rearticulated in Principle 2 of the Rio Declaration of the United Nations Conference on Environment and Development (adopted in 1992). This principle is a basis of the CBD, as noted in its Preamble and implemented in Articles 3 and 15(1) of the CBD.

Recalling further Article 15 of the Convention,

Article 15 of the CBD creates and governs the legal regime pertaining to access to genetic resources and the fair and equitable sharing of benefits resulting from their use. Its full implementation is one of the bases for the negotiation and adoption of the Nagoya Protocol. Furthermore, it should be noted that Article 3 of the Protocol establishes that its scope is linked to Article 15 of the CBD.

Recognizing the important contribution to sustainable development made by technology transfer and cooperation to build research and innovation capacities for adding value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention,

The implementation of Articles 16 (Access to and Transfer of Technology) and 19 (Handling of Biotechnology and Distribution of its Benefits) of the CBD is meant to further sustainable development, which is one of the underlying principles of the CBD and a fundamental challenge facing contemporary societies. This preambular paragraph recognizes the importance of both provisions and thus foreshadows the obligations of Parties in Article 23 of the Nagoya Protocol regarding technology transfer, collaboration, and co-operation.

1 *Permanent Sovereignty over Natural Resources,* UNGA Res. 1803 (XVII), U.N. Doc. A/5217 (1962).

Recognizing that public awareness of the economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components,

Public awareness about the economic value of ecosystems and biodiversity and the fair and equitable sharing of this value with the custodians of biodiversity are important incentives for biodiversity conservation and sustainable use. The series of reports produced by The Economics of Ecosystems and Biodiversity Initiative hosted by the United Nations Environment Programme drew attention to the global economic benefits of biodiversity, highlighted the growing costs of biodiversity loss and ecosystem degradation, and brought together scientific, economic, and policy expertise to recommend practical actions for policy-makers, citizens, and businesses (Kumar, 2010; ten Brink, 2011; Bishop, 2011). Public awareness and education on such topics is an important aspect of the CBD, as indicated in its Article 13. Awareness-raising activities under Article 21 of the Nagoya Protocol can contribute to this.

Acknowledging the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability and thereby contributing to achieving the Millennium Development Goals,

This preambular paragraph recalls that ABS is directly linked to meeting the other two objectives of the CBD: conservation and sustainable use of biodiversity. It also expresses the hope that ABS will spread economic benefits more widely, thus reducing poverty for those communities that are the custodians of biodiversity and promoting environmental sustainability because communities will have an incentive to protect their natural resources if they see the benefits of doing so. Eradicating extreme poverty and hunger, as well as ensuring environmental sustainability, are two of the eight Millennium Development Goals with time-bound targets adopted by the United Nations General Assembly in the 2000 Millennium Declaration.[2]

Acknowledging the linkage between access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources,

This paragraph recognizes the fact that there can be no benefit-sharing without access to genetic resources for utilization. Article 15 of the CBD already lays out a connection between access to genetic resources and fair and equitable benefit-sharing. This connection is further developed in the 2002 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (the Bonn Guidelines) (SCBD, 2002). In the Nagoya Protocol, the link is mainly established through Articles 3 (Objective), 5 (Fair and Equitable Benefit-sharing), and 6 (Access to Genetic Resources).

2 *Millennium Declaration,* GA Res. 55/2, 18 September 2000.

Recognizing the importance of providing legal certainty with respect to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization,

One of the challenges with implementation of the ABS provisions of the CBD is that in many countries ABS legal frameworks are not sufficiently clear and therefore do not provide the necessary legal certainty for either users or providers of genetic resources. This has often prevented ABS from becoming a fully functional system for the research and development of genetic resources and traditional knowledge associated with genetic resources. The Bonn Guidelines have provided guidance for the development of ABS frameworks but are voluntary and thus do not provide full legal certainty. The Nagoya Protocol attempts to establish greater legal certainty, thus providing a basis for greater trust between users and providers. In particular, Article 6(3) of the Protocol and its compliance provisions aim to address this issue.

Further recognizing the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources,

Article 15(4) of the CBD requires that access to genetic resources be on mutually agreed terms (MAT). However, the providers and users of genetic resources may be on unequal footing. This can lead to unfair and inequitable contracts for access, especially for some indigenous and local communities (ILCs), foiling the intent of the CBD that benefits be shared in a fair and equitable manner. The Nagoya Protocol recognizes this and aims to promote negotiations that are fair rather than exploitative through different provisions, such as on capacity-building, including the promotion of equity and fairness in negotiations (Article 22(5)(b)) or model contractual clauses for MAT (Article 19(1)).

Recognizing also the vital role that women play in access and benefit-sharing and affirming the need for the full participation of women at all levels of policy-making and implementation for biodiversity conservation,

The CBD Preamble recognizes the vital role of women in the conservation and sustainable use of biodiversity, meriting full participation at all levels of biodiversity conservation policy-making and implementation. This paragraph builds upon the CBD reference by giving particular recognition to the vital role of women in ABS. Women globally are users and custodians of biological diversity. They have a unique relationship with biodiversity and predominate as wild-plant gatherers, home gardeners, plant domesticators, herbalists, and seed custodians (Aguilar et al., 2008). In some societies, women regulate the harvesting of wild species to ensure sustainability (Glowka et al., p. 12).

Based on their role as custodians, this paragraph affirms that women should be able to fully participate at all levels of policy-making and implementation for biodiversity conservation, which includes participation in decision-making processes on the use of genetic resources and traditional knowledge associated with genetic resources, such as prior informed consent (PIC) and MAT negotiations. Reference to women appears in the Protocol in Articles 12(3) (Traditional Knowledge Associated with Genetic Resources), in 22(3) and (5) (Capacity), and in 25(3) (Financial Mechanism and Resources). Further gender mainstreaming in the implementation of the Nagoya Protocol could contribute to

realizing obligations under human rights law, sustainable development law, and the CBD (Quesada-Aguilar et al., 2008).

Determined to further support the effective implementation of the access and benefit-sharing provisions of the Convention,

This paragraph underlines the Parties' desire to make the ABS provisions of the CBD work effectively. Parties recognized that adequate ABS implementation was lacking within the first decade after the adoption of the CBD. This led to the development of the Bonn Guidelines at the sixth meeting of the Conference of the Parties to the CBD (CBD COP 6) in 2002 and the call for action later that year at the World Summit on Sustainable Development to negotiate an international ABS regime.[3]

Recognizing that an innovative solution is required 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,

Because biodiversity and traditional knowledge are not constrained by national boundaries, in some situations the genetic resources are present in multiple States, and traditional knowledge pertaining to those genetic resources is distributed among communities that are located in different States. These situations are addressed by this preambular paragraph, which feeds into Articles 10 (Global Benefit-sharing Mechanism) and 11 (Transboundary Cooperation) of the Protocol. Article 10 addresses the possible development of a global multilateral benefit-sharing mechanism. Article 11 reaffirms the need for co-operation to address transboundary genetic resources and traditional knowledge associated with genetic resources.

Recognizing the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaptation to climate change,

This paragraph acknowledges the key role of genetic resources in addressing issues relevant to humans and the environment and describes some key drivers behind the need to access genetic resources. The first three topics foreshadow Article 8 of the Nagoya Protocol, which lays out special considerations for Parties when developing and implementing ABS laws or regulations. These special considerations include creating conditions for research that contributes to the conservation and sustainable use of biodiversity, including through measures on access for non-commercial research purposes; paying due regard to emergencies that threaten or damage human, animal, or plant health; and considering the importance of genetic resources for food and agriculture and their special role in food security. As climate change is not mentioned in the Nagoya Protocol except in the Preamble, it was important to note in this paragraph the significance of genetic resources in ensuring species survival in face of climate change.

3 *Plan of Implementation of the World Summit on Sustainable Development,* para 44(o).

Recognizing the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions,

Agricultural biodiversity is fostered by humans rather than being a process of natural evolution and is thus distinct from biodiversity generally. Decisions by the CBD COP have recognized the particular characteristics of agricultural biodiversity, leading to a Programme of Work on Agricultural Biodiversity under the CBD.[4] The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is one solution to the challenges facing plant agricultural biodiversity in harmony with the CBD.

Recognizing the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard,

Humanity depends on a number of genetic resources for food and agriculture traded globally. This paragraph recognizes the interdependence of countries on such genetic resources and their importance for food security and sustainable development of agriculture in line with the provisions of the ITPGRFA and the work of the Commission on Genetic Resources for Food and Agriculture (CGRFA) of the United Nations Food and Agriculture Organization (FAO). The FAO played a key role in the protection of such resources and oversaw the adoption of the ITPGRFA (see section E of the Introduction). The operative text of the Nagoya Protocol does not mention the ITPGRFA but makes the treaty subject to Article 4(4) on the relationship with other relevant international agreements and instruments.

Mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes,

During negotiations of the Nagoya Protocol, concerns arose among the Parties that access to pathogenic materials relevant to human health could be hindered by the rules it established. Reference to the International Health Regulations—global rules established by the World Health Organization (WHO) to enhance national, regional, and global public health security—was made in the Preamble to remind Parties of their international duties in health security and that access to pathogens is important for pandemic preparedness and response. In April 2011, six months after the adoption of the Nagoya Protocol, the WHO adopted the Pandemic Influenza Preparedness Framework (PIPF) for the sharing of influenza viruses and access to vaccines and other benefits (see section E of the Introduction). Although the PIPF emphasizes the norm of sharing viruses, it does not create legally binding obligations (Fidler and Gostin, 2011).

4 COP 2 Decision II/15 and COP 5 Decision V/5.

Acknowledging ongoing work in other international forums relating to access and benefit-sharing,

The issue of ABS has been discussed in several different forums (see section E of the Introduction), including the CGRFA, ITPGRFA, World Intellectual Property Organization, WHO, World Trade Organization, and the United Nations Convention on the Law of the Sea (Andersen et al., 2010). This paragraph foreshadows Article 4(3) of the Nagoya Protocol, which refers to mutual supportiveness with ongoing work and practices related to ABS under other relevant international instruments and organizations.

Recalling the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture developed in harmony with the Convention,

Ensuring access to genetic resources for food and agriculture is critical for food security. The ITPGRFA establishes a Multilateral System for ABS to facilitate access to 35 food crops and 29 forage plants listed in Annex I that are in the public domain and under the management and control of the Contracting Parties. It also includes non-Annex I plants coming from *ex-situ* collections of the International Agricultural Research Centres of the Consultative Group on International Agricultural Research (see section E of the Introduction). As the Multilateral System fulfils the objective of the ITPGRFA to operate in harmony with the CBD, it is one example of a specialized ABS regime addressed by Article 4(4) of the Nagoya Protocol. The system may therefore provide useful ABS practices that should be given due regard in accordance with Article 4(3) of the Protocol.

Recognizing that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention,

This recitation is a recognition that international instruments on ABS, such as the ITPGRFA and the Nagoya Protocol, should not work at cross-purposes but rather work synergistically to meet the objectives of the CBD. Building on this, Article 4(3) of the Protocol requires mutually supportive implementation with other relevant international instruments and that useful and relevant ongoing work or practices under such instruments and relevant international organizations be given due regard, provided they are supportive of and do not run counter to the objectives of the CBD and the Protocol.

Recalling the relevance of Article 8(j) of the Convention as it relates to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising from the utilization of such knowledge,

Article 8(j) of the CBD is one of the bases for the protection of traditional knowledge associated with genetic resources and contributes to this substantive aspect of the Nagoya Protocol. It requires Parties—as far as possible and as appropriate, and subject to national legislation—to respect, preserve, and maintain traditional knowledge, innovations, and practices of ILCs relevant to the conservation and sustainable use of biodiversity; to promote their wider application with approval and involvement of its holders; and to encourage equitable sharing of benefits arising from its utilization. The Protocol

provides certainty for the holders of traditional knowledge associated with genetic resources, in particular through Article 5(5) with regard to fair and equitable benefit-sharing, Article 7 with regard to PIC or approval and involvement as well as MAT, and Article 12 with regard to ILC's customary laws, community protocols, and procedures.

Noting the interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities, the importance of the traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities,

Traditional knowledge forms the cultural heritage and intellectual property of ILCs. This paragraph refers to the connection between the knowledge of ILCs and genetic resources, the holistic worldview of indigenous communities, and their cultural relationship with nature. The specific wording results from the final report of the meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-sharing, which met in Hyderabad, India, from 16 to 19 June 2009.

Recognizing the diversity of circumstances in which traditional knowledge associated with genetic resources is held or owned by indigenous and local communities,

This paragraph recognizes that traditional knowledge exists in many different situations, which must be taken into account in access. For example, traditional knowledge associated with genetic resources may be held individually or collectively, and customary law, procedures, or practices may limit its outside use.

Mindful that it is the right of indigenous and local communities to identify the rightful holders of their traditional knowledge associated with genetic resources, within their communities,

This paragraph recognizes that ILCs have the right to determine who may share their traditional knowledge, thus to identify the appropriate source for users to obtain PIC (or ensure approval and involvement) and negotiate MAT for the sharing of benefits resulting from its use. Some of the information being accessed from these communities under the terms of the Nagoya Protocol may hold special value or be sacred knowledge, highlighting the importance of engaging with the rightful holder(s). This foreshadows Article 12 of the Protocol and the need for ILC community protocols, which are promoted by Article 12(3)(a). Furthermore, it is important to note that the Protocol requires Parties in accordance with domestic law to take into consideration customary laws, community protocols, and procedures of ILCs in the implementation of their obligations under the Protocol (Article 12(1)) and, with the effective participation of ILCs, to establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations (Article 12(2)).

Further recognizing the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity,

This paragraph recognizes that traditional knowledge associated with genetic resources is not necessarily held by any particular community but may rather be the result of a shared cultural heritage and may be held by States rather than communities. This type of widely held knowledge includes medical systems such as traditional Indian medicine (e.g., Ayurveda, Unani, and Siddha) and traditional Chinese medicine. The paragraph also recognizes the importance of traditional knowledge for biodiversity conservation and its sustainable use.

Noting the United Nations Declaration on the Rights of Indigenous Peoples, and

The Declaration on the Rights of Indigenous Peoples (UNDRIP) was adopted almost unanimously at the United Nations General Assembly in 2007 and has since been endorsed by the four dissenting countries (Australia, Canada, New Zealand, and the United States). It has a number of provisions that are relevant to the interpretation and implementation of the Nagoya Protocol, in particular to Articles 6(2) (Access to Genetic Resources), 7 (Access to Traditional Knowledge Associated with Genetic Resources) and 12 (Traditional Knowledge Associated with Genetic Resources). Specific examples include the right to natural resources, the right to control access to their resources and territories, the right to traditional knowledge and culture, and the right to free, prior, and informed consent in their traditional territories. This reference is the first time the UNDRIP has been referred to in an international treaty (Koutouki, 2011. p. 5) and is the only place in the Nagoya Protocol where it appears.

Affirming that nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities,

This affirmation was made to recognize the existing rights of ILCs and prevent interpretations of the Nagoya Protocol that would diminish or extinguish those rights.

Article 1
Objective

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

A. Background

Article 1 designates the objective of the Nagoya Protocol and some of its core functions. The objective provides context for interpretation, gives guidance to the Parties in national implementation, and is relevant to future work at the international level when the Protocol enters into force (Nijar, 2011b, p. 1). This includes work by the Conference of the Parties of the Convention on Biological Diversity (CBD) serving as the meeting of the Parties to the Nagoya Protocol and work in developing other relevant instruments, which must be supportive and not run counter to the objectives of the Protocol. The objective also provides the "measuring stick" against which effectiveness of the Nagoya Protocol will be evaluated (Nijar, 2011b).

The first objective of the Protocol is recited verbatim from the third objective of the CBD: the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources, appropriate transfer of relevant technologies (taking into account all rights over those resources and to technologies), and appropriate funding (Article 1 of the CBD). The complementary objective of the Protocol is to ensure that benefit-sharing also contributes to the first and second objective of the CBD: the conservation of biological diversity and the sustainable use of its components. It is interesting to note that Article 1 of the Nagoya Protocol does not directly mention traditional knowledge associated with genetic resources despite it being addressed in the operative text of the Protocol.

B. Explanation

The Protocol has as its objective the fair and equitable sharing of benefits resulting from the utilization of genetic resources. Meeting this objective necessarily involves appropriate access to genetic resources by "users" as well as appropriate transfer of relevant technologies to "providers". In this regard, recognition must be given to all rights over genetic resources and to technologies. In addition, funding from the public and private sector must be provided in ways that are again "appropriate".

The Nagoya Protocol puts forward the objective of fair and equitable benefit-sharing with the expectation that its implementation will contribute to the conservation of biological diversity and the sustainable use of its components. This direct link between access and benefit-sharing (ABS), conservation, and

sustainable use is made explicit in the objective to the Protocol as the connection is not made directly in the objective of the CBD, despite the need to achieve all three objectives harmoniously.

As a subsidiary legal instrument, the Nagoya Protocol exists to implement the terms of its governing treaty. Its objective thus makes reference to a number of different but interrelated concepts in the context of the CBD, notably Articles 15 (Access to Genetic Resources), 16 (Access to and Transfer of Technology), 19 (Handling of Biotechnology and Distribution of its Benefits), 20 (Financial Resources), and 21 (Financial Mechanism) of the CBD. The Protocol implements some of these concepts in its Articles 5 (Fair and Equitable Benefit-sharing), 6 (Access to Genetic Resources), 9 (Contribution to Conservation and Sustainable Use), 10 (Global Multilateral Benefit-sharing Mechanism), 23 (Technology Transfer, Collaboration and Cooperation), and 25 (Financial Mechanism and Resources). Furthermore, the objective of the Nagoya Protocol is mentioned in other parts of the treaty, such as Articles 4, 14, 21, and 23. Given this, it is important to emphasize the role that the objective plays in the interpretation of the terms of the entire Protocol.

Fair and Equitable Sharing of Benefits Arising from the Utilization of Genetic Resources

The imperative of fairly and equitably sharing the benefits resulting from the use of genetic resources with the Parties providing them is a key objective of the CBD and the basis for its Article 15 on access to genetic resources (Glowka, 1998, p. 3). Article 15(7) of the CBD in particular requires Parties to take legislative, administrative, or policy measures that aim toward fair and equitable benefit-sharing with the Party providing genetic resources, based on mutually agreed terms (MAT) (Glowka, 1998, p. 10). The CBD lists some examples of benefit-sharing with Parties providing genetic resources in Articles 15(6), 15(7), 16(3), 16(4), 19(1), and 19(2). The controversy over the exact content of these provisions and the complexity of implementing them was in part behind the negotiation of the Nagoya Protocol, which gives more clarity to fair and equitable benefit-sharing in its Article 5.

Appropriate Access to Genetic Resources

Article 15(2) of the CBD requires Parties to facilitate access for environmentally sound uses and not restrict access in a manner that runs counter to the objectives of the CBD. Article 15(3) of the CBD establishes that the provider of a genetic resource is the Party that is a country of origin or that has acquired the resource in accordance with the CBD. Article 15(4) of the CBD makes access subject to MAT and to Article 15 as a whole. Article 15(5) of the CBD makes prior informed consent of the provider necessary for access, unless that Party determines otherwise. The Nagoya Protocol re-affirms and clarifies these principles in Article 6 on Access to Genetic Resources.

Appropriate Transfer of Relevant Technologies

Access to and transfer of technology, referred to in Article 16 of the CBD, is an integral part of the CBD framework and is central to attaining its objectives, especially its ABS provisions. The Parties to the CBD have overtly recognized that the extent to which developing countries can implement their commitments depends on the effective implementation of commitments by developed countries relating to the transfer of technology.

The concept of appropriate transfer of relevant technologies ties the obligation to share technologies to particular needs and conduct. “Relevant” technologies are those that are relevant to the conservation and sustainable use of biodiversity or make use of genetic resources and do not cause serious environmental harm. “Appropriate” transfer should take place on fair and most favourable terms, including on concessional and preferential terms. It can take place between governments and/or the private sector. It requires respect for intellectual property rights (IPRs) but mandates that IPRs not undermine the objectives of the CBD (Article 16(5) of the CBD). The specifics of technology transfer in the context of ABS are provided in Article 23 of the Nagoya Protocol.

Rights over Genetic Resources and Technologies

Articles 3 and 15(1) of the CBD establish that States have sovereign rights over their natural resources, including genetic resources, and thus the right to legislate on access to genetic resources. However, this does not grant the State a property right over genetic resources but rather allows it to determine ownership of genetic resources in national law (Glowka et al., 1994, p. 76). National laws could place ownership rights in genetic resources in the hands of, for instance, private landowners, indigenous and local communities, other stakeholders, or the State. Other laws grant stakeholders property rights over biological resources but require authorization by the State for utilization of genetic resources. Yet others could have some genetic resources and technologies in the public domain (Cabrera Medaglia and López Silva, 2007, p. 3).

Some countries may choose not to change existing legal rights regarding access to biological resources on private land or to create specific rights over the genetic resources for certain categories of stakeholders. Others may require explicit authorization from the national government for access to genetic resources for utilization. Neither the CBD nor the Nagoya Protocol determines the content of these rights over genetic resources and technologies, leaving this determination up to each different legal system, taking into account the diversity of legal approaches.

Appropriate Funding

Funding is also vital to achieving the goals of ABS and enabling developing countries to adopt and implement their commitments under the CBD. It finds its roots in Articles 20 (Financial Resources) and 21 (Financial Mechanism) of the CBD and is implemented in Article 25 of the Nagoya Protocol. The term “appropriate” links funding to the concerns of both developed and developing countries and the particular needs, capacities, and objectives of Parties.

Contribution to Conservation and Sustainable Use of Biodiversity

The conservation of biological diversity and the sustainable use of its components are two of the three objectives of the CBD. Because the three objectives of the CBD are considered a package, access to genetic resources and the fair and equitable sharing of benefits resulting from their utilization has always been intended to feed back into the first two objectives. Paragraph 48 of the 2002 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization was the first to concretely state that benefits should be directed in such a way as to promote conservation and sustainable use (SCBD, 2002). The Nagoya Protocol is innovative in that it recognizes the potential role of ABS to contribute to conservation and sustainable use in its

Preamble, links benefits to conservation and sustainable use in its objective, and requires Parties to both encourage users and providers to direct benefits to conservation and sustainable use (Article 9) and consider a Global Multilateral Benefit-sharing Mechanism that would support conservation and sustainable use globally (Article 10).

Article 2
Use of Terms

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Convention" means the Convention on Biological Diversity;

(c) "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;

(d) "Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

(e) "Derivative" means 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.

A. Background

A provision explaining the meaning of important terms used throughout the text of a treaty is a frequently used technique in international law, including multilateral environmental agreements. The list of defined terms helps provide clarity and legal certainty on the meaning attributed to specific terms in the treaty, which may differ from those in ordinary, scientific, or technical use. It also facilitates the drafting of operative provisions in the agreement.

Legal definitions are specific to a particular legal text and are intended solely to facilitate the interpretation of the terms used in the given agreement. For the Nagoya Protocol, this means that its definitions (e.g., utilization of genetic resources) are independent from those in the Convention on Biological Diversity (CBD) unless otherwise mentioned; conversely, the definitions in the CBD do not automatically apply to the Nagoya Protocol.

The Nagoya Protocol defines relatively few new terms. Yet the two that are innovations – "utilization of genetic resources" and "derivative" – resolved some of the major points of contention during the negotiations of the Protocol. Along with the repeated definition of "biotechnology", they form part of a compromise package put forward by the Japanese Presidency to the tenth meeting of the Conference of the Parties to the CBD (CBD COP 10) on the final day of negotiations, and they inform the scope of the main operational provisions of the Nagoya Protocol (Tsioumani, 2010, p. 289; Buck and Hamilton, 2011). The definitions were strongly influenced by the report of the meeting of the Group of Technical

and Legal Experts on Concepts, Terms, Working Definitions and Sectoral Approaches (GTLE) held in Windhoek, Namibia, in December 2008.[1]

However, many other terms used in the Nagoya Protocol are not specifically defined. Examples include the terms "access to genetic resources", "access to traditional knowledge associated with genetic resources", "research and development", and "utilization of traditional knowledge associated with genetic resources". To determine the content of these undefined terms, the general rule of interpretation in international law should be applied: that is, in the absence of a special meaning, terms used in a treaty are to be interpreted in good faith with the ordinary meaning to be given to the terms in their context and in light of the treaty's object and purpose (Article 31(1) of the Vienna Convention on the Law of Treaties). This is consistent with the approach taken by many common law countries for statutory interpretation.

B. Explanation

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:

The chapeau to Article 2 of the Nagoya Protocol adopts all the definitions found in the CBD and defines five further terms. It makes clear that all the definitions contained in Article 2 of the CBD apply to the Nagoya Protocol without having to repeat them. However, the definition of "biotechnology" is reproduced in the Nagoya Protocol because it is relevant to the definition of new terms such as "utilization of genetic resources" and "derivative".

Box 6: Relevant Terms from the Convention on Biological Diversity

Definitions in Article 2 of the CBD that are not mentioned in the Nagoya Protocol but are relevant to understanding its nature and the definitions found in Article 2 of the Protocol include:

- *"Biological diversity"* means the variability among living organisms from all sources including, *inter alia,* terrestrial, marine, and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species, and of ecosystems.
- *"Biological resources"* includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.
- *"Country of origin of genetic resources"* means the country which possesses those genetic resources in *in-situ* conditions.
- *"Country providing genetic resources"* means the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country.

▶

1 Report of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, UNEP/CBD/WG-ABS/7/2, 12 December 2008.

- *"Ex-situ conservation"* means the conservation of components of biological diversity outside their natural habitats.
- *"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.
- *"In-situ conditions"* means conditions where genetic resources exist within ecosystems and natural habitats and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.
- *"In-situ conservation"* means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

The Nagoya Protocol was negotiated and adopted under the aegis of the CBD. Therefore, it is important to note that when the Conference of the Parties is referred to in the text, it means the COP to the CBD and not the Nagoya Protocol. Indeed, according to Article 26 of the Nagoya Protocol, the CBD COP serves as the meeting of the Parties to the Protocol.

(b) "Convention" means the Convention on Biological Diversity;

This paragraph clarifies that the term "Convention" throughout the text refers to the CBD. The Nagoya Protocol is a subsidiary legal instrument adopted in conformity with Article 28 of the CBD.

(c) "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;

Despite being a key part of the third objective of the CBD and its Article 15(7) on benefit-sharing, the CBD does not define the term "utilization of genetic resources". Before the adoption of the Nagoya Protocol, experts and national legislation offered different interpretations of what activities were covered by this term (FNI, 2010). This made it difficult in many cases to determine the exact scope of access systems and benefit-sharing obligations.

Late in the Protocol negotiations, it became clear that many of the contentious technical issues could be solved if there were a clear understanding of the concept of utilization (Tvedt and Rukundo, 2010, pp. 14–15; Bavikatte and Tobin, 2010; Buck and Hamilton, 2011, p. 56). Building on the report of the GTLE, the Parties inserted Subparagraph (c) defining the term "utilization of genetic resources" in the Protocol (Tvedt and Rukundo, 2010; Bavikatte and Tobin, 2010). This definition helps to provide legal certainty through specific indicators that enable a clear test for determining whether the Nagoya Protocol governs a particular activity and when it triggers the obligation to share benefits (Tvedt and

Rukundo, 2010). Indeed, the term utilization or its alternative forms (e.g., utilized, use, or used) inform the scope of the main operational provisions (Buck and Hamilton, 2011, p. 56; Oliva, 2011, p. 1224), such as Articles 5 (Fair and Equitable Benefit Sharing), 6 (Access to Genetic Resources), 15 (Compliance with Domestic Legislation or Regulatory Requirements on ABS), or 17 (Monitoring the Utilization of Genetic Resources).

However, the Nagoya Protocol does not contain a list of specific uses of genetic resources that would be covered, as envisioned in earlier deliberations. Ultimately, the definition of utilization itself was considered comprehensive enough to cover all possible uses of genetic resources, allowing for rapidly evolving techniques and the changing uses of genetic resources occurring with advances in knowledge and technology. This is because the definition of genetic resources is interrelated to the definition of genetic material and therefore covers any material of biological origin with functional units of heredity that has either an actual or a potential value because of them. Since the potential value and the level of knowledge on functionality in biology change, the wording of the definition suggests being dynamic in the sense that it captures evolving knowledge and technological state of the art (FNI, 2010).

Box 7: Different Uses of Genetic Resources

The Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches established the following non-exhaustive list of uses of genetic resources:

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

Source: Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, UNEP/CBD/WG-ABS/7/2, 12 December 2008.

To fully understand the definition of "utilization of genetic resources", it is important to take a close look at these references included in Article 2(c):

- research and development;
- biochemical composition of genetic resources; and
- application of biotechnology.

They expand the previously limited conception of genetic resources in the CBD (Glowka, 1998, p. 4) to ensure that benefit-sharing also takes place for so-called research and development based on so-called derivatives. They also clarify that the "utilization of genetic resources" finishes when the research and development process ends. Any subsequent application or commercialization may then be covered by the benefit-sharing provisions found in Article 5(1) of the Nagoya Protocol. Another consequence is that Parties that decide to require prior informed consent (PIC) for access to their

genetic resources will need to regulate research and development on both the genetic material and any naturally occurring biochemical compounds contained in material acquired under their domestic ABS framework (Glowka, 1998, p. 57).

The terms research and development are not defined in the Nagoya Protocol. Based on Article 31(1) of the Vienna Convention on the Law of Treaties, the ordinary meaning of these terms in the context of the Nagoya Protocol is applicable. The *Oxford Dictionary*'s definition of research is "the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions". In particular, for the Nagoya Protocol research means the investigation and study of the genetic and/or biochemical composition of genetic resources in order to establish facts and reach conclusions. In addition, development includes the creation of innovations and practical applications (e.g., applied research).

The Nagoya Protocol covers research and development on the biochemical composition of genetic resources, including through the application of biotechnology. The references to the biochemical composition and the application of biotechnology links Article 2(c) with the definitions of biotechnology as "any technological application" in Article 2(d) and derivative as "a naturally occurring biochemical compound" in Article 2(e). Therefore the "utilization of derivatives" is also covered by the Nagoya Protocol.

It is important to note that the definition of derivative seems to create more certainty about the meaning of "biochemicals" by clarifying that they may not have "functional units of heredity". This means that, for instance, the extraction of chemicals for the development of drugs is included, and benefit-sharing is supported by the Nagoya Protocol.

(d) "Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

The Organisation for Economic Co-operation and Development defines biotechnology as "the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods, and services" (OECD, 2005). The definition in Article 2(d) of the Nagoya Protocol generally seems to follow this definition.

It is important to note that the Nagoya Protocol does not change the definition of biotechnology found in the CBD. Indeed, it repeats verbatim the formulation found in Article 2 of the CBD. The main justification for this repetition is that the definition of biotechnology clarifies the link between the definition of "utilization of genetic resources" (where a reference to the term biotechnology is made) and the definition of "derivative" (to which the definition of biotechnology refers).

Box 8: Products of Biotechnology

Products that are not genetic resources themselves are not subject to PIC but should be addressed under mutually agreed terms (MAT) in order to ensure the sharing of benefits. Some proposed indicators against which a derivative could be judged to have become a product are:

- commercialization and availability on the open market or sale to the public;
- seeking marketing or other approvals, such as product registration;
- submission of applications for intellectual property protection; or
- identification of a specific use for a derivative.

Source: Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, UNEP/CBD/WG-ABS/7/2, 12 December 2008.

(e) "Derivative" means 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.

Since the negotiations of the 2002 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (the Bonn Guidelines), and particularly in the CBD COP 6, one of the most controversial topics was that of derivatives and products and their relationship to PIC and MAT. Examples of derivatives include aromas, biochemicals in cells, resins, and snake venoms. These compounds are the basis for a wide range of products, from drugs to food and cosmetic ingredients. Flavanoids, for example, are among the biochemical compounds found to have unique skin care properties and are now widely used in cosmetic formulations. Alkaloids such as those found in seeds of coffee, cola, and guarana are other biochemical compounds broadly used in functional foods and beverages (UEBT, 2010a).

The Bonn Guidelines addressed this discussion in the context of benefit-sharing. Indeed, Paragraph 44(i) of the Guidelines provides an indicative list of typical MAT that includes "provisions regarding the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products". Paragraph 36 provides an indicative list of information that could be requested in PIC processes. Amongst others, the list refers to information on the kinds and types of benefits that could result from obtaining access to the resource, including benefits from derivatives and products arising from the commercial or other utilization of the genetic resource.

The Nagoya Protocol defines derivative as "a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources". It also covers compounds that do not contain functional units of heredity. The language used in Article 2(e) of the Protocol resolved the difficult issue of whether biochemicals would be included in the scope of ABS in addition to the genetic resources/material per se (that is, material containing "functional units of heredity") (Glowka et al., 1994) and, if so, to what extent.

In this context, it is important to understand that the term derivative does not appear outside of Article 2 in any other operative text of the Nagoya Protocol (Tsioumani, 2010, p. 289). However, it appears in the definition of "biotechnology" in Article 2(d), its reference to biochemicals is shared with the definition of "utilization of genetic resources" in Article 2(c), and a reference to benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization is made under Article

5(1) on benefit sharing (Tsioumani, 2010, p. 289). As a result, derivatives are covered by benefit-sharing obligations under the Nagoya Protocol, which mirrors the approach applied by Article 44(i) of the Bonn Guidelines.

Furthermore, it seems that most research on the use of extracts and molecules from plants, as well as the development and production of pharmaceuticals, cosmetics, or nutraceuticals, is now subject to PIC and MAT (Oliva, 2011, p. 1224). For the use of derivatives to trigger PIC under Article 6(1) of the Nagoya Protocol, utilization must be based on the biochemical components of genetic resources. These are the non-modified chemical components, other than DNA or RNA, formed by the organisms' metabolic processes that exist in samples of biological materials (that is, active biological components found in collected plant material) and that have yet to be modified and used in technological applications.

The definition of "utilization" however, refers to research and development on the biochemical composition of genetic resources. This linkage between biochemical compounds and genetic resources has led to some different interpretations, especially as to whether biochemicals must be accessed simultaneously with access to genetic resources. Therefore, there is no consensus on the situation of "isolated derivatives" (e.g., an extract from a plant stored in a lab) that have not been accessed simultaneously with the genetic resources.

Box 9: Differences in Terminology Regarding Derivatives

Members of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches proposed different options for defining derivative:

- A naturally occurring chemical compound (metabolite) produced as a result of the expression of an organism's genetic makeup.
- A chemical compound produced by human activity using genetic material.
- Gene segments produced or isolated by human manipulation of genetic material.
- Synthetic gene segments produced by human manipulation (one segment being a derivative of all the various genetic materials used in its construction).
- Information or knowledge derived from genetic materials in general or a specific gene sequence in particular.
- Synthetic analogue chemicals or gene segments inspired by a particular naturally occurring metabolite or gene segment.
- The result of the utilization of a genetic resource through human activity: a) genetic resources used for research (research not aiming at commercialization), b) products under development (research and development aiming at commercialization), and c) products (commercialization).
- The meaning should be mutually agreed between the provider and the user of genetic resources.

▶

- Any and all parts found within a biological resource even if the material obtained no longer contains any genetic material of functional units of heredity.
- Something derived from biological and genetic resources such as varieties, strains or breeds, blood, proteins, oils, resins, gums, genes, seeds, spores, pollen, urine, bark, wood, leaf matter, and the like as well as the products derived from, patterned on, or incorporating manipulated compounds and/or genes.

Source: Group of Technical and Legal Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, UNEP/CBD/WG-ABS/7/2, 12 December 2008.

Article 3
Scope

This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

A. Background

Article 3 establishes the scope of application of the Nagoya Protocol over access to genetic resources as well as traditional knowledge associated with genetic resources and the sharing of benefits resulting from the utilization of such resources and knowledge. The scope of the Nagoya Protocol was one of the most difficult issues to resolve during the negotiation process, as some countries desired a broad range of application while others sought to limit the breadth of the Protocol (Chiarolla, 2010; Buck and Hamilton, 2011; Nijar, 2011a).[1]

For many countries, it was important to ensure that provisions on scope were broad enough to cover the most important uses of biodiversity for research and development (Oliva, 2011, p. 1223). For example, Parties proposed that the scope of the Nagoya Protocol be retroactive and apply to continuing benefits and benefits from new uses arising from commercial and other utilization of genetic resources, biological resources, products, derivatives, and traditional knowledge associated with genetic resources acquired prior to the entry into force of the Convention on Biological Diversity (CBD) or arising from commercial and other uses taken prior to the coming into force of the CBD. There was also language proposed on intellectual property rights associated with research and technology arising from the use of all genetic resources and biological resources, their derivatives and products, and traditional knowledge associated with genetic resources of indigenous and local communities (ILCs).[2]

The compromise text proposed by the Japanese Presidency of the tenth meeting of the Conference of the Parties to the CBD (CBD COP 10) radically simplified the scope and proposed addressing many of the scoping issues in other articles of the Protocol (e.g., Articles 2, 4, and 8) (Tsioumani, 2010, p. 289).

B. Explanation

Despite its brevity, Article 3 has significant ramifications for the application and implementation of the Protocol, especially Articles 5 (Fair and Equitable Benefit-Sharing), 6 (Access to Genetic Resources), 7 (Access to Traditional Knowledge Associated with Genetic Resources), and 12 (Traditional Knowledge Associated with Genetic Resources).

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1 See also draft Article 3 in the Draft Protocol in *Report of the Second Part of the Ninth Meeting of the Ad Hoc Open Ended Working Group on Access and Benefit-sharing,* UNEP/CBD/COP/10/5/ADD4 for some different proposals on the scope of the Protocol.

2 Report of WG-ABS 8, UN Doc. UNEP/CBD/WG-ABS/8/8, Annex, Part II.

Genetic Resources

The first sentence of Article 3 limits the scope of the Nagoya Protocol to genetic resources that fall within the scope of Article 15 of the CBD and the benefits arising from their utilization. Article 15(1) of the CBD establishes a sovereign right to legislate over genetic resources. Article 15(3) specifies that only those genetic resources provided by Parties that are countries of origin or that acquired the genetic resources in accordance with the CBD can avail themselves of the access and benefit-sharing (ABS) provisions (Glowka et al., 1994, p. 77; Nijar, 2011a, p. 27; Buck and Hamilton, p. 51). If the prerequisite is met, Article 15(7) of the CBD supports national measures to ensure the fair and equitable sharing with the providing Party of results of research and development and the benefits arising from the commercial and other utilization of genetic resources.

Box 10: Definitions Relevant to the Scope of the Protocol

Apart from the definitions introduced through Article 2 of the CBD (see Box 6), Article 2 of the Nagoya Protocol includes a few definitions that are important to fully understand the scope of the Protocol:

- *"Utilization of genetic resources"* means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.
- *"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 or genetic resources, even if it does not contain functional units of heredity.

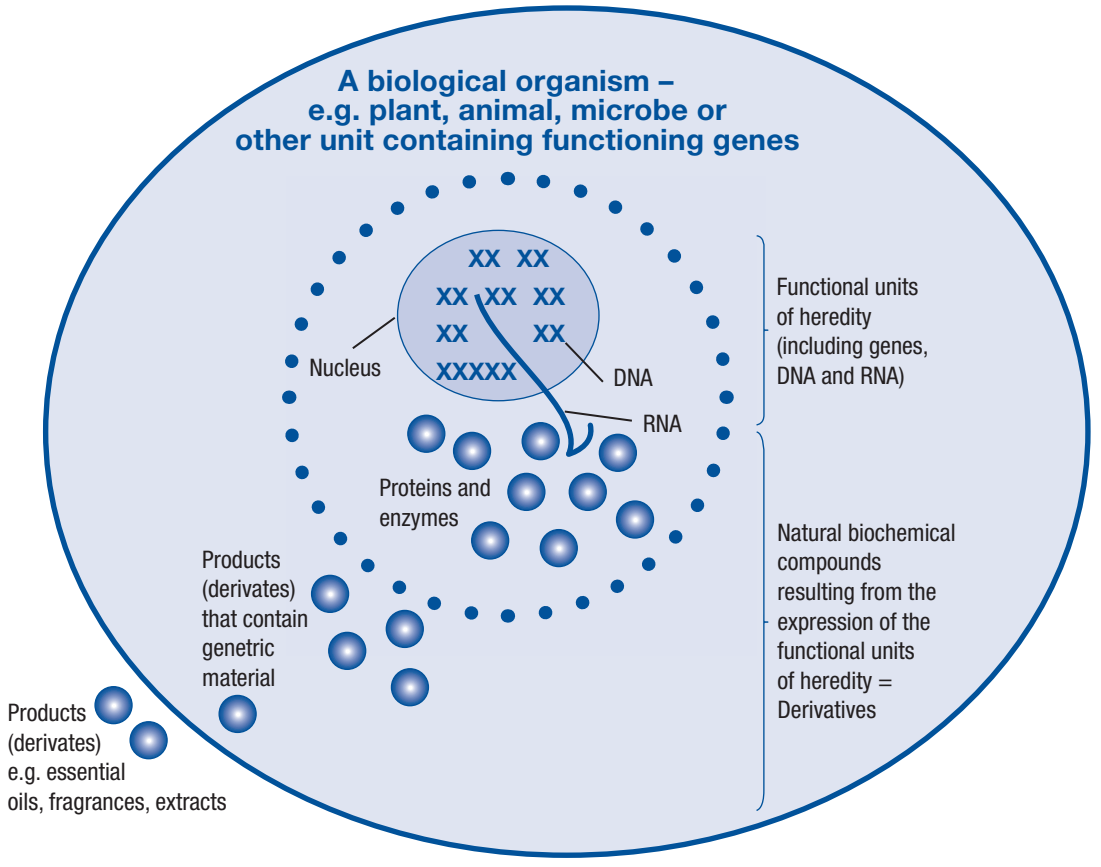
The reference to utilization of genetic resources in the first sentence of Article 3 means that the definition of that term has to be used to clarify the scope of benefit-sharing. Accordingly, it captures benefits arising from research and development on the genetic and/or biochemical composition of the genetic resources, including through the application of any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. This includes the use of biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources, even if they do not contain functional units of heredity. While roughly following the benefit-sharing model laid out in Article 15(7) of the CBD, this expands the material scope of application to naturally occurring biochemical compounds.

Derivatives were mentioned in draft text for Article 3 but were removed as part of the compromise text put forward by the Japanese COP 10 Presidency (Tsioumani, 2010, p. 289). Thus, Article 3 in its final version does not use the term derivatives but includes only a reference to utilization of genetic resources. Still, Article 2 of the Protocol defines both utilization of genetic resources and derivatives in a way that the Protocol covers a specific type of derivative within its scope: biochemicals (Joseph, 2010, p. 91). Research and development on naturally occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources is now covered by ABS requirements (Kamau, Fedder and Winter, 2010, p. 256). This means that research on the use of extracts and molecules from plants, as well as the development of pharmaceuticals, cosmetics, or

nutraceuticals, is covered by requirements for prior informed consent (PIC) and mutually agreed terms (MAT) (Oliva, 2011, p. 1224). However, it is important to understand that because Article 15 of the CBD is limited to the utilization of genetic resources and Article 2 of the Nagoya Protocol links utilization to the genetic and/or biochemical composition of genetic resources, naturally occurring biochemical compounds accessed independently of genetic resources fall outside the scope of the Protocol.

Furthermore, it has to be noted that Parties agreed to leave human genetic resources outside the framework of the Nagoya Protocol. However, human genetic resources may be subject to further consideration by the CBD COP serving as the meeting of the Parties to the Nagoya Protocol.[3]

Figure 4: Understanding Genetic Resources



Source : Based on a graph provided by Delphine Morandeau, Ministère de l'environnement, France, and Isabelle Clément-Nissou, Groupement interprofessionnel des semences, France.

Genetic resources are defined by the CBD as "genetic material of actual or potential value". That definition required further clarification as to what "genetic material" is. The CBD defines genetic material as "any material of plant, animal, microbial or other origin containing functional units of heredity".

Functional units of heredity are genes. A gene is a segment of DNA (on a specific site on a chromosome) that is responsible for the physical and inheritable characteristics or phenotype of a living entity (the way an organism looks).

3 CBD COP Decision X/1/5

DNA contains the information for the function and characteristics of living organisms. In this sense, DNA contains the instructions or information (called genes) needed to conduct cellular components and the way that living organisms function.

A range of natural biochemical compounds result from the expression of genes. Compounds such as proteins and enzymes occur within cells – the smallest unit of a living organism – and retain functional units of heredity. Cells release biochemical compounds necessary for organism function into tissues. These compounds also retain genetic material.

Finally, other biochemical compounds are produced through human intervention, such as extraction, concentration, or dilution. These compounds may or may not retain genetic material. Examples include oils, plant extracts and synthetic (man-made) biochemical compounds.

Traditional Knowledge Associated with Genetic Resources

Article 8(j) of the CBD addresses the traditional knowledge, innovations, and practices of ILCs living traditional lifestyles relevant for the conservation and sustainable use of biological resources. The second sentence of Article 3 of the Nagoya Protocol refers to a subset of such knowledge innovations and practices, namely traditional knowledge associated with genetic resources. The sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources is encouraged by Article 8(j) of the CBD and covered by Article 3 of the Nagoya Protocol.

Temporal Scope

Negotiations over including the temporal scope of the Nagoya Protocol in Article 3 did not succeed, and the proposed text in the draft Protocol was abandoned. Thus, the Nagoya Protocol contains no explicit provision dealing with its temporal scope.

Instead, the default provision on retroactivity of the Vienna Convention on the Law of Treaties applies. According to Article 28 of that convention, a treaty shall not be applied retroactively unless countries choose to give a treaty such effect. Additionally, a treaty cannot apply to any act or fact that took place or any situation that ceased to exist before entry into force of the treaty for that party. This means that access to genetic resources before the entry into force of the CBD is outside the temporal scope of the CBD because ABS obligations only came into existence once the CBD entered into force. Also, to suggest that the Nagoya Protocol applies to situations before the CBD entered into force would be against the principle of retroactivity.

However, this does not imply that temporal issues have been entirely resolved. One open question is whether genetic resources and traditional knowledge associated with genetic resources acquired after the entry into force of the CBD but before the entry into force of the Nagoya Protocol are in the scope of the Protocol once it enters into force. On the one hand, pre-Protocol access could be considered a fact that took place or a situation that ceased to exist before the date of the entry into force of the treaty with respect to that party. On the other hand, Article 3 applies to genetic resources within the scope of Article 15 of the CBD, which came into force in 1993, and to the benefits arising from their utilization. Since then, Article 15(5) of the CBD requires PIC for access to genetic resources for their utilization (unless a Party determines otherwise), and Article 15(7) speaks to benefit-sharing on results of research and development and benefits arising from the commercial and other utilization of genetic resources.

Article 5(1) of the Nagoya Protocol on benefit-sharing provides for Parties to the Protocol to share in a fair and equitable way benefits arising from the utilization of genetic resources, as well as subsequent applications and commercialization with the Party legally providing the genetic resource. This entails sharing benefits arising from new and continuing uses of genetic resources and traditional knowledge associated with genetic resources when the use took place after the entry into force of the Protocol, despite cases where the resources/knowledge were acquired after the entry into force of the CBD. This is not retroactive application of the Nagoya Protocol since the obligation results from new facts, and the general rule of interpretation on retroactivity states that treaty obligations apply to any fact, act, or situation that has not ceased to exist.

Thus, in sum, the Nagoya Protocol applies to genetic resources and traditional knowledge associated with such resources acquired after entry into force of the Protocol for a Party. The Protocol does not apply to pre-CBD acquisitions of genetic resources or traditional knowledge associated with such resources. Benefits from genetic resources and traditional knowledge associated with such resources accessed before the entry into force of the Protocol but after the entry into force of the CBD may also be regulated by Parties in the case of new and continuing uses.

Geographic Scope

Article 15 of the CBD applies only to genetic resources over which States exercise sovereign rights. The question therefore arises about what happens outside those limits, in particular in marine areas beyond national jurisdiction (ABNJ) and Antarctica (see also section E of the Introduction).

- Marine Areas Beyond National Jurisdiction

The relationship between the CBD and the law of the sea is regulated in Article 22(2) of the CBD, which requires Parties to the CBD to implement measures on the marine environment consistently with their rights and obligations under the law of the sea. This includes both customary law and that deriving from the United Nations Convention on the Law of the Sea (UNCLOS). Article 4(a) of the CBD foresees that its provisions, including Article 15, apply to areas within the limits of national jurisdiction. According to the UNCLOS, the rights and responsibilities of costal States extend to their internal and territorial waters, exclusive economic zones, and extended continental shelves, so they are covered by the scope of the Nagoya Protocol.

With regard to ABNJ – the high seas and the deep seabed – Article 4(b) of the CBD foresees that a State is also responsible for the regulation of those activities carried out under its jurisdiction or control. Arguably this could include the exploitation of genetic resources carried out by nationals and ships sailing under a State's flag.

However, it is important to note that Article 3 of the Nagoya Protocol refers to the scope of Article 15 of the CBD rather than to the "general" scope of the CBD in its Article 4. This indicates that Parties did not wish to link the geographical scope of the Nagoya Protocol to the jurisdictional scope of Article 4(b) of the CBD, since this could have raised the question of whether the Protocol would apply to ABNJ. Therefore, the starting point for ABS in ABNJ is that it does not fall under the scope of the Nagoya Protocol (Koester, 2012, p. 16).

- Antarctica

The Antarctic Treaty System is a set of agreements governing the area south of 60° south latitude. Its main principles are the dedication of Antarctica for peaceful purposes, the continuance of scientific

investigation, and the preservation of the Antarctic environment (Andersen et al., 2010, p. 21). The Nagoya Protocol does not currently apply to material collected in the Antarctic Treaty Area (ATA). Parties to the Antarctic Treaty have agreed not to assert their territorial claims as between themselves, making material from the ATA like material from ABNJ. Such material is also beyond the jurisdiction of States that are neither claimants nor Parties to the Antarctic Treaty (Buck and Hamilton, 2011, p. 57). Ultimately, there is no regulation of property rights to living organisms in the Antarctic area and therefore no party to provide PIC or MAT (Andersen et al., 2010, p. 21).

Box 11: Resources Outside the Scope of the Nagoya Protocol

The following are not covered by the access provisions of Article 15 of the CBD and do not fall within the definitions found in Article 2 of the Nagoya Protocol and therefore do not trigger ABS provisions under the Protocol:

- genetic resources used as bulk commodities (typical uses of biological resources);
- genetic resources acquired before the entry into force of the CBD;
- genetic resources acquired from areas beyond the limits of national jurisdiction (e.g., high seas, deep seabed, Antarctic Treaty Area);
- genetic resources that a Party determines do not require PIC (Article 15(5) of the CBD);
- human genetic resources; and
- derivatives accessed independently of genetic resources.

Article 4
Relationship with International Agreements and Instruments

1. **The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.**
2. **Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.**
3. **This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.**
4. **This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.**

A. Background

The Johannesburg Plan of Implementation (JPOI) of the World Summit on Sustainable Development (2002) provided a general mandate to negotiate an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources within the framework of the Convention on Biological Diversity (CBD), bearing in mind the Bonn Guidelines (Paragraph 44(o) of the JPOI). Yet Parties were divided between those that sought an overarching framework instrument on access to genetic resources and the fair and equitable sharing of benefits resulting from their utilization (ABS) and those that sought an outcome that recognized a broader international regime on genetic resources, with the Nagoya Protocol as the default instrument (Buck and Hamilton, 2011, p. 58).

Because the Nagoya Protocol, in principle, applies to all types of genetic resources and all potential uses, Parties explicitly recognized in Article 4 that relevant ABS provisions also exist in a range of international instruments and processes outside the CBD (Buck and Hamilton, 2011, p. 58). Article 4 addresses the relationship of the Nagoya Protocol with other relevant international instruments and

processes related to its objective, content, and operational mechanisms, such as the following (see also section E of the Introduction):

- International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA);
- International Convention for the Protection of New Varieties of Plants;
- United Nations Convention on the Law of the Sea;
- Antarctic Treaty System;
- World Trade Organization (WTO);
- World Intellectual Property Organization (WIPO);
- World Health Organization (WHO); and
- United Nations Food and Agriculture Organization (FAO) Commission on Genetic Resources for Food and Agriculture (CGRFA).

Furthermore, Article 4 links the Nagoya Protocol to the work and practices of relevant international organizations.

Box 12: Definition of Terms: International Agreement, Instrument, and Organization

The term "international agreement" used in Article 4 refers specifically to agreements that create rights and obligations, formally known as a treaty. By definition, treaties are agreements that are written, binding (e.g., create legal rights and duties), concluded by States or international organizations with treaty-making power, and governed by international law. International agreements binding as international law are often called treaties, agreements, conventions, charters, or protocols.

The term "international instrument" is broader in nature, referring to all written diplomatic documents established by authorized persons that constitute an international act and define its content. This could include decisions taken by Parties under the aegis of an international agreement or international organization that do not qualify as a treaty. While it is not entirely clear whether the term "instrument" also covers arrangements that are not legally binding (Koester, 2012, note 79), the use of the term appears to allow greater flexibility in the creation of specialized ABS regimes.

An international organization is an intergovernmental organization. It functions according to its own rules: the constituent instruments, decisions, and resolutions adopted in accordance with them and the established practice of the organization. Negotiations may also take place within the organization to develop new agreements and instruments. They should be paid due regard to in the mutually supportive implementation of the Nagoya Protocol.

Sources: *Vienna Convention on the Law of Treaties between States and International Organizations or between International Organizations; Parry et al., 2009.*

B. Explanation

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.

The first sentence of Paragraph 1 essentially repeats the rule included in Article 22(1) of the CBD: that the rights and obligations of Parties under existing agreements are not affected except when exercising those provisions would seriously damage or threaten biological diversity (Glowka et al., 1994, p. 109). The second sentence addresses an aspect not covered in Article 22 of the CBD but found in other multilateral environmental agreements (MEAs): a clarification that the provision is not intended to create a hierarchy between the Nagoya Protocol and other instruments.

Many recent MEAs contain such a clause, sometimes referred to as a "saving clause", in their Preambles or operative texts stating the relationship between the treaty and other agreements. When such a clause appears in the operative text of a treaty, it may indicate specifically how the new agreement affects the obligations of existing agreements and which agreement prevails in the case of a conflict. This is because a State is bound to comply with all the treaties to which it is a party and perform them in good faith (Article 26 of the Vienna Convention on the Law of Treaties). In consequence, States must ensure that the terms of newly negotiated treaties do not conflict with or override existing obligations unless clearly intended (Article 30 of the Vienna Convention on the Law of Teaties).

Box 13: Examples of Saving Clauses in Other International Instruments

- Article 311(2) of the United Nations Convention on the Law of the Sea

"This Convention shall not alter the rights and obligations of States Parties which arise from other agreements compatible with this Convention and which do not affect the enjoyment by other States Parties of their rights or the performance of their obligations under this Convention."

- Preamble to the Cartagena Protocol on Biosafety

"Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development."

"Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements."

"Understanding that the above recital is not intended to subordinate this Protocol to other international agreements."

- Preamble to the International Treaty on Plant Genetic Resources for Food and Agriculture

"Recognizing that this Treaty and other international agreements relevant to this Treaty should be mutually supportive with a view to sustainable agriculture and food security."

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"Affirming that nothing in this Treaty shall be interpreted as implying in any way a change in the rights and obligations of the Contracting Parties under other international agreements."

"Understanding that the above recital is not intended to create a hierarchy between this Treaty and other international agreements."

- Article 20(1) of the UNESCO Convention on the Cultural Diversity

"Parties recognize that they shall perform in good faith their obligations under this Convention and all other treaties to which they are parties. Accordingly, without subordinating this Convention to any other treaty:

a) They shall foster mutual supportiveness between this Convention and other treaties which are parties; and

b) When interpreting and applying the other treaties to which they are parties or when entering into other international obligations, Parties shall take into account the relevant provisions of this Convention."

It is important to note that the first drafts of the Nagoya Protocol already indicated that the purpose was not to "subordinate" the Protocol to other international instruments. Article 4(1) of the Protocol itself reminds States that the intention is not to create a hierarchy with other existing international agreements (e.g., in favour of the Protocol or of the other agreement). The relationship with new relevant international agreements is governed by Paragraph 2, and that with specialized instruments on ABS is regulated in Paragraph 4.

2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

Paragraph 2 reflects the fact that during negotiations of the Nagoya Protocol, deliberations or negotiations of related issues were taking place in different fora and organizations (at FAO, WHO, WIPO, and WTO). The final outcome of some of them could be a new international agreement on ABS, such as a sectoral agreement addressing specific types of genetic resources (e.g., a regime focusing on animal genetic resources could be developed under the FAO umbrella).

The notion that "one size does not fit all" was raised during negotiations of the Nagoya Protocol and was also considered by the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches. The possibility for the development and implementation of new specialized ABS agreements (that is, a sectoral approach) was supported by some Parties. These countries suggested the option that the Nagoya Protocol could include a general provision recognizing existing or future specialized ABS sectoral approaches. These agreements would take priority over the Protocol at least for the genetic resources or types of uses covered. In practice, several basic distinctions could be used for the development of national or international regulations, such as the nature of the application or the intended use (e.g., commercial versus non-commercial, for food and

agriculture, for pharmaceutical purposes) or the physical nature of the resources or their location (e.g., marine, terrestrial, higher plants, microorganisms, found *ex-situ* or *in-situ*).

Paragraph 2 reaffirms the right of Parties to develop and implement other relevant international agreements in general and, in particular, other specialized ABS agreements (existing specialized ABS systems are addressed in Paragraph 4). It is important to note that the legal capacity of a Party to develop and implement any international instrument comes from international law directly (see Article 6 of the Vienna Convention on the Law of Treaties). The provision therefore reiterates this principle.

At the same time, however, there was a concern that new international agreements and their implementation, especially new ABS sectoral agreements, might run counter to the objectives of the CBD and the Nagoya Protocol, thus creating a loophole and making it difficult to satisfy the demand for fair and equitable benefit-sharing. Therefore, Paragraph 2 contains a safeguard clause: Parties may negotiate and implement any new international agreement to the extent that these agreements are "supportive of and do not run counter to the objectives of the Convention and this Protocol". This qualification applies to both general international instruments and specialized ABS agreements and is subject to Article 30 of the Vienna Convention on the Law of Treaties, which regulates the application of successive treaties relating to the same subject matter.

3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

The first sentence of Paragraph 3 addresses the obligation of Parties to implement the relevant international instruments and the Nagoya Protocol in a mutually supportive manner. The term "mutually supportive" has taken a particular meaning in the trade and environment context and can be found in recently adopted MEAs, such as the Cartagena Protocol on Biosafety. The imperative that environmental treaties and trade objectives must be mutually supportive is also prescribed by Paragraph 92 of the JPOI. The principle of mutual supportiveness can be used as an interpretative principle governing the interface between MEAs and related treaties that requires a conciliatory reading of potentially conflicting rules in those agreements (Pavoni, 2010).

The second sentence of Paragraph 3 is rather unusual in international law as it addresses the relationship between international treaties and relevant and useful work and practices under other relevant agreements or international organizations. Several aspects are worth highlighting in this regard.

First, work could include actions like negotiations, discussions, and resolutions, while practices could be any type of concrete measures taken to implement an instrument.

Second, Parties should solely pay "due regard" to useful and relevant work or practices, which does not create a legal obligation to implement the Nagoya Protocol in a mutually supportive manner. Current practice in international law only recognizes this obligation in relation to binding international agreements, not to relevant and useful practices or work that have no legal status (Nijar, 2011b, p. 17).

There is also no common view on how regard should be paid, because "ongoing" can be interpreted as meaning that there is a lack of consensus on the subject matter, which creates legal uncertainty

(Tvedt and Rukundo, 2010, pp. 19–20; Nijar, 2011b, p. 17). It may therefore simply denote the need to take into consideration work that, in spite of not being finalized, concluded, or accepted, relates in one way or another to the Nagoya Protocol. An example of such "ongoing work" could be the discussions of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, which were expressly recognized by the tenth meeting of the Conference of the Parties to the CBD (Decision X/1).

Furthermore, not all kinds of work or practices should deserve due regard, just those that are "useful" and "relevant", and provided that they are supportive of and do not run counter to the objectives of the CBD and the Nagoya Protocol.

It is important to note that Paragraph 3 does not explicitly mention which international instruments and what work and practices of international organizations are relevant. However, there are indications in the Preamble of the Nagoya Protocol as to which other instruments and processes are relevant. The Preamble gives special recognition to the ITPGRFA and its Multilateral System of ABS as well as the CGRFA in the realm of genetic resources for food and agriculture. It also refers to human health concerns related to pathogens, which are mainly addressed internationally by WHO, the World Organisation for Animal Health, and the International Plant Protection Convention. Apart from the WHO International Health Regulations (IHR 2005), which are mentioned in the Preamble, the WHO Pandemic Influenza Preparedness Framework might also be covered by this provision as a relevant international instrument or the practices of a relevant organization to deal with the concern over pathogens that should be given due regard in the implementation of the Protocol (WHO, 2011; see also Fidler and Gostin, 2011).

Finally, while the obligations to implement the Nagoya Protocol in a mutually supportive manner and to pay due regard are addressed to the Parties, the particulars of such implementation may be discussed or negotiated at the Conference of the Parties serving as the meeting of the Parties to the Protocol.

4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

Paragraph 4 is highly relevant to understanding the place of the Nagoya Protocol in international law. During the course of the negotiations, some negotiators were of the view that the Protocol would be just another instrument dealing with ABS in addition to, for instance, the ITPGRFA. However, Article 4(4) clarifies that the Protocol is the instrument for implementing the provisions on ABS of the CBD and that it will not operate in situations where a specialized instrument applies that is consistent with the objectives of the CBD and the Nagoya Protocol in respect to the specific genetic resource covered by and for the purpose of the instrument (Buck and Hamilton, 2011, p. 58). This indicates several conditions that govern the relationship between the Nagoya Protocol and specialized instruments: Early drafts of the Protocol explicitly excluded the ITPGRFA from the scope of the Protocol, but this did not make it into the final text. However, Article 4(4) works to exclude the sharing of genetic resources for food and agriculture covered by the ITPGRFA (Ruiz and Vernooy, 2012, p. 14).

First, the specialized instrument shall be "consistent" with and not run counter to the objectives of the CBD and the Nagoya Protocol. This is weaker than the other paragraphs of Article 4 in that it is only

required that a specialized instrument be consistent with rather than supportive of the Protocol. This is recognition of the fact that a specialized instrument on ABS may include different approaches and implementing mechanisms that depart from the bilateral approach found in the CBD and the Protocol.

The second condition relates to membership. If a Party is not a Party to the specialized instrument, then the Nagoya Protocol's provisions will apply to all transactions of genetic resources. This is, for example, relevant in the context of the ITPGRFA because some CBD Parties are not Parties to the ITPGRFA.

Furthermore, the priority given to specialized instruments over the Nagoya Protocol only applies to the "genetic resources covered by" and "for the purpose of" the specialized instrument (Buck and Hamilton, 2011, p. 58). Regarding the purpose, Article 4(4) makes clear that only uses of genetic resources for the purposes of the instrument are excluded from the Nagoya Protocol – for instance, uses for food and agriculture but not for pharmaceutical or other uses in the case of the ITPGRFA. In other words, if a crop listed in Annex I of the ITPGRFA was used for an unrelated purpose, such as a cosmetic or drug, the Nagoya Protocol would apply to such use (Buck and Hamilton, 2011, p. 58). Regarding the genetic resources covered by the specialized instrument, Article 4(4) is not as clear. For example, the scope of the ITPGRFA is over all genetic resources for food and agriculture, but the scope of the Multilateral ABS System is much narrower: only the genetic resources included in Annex I. The question therefore arises as to which one can be considered the resources covered by the ITPGRFA: only Annex I plant genetic resources or also non-Annex I plant genetic resources included by the Consultative Group on International Agricultural Research and similar centres (Article 15 of the ITPGRFA)? An interpretation consistent with the subject matter dealt with in this paragraph may indicate that the latter is correct.

Article 5
Fair and Equitable Benefit-sharing

1. **In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with 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. Such sharing shall be upon mutually agreed terms.**
2. **Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.**
3. **To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.**
4. **Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.**
5. **Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.**

A. Background

The fair and equitable sharing of the benefits arising out of the utilization of genetic resources – including through appropriate access to genetic resources, transfer of relevant technologies, and funding – is at the core of the Convention on Biological Diversity (CBD) (Article 1 of the CBD). Fair and equitable sharing of benefits is one of three closely interlinked objectives of the CBD. Through benefit-sharing, the CBD seeks to ensure that the benefits of biodiversity – both monetary and non-monetary – provide biodiversity-rich countries and communities with the incentives and financial support required for conservation and sustainable use. In addition, in the context of access to genetic resources, equitable benefit-sharing has been described as part of a "grand bargain" (Gollin, 1993, pp. 159, 163). Benefit-sharing can be seen as a logical consequence of the recognition of the rights of countries and communities over genetic resources and the traditional knowledge associated with those resources. It also follows from the application of the principle of equity, which would demand that benefits be shared with all those who contributed to the management, scientific, and development processes that generated these benefits.

Yet fair and equitable sharing of the benefits – in spite of its fundamental role in the CBD – has been largely overlooked in legal and policy implementation. Most legislation, policies, and studies on access and benefit-sharing (ABS) have considered only one side of the equation, focusing on asserting rights over genetic resources and traditional knowledge associated with those resources and establishing access procedures and requirements (Tvedt and Young, 2007). As a result, an important element in discussions leading to Article 5 of the Nagoya Protocol was the clarification of the triggers, obligations, and possible approaches towards the fair and equitable sharing of benefits, as well as of the link between these obligations and access requirements. It is important to note that although Article 5 is mainly concerned with genetic resources, Paragraph 5 also addresses benefit-sharing in the context of traditional knowledge associated with genetic resources held by indigenous and local communities (ILCs).

B. Explanation

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with 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. Such sharing shall be upon mutually agreed terms.

Paragraph 1 of Article 5 of the Nagoya Protocol, together with Paragraph 3, outlines the obligation to share the benefits arising from the utilization of genetic resources. Article 5 reaffirms benefit-sharing requirements established by Article 15 of the CBD. Nevertheless, Article 5(1) uses stronger language on the obligation to share benefits. In addition, taking into account the definition of "utilization of genetic resources" in the Protocol, Article 5(1) advances important points in understanding the link between benefit-sharing and access requirements.

Obligation to Share Benefits

Article 5 of the Nagoya Protocol begins by stating that benefits "shall be shared". It thus reaffirms benefit-sharing requirements in the CBD, which obliges Parties to take "legislative, administrative or policy measures" with the aim of sharing the benefits arising from the utilization of genetic resources with the Contracting Party providing such resources. Requiring such measures, rather than benefit-sharing itself, was a recognition that most benefits from the use of genetic resources are generated within the private sector and would be shared primarily on the basis of mutual agreements (Glowka et al., 1994). Now, Article 5(1) emphasizes the obligation to share benefits, with Article 5(3) referring to legislative, administrative, or policy measures as the manner in which this obligation would be implemented.

Utilization of Genetic Resources

Paragraph 1 establishes that the benefits to be shared, in accordance with the scope of the Nagoya Protocol, are those arising from the "utilization of genetic resources". The CBD already refers to the fair and equitable sharing of the benefits "arising from the utilization of genetic resources". With the Nagoya Protocol now defining and more clearly distinguishing the "utilization of genetic resources" from access to those resources, benefit-sharing is confirmed as a separate set of requirements, which

may or may not be connected to access procedures. The definition of "utilization of genetic resources", which could take place long after the acquisition of the genetic resources and involve other countries or organizations, affects the manner in which access requirements, including prior informed consent (PIC), are understood and applied (see explanation of Article 6 for a comprehensive analysis of use of the term "access"). It also means that with research and development on the genetic and/or biochemical composition of genetic resources, beyond the applicability of access requirements, fair and equitable benefit-sharing would be pertinent.

Subsequent Applications and Commercialization

Additionally, Article 5(1) refers to the need to share the benefits arising from "subsequent applications and commercialization". This reference responds to concerns that benefit-sharing can only be effective if it extends to products and processes developed along the value chain. During negotiations, there were different views as to whether and how benefit-sharing requirements covered these products and processes. This discussion was often linked to the term "derivatives", which among its various meanings was also understood as the results of human activities utilizing genetic resources. Article 2 defines a derivative as a "naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources" – adopting another of its interpretations. Yet Article 5(1) clarifies that benefit-sharing requirements cover "subsequent applications and commercialization" of genetic resources. For example, benefit-sharing obligations extend to the benefits arising from the characterization and assessment of the medicinal properties of the molecules of a type of berry, the development of a composition based on these molecules as an ingredient in nutraceutical products, and the commercialization of such an ingredient. It should be noted, however, that benefit-sharing in relation to final products was not resolved and is not mentioned in the Nagoya Protocol.

Fair and Equitable

Benefits must be shared "in a fair and equitable way." Again, this is the same terminology as in Article 15 of the CBD. As in the CBD, the concept of "fair and equitable" is not defined. Arguably, there could not be a single definition of what is "fair and equitable", given that the substantive content of these concepts depends on the particular situation or specific case. As stated by the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (the Bonn Guidelines), what is regarded as fair and equitable in the types of benefits and the benefit-sharing obligations and procedures varies "in light of the circumstances" (Paragraph 45).

Nevertheless, as other international instruments have agreed on factors to assess fairness and equity, similar criteria could be found in the ABS context. For example, the Bonn Guidelines declare that benefits should be shared "with all those who have been identified as having contributed to the resources management, scientific and/or commercial process" (Paragraph 48). Fairness and equity would thus entail reflecting, in the distribution of benefits, the various proportionate contributions – be it knowledge, innovation, or value addition – made by individuals, communities, or organizations to the research, development, or commercialization process that generated these benefits. Another approach, which could also find basis in the Bonn Guidelines, would be to say that it is the fairness and equity of the process that defines that of the result. Accurate information on the intended uses, how the research and development will take place, third-party involvement, and potential benefits – all listed by the Bonn Guidelines as information that may be required in applications for access – would thus be factors that allow Parties and other stakeholders to effectively determine what is fair and equitable in the specific circumstances.

Party Providing the Resources

According to Paragraph 1, benefits deriving from the utilization of genetic resources must be shared with the Party providing the resources "that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention". This language is taken verbatim from Article 15(3) of the CBD – a provision that excludes two circumstances from benefit-sharing requirements:

- genetic resources acquired from the provider prior to the entry into force of the CBD, and
- genetic resources illegally acquired after the entry into force of the CBD (for example, if a Party that obtained genetic resources illegally sought to benefit by providing these resources to a third Party).

Mutually Agreed Terms

Article 5(1) confirms that the sharing of benefits is based on mutually agreed terms (MAT), as established in the CBD. MAT constitutes the agreement reached between the providers and users of genetic resources on the conditions of utilization of the resources and the benefits to be shared. For example, MAT may cover the conditions, obligations, procedures, types, timing, distribution, and mechanisms of benefits to be shared, with the Bonn Guidelines and the Nagoya Protocol itself containing guidance in this regard. In general, negotiations towards MAT have been envisioned as conducted alongside the PIC process, yet this is not necessarily the case. MAT may be negotiated later, including upon intended or effective utilization of the genetic resources or achievement of certain research, development, or commercialization milestones.

2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.

Paragraph 2 of Article 5 focuses on the benefits arising from the utilization of genetic resources that are held by ILCs. The explicit recognition that ILCs may hold rights with regards to genetic resources has been considered progressive in the context of the Nagoya Protocol (Bavikatte and Robinson, 2011, p. 35). ILCs had long criticized the CBD for only acknowledging States as sovereign over genetic resources, ignoring the proprietary rights of indigenous peoples in the same territories (Harry and Kanehe, 2005). The Bonn Guidelines had only gone as far as calling for the respect of the rights of communities "associated with the genetic resources being accessed" (Paragraph 31). Nevertheless, the reference in the Bonn Guidelines to the need to respect "the established legal rights of indigenous and local communities" did provide recognition that such rights existed, paving the way for stronger language in the Nagoya Protocol. In addition, the United Nations Declaration of the Rights of Indigenous Peoples (adopted in 2007) recognized the "inherent rights" of indigenous peoples, including in relation

to their lands, territories, and resources. Integrating such rights into the Nagoya Protocol and providing substance and meaning to the provisions of the CBD on these issues therefore follows this spirit.[1]

Nevertheless, the language in Article 5(2) remains less forceful than Article 5(1). Article 5(1) obliges the sharing of benefits arising from the utilization of genetic resources. Article 5(2) refers to "legislative, administrative or policy measures, as appropriate, with the aim of ensuring" fair and equitable sharing of benefits. In addition, Article 5(2) refers to genetic resources held by ILCs "in accordance with domestic legislation" regarding the "established rights" of these communities over genetic resources. Benefit-sharing requirements, in the case of genetic resources held by ILCs, are thus linked to domestic legislation and the recognition of their rights over genetic resources. The question, however, arises whether in this context the reference to "in accordance with domestic legislation" suggests a focus on the facilitative role of the State in implementing rights of ILCs over genetic resources rather than on its determination of these rights. One argument in favour of the first interpretation could be that during negotiations of the Nagoya Protocol the term "in accordance with domestic legislation" was seen as less restrictive than "subject to national legislation", a formulation used in Article 8(j) of the CBD.

3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.

Paragraph 3 of Article 5 resumes discussion of the benefits derived from the utilization of genetic resources more generally, incorporating references to legislative, administrative, or policy measures as possible approaches to implementation of the obligations established in Paragraph 1. As in Article 15(7) of the CBD, which requires all Parties to take measures with the aim of fair and equitable benefit-sharing, the obligation in Article 5(3) of the Nagoya Protocol extends not only to countries providing access to genetic resources but also to countries where biodiversity-based research, development, and commercialization usually take place. As a result, Article 5(3) is closely linked to other provisions of the Nagoya Protocol on advancing compliance with ABS requirements, including Articles 15, 16, and 17.

Box 14: References to "as appropriate" in Article 5

Article 5 contains references to "as appropriate" in paragraphs 2, 3, and 5. The use of the term was a source of discord during negotiations of the Nagoya Protocol, as some countries understood it as implying that States' obligations to take measures to ensure benefit-sharing are not compulsory. In all three cases, "as appropriate" does refer to the Parties' obligations to take measures. This is worth underlining, particularly in relation to Article 5(5), as there is no potential for such qualification to affect the recognition of ILCs' underlying rights. Nevertheless, the most plausible understanding of the term does not refer to the optional nature of benefit-sharing measures, which would be odd in a legally binding document with fair and equitable benefit-sharing as its objective. Rather, the reference to "as appropriate" implies that Parties are free to choose measures, i.e. to pick those "appropriate", for implementing benefit-sharing.

1 Buck and Hamilton also note that the recognition in the Nagoya Protocol of that ILCs hold rights over genetic resources is a result of recent developments within the indigenous peoples' rights discourse. See Buck and Hamilton, 2011, p. 48.

4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.

The Nagoya Protocol, through Article 5(4), expressly recognizes that there may be both monetary and non-monetary benefits derived from the utilization of genetic resources. Paragraph 4 also refers to the Protocol's Annex, which contains an indicative list of monetary and non-monetary benefits, taken from Appendix II of the Bonn Guidelines. Article 15 of the CBD already covered monetary and non-monetary benefits. In particular, it noted the benefits to be shared as the results of research and development and those arising from the commercial and other use of genetic resources. Article 15 also referenced Articles 16 and 19 of the CBD, which address transfer of technology and benefits arising from the biotechnological use of genetic resources.

The reference to monetary and non-monetary benefits in this paragraph, as well as the extensive and diverse list of possible benefits in the Annex, highlights the different ways in which research, development, and commercialization related to genetic resources can be negotiated and structured for the fair and equitable sharing of benefits. It is important to note that many of the non-financial benefits listed in the Annex are more direct, immediately available, long-term, and – what is important – suited to contributing to conservation. In this regard, Paragraph 4 of Article 5 is also closely connected to Article 9 of the Protocol, which stresses the link between benefit-sharing and the conservation of biodiversity and the sustainable use of its components. In addition, non-monetary benefits are important in trying to define "win-win" scenarios. They are particularly suited to the application of the principle of "high value to the provider, low marginal cost to the user". For example, sharing information on issues such as the presence of invasive species or illegal fishing in remote areas of a marine reserve, easy for researchers to assess, can be extremely useful for local authorities monitoring such developments.

5. Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

Together with Article 7, Article 5(5) constitutes the Nagoya Protocol's core provision on traditional knowledge associated with genetic resources. The two provisions thus must be jointly considered and construed. Article 5(5) addresses the Parties' obligation to ensure benefit-sharing with ILCs, based on MAT, when traditional knowledge associated with genetic resources held by them is being used. Doing so, Article 5(5) – along with Article 7 – indirectly confirms that under the Protocol traditional knowledge associated with genetic resources vests with the ILCs having generated such knowledge. This conclusion follows from the Protocol only envisioning benefit-sharing with ILCs in the context of traditional knowledge associated with genetic resources, and not with Parties.[2] Although the Preamble recognizes "unique circumstances" where traditional knowledge associated with genetic resources is perceived as a broader national heritage, such circumstances are not contemplated in the operative provisions of the Nagoya Protocol, including regarding access and benefit-sharing requirements.[3] It would thus seem that Article 5(5) of the Protocol only pertains to traditional knowledge that can be traced back to one or more identified ILCs.

2 For a concurring opinion, see Buck and Hamilton, 2011, p. 48.

3 For a criticism of this position of the Nagoya Protocol, see Nijar, 2011a, pp. 28–29.

Box 15: Rights to Traditional Knowledge Associated with Genetic Resources within the World Intellectual Property Organization and the World Bank

The Nagoya Protocol's position on who holds rights to traditional knowledge associated with genetic resources is in line with the approach taken in the current negotiations on traditional knowledge conducted under the auspices of the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organization (WIPO), as well as with the World Bank's Operational Policy on Indigenous Peoples.

The WIPO member states are currently negotiating an international instrument on regulation of and rights to traditional knowledge (the WIPO Draft TK Instrument). Article 2 of the WIPO Draft TK Instrument presently contains a number of alternative draft proposals on who are the beneficiaries of traditional knowledge protection. All of these take the principal position that, as a general rule, rights to traditional knowledge vest with the indigenous people or local community that have generated the knowledge, as long as such a people or community can be identified.

In the same vein, the World Bank's Operational Policy on Indigenous Peoples (OP 4.10) in Paragraph 19 proclaims that indigenous peoples must agree before their cultural resources and knowledge are commercially developed by non-members. Further pursuant to Paragraph 19, when a borrower commercially develops indigenous peoples' cultural resources and knowledge, there shall be arrangements enabling benefit-sharing by affected indigenous peoples.

Obligation to Share Benefits

As to the content of the provision, as indicated, Article 5(5) obliges Parties to take measures so that when traditional knowledge associated with genetic resources is used, benefits arising out of such use are shared with relevant ILCs. Pursuant to Article 5(5), benefit-sharing with ILCs is thus obligatory. The language in Article 5(5) is particularly forthright, considering the CBD language on traditional knowledge associated with genetic resources. The CBD, in Article 8(j), had only required Parties, subject to their national legislation, to "encourage" the equitable sharing of the benefits arising from the utilization of traditional knowledge associated with genetic resources. In contrast, Article 5(5) of the Protocol reinforces the imperative towards benefit-sharing with regard to traditional knowledge associated with genetic resources. This reflects the growing international recognition of the rights of ILCs to maintain, control, and develop their traditional knowledge associated with genetic resources, as well as the obligations of States to take effective measures to recognize and protect the exercise of these rights (see Article 31 of the United Nations Declaration on the Rights of Indigenous Peoples).

It is also important to note that, compared with other provisions in the Nagoya Protocol, Article 5(5) contains fewer caveats (regarding the qualification of "as appropriate", see Box 14). The wording of Paragraph 5 is also stronger than in other provisions for benefit-sharing in the Protocol. In comparison with Paragraph 2, for instance, Parties are obliged to take measures for the fair and equitable sharing of benefits derived from the use of traditional knowledge associated with genetic resources, rather than more-general measures "with the aim of ensuring" that such benefit-sharing takes place. Moreover, there are no references to benefit-sharing depending on the existence of specific rights over traditional knowledge associated with genetic resources, on how these rights were established, or on conformity

with domestic legislation. As indicated, the reference to traditional knowledge being "held" by ILCs must be understood to mean that the knowledge can be traced back to one or more ILCs in order for the Nagoya Protocol to apply.

Utilization of Traditional Knowledge

The Nagoya Protocol does not define "utilization of traditional knowledge". In both the CBD and the Protocol, however, requirements on the fair and equitable sharing of benefits aim to recognize and reward the contribution of the knowledge, innovations, and practices of ILCs towards research and development on genetic resources. Indeed, traditional knowledge associated with genetic resources continues to be widely considered in research and development, given that it often reflects useful information on the properties and management of the components of biodiversity. Article 5(5) clearly establishes the obligation for Parties to take measures so that, in these cases, there is fair and equitable sharing of benefits with the ILCs holding the traditional knowledge associated with the genetic resources utilized.

Mutually Agreed Terms

As in Article 5(1), this paragraph confirms that the sharing of benefits is based on MAT. That is, the conditions, obligations, procedures, types, timing, distribution, and mechanisms of benefit-sharing must be agreed upon jointly by the providers and users of the traditional knowledge associated with genetic resources. Generally, these negotiations are conducted alongside the PIC process, but – as in the case of the utilization of genetic resources – this is not always or necessarily the case.

Indeed, the extent to which access and benefit-sharing requirements are connected is an issue, particularly in regards to traditional knowledge associated with genetic resources, linked to the temporal scope of the Nagoya Protocol. It has been pointed out that the access provisions in the Protocol are formulated in a way that suggests that they only apply to genetic resources and traditional knowledge associated with genetic resources accessed following the entry into force of the Protocol. It has also been argued, however, that from this conclusion it naturally follows that the same applies to the benefit-sharing provisions (Buck and Hamilton, 2011, p. 57). That is not necessarily the case, however. True, absent an explicit provision to that effect, the Protocol can hardly be interpreted as having a retroactive effect in the sense that there shall be benefit-sharing also with regard to past use. However, it is a different matter if the traditional knowledge associated with genetic resources has been accessed prior to the Nagoya Protocol but its utilization continues after the Protocol has entered into force. Nothing in the wording of Article 5(5) suggests that the provision should not apply in such instances.

Monetary and Non-monetary Benefits

Finally, it is worth noting that, despite the sequence of the paragraphs, both monetary and non-monetary benefits are equally relevant in situations involving the rights, knowledge, and practices of ILCs. Similarly, there is also a range of measures that Parties, both providers and users of genetic resources, may take to advance fair and equitable sharing of benefits resulting from the use of traditional knowledge associated with genetic resources.

Box 16: The Terms "Traditional Knowledge" and "Indigenous and Local Communities"

"Traditional knowledge" is not a term of art. There is currently no formal legal definition of the term, including in the CBD. In negotiations on the Nagoya Protocol, some delegations argued that it should include a formal definition of traditional knowledge in order to clearly define the boundaries of the object of protection. Others held that the term was sufficiently self-explanatory for the purposes of the Protocol, particularly against the backdrop of Article 8(j) of the CBD. The latter position prevailed. Given the lack of a definition of the term, "traditional knowledge" in the Protocol must be understood in light of Article 8(j) of the CBD. This suggests that the Protocol, generally speaking, pertains to knowledge associated with genetic resources developed by ILCs in a cultural context through their traditional lifestyles (see also the proposals for a definition of traditional knowledge made during negotiations on the WIPO Draft TK Instrument). Furthermore, it should be underlined that knowledge does not necessarily need to be old to qualify as traditional. Instead, the term "traditional" refers to the context in which the knowledge was generated rather than to when this occurred.

As in the CBD itself, the Nagoya Protocol, including Article 5(5), merges "indigenous peoples" and "local communities" together under the joint heading "indigenous and local communities". Although using the term "ILCs" conforms with standard CBD practice, doing so may not necessarily be without complications. International law recognizes indigenous peoples as distinct legal subjects. As international legal subjects, indigenous peoples enjoy certain rights to traditional knowledge and genetic resources rooted in international legal sources other than the Nagoya Protocol. Debate on the exact nature and scope of those rights is ongoing. But as the general existence of such rights is undisputed, the Protocol must be implemented in accordance with these rights. "Local communities", on the other hand, are not legal subjects for international legal purposes and hence cannot benefit from international legal obligations. Consequently, with regard to local communities, the Nagoya Protocol must be implemented without consideration of international legal sources relevant to indigenous peoples. The Protocol must of course still interplay with any domestic constitutions and laws recognizing and awarding rights to local communities. Still, as indigenous peoples hold underlying rights to genetic resources and traditional knowledge associated with genetic resources under international law while local communities hold such rights only under domestic law, the provisions of the Nagoya Protocol referring to ILCs may apply differently for indigenous peoples and local communities.

Article 6
Access to Genetic Resources

1. 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 utilization 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.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

   (a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;

   (b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;

   (c) Provide information on how to apply for prior informed consent;

   (d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;

   (e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;

   (f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

   (g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia:*

      (i) A dispute settlement clause;

      (ii) Terms on benefit-sharing, including in relation to intellectual property rights;

      (iii) Terms on subsequent third-party use, if any; and

      (iv) Terms on changes of intent, where applicable.

A. Background

Prior to the Convention on Biological Diversity (CBD), genetic resources were regarded as freely accessible without the users' obligation to share benefits with provider countries. The CBD changed that perception by confirming that these resources lay under the territorial sovereignty of individual countries where they were found (Preamble and Articles 3 and 15(1) of the CBD). It implies that States have the right to determine the rules and conditions of access to genetic resources according to their national laws including, if existent, access and benefit-sharing (ABS) legislation. The CBD also subjected access to genetic resources to the prior informed consent (PIC) of the Party providing such resources, unless otherwise determined by that Party (Article 15(5)) and to mutually agreed terms (MAT) (Article 15(4)). It nonetheless required States providing genetic resources to facilitate access and not to impose restrictions that run counter to its objectives (Article 15(2)). In return for access, users of genetic resources have an obligation to share benefits with providers (Article 15(7)). Genetic resources within the scope of the CBD thus cannot be treated *per se* as freely accessible. The CBD defined its scope of application in Article 15(3) to genetic resources provided by a Contracting Party that is a country of origin of such resources or a Party that has acquired them in accordance with the CBD.

The CBD thus became the first international instrument that:

- acknowledged the sovereign rights of States over the genetic resources within their jurisdictions,
- acknowledged the authority of States deriving from the sovereign rights to regulate and control access,
- clarified the link between sovereign rights and access to genetic resources, and
- established the principle of benefit-sharing.

Article 6 of the Nagoya Protocol mainly builds on the various elements of Article 15 of the CBD (under Paragraphs 1, 2, 3, and 5) that deal with the status of genetic resources and the conditions/requirements for access. Article 6 is the key provision addressing access to genetic resources in the Protocol. It stipulates the rights and obligations of providers in regulating access to genetic resources.

Paragraph 1 reaffirms the sovereign right of States over their natural resources and, consequently, the authority to regulate access to genetic resources according to domestic ABS legislations and regulatory requirements and subject to the PIC of the Party providing such resources. In Paragraph 2, a new scenario is introduced that did not exist in the international law of access before the Nagoya Protocol: the right of indigenous and local communities (ILCs) to determine access to genetic resources where they have the established right to grant access to such resources. Finally, Paragraph 3, containing seven subparagraphs, presents a list of measures that Parties providing genetic resources subject to PIC requirements must take. Under the CBD, no concrete measures were foreseen to facilitate access to genetic resources and to hinder the imposition of restrictions that run counter to its objectives as foreseen under Article 15(2) of the CBD. The measures under Article 6(3) of the Nagoya Protocol can be seen as a concretization of Article 15(2) of the CBD.[1]

1 See CBD COP 7 Decision VII/19, Document UNEP/CBD/COP/DEC/VII/19.

B. Explanation

1. 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 utilization 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.

Paragraph 1 reaffirms the sovereign rights of States over natural resources. Based on those rights, States have the authority to regulate and control access to genetic resources subject to their national ABS legislations or regulatory requirements.

Prior Informed Consent

Article 6(1) of the Nagoya Protocol states that access to genetic resources for their utilization is subject to the PIC of the Party providing such resources, unless otherwise determined by that Party. The formulation "subject to the prior informed consent" seems to imply that access requires PIC, which is the permission given by the Party providing the genetic resource to a user prior to access.

The concept of PIC originated in the early 1980s when the United Nations Food and Agriculture Organization promoted the International Code of Conduct on the Distribution and Use of Pesticides.[2] It is based on the principle that prior to a risky activity, those affected and those authorized to make decisions should be informed in detail about the potential risks in order to be able to make a fully informed decision. In this sense, it is used to protect importing States from environmental and health hazards. Under the CBD, the concept has been used differently. First, it is meant to protect the Party that provides genetic resources and not the one that acquires them. In other words, the risk addressed by PIC in the CBD context is legal uncertainty. Second, it precedes consent for access to genetic resources and their subsequent export from the providing Party. For this, the provider country (represented by its competent national authority) must be informed in advance and in detail about the planned research or bioprospecting activity (that is, the access activity). It is on the basis of the information that a potential user furnishes that the providing Party makes a decision about whether to allow access.

In practice, the providing Party certifies its PIC by issuance of a permit of access. The issuance of a permit or its equivalent becomes a mandatory requirement under the Nagoya Protocol where access is subject to PIC (Article 6(3)(e)). The manner, extent, and procedure in which PIC should be obtained are governed by national access regulations. These may require that PIC be obtained also from other stakeholders, for example from ILCs, if access is requested to genetic resources for which the ILCs have the established right to grant access (see Article 6(2)) or to traditional knowledge associated with genetic resources (see Article 7). The 2002 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (the Bonn Guidelines) list and elaborate possible elements of a PIC in Paragraphs 27-40 (see Supplementary Materials).

2 See www.pan-uk.org/archive/Internat/IPMinDC/pmn5.pdf (last visited 8 January 2012).

The "Conditionality" of PIC

However, it is important to note that Paragraph 1 leaves it to the providing Party to decide whether PIC shall be required or not. In line with Article 15(5) of the CBD, Article 6(1) of the Nagoya Protocol states that: "access … is subject to prior informed consent … unless otherwise determined by that Party". This gives the State a number of options:

- to demand PIC in all cases of access,
- to demand PIC for access to certain types of genetic resources,
- to demand PIC for access to genetic resources for particular purposes, or
- to fully exempt PIC in all cases of access (a Party may also waive PIC but require a notification of access).

Difficulty arises when the State is silent in regard to access requirements – that is, when it is not expressly stated whether PIC of the State is required. A reading of Paragraph 1 suggests that PIC is mandatory unless waived by the relevant Party. In fact, at one point of the negotiation process the option for this clause was "unless a Party waives its sovereign right through a national decision posted on the Access and Benefit-sharing Clearing-House".[3] Based on this, there is an indication that the intention of the negotiators was to conclude that as long as a country does not clearly declare that PIC is not required, it should be assumed that PIC is required. Still, some countries – commonly, industrialized countries – have traditionally not regulated access to genetic resources. The general assumption that genetic resources can be accessed in such countries without any need to consult State authorities is risky. Indeed, it might not be clear why a particular country does not regulate access - for example, silence might indicate that the country is not yet in compliance with its obligations under Article 6 (Koester, 2012, note 102). In any case, the entity requiring access to genetic resources should take a cautious approach similar to cases of silence; that is, it should be assumed that PIC is required unless the providing Party has clearly given up its right for PIC under Article 6(1) of the Protocol. Some users, such as the fish industry, even consider it wise to confirm with the national focal point where PIC has been waived (Ornamental Aquatic Trade Association Ltd, 2011).

Definition of Access to Genetic Resources

The CBD and the Nagoya Protocol do not define "access to genetic resources". The former only defines "genetic resources" (Article 2). These are genetic material of actual or potential value. "Genetic material" is any material of plant, animal, microbial, or other origin containing functional units of heredity (Article 2). Hence, genetic resources are any material of plant, animal, microbial, or other origin containing functional units of heredity that possess actual or potential value. They are the parts of biological resources needed or used for their genetic material and not for their other attributes (Glowka et al., 1994, p. 76). They are not commodities or goods in trade.

However, Paragraph 1 states that access to genetic resources is subject to PIC when such resources are requested with the aim of utilizing them (that is, for their utilization as defined under Article 2 of the Nagoya Protocol and not for other purposes). The vital question in deciding whether PIC is required is therefore: For what purpose is access to a natural resource containing genetic resources requested? Two scenarios are possible:

3 UNEP/CBD/WG-ABS/9/ING/1.

- Access to a natural resource is requested for its use as a commodity – This means, for example, that access to a forest is requested for timber extraction or hunting. This request will be out of the scope of the Nagoya Protocol. It is not covered either by Article 15 of the CBD (Glowka et al., 1994, p. 76) or by Article 6 of the Nagoya Protocol.
- Access to genetic resources is requested for their utilization as defined under Article 2 – The request will be within the scope of the Nagoya Protocol and the PIC requirement would be triggered unless otherwise determined by the Party providing the genetic resources.

Thus, in order to differentiate these two cases, a Party providing genetic resources shall check a request for access for the utilization of its genetic resources against its ABS legislation or measures. Nevertheless, the Nagoya Protocol seems to leave some access scenarios unresolved. The regulation of access to genetic resources for their genetic qualities (that is, not for their use as commodities) but without a clear link to utilization seems to be unclear. Furthermore, it is unclear how the PIC and benefit-sharing requirements play out with regard to genetic resources accessed either as commodities or without a clear link to utilization if an interest in utilizing them arises later.

Regarding the first instance, a reading of Article 6(1) indicates that the Nagoya Protocol does not exclude access to genetic resources without a clear link to utilization from regulation by the ABS legislation but rather from the mandatory PIC requirement. Furthermore, Article 3 of the Nagoya Protocol states that the Protocol shall apply to genetic resources within the scope of Article 15 of the CBD, which subjects (all) access to genetic resources to the national legislation of the relevant State. A concrete example of access to genetic resources without a clear link to utilization is access for basic research purposes. According to Article 8 of the Nagoya Protocol, access for basic research purposes is still subject to ABS legislation of the Party providing genetic resources (see explanation of Article 8). Consequently, it can be argued that the Protocol also covers cases of access to genetic resources for their genetic material but excluding their utilization.

In the second instance, in which an interest in utilizing the genetic resources arises later, the question is whether it is the taking of a resource that triggers the PIC requirement or (only) the moment where the intent of using it develops (so-called change of intent). Regarding the first understanding, it is important to note that the Nagoya Protocol makes numerous references to “access to genetic resources”. A closer look at these provisions indicates that the Protocol distinguishes two acts: accessing (taking) genetic resources and using them (see, for example, Paragraph 8 of the Preamble, Article 6(1), and Annex 1(a)). If accessing were synonymous with using, the term “utilization” would be superfluous. While the Protocol seems to indicate that PIC precedes utilization (best case scenario), cases of utilization prior to PIC can be imagined as well. In other words, an *a posteriori* quasi access situation might arise as a result of a change of the initial purpose of taking/accessing genetic resources – that is, after genetic resources have left the territory of a Party. This suggests that the PIC requirement can also be triggered at any downstream stage of research, which supports the latter understanding.

The definition of utilization of genetic resources therefore is useful for interpreting “access to genetic resources for their utilization”, as it seems to expand the concept of genetic resources to derivatives/biochemical compounds. That would mean the intent to carry out research and development on derivatives/biochemical compounds would trigger the PIC requirement. For genetic resources that are accessed as commodities or for purposes other than utilization from Parties that require PIC for utilization, the need to include a come-back clause in case the intent changes as well as the importance of compliance and monitoring measures is therefore clear.

Utilization is therefore vital not only as the trigger for benefit-sharing (see also discussion on Article 5) but also in the context of access.

Provider Party

Article 6(1) further states that the provider Party is either the country of origin of such resources or a Party that acquired the genetic resources in accordance with the CBD.

Article 2 of the CBD defines the country of origin as a country where those genetic resources are found in *in-situ* conditions – that is, where they exist within their ecosystems and natural habitats (Glowka et al., 1994, p. 18). However, some species have existed for a long time away from their original *in-situ* conditions and have become part of new ecosystems and habitats. A country where such species exist would also be regarded as a country of origin (Glowka et al., 1994, p. 18). But there are often also domesticated and cultivated genetic resources. Domestication and cultivation are the result of human intervention through selection and breeding of plants, animals, or microbes over centuries in order to meet human needs. This process gives new or very different traits to these organisms that vary from those they possessed in *in-situ* conditions. For such genetic resources, the country of origin is considered the one where they have developed their distinctive properties (Glowka et al., 1994, p. 18).

A Party would be considered to have acquired genetic resources in accordance with the CBD if MAT were established and PIC were granted (Article 15(4) and (5) of the CBD). Two situations need to be distinguished here:

- Where genetic resources were acquired prior to the entry into force of the CBD (before 29 December 1993) – This is a question of scope. The MAT and PIC requirements of the CBD only became binding after the CBD entered into force. Thus genetic resources acquired before this moment cannot be considered as having been acquired in violation of the CBD. In addition, such genetic resources are out of the scope of the CBD in line with the legal principle of non-retroactivity of treaties that is well established in international law (see also explanation of Article 3). That means the provisions of a treaty cannot bind a Party for acts or facts or for situations preceding its existence as well as its entry into force for that Party.
- Where genetic resources were acquired by a Party after the CBD entered into force but without meeting the MAT and PIC requirements of the providing Party – This is a question of legality. Such acquisition may be referred to as a violation of the CBD if two conditions are fulfilled. First, access must have taken place after the CBD had entered into force for the Party that acquired the genetic resources. Second, access to genetic resources of the providing Party must be subject to the requirement of PIC, as explained before.

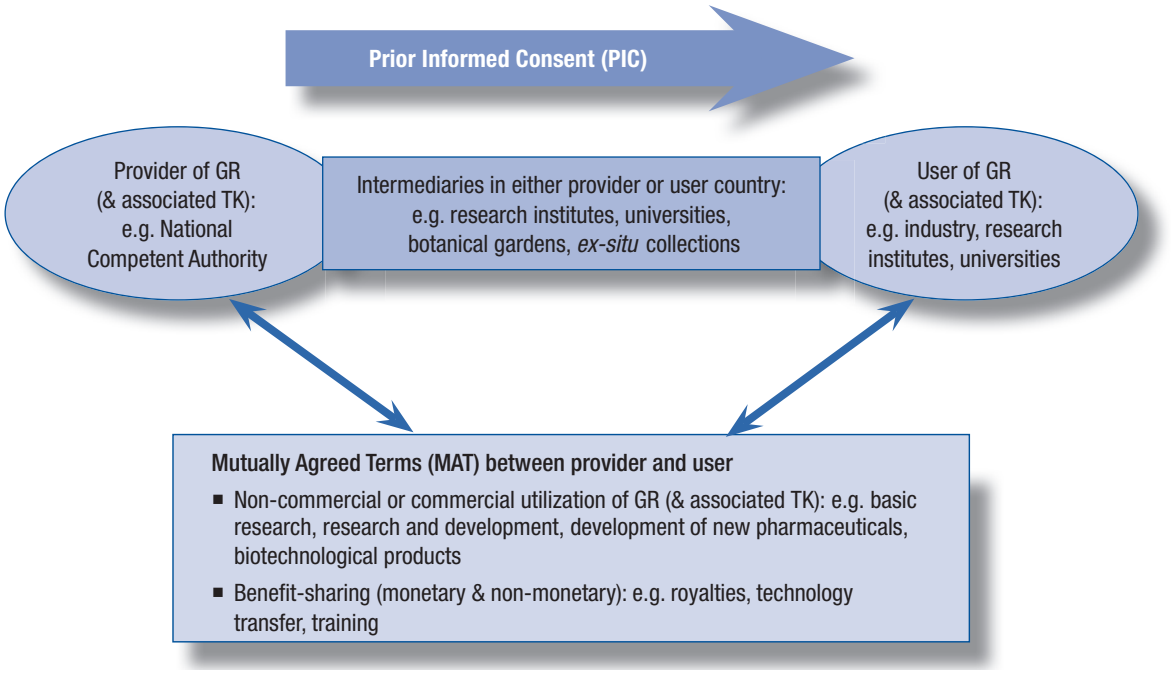
A party in possession of genetic resources that were acquired in violation of the CBD requirements cannot be considered as a provider Party.

Relationship between PIC and MAT

Finally, in the context of Article 6(1) it is also important to understand the relationship between PIC and MAT. The CBD requires that "[A]ccess, where granted, shall be on mutually agreed terms" (Article 15(4)). According to the logic of this Article, MAT would precede PIC, as consent for access follows (or is based on) MAT. However, MAT could be accomplished within the PIC procedure created by the provider (Glowka et al., 1994, p. 81). "Mutually agreed terms" clearly indicates that the terms reached by the parties and upon which access to genetic resources is based should be a result of consensus. The establishment of MAT, which again are the terms and conditions of ABS (see also explanation of Article 5), hence is a quasi negotiation phase between the Party providing genetic resources and the Party requesting access – be it an individual, a company, an institution, a community, or a State. An indicative list of typical MAT is provided under Paragraph 44 of the Bonn Guidelines (see Supplementary

Materials). MAT normally form the content of the agreement between the parties, which is often referred to as a material transfer agreement.

Figure 5: Visualization of ABS Actors and their PIC and MAT Obligations



Source: *CBD, Frequently Asked Questions on Access and Benefit-Sharing (ABS), at:* www.cbd.int/abs/doc/abs-factsheet-faq-en.pdf.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

Article 6(2) of the Nagoya Protocol regulates access to genetic resources where the PIC or approval and involvement of ILCs is required. That is a new approach in the international law of ABS. Under Article 8(j) of the CBD, States shall, as far as possible and as appropriate, (only) promote the wider application of traditional knowledge with the approval and involvement of the holders of such knowledge and encourage the equitable sharing of benefits arising from its utilization. Article 6(2) of the Nagoya Protocol now acknowledges that the ILCs may have the right to grant access not only to traditional knowledge associated with genetic resources but also to genetic resources as such – that is, genetic resources without traditional knowledge associated with them. It also introduces a requirement for PIC or approval and involvement of the ILCs for access to such resources. In addition, it defines the role of a Party in the process of obtaining the PIC or approval and involvement of ILCs.

In Accordance with Domestic Law and as Appropriate

It is important to mention first that there is a mandatory obligation for each Party to take measures with the aim of ensuring that the prior informed consent or approval and involvement of ILCs is obtained where they have the established right to grant access to genetic resources. This is indicated by the use of the term "shall".

However, the obligation is to be fulfilled "In accordance with domestic law", a formulation used several times in the Nagoya Protocol in the context of ILCs (see also Articles 5(2), 7, and 12(1)). This could imply that each Party is free to determine on its own which measures it shall take. It could also mean that each Party is at liberty to take measures according to what its domestic law permits or requires. However, some authors are of the opinion that Article 6(2) limits the State's role to a facilitative one in implementing rights of ILCs over genetic resources rather than one of determining these rights. Such an approach has been considered as more favourable to community rights (Bavikatte and Robinson, 2011, p. 47). An argument in favour of such an understanding is the language "in accordance with", which is different from the language used in Article 8(j) of the CBD, which subjected the Parties' obligations vis-á-vis ILCs to national legislation ("subject to …").

In any case, Paragraph 2 is not prescriptive concerning the measures to be taken by the Parties. It states that "each Party shall take measures, as appropriate". Thus, such measures could be legislative, administrative, or policy measures or any other measures the Party deems appropriate to implement its obligation under Article 6(2). The focus therefore is not on the type of measures to be taken but rather on the aim. Therefore it is expected that there will be a diversity of measures from country to country, depending on national legal systems as well as local circumstances (see also Box 14 on the term "as appropriate" in the context of Article 5).

Ensuring PIC or Approval and Involvement of ILCs

In taking such measures, each Party should have a concrete aim: to ensure that the PIC or approval and involvement of ILCs is obtained for access to genetic resources. This confirms that it is not the type of measure that matters but rather whether such measures are effective to ensure that PIC or approval and involvement of ILCs is obtained.

It is important to note in this context that Article 6(2) of the Nagoya Protocol seems to give an option between PIC and approval and involvement, indicating that a Party's measures could aim at ensuring that either is obtained. However, it is not always clear what "approval and involvement" mean or entail and how they differ from PIC (see explanation of Article 7 where these terms first appeared in the negotiations in regard to access to traditional knowledge associated with genetic resources).

Established Rights of ILCs

The obligation to obtain PIC or approval and involvement of ILCs under Article 6(2), however, is only triggered where ILCs have the established right to grant access to such resources. In other words, if ILCs do not have that right, a Party is under no obligation to take measures with the aim of ensuring that their PIC or approval and involvement is obtained. Once the PIC or approval and involvement obligation under Paragraph 2 is triggered, Paragraph 3(f) is also triggered.

Article 6(2) of the Nagoya Protocol is built on Paragraph 31 of the Bonn Guidelines, where the established rights of ILCs associated with genetic resources were first recognized. Still, the use of the formulation "where they have the established right" is not very clear. Looking back to the negotiations, one view

is that its origin was the attempt by ILCs to have their rights acknowledged in the Nagoya Protocol as they are recognized in international law (Bavikatte and Robinson, 2011, p. 46). The Protocol does not make any direct reference to this effect but notes in the Preamble the existence of the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) and affirms that nothing in the Protocol "shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities". Essentially these paragraphs in the Preamble give an indication that such rights already exist.

The relevant rights of ILCs under Article 6(2) encompass rights over their territories and the resources found thereon as well as their PIC (see also explanation of the Preamble). Such rights include those established by international law as well as domestic law.

- International law – The UNDRIP, for example, is an international law instrument that recognizes the rights of ILCs. However, it should be noted that UNDRIP is not a legally binding instrument and therefore its implementation by States is voluntary. Furthermore, even those rights recognized by a legally binding instrument will only have effect at the national level if they are transposed by a Party into domestic law. Indeed, the Nagoya Protocol does not oblige Parties to implement other international law instruments.
- Domestic law – Some domestic laws recognize the rights of ILCs over their territories and resources thereon. If this is the case, then a Party is obliged to take appropriate measures in accordance with domestic law with the aim of ensuring that the PIC or approval and involvement of the ILCs is obtained for access to such resources. There is no indication in the Nagoya Protocol that Parties are obliged to establish rights domestically in regard to ILCs where such rights are not yet established. But there is also no indication that such rights cannot be established through domestic law.

Finally, it is important to note that although Article 6(2) obliges only States to take measures to ensure that PIC or approval and involvement of ILCs is obtained where they have the established right to grant access to genetic resources, ILCs are not deprived of their rights to take measures within the confines of relevant domestic law should they have the capacity to do so.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

Paragraph 3 should be read and understood in conjunction with Paragraph 1. It means that in regulating or determining access to genetic resources subject to PIC, a Party providing such resources must take prescribed legislative, administrative, or policy measures, as appropriate, to create a certain level of ease and predictability in the access process for users of the resources. As the term "as appropriate" indicates, a Party is free to take any of the three measures: legislative, administrative, or policy. Paragraph 3(a)-(g) gives a list of what a Party requiring PIC should aim to achieve with such measures.

If a providing Party does not require PIC, however, this would not imply that it is exempt from the obligation to facilitate access as required under Article 15(2) of the CBD (Glowka et al., 1994, p. 81). Indeed, Article 15(2) already obliges each Contracting Party to "endeavour to create conditions to facilitate access to genetic resources … and not to impose restrictions that run counter to the objectives of this Convention". But the CBD neither specifies nor prescribes specific facilitation measures. It also uses very soft and unclear legal terminology ("shall endeavour"), which led to different views regarding the level of voluntariness or involuntariness in the implementation of this obligation.

It should be recognized that lack of legal clarity was one reason for the development of restrictive ABS laws in many (traditional) provider countries. Providers mostly took the authority granted under Article 15(1) of the CBD but did not balance it appropriately with their obligation under Article 15(2). Consequently, many obstacles and challenges for users were created contrary to what the CBD hoped to achieve. This caused reluctance to access and use genetic resources and, as a side effect, the loss of potential benefits for providers of genetic resources and other ABS stakeholders.[4]

Table 4: Characteristics Identifiable in and Impacts Created by Restrictive Regulations

Identifiable (negative) characteristics	Possible negative impacts						
	Delay	Expensive	Complicated	Cumbersome	Uncertainty	Ambiguity	High transactional costs
Long procedures	✓	✓				✓	✓
Multiple permits	✓	✓	✓	✓	✓	✓	✓
Multiple PICs	✓	✓	✓	✓	✓	✓	✓
Multiple fees		✓	✓		✓		✓
Other likely fees		✓	✓		✓	✓	✓
Overlapping procedures	✓	✓	✓	✓	✓	✓	✓

Source: Kamau and Winter, 2009.

(a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;

Subparagraph (a) requires that legislative, administrative, or policy measures taken by a Party provide for legal certainty, clarity, and transparency. Legal certainty, clarity, and transparency are vital for the ABS process, as they have the ability to facilitate access to and use of genetic resources and contribute to MAT in line with the aims of the CBD.[5]

"Legal certainty" is a national and international law principle that holds that the law must provide those subject to it with the ability to regulate their conduct with certainty and to protect those subject to it from arbitrary use of State power. As such, legal certainty entails a requirement for laws not to be changed suddenly and for decisions to be made according to legal rules – that is, be lawful. It also

4 UNEP/CBD/WG-ABS/4/2.

5 CBD COP 5 Decision V/8, Document UNEP/CBD/COP/5/8.

serves frequently as the central principle for the development of legal methods by which law is made, interpreted, and applied (Maxeiner, 2010).

Both civil and common law legal systems recognize the concept of legal certainty. In both legal traditions it is regarded as grounding value for the legality of legislative and administrative measures taken by public authorities (Claes et al., 2009, pp. 92–93). However, the degree to which the concept of legal certainty is incorporated into law depends on national jurisprudence.

The principle of legal clarity is another central tenet of the rule of law as understood around the world (Zolo, 2007). It requires that all law be sufficiently precise and not contradictory to allow the person to foresee, to a degree that is reasonable in the circumstances, the consequences of a given action (Maxeiner, 2010).

Legal transparency aims at clear decision-making processes – that is, it refers to the existence of a clear set of laws that are freely and easily accessible to all, strong enforcement structures, and an independent judiciary that is able to offer protection against the arbitrary use of power.

Box 17: The Principle of Legal Certainty in European Union Law

The concept of legal certainty has a long history as a general principle of European Union (EU) law with application in the practice of the European Court of Justice (ECJ). In its interpretation of EU law, the ECJ holds that legal certainty requires the law to be certain, in that it is clear and precise, and foreseeable in its legal implications (especially when applied to financial obligations). The adoption of laws that will have legal effect in the EU must therefore

- have a proper legal basis,
- be worded in a way that is clearly understandable by those who are subject to the law,
- not take effect before publication (the non-applicability of retroactivity), and
- be made public to enable parties to know what the law is and thereby comply with it.

Source: Raitio, 2003; Chalmers et al., 2010.

(b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;

According to Subparagraph (b), a provider State's rules and procedures on accessing genetic resources must be "fair" and "non-arbitrary". Both have to do with the treatment the providing Party accords to parties that request access to its genetic resources. "Fairness" means that equal treatment in applications for access to genetic resources is accorded to similar domestic and foreign applicants and to similar foreign applicants of different Parties. "Non-arbitrariness" is the non-dependence on arbitrary (that is, individual or one-sided) discretion. It is rather fixed on standards and/or rules of law. It also means restrained exercise of power.

However, in the exercise of its authority to determine access, a providing Party may develop PIC criteria pertaining to points of special State interests within which exceptions from non-arbitrary and non-discriminatory requirements may be freely exercised. In regard to the non-discriminatory requirement, for example, a Party may choose to develop rules that aim at advancing local, non-commercial

biodiversity and ecosystem research and education. For this, access rules and procedures may grant a local user a permit to collect genetic resources in a territory that is of strategic importance to the country but deny a permit for a foreign user. It may also grant access to genetic resources of a depleted species for research aimed at restoring the species but deny access to the same for commercial purposes.

(c) Provide information on how to apply for prior informed consent;

Subparagraph (c) obliges Parties requiring PIC to give guidance to users on how to apply for PIC. Such guidance may include information on:

- national authorities granting PIC (competent national authorities and/or national focal point),
- specific requirements to fulfil (e.g., application and particular information to be provided),
- specific procedures to follow, etc.

(d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;

Subparagraph (d) spells out the obligation of the providing Party to issue a decision through a competent national authority in written form. If read separately, the Subparagraph does not give a clear picture of the decision implied. However, in the logic of Subparagraphs (c) and (e), it is evident that it refers to the decision to grant PIC. Such a written decision must be:

- clear and transparent,
- provided in a cost-effective manner, and
- taken within a reasonable period of time.

The provision aims to ameliorate some of the challenges that users of genetic resources have sometimes faced, which include lack of reliability of provider measures, delay in granting decisions, and high transaction costs. The decision should therefore not be oral but written as well as clear – that is, readily understood and straightforward in order to avoid varying interpretations by parties. In addition, it should be cost-effective in terms of the expected benefits overweighing transaction costs and in general minimizing costs as much as possible. Finally, it should be timely by avoiding undue delay, which may disadvantage the (potential) user as well as increase transaction costs.

It is difficult to define cost-effectiveness and reasonable time frames in terms of exact money figures or time duration. In addition, it will be difficult to achieve uniform implementation of these requirements by all Parties, as existing infrastructures and human resources as well as administrative complexities will differ from country to country. However, understanding the varying concerns of different users – often dictated by distinct sectorial attributes – and having a simple and flexible procedure that is able to address them on a case-by-case basis while avoiding increased bureaucracy could prove very helpful.

(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;

Under Subparagraph (e), the provider shall ensure that measures applied allow for the issuance of a permit or its equivalent to the user at the time of access. Such a permit shall be evidence that PIC was granted and that MAT were established. The access permit must reflect the terms mutually agreed between the applicant and one or more competent national authority(ies) or a national focal point. From the practice of numerous States, such a permit may include the following content:

- description of the species or organisms to be accessed, including their sex and developmental stage;
- description of the sites where collection is permitted;
- the number and volume of samples that may be collected;
- the time period for which access is granted;
- consent of any group or community involved;
- restrictions on third-party use of the genetic resources subject to the permit;
- requirements for sharing of benefits resulting from use of the genetic resources subject to the permit;
- provisions guaranteeing the participation of nationals and national institutions in any research carried out with the genetic resources;
- requirements for technology transfer;
- reporting requirements; and
- any other conditions that the competent national authority(ies) or national focal point may consider appropriate.

Once the permit has been granted, the same is to be notified by the provider to the Access and Benefit-sharing Clearing-House (ABS CH) established under Article 14 of the Nagoya Protocol. Such a permit notified to the ABS CH shall constitute an internationally recognized certificate of compliance (Article 17(2) of the Protocol) and serve as evidence that genetic resources were accessed in accordance with the PIC of the Party providing such resources and that MAT were established (Article 17(3)).

(f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

Subparagraph (f) requires Parties to develop criteria and/or processes for obtaining PIC or approval and involvement of ILCs for access to genetic resources (see Paragraph 2). However, not every Party providing genetic resources is obliged to do so, as the provision's wording of "where applicable" implies. As this Subparagraph is directly related to Article 6(2) of the Nagoya Protocol, "where applicable" could be referring to the fact that the obligation under this Subparagraph only applies to a Party within the jurisdiction of which ILCs have the established right to grant access to genetic resources.

It is also interesting to note that a Party shall set out such criteria and/or processes "subject to domestic legislation". This could mean that each Party has the prerogative to decide which criteria and/or processes are feasible under its domestic legislation. This means again that there would be a diversity of such criteria and/or processes due to varying national legislations.

(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia:*

Finally, a Party requiring PIC for access to genetic resources for their utilization should aim to develop rules and procedures for requiring and establishing MAT. That means such a Party must establish grounds when MAT shall be required and make clear how the terms shall be established – that is, the procedure the parties must follow to establish them. The provision further demands that such rules and procedures be clear (see Subparagraph (d) above) and that any terms established by the parties are put in written form. Written terms help to boost certainty and transparency as they cushion the parties against sudden change of conditions by either party or unfounded claims.

Subparagraph (g) also provides a short list of terms that may be required by a providing Party as well as established between parties. The formulation "may include, *inter alia*" means that these terms do not form an exhaustive but rather indicative list. It also means the list is not prescriptive, and therefore it is left to the Parties to decide whether to include them in their MAT or not. Such measures shall likewise serve as complementary components of the elements under Article 18 of the Nagoya Protocol.

(i) A dispute settlement clause;

This could regulate:

- how notifications of disputes should be served, such as through a sworn statement, fax, or electronic communication means;
- a timeline;
- options for dispute resolution, such as by negotiation in good faith, mediation, or arbitration;
- the jurisdiction to which the parties will subject any dispute resolution process; and
- applicable law (see also explanation of Article 18(1) of the Nagoya Protocol).

(ii) Terms on benefit-sharing, including in relation to intellectual property rights;

These could clarify:

- forms of benefits to be shared, such as monetary and/or non-monetary,
- shares in percentage or fixed amounts, and
- royalties or milestone payments.

(iii) Terms on subsequent third-party use, if any; and

These could regulate such questions as:

- Is the user permitted to transfer the resource(s) to a third party?
- If yes, under what conditions (that is, what are the obligations of the initial recipient and what are the obligations of the subsequent recipient)?

(iv) Terms on changes of intent, where applicable.

These could clarify such questions as:

- How should a user for non-commercial purposes act if commercial potential is discovered and desired (that is, should the user go back to the provider in order to renegotiate MAT, and do benefits change from non-monetary to monetary, or should both types of benefits be shared)?
- What happens to vaccines from pathogens accessed under Article 8(b) of the Nagoya Protocol after emergency situations have ceased?

Article 7
Access to Traditional Knowledge Associated with Genetic Resources

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

A. Background

Article 7 and Article 5(5) constitute the Nagoya Protocol's core provisions on traditional knowledge associated with genetic resources. It is important to note that these core provisions significantly expand the traditional knowledge and access and benefit-sharing (ABS) provisions of the Convention on Biological Diversity (CBD). The main ABS provision in the CBD – Article 15 – only covers genetic resources and does not address traditional knowledge. Furthermore, the CBD provision explicitly pertaining to traditional knowledge associated with genetic resources – Article 8(j) – is primarily concerned with the preservation and maintenance of such knowledge. Still, Article 8(j) includes ABS references that establish a link to Article 15. This link provided a basis for the inclusion of traditional knowledge associated with genetic resources in the negotiations on the ABS regime. (See the negotiating mandate agreed at the seventh meeting of the Conference of the Parties to the CBD (Kuala Lumpur, Malaysia, 2004), which instructed Parties to "elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8(j) of the CBD".)[1]

Articles 7 and 5(5) formally only address States' obligations to take measures to ensure benefit-sharing and adherence with access standards. Still, by identifying indigenous and local communities (ILCs) as beneficiaries of benefit-sharing and as relevant entities for access agreements, Articles 5(5) and 7 indirectly affirm ILCs as holders of traditional knowledge associated with genetic resources and, presumably therefore, as holders of rights to such knowledge (see also Box 16 on the terms "traditional knowledge" and "ILCs").

The CBD rests on the presumption that States hold sovereign rights to genetic resources. Against this background, it was expected that with regard to genetic resources, the Nagoya Protocol would focus on ABS requirements vis-à-vis States, although the Protocol also recognizes that entities other than States can be holders of genetic resources. With regard to traditional knowledge associated with genetic resources, the situation is somewhat different. Unlike genetic resources, the CBD does not proclaim that Parties hold rights to traditional knowledge associated with genetic resources, but it does not exclude this possibility either. However, Article 8(j) of the CBD through the formulation "knowledge, innovations and practices of indigenous and local communities" seems to assume that traditional knowledge associated with genetic resources most often vests with ILCs.

1 COP Decision VII/19 D, "International Regime on Access to Genetic Resources and Benefit Sharing".

Against this background, some delegations entered negotiations on the Nagoya Protocol with an understanding that its access provision on traditional knowledge associated with genetic resources should recognize ILCs as those entities entitled to approve access. Other delegations were, however, of the opinion that Parties should have the right to offer prior informed consent (PIC) also with regard to traditional knowledge associated with genetic resources. The latter opinion was motivated by the understanding of some Parties that traditional knowledge vests with the State and by the concern of other Parties that ILCs in their countries lack the capacity to handle PIC processes by themselves and hence are in need of government assistance in this regard.

These basic positions were reflected in the negotiations on Article 7 of the Nagoya Protocol. The States arguing for a role of the State in the PIC process generally sought to address their concerns through various wordings proposed in submissions for draft texts that concluded in the final text of the Protocol in references to "[i]n accordance with domestic law" and "or approval and involvement", which derives directly from Article 8(j) of the CBD, as an alternative wording to PIC.

B. Explanation

Article 7 proclaims that States have an obligation to take measures aiming to ensure that traditional knowledge associated with genetic resources held by ILCs is accessed with their PIC or approval and involvement, based on mutually agreed terms (MAT). The obligation of Parties under Article 7 is limited or qualified in different ways.

Traditional Knowledge Associated with Genetic Resource Held by ILCs

As the explanation to Article 5(5) notes, the scope of the Nagoya Protocol is limited to traditional knowledge associated with genetic resources held by ILCs. This implies that in as far as the CBD applies also to traditional knowledge held by entities other than ILCs, the Protocol includes no access requirements with regard to the latter category of traditional knowledge.

Furthermore, as far as traditional knowledge is concerned, Article 3 clearly limits the Protocol's applicability to traditional knowledge associated with genetic resources. It is worth noting that this is not the same thing as saying that traditional knowledge need always be accessed in combination with a genetic resource. Instead, it is quite possible that in certain instances, a potential user would be interested only in the traditional knowledge and not in the genetic resource associated with it. The Nagoya Protocol, including Article 7, applies to such situations as well. In other words, Parties shall take measures aiming to ensure compliance with PIC or approval and involvement requirements also in situations where the State is not involved in the transaction, as no genetic resources are being accessed.

PIC or Approval and Involvement of ILCs

The key words in the terms "prior informed consent" and "approval and involvement" are "consent" on the one hand and "approval" on the other hand. "Prior" and "informed" merely provide a helpful clarification and underline that consent must be voluntarily offered, not coerced or fraudulent. Still, even in the absence of these qualifiers, "consent" must reasonably be presumed as referring to genuine consent. In other words, it seems farfetched to conclude that had qualifiers such as "prior" and

"informed" been absent in Article 7, the provision could have been interpreted as stipulating that any form of consent is sufficient, even if fraudulent, coerced, etc. In the same vein, the word "involvement" does not add much meaning to "approval", as it is hard to see how anyone can approve access without being involved in the decision-making process. Consequently, a proper understanding of the terms PIC and "approval and involvement" essentially boils down to a comparison between the terms "consent" and "approval".

Generally speaking, "consent" and "approval" have a similar meaning in the English language. There might be differences in the nuances, but not more significant than it being reasonable to conclude that the terms "approval" and "consent" have essentially the same meaning when appearing alongside each other in the Nagoya Protocol. The addition of "or approval and involvement" to the term PIC could therefore appear redundant.

However, it must be recognized that "consent" may almost be referred to as a term of art, appearing in the CBD itself as well as in numerous other international instruments pertaining to, for example, traditional knowledge. This means that PIC has acquired a particular status under international law, where certain elements automatically attach to the concept, such as, for instance, definitions of what is implied in "prior" and "informed". The term "approval", on the other hand, although appearing in Article 8(j) of the CBD, is rarely employed in international legal instruments, and can hardly be referred to as a term of art with specific elements automatically attached to it. Consequently, to the extent that PIC has acquired a particular status under international law, there might be a material difference between references to "PIC" and to "approval and involvement". In the same vein, certain domestic jurisdictions may have a formal definition of PIC. Such States may use the flexibility offered by Article 7 to adopt the language "approval and involvement" in their ABS legislation, with the exact intent of avoiding the incorporation of certain elements of the defined concept of PIC into their ABS legislation.

In sum, pursuant to Article 7 of the Nagoya Protocol, ILCs are entitled to determine access to traditional knowledge associated with genetic resources held by them.[2] In implementing the provision, Parties have the flexibility to opt for measures aiming to ensure either that access is determined based on PIC or on "approval and involvement". The distinction is relevant to the extent that PIC has acquired a distinct meaning either as a term of art under international law or through definitions in national legislation.

Furthermore, it should be noted that the formulation "prior informed consent or approval and involvement" appears also in Articles 6(2) and 16 of the Nagoya Protocol. It was introduced there when informal agreement had been reached on Article 7. Naturally, the understanding of the formulation must be the same in all three provisions.

In Accordance with Domestic Law and As Appropriate

References to "[i]n accordance with domestic law" and "as appropriate" can also be found in other provisions of the Nagoya Protocol (see Articles 5(2), 5(5), 6(2), and 12(1)). As explained under Article 5, the reference to "as appropriate" there does not qualify the underlying rights of ILCs to traditional knowledge associated with genetic resources. Rather, the reference was introduced to offer Parties flexibility when deciding what sorts of measures to take to implement the provision (see also Box 14

2 For a concurring opinion, see Buck and Hamilton, 2011, p. 55. They observe that access to traditional knowledge associated with genetic resources can occur following the "agreement" by ILCs. See also p. 48, where the authors underscore that the holders of traditional knowledge are individuals and communities, not States.

on the term "as appropriate" in the context of Article 5). This understanding equally applies to the reference of "as appropriate" in Article 7 of the Nagoya Protocol.

Regarding the reference to "[i]n accordance with domestic law", it has been argued that this reference in Article 7 implies that the State has a facilitative role in PIC of approval and involvement processes when ILCs are in need of such support (Bavikatte and Robinson, 2011, p. 45). Others have gone further, suggesting that the cumulative effect of the references to "as appropriate" and "[i]n accordance with domestic law" renders the PIC or approval and involvement requirement at the "absolute discretion" of a Party (Nijar, 2011b, p. 26). However, these positions do not find support in the wording of this provision. It follows from the structure of Article 7 that the formulation "[i]n accordance with domestic law" refers only to the manner in which Parties shall take measures. In other words, it is proclaimed that Parties shall take measures in accordance with national law. This is probably a given in most States, but it now nonetheless explicitly follows from the Nagoya Protocol. Indeed, the reference to "[i]n accordance with domestic law" does not qualify States' material obligation to take measures aiming to ensure that PIC or approval and involvement requirements are complied with before traditional knowledge associated with genetic resources held by ILCs is being accessed. For the same reason, it is difficult to see how the reference to "[i]n accordance with domestic law" indicates a facilitative role of the State. That said, if a relevant ILC is in need of, and requests, the State's support, it would appear to be in conformity with Article 7 of the Protocol for the State to offer such support.

In conclusion, some delegations arguing for the inclusion of the references to "[i]n accordance with domestic law" and "as appropriate" may have intended the language to bring certain meanings to Article 7 of the Nagoya Protocol. Still, Article 7, as with all other provisions in the Protocol, must as a starting point be understood in accordance with a reasonable reading of the wording of the provision (see Article 31 of the Vienna Convention on the Law of Treaties). This implies that Article 7 provides that Parties shall, if appropriate, take measures (through domestic law) aiming to ensure that ILCs can consent or approve before traditional knowledge associated with genetic resources held by them is being accessed, according to MAT.

Obligation to Take Measures

The references to "[i]n accordance with domestic law" and "as appropriate", as well as the qualifier "aim of ensuring", do offer States flexibility when it comes to what measures to take in order to implement Article 7 of the Nagoya Protocol, and when. First, the fact that States shall only take measures "as appropriate" implies that States are under no general obligation to take measures. They need only take measures when there is an identified need for such. In addition, the references to both "as appropriate" and "[i]n accordance with domestic law" clarify that the State is free to determine what sorts of measures are most suited to satisfy the identified need. Finally, the measures must merely "aim" to ensure that traditional knowledge associated with genetic resources is accessed with the PIC or approval and involvement of ILCs, based on MAT. This indicates that the measures can be of a kind that generally provides for PIC or approval and involvement. But if the measures fail to accomplish this task on occasion, this would not amount to a violation of Article 7.

At the same time, it must be noted that the discussed caveats do not offer States the option not to take measures when there is an identified need for such. Article 7 proclaims that States "shall" take measures. The obligation is thus mandatory. The flexibility only applies to what measures to take and the fact that they can be of a nature that does not ensure PIC or approval and involvement in each instance or that MAT has been established.

Traditional Knowledge and Intellectual Property Rights

During the negotiations on the Nagoya Protocol, the focus of most delegations was on genetic resources. Less attention was paid to traditional knowledge associated with such resources. As is evident throughout the Protocol, negotiators often first sought agreement on how to deal with a particular issue in the context of genetic resources. Subsequently, the same solution was used also with regard to traditional knowledge associated with genetic resources. Consequently, little attention was paid to matters rendering traditional knowledge substantially different from that of genetic resources. In most instances, addressing traditional knowledge in essentially the same manner as genetic resources constitutes no problem or is even beneficial, as it brings coherence to the Protocol. But in at least one respect, the issue of intellectual property rights, it might have been beneficial had the negotiators paid attention to the particular characteristics of traditional knowledge.

Access to all forms of genetic resources falling under the scope of the Nagoya Protocol requires PIC from Parties within which the genetic resource is situated or, when applicable, by ILCs having established rights to such resources. Article 7 also requires the PIC or approval and involvement of relevant ILCs before any form of traditional knowledge associated with genetic resources within the general scope provided for by Article 3 is accessed. However, this seems to contrast with the conventional intellectual property rights system, which has hitherto predominantly informed people of the extent to which someone can establish exclusive rights over knowledge – or, to be more precise, over innovations derived from knowledge.

Inherent in the protection offered to human creativity by conventional intellectual property rights are a number of limitations restricting such rights' applicability to traditional knowledge in various ways. For instance, traditional knowledge must first "take the form of" or result in an innovation and, even so, must be sufficiently novel and must not have been exposed to a wider public prior to registration to be eligible for patent protection. And even if it meets these demands, patent protection lasts for a relatively short period of time. These features of the patent system mean that, viewed through the prism of intellectual property rights, the vast majority of traditional knowledge is found in the so-called public domain – that is, it is free for anyone to use. In addition, the intellectual property rights system may have allowed third parties to acquire rights to traditional knowledge originally created by ILCs by using the knowledge to develop an invention that has in turn been patented.

The way the Nagoya Protocol relates to these features of the intellectual property rights system may be of considerable importance to its applicability as far as traditional knowledge associated with genetic resources is concerned. Given the inherent limitations embedded in the conventional intellectual property rights system, if such norms prevail over the Nagoya Protocol, the Protocol's access requirements pertaining to traditional knowledge associated with genetic resources seem to essentially apply only to traditional knowledge that has not yet been disclosed. That is so because traditional knowledge as such is not eligible for protection under the intellectual property rights system, and, for the reasons described, the possibilities of doing so even if the knowledge is included in an innovation are also limited. If, on the other hand, the Nagoya Protocol takes precedent, the consequence appears to be that the scope of the public domain is considerably reduced, as far as traditional knowledge is concerned, as Article 7 does not distinguish between traditional knowledge that has not yet

been shared with a wider public, that is already publicly available,[3] and to which third party rights pertain.

Article 4 supposedly regulates the Protocol's relationship with other international agreements and instruments. Article 4(1) declares that the provision does not intend to create a hierarchy between the Protocol and other international instruments. At the same time, however, the provision proclaims that the Protocol shall not affect Parties' rights and duties derived from international agreements entered into prior to the Protocol, unless these rights and duties cause a serious threat to biodiversity. The wording seems to suggest that existing intellectual property rights derived from international intellectual property law – such as patent treaties – pertaining to innovations based on traditional knowledge are not affected by the Nagoya Protocol, provided that these rights do not cause a serious threat to biodiversity.

With regard to potential future intellectual property rights instruments – or perhaps more relevant for the present purposes, to intellectual property rights similar instruments[4] – pertaining to traditional knowledge, a different situation occurs. Pursuant to Article 4(2), Parties to the Nagoya Protocol are free to enter into other international agreements pertaining to traditional knowledge. These must, however, not cause a serious threat to biodiversity – the qualifier found in Article 4(1) – and they must not run counter to the objective of the CBD and the Nagoya Protocol. Article 1 of the Protocol clarifies that appropriate access standards form part of the objective of the Protocol. It would seem, therefore, that Article 4(2) places certain limitations on the possibility of Parties to the Protocol entering into future intellectual property rights agreements that affect their obligations to take measures aiming at ensuring that the PIC or approval and involvement requirements of Article 7 are met. Reasonably, a future agreement rendering the access requirements set forth in the Nagoya Protocol ineffective must be regarded as running counter to the objective of the Protocol. The level of limitations that Article 4(2) establishes with regard to future intellectual property agreements is difficult to determine, however.

Article 4(3) of the Nagoya Protocol clarifies that what has been outlined with regard to Article 4(2) applies also to international intellectual property rights agreements currently being negotiated. Article 4(3) is particularly relevant with regard to the international instrument on traditional knowledge currently being elaborated under the auspices of the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC) of the World Intellectual Property Organization (WIPO).

Article 4(4) of the Protocol addresses "specialized international access and benefit-sharing instruments". Pursuant to Article 4(4), as a general rule such instruments take precedent over the Protocol for those Parties that are also Parties to the specialized instrument. As will be discussed below, benefit-sharing constitutes a central element of the traditional knowledge instrument currently under negotiation under the auspices of the WIPO IGC. This instrument, if adopted, may hence qualify as a specialized international ABS instrument, for the purposes of the Nagoya Protocol. Notwithstanding, this would not, it seems, affect the applicability of the access requirements pursuant to Article 7 of the Nagoya Protocol, as essentially the same qualifier applies to Article 4(4) as to Articles 4(2) and 4(3). Also pursuant to Article 4(4), in order to have priority over Article 7 of the Nagoya Protocol a specialized instrument must be consistent with, and not run counter to, the objective of the CBD and the Nagoya Protocol. In

3 The difference between the terms "publicly available" and "public domain" is, put simply, that the former denotes only a fact – namely, that traditional knowledge has been disseminated to a wider public. Unlike "public domain", "publically available" does not infer that it follows from this fact that the traditional knowledge is legally free to use.

4 Intellectual property rights similar agreements are more interesting in this context; as such, unlike intellectual property rights, they potentially can apply directly to knowledge and not just protect innovations.

other words, Article 4(4) places the same limitations on Parties to the Nagoya Protocol in the WIPO IGC negotiations on a traditional knowledge instrument that apply in general to future intellectual property rights and intellectual property rights similar instruments, as discussed above.

In conclusion, Article 7 of the Nagoya Protocol, read in conjunction with Article 4, seems to suggest that the Protocol does not have an impact on existing intellectual property rights agreements – such as patent treaties – that have resulted in third parties establishing intellectual property rights to innovations based on traditional knowledge associated with genetic resources generated by ILCs. Nor does the Nagoya Protocol affect Parties' obligations to grant in the future such intellectual property rights under existing intellectual property rights agreements, provided that such agreements do not cause serious damage or threat to biodiversity. At the same time, Articles 4(2) through 4(4) of the Protocol place certain limitations on Parties' ability to enter into any new intellectual property rights agreements or intellectual property rights similar agreements that could have an impact on their obligation to take measures aimed at ensuring that the PIC or approval and involvement requirements of Article 7 are met. Moreover, once existing intellectual property rights to innovations based on traditional knowledge associated with genetic resources held by third parties expire, ILCs' right to offer PIC or approval before continued use of such traditional knowledge kicks in, as Article 7 applies to all forms of traditional knowledge as long as that knowledge falls under the scope of the Nagoya Protocol.

Furthermore, it is important to note that Article 7 establishes no limitation as to the term of protection. Hence, the access requirements established by Article 7 of the Nagoya Protocol apply to traditional knowledge associated with genetic resources regardless of how long ago the knowledge was generated or how long the knowledge has been publicly available. Indeed, traditional knowledge need not necessarily be old, as the description of knowledge as "traditional" refers to the context in which the knowledge has been generated rather than to when this occurred (see also Box 16). This position of the Nagoya Protocol is in line with current WIPO processes.

In short, the Nagoya Protocol obliges Parties to take measures aiming at ensuring PIC or approval and involvement of ILCs not only with regard to traditional knowledge associated with genetic resources still within their imminent control but also with regard to such knowledge already publicly available, or – to use intellectual property rights parlance – in the public domain. However, this only applies within the framework established by Article 4.

Box 18: The WIPO Traditional Knowledge Instrument

The World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore is engaged in text-based negotiations on an instrument containing intellectual property rights, or perhaps more likely intellectual property similar rights, specifically designed for traditional knowledge (draft WIPO TK Instrument). The current mandate of the WIPO IGC, as determined by the WIPO General Assembly, asks the Committee to submit to the General Assembly a draft instrument for the effective protection of traditional knowledge, to be adopted at a WIPO diplomatic conference. It is worth noting that the WIPO IGC in parallel also addresses genetic resources. Although negotiations are in progress, certain general conclusions can be gleaned from the present draft, reflecting the current status of the deliberations.

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Contrary to the Nagoya Protocol, the draft WIPO TK Instrument places considerable focus on the scope and the subject matter eligible for protection and on what forms of protection are awarded. Articles 3 and 6 of the present draft contain a number of alternative proposals. Still, it is evident that the draft WIPO TK Instrument, in contrast to the Nagoya Protocol, will contain detailed regulations as to what forms of traditional knowledge enjoy protection, in what way, and to what extent. Judging by the current draft, it appears likely that the future WIPO TK Instrument will differentiate between, for example, sacred traditional knowledge and knowledge that is less culturally sensitive, as well as between secret traditional knowledge and knowledge that is already publicly available.

As to manners of protection, a number of delegations seem to favour a protection system in which not all traditional knowledge is subject to PIC requirements. Rather, they envisage complete protection for secret, sacred, and perhaps in other ways culturally sensitive traditional knowledge, whereas already publicly available traditional knowledge of less sensitive character may merely be subject to benefit-sharing requirements and formal and public recognition of the source of the knowledge.

Article 8
Special Considerations

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, 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 for such research;

(b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;

(c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

A. Background

Article 8 of the Nagoya Protocol addresses certain cases or situations of access and benefit-sharing (ABS) in connection with:

- Non-commercial research

During the negotiations of the Nagoya Protocol, the call for a special regime for non-commercial research was controversial. On the one hand, providers of genetic resources held concerns and perceptions regarding non-commercial research with respect to change of intent (see below), use of materials by third parties, and use of research results by commercial entities. On the other hand, the scientific community had concerns *vis-á-vis* access requirements and procedures in provider countries. These concerns centred on the fact that restrictions on access readily impede non-commercial research, as it does not aim at monetary benefits.

- Emergency cases related to human, animal, or plant health

Another controversial issue during the negotiations was whether the Nagoya Protocol would also apply to pathogens and, if so, what ABS obligations would be created. ABS related to pathogens is important in order to address public concerns for human, animal, or plant health in a responsible but also fair and equitable way. Industrialized countries in particular were concerned that the ability of the international community to respond to pandemic threats could be limited by the Nagoya Protocol.

- Genetic resources for food and agriculture

Furthermore, as recognized in the Preamble of the Nagoya Protocol, genetic resources play an important role in food security and sustainable development of agriculture.

Article 8 seeks special treatment for such cases/situations by requiring each Party to take them into consideration while developing and implementing ABS legislation or regulatory requirements.

B. Explanation

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

The chapeau of Article 8 indicates that Parties have the mandatory obligation ("shall") to take measures foreseen under Paragraphs (a)-(c) at the development and implementation stages of their ABS legislation or regulatory requirements.

First of all, it is important to note that the provision uses the formulation "development and implementation" instead of "development or implementation". This raises the question of whether Parties that have already developed their ABS legislation or regulatory measures are excluded from the obligation.

The meaning of the terms "development" and "implementation" is not further clarified in the Nagoya Protocol. However, both terms are also used under Article 22, on Capacity. Articles 22(4)(a) and (c) state that "[I]n support of the implementation of this Protocol, capacity-building … may address … [C]apacity to implement, and to comply with the obligations of, this Protocol", and "[C]apacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing". These provisions depict a situation in which capacity is required for implementation of and compliance with an existing ABS legislation (Article 22(4)(a)) and also for development, then implementation and enforcement (Article 22(4)(c)), due to either the non-existence of any ABS legislation or its formation still being at a (very) early stage.

As the terms development and implementation were first merged during the eighth meeting of the Ad Hoc Open-ended Working Group on ABS in connection with the issue of capacity-building,[1] it can be argued that they have a similar meaning in the chapeau of Article 8 as they have under Article 22(4)(a) and (c). Consequently, Parties that have not yet developed any ABS legislation or regulatory requirements would have to implement their obligation(s) under Article 8 while developing such legislation or regulatory requirements, whereas those that already have ABS legislation or regulatory requirements would have to do so while implementing. The latter would involve revision of existing legislation and regulatory requirements to accommodate this obligation. Hence, an interpretation of these terms to suggest that only Parties having no ABS legislations or regulatory requirements in place are under the obligation of Article 8, thus exempting existing legislation and regulatory requirements, has no ground.

Furthermore, it should be noted that although the chapeau refers to each Party, there is an indication that not every Party of the Nagoya Protocol must undertake some action under Article 8. The obligation referred to here is not to coerce a Party to develop and implement ABS legislation or regulatory requirements, a task that is beyond the mandate of the Nagoya Protocol. Instead, the obligation seems to be addressed only to Parties that choose to regulate ABS in a specific way, namely through ABS legislation or regulatory measures. This would exempt other Parties, such as those that take administrative or policy ABS measures.

1 See UNEP/CBD/WG-ABS/8/8.

(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, 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 for such research;

Whereas Article 15(2) of the Convention on Biological Diversity (CBD) requests Parties to create conditions for access for environmentally sound uses that do not run counter to the Convention, Article 8(a) of the Nagoya Protocol goes one step further. Paragraph (a) requires Parties to create special conditions in order to promote and encourage research that contributes to the first and second objectives of the CBD – that is, conservation and sustainable use of biological diversity, especially in developing countries (see Article 1 of the CBD).

Conditions to Promote and Encourage Research

Article 8(a) does not clearly define what is meant by "conditions". It only specifies that whatever conditions a Party creates, the aim should be to promote and encourage research that falls under Paragraph (a). One condition that can contribute towards promotion and encouragement of such research is directly identified in the provision – namely, simplified measures on access for non-commercial research purposes.

Furthermore, it should be noted that the need to facilitate access to genetic resources for environmentally sound uses as well as to avoid restrictions that impede the implementation of the objectives of the CBD in line with its Article 15(2) is also underlying Article 6(3) of the Nagoya Protocol. Article 6(3) enumerates measures that Parties requiring prior informed consent (PIC) must enact in order to ease access to genetic resources. Non-commercial research would equally benefit from such measures.

Still, it is important to recognize that Article 8(a) of the Protocol provides a stand-alone clause to exclusively address further, distinct needs of research undertaken for non-commercial purposes. As no list of other possible conditions has been provided, each Party seems to have a wide discretion to decide which action to undertake.

Commercial vs. Non-commercial Research

Another challenge in understanding Article 8(a) is the distinction of commercial research from non-commercial research. This is difficult for the following reasons:

- Both the private sector and research institutions (e.g., universities) can be involved in commercial as well as non-commercial research.
- Similar research methods and processes are generally used in commercial as well as non-commercial research.
- Both types of research usually require access to the same biological materials and genetic resources.
- Both types of research can be beneficial for conservation and the sustainable use of biological diversity.[2]

2 UNEP/CBD/WG-ABS/7?INF/6, p. 5.

In response to concerns about links to commercial research, the non-commercial research sector (including museums, funding organizations, botanical gardens, herbaria, universities, genebanks, and conservation organizations) came together at a workshop in Bonn in 2008 on "Access and Benefit Sharing in Non-commercial Research". The participants compiled tangible indicators to separate commercial from non-commercial research, including the following.[3]

Commercial research:

- is normally designed to produce at least some results and benefits that will have real or potential commercial value; and
- creates benefits that are held privately rather than entered into the public domain and are restricted in different forms.

Non-commercial research:

- normally lacks all of the above characteristics;
- is mostly willing to put the results in the public domain;
- is often publicly or benevolently funded; and
- differs in that certain regulatory measures on commercial research might not be relevant but rather impose unnecessary time and cost imposts.[4]

In creating special conditions for non-commercial research, however, it has to be taken into account that this research or its results can easily be turned to commercial ends, a situation that Parties are also required to concurrently address in their ABS legislation or regulatory requirements. This is reflected in the formulation "taking into account the need to address a change of intent for such research". That is to say, if the research began with a non-commercial intent (at the time of access), the user should renegotiate PIC and mutually agreed terms (MAT) in case a commercial intent emerges during the project (post-access).

In summary, it can be concluded that Article 8(a) of the Nagoya Protocol is centred on two major points:

- the need to provide simplified access rules to pure scientific research and other research for non-commercial purposes; and
- the need to address the situation of a post-access intent that deviates from MAT at the time of access through renegotiation of PIC and MAT.

Box 19: Examples of Access Legislation for Non-commercial Research

Many Parties have recognized the importance of facilitating research that contributes to achieving the objectives of the CBD and have already introduced national access and benefit-sharing legislation that foresees simplified measures for access for non-commercial research, as the following examples illustrate.

▶

3 UNEP/CBD/WG-ABS/7?INF/6.

4 See UNEP/CBD/WG-ABS/8/INF/6; UNEP/CBD/WG-ABS/8/8.

Brazil: Certain types of basic research and scientific activities are not subject to access authorizations when undertaken by authorized Brazilian researchers or research institutions (Resolutions 28/2007 and 30/2008 of the Brazilian Council on GR Management (CGEN)).

Indonesia: There is a less costly online process to obtain access for non-commercial research projects of less than 30 days, and an even simpler process for Indonesian national researchers (current interim arrangements in expectation of Draft Law on Traditional Knowledge and Traditional Cultural Expressions (RUU PTEBT), Draft Law on Protection of Genetic Resources (RUU PSDG) 2012).

Australia: Permits are required for access to biological resources from a Commonwealth area. The online permit application system provides a facilitated process for access for non-commercial purposes as opposed to access for commercial/potentially commercial use (The Environment Protection and Biodiversity Conservation Regulations 2000).

Ethiopia: Ethiopian ABS legislation clearly differentiates between commercial and non-commercial research with a simplified permit application system for basic non-commercial research and for foreign university researchers working with an Ethiopian counterpart (Regulation no 169/2009 of Ethiopia's Access to Genetic Resources and Community Knowledge and Community Rights Proclamation Act 2006).

Ecuador: Domestic legislation distinguishes between access to genetic resources and access to biological resources, and there is a simplified procedure for non-commercial research (National Regulations implementing Decision 391 1996 of the Andean community).

(b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;

The first sentence in Article 8(b) establishes the obligation of Parties to pay due regard to cases of emergencies that threaten or damage human, animal, or plant health. The second sentence elaborates on this obligation by indicating how due regard could be paid in such cases.

Pay Due Regard

It is important to note that although the first sentence of Paragraph (b) includes an obligation (see the term "shall" in the chapeau), this obligation is limited through the formulation "pay due regard". This phrase is not further defined in the Protocol but it is also used in Article 4(3). Under both provisions, this formulation should be understood in a consistent way. Consequently, under Article 8(b) it does not create a legal obligation to take specific measures regarding emergency cases, but rather it denotes the obligation to take such cases into consideration. Such an understanding is supported by the second sentence of Article 8(b), which explains further the obligation of the first sentence by stating that Parties "may take into consideration" the need for certain measures in response to emergency cases.

Present or Imminent Emergencies

In addition, the obligation to pay due regard to emergency cases is further qualified by the terms "present" and "imminent". This means that not all kinds of emergency cases deserve due regard, only those that are present or imminent. "Present" refers to emergency cases that already exist or that have already occurred, while "imminent" denotes those that have not yet occurred but are likely or about to occur.[5] Whereas the former consist of cases that demand immediate action, the latter refer to cases that demand preparedness against threats to health that are likely to occur or reoccur, or mitigation or prevention measures of health cases that can turn into emergency cases. The decision as to whether a health situation should be regarded as a currently threatening or damaging case or one imminently bound to arise is to be determined either nationally or internationally.

Expeditious Access

The second sentence of Article 8(b) elaborates on the obligation to pay due regard to present or imminent cases of emergencies. It states that to address such situations, Parties "may take into consideration" the need for allowing "expeditious access" to genetic resources.

Before the term "expeditious access" was included in the final text of the Nagoya Protocol, the alternative formulations, "immediate access" and "simplified measures for access", were proposed in draft texts.[6] This indicates that the intended meaning of expeditious access is somehow different – namely, that the term "expeditious" implies fast or speedily. Furthermore, the use of "may take into consideration" gives an indication that each Party has discretion to decide which action to undertake.

In general, the paragraph does not seem to prescribe any concrete outcome. Whereas it is possible to consider denial of expeditious access in regard to cases of preparedness for future emergencies, it is not imaginable for a case determined as a present emergency either nationally or internationally. Therefore, this clause should probably also be seen as a way of creating room for providers to exercise their authority to determine access[7] whilst at the same time applying reason not to deny expeditious access in urgent cases.[8]

Expeditious Benefit-sharing

Parties are required to facilitate expeditious fair and equitable sharing of benefits that arise from the utilization of the genetic resources accessed expeditiously for the said purpose. One of the forms of benefits identified here, which is also proportionate to the use to be made of the genetic resources, is provision of affordable medicines or treatments to those in need, especially in developing countries.

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5 See also the application/use of the concept of imminent threat of damage in general, UNEP/CBD/BS/GF-L&R/3/INF/2.

6 See Cali draft parts I, II, III, UNEP/CBD/WG-ABS/9/3, UNEP/CBD/COP/10/5/Add.4 and UNEP/CBD/COP/10/5/Add.5.

7 See submission by Switzerland concerning expeditious access ("accelerated access procedures") in emergency situations under "Recognition of the sovereign rights and the authority of Parties to determine access", UNEP/CBD/WG-ABS/8/6/Add.

8 According to the submission by Switzerland, it is likely that the intent was to hinder delay resulting from access procedures of Parties requiring PIC when a situation presents serious threat, including in regard to food security.

Parties may agree to share any other benefits that arise from utilization of such genetic resources. Again, this obligation is limited through the formulation "may take into consideration" to one that has to be implemented based on individual discretion of each Party.

In this context, it is important to recall that under Article 4(3), the Nagoya Protocol allows for the development and use of specialized international instruments in cross-cutting areas to regulate ABS and requires Parties to pay due regard "to useful and relevant on-going work or practices under such international instruments and relevant international organizations". In some cases, that is where a specialized ABS instrument applies; it exempts or waives the application of the Nagoya Protocol for the Party or Parties to the specialized instrument "in respect of the specific genetic resources covered by and for the purpose of the specialized instrument". The World Health Organization (WHO) has a new framework agreement, the Pandemic Influenza Preparedness Framework (PIPF),[9] with two Standard Material Transfer Agreements (SMTAs) for regulating ABS between the provider and the institutions within WHO's Global Influenza Surveillance and Response System (SMTA1) and between WHO and third parties (SMTA2).[10] It is not yet clear whether this framework qualifies as a specialized instrument in accordance with Article 4(4) of the Nagoya Protocol. However, while implementing their obligations under Article 8(b), Parties may take into consideration the need to give special treatment to ABS cases conducted under the PIPF in order to enable the WHO to fulfil its mandate under the International Health Regulations of 2005.

(c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

Paragraph (c) refers to "the importance of genetic resources for food and agriculture and their special role for food security". The provision does not seem to suggest a strong obligation, as it only requires Parties to "consider the importance" of those resources and does not demand any specific result or action.

While developing and implementing their ABS legislation or regulatory requirements to implement Article 8(c), States may take into consideration two situations in regard to access to genetic resources for food and agriculture and benefit-sharing. The first one involves plant genetic resources for food and agriculture listed under Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). The second involves all other genetic resources for food and agriculture.

The ITPGRFA is a specialized international ABS instrument regulating issues pertaining to plant genetic resources for food and agriculture. In order to facilitate ABS for plant genetic resources for food and agriculture listed under its Annex I, which consist of 64 crops, the Treaty has created a multilateral ABS system that is in operation.[11] These crops have been identified according to criteria for food security and interdependence (Article 11(1) of the ITPGRFA). The facilitation of access to the crops is meant for the purposes of conservation for research, breeding, and training for food and agriculture. Accordingly, Parties to the ITPGRFA, in exercise of their sovereign rights, agree not to subject recipients to conditions

9 The Pandemic Influenza Preparedness Framework (Agreement) for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP Framework) was adopted by the World Health Assembly at its 64th meeting in May 2011.

10 WHA 64.5, 24 May 2011, Sixty-Fourth Health Assembly, Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits (Resolution), and WHO A64/8, 5 May 2011, Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits. Report by the Open-Ended Working Group of Member States on Pandemic Influenza Preparedness (Framework).

11 For details including organization and functionality of the multilateral system see Kamau, 2011.

of bilateral benefit-sharing and instead to expeditiously make their Annex I plant genetic resources for food and agriculture available to all and without restrictions according to rules established in an SMTA (Articles 12 and 13 of the ITPGRFA). The ITPGRFA has created a benefit-sharing fund that is a core part of the multilateral system and has also set out criteria for sharing benefits as well as distributing funds (Articles 13 and 19(3)(f) of the ITPGRFA as well as its SMTA).

A reading of Article 4(4) of the Nagoya Protocol suggests that plant genetic resources for food and agriculture regulated by the ITPGRFA are waived from the provisions of the Nagoya Protocol. A Party to the Nagoya Protocol that is also a Party to the ITPGRFA may thus consider inserting a clause in its ABS legislation or regulatory requirements waiving Annex I plant genetic resources for food and agriculture used for the purposes stated in the ITPGRFA – that is, conservation for research, breeding, and training for food and agriculture. However, it is important to underline in this context that the ITPGRFA does not apply to Annex I crops accessed for the purposes of chemical, pharmaceutical, and/or other non-food/feed industrial uses (Article 12(3)(a) of the ITPGRFA). Therefore, species listed under Annex I would only be waived if they are used for research and development that leads to a non-food/feed industrial product. For crops referred to as "multiple-use" crops – that is, crops that can be used for both food and non-food purposes – it is their importance to food security that determines their inclusion in the multilateral system and availability for facilitated access, and thus for their waiving.

Parties may also consider other genetic resources for food and agriculture that are important for food security while developing and implementing their ABS legislation or regulatory requirements in accordance with the Nagoya Protocol. There is currently ongoing work under the United Nations Food and Agriculture Organization's Commission for Genetic Resources for Food and Agriculture to identify other genetic resources for food and agriculture that are equally important for food security as those listed under Annex I of the ITPGRFA. At the moment, animal genetic resources,[12] forest genetic resources, aquatic genetic resources, microbial genetic resources, and biochemical agents have been identified.[13] In connection to such genetic resources, a Party may consider implementing Paragraph (c) in conjunction with Article 4(3) of the Nagoya Protocol, which requires due regard to be paid to "useful and relevant on-going work or practices under … relevant international organizations" as long as they are supportive of and do not run counter to the objectives of the CBD.

12 The report of the sixth meeting of the AHWG (UNEP/CBD/COP/9/6) recommended that animal genetic resources for food and agriculture are accorded special consideration.

13 The report of the sixth meeting of the AHWG (UNEP/CBD/COP/9/6) recommended that animal genetic resources for food and agriculture are accorded special consideration. In Decision IX/12 of the ninth meeting of the Conference of the Parties to the CBD, a clause was adopted requiring special consideration for "[g]enetic resources within the remit of the FAO Commission on Genetic Resources for Food and Agriculture" in addition to genetic resources for food and agriculture covered by the ITPGRFA and animal genetic resources. See also background study papers available at www.fao.org/nr/cgrfa/cgrfa-back/en/?no_cache=1 (last visited on 31 August 2011).

Article 9
Contribution to Conservation and Sustainable Use

The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

A. Background

Access to genetic resources, their utilization, and even the sharing of resulting benefits do not themselves guarantee that there will be interest or support for the conservation and sustainable use of biological diversity. Article 9 of the Nagoya Protocol recognizes the need for Parties to take measures to promote the flow into sustainable development of the benefits from the utilization of genetic resources. The inclusion of Article 9 is recognized as an important step in reflecting the interlinkages among the different objectives of the Convention on Biological Diversity (CBD) (IUCN, 2010).

B. Explanation

Article 1 of the CBD identifies three concerted objectives of the Convention: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and appropriate transfer of relevant technologies. Furthermore, the list of objectives of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (the Bonn Guidelines) refers to contributing to the conservation and sustainable use of biological diversity, as well as to promoting the provision of financial resources for implementation and contributing to poverty alleviation. The Bonn Guidelines also explicitly mention that "benefits should be directed in such a way as to promote conservation and sustainable use of biological diversity". Last but not least, Appendix II of the Bonn Guidelines, which was incorporated into the Nagoya Protocol as an Annex, mentions potential benefit-sharing options supporting conservation and the sustainable use of biological diversity: trust funds supporting conservation and sustainable use of biodiversity; capacity-building for indigenous and local communities to conserve and sustainably use their genetic resources; access to scientific information relevant to conservation and sustainable use of biological diversity; and contributions to the local economy. Yet discussions, legal requirements, and initiatives related to access and benefit-sharing (ABS) are generally unconnected from conservation and sustainable use concepts and efforts. Indeed, there is often little consideration of how decisions and policies on ABS may effectively provide incentives for conservation and sustainable use.

Article 9 of the Nagoya Protocol for the first time provides for measures to be taken to ensure that benefits deriving from the utilization of biodiversity flow to efforts linked to its conservation and sustainable use. It foresees a mandatory obligation of all Parties to "encourage users and providers to

direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components." Article 9 does not define, however, how Parties must encourage benefits to focus on conservation and sustainable use, nor does it highlight the types of benefits – particularly non-monetary – with value for conservation and sustainable use in different circumstances. It therefore gives great flexibility for Parties to implement this obligation.

It should be noted that given the limited information on the effectiveness of benefit-sharing in the context of conservation and sustainable use of biological diversity (Richerzhagen and Holm-Mueller, 2005), the sharing of information on measures taken under Article 9 through the ABS Clearing-House (see Article 14) will also be valuable for other Parties and stakeholders trying to enhance the role of benefit-sharing in the conservation and sustainable use of biodiversity.

Furthermore, it should be noted that despite the fact that Article 9 gives great flexibility to Parties and does not foresee any specific measures to undertake, its inclusion in the Nagoya Protocol can be assessed as a positive development towards enhancing the role of ABS in the conservation and sustainable use of biodiversity and as an important step towards strengthening the link between ABS and the conservation and sustainable use of biodiversity – that is, all three objectives of the CBD.

Article 10
Global Multilateral Benefit-sharing Mechanism

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism 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. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

A. Background

Though not unprecedented, the idea of a multilateral approach to situations in which requirements linked to access to genetic resources and the sharing of benefits resulting from their utilization cannot be met on a bilateral level was only a last-minute addition to the text of the Nagoya Protocol. Article 15(7) of the Convention on Biological Diversity (CBD) already contains an indirect reference to a multilateral approach – namely, the consideration of the financial mechanism under the Convention as a plausible instrument for benefit-sharing. For years, a multilateral approach had also been mentioned during negotiations towards an international regime as a possible solution for situations in which compliance with access and benefit-sharing (ABS) requirements was too complex from a political or practical perspective (see Nijar, 2011b, p. 32). It was noted that a global fund could be used to address cases, for example, in which genetic resources had been accessed prior to the new international rules on ABS or in which the traditional knowledge utilized was dispersed across national boundaries.

Yet Article 10 emerged in the context of the final compromise language of the Nagoya Protocol. In this regard, and apart from the significance of the issues addressed in the provision, its introduction must be understood as part of a strategy geared towards pushing aside some difficult issues during the Protocol's concluding negotiations. Article 10 was constructed as a "catch-all" provision, which would also defer or bypass the definition of fundamental yet controversial topics such as the temporal and geographical scope of the Protocol.

This background to Article 10 is relevant as an indication of the opportunities and challenges in its implementation. In terms of opportunities, a multilateral mechanism for benefit-sharing, which already exists in other frameworks, could prove a useful element in facilitating and ensuring benefit-sharing in certain scenarios that have so far escaped bilateral solutions. Nevertheless, there is enduring controversy around the issues that Article 10 expressly and implicitly addresses. Navigating these political differences will be a challenge as countries seek to determine the need for a global multilateral benefit-sharing mechanism and its modalities in order to complement bilateral arrangements and enhance benefit-sharing under the Nagoya Protocol.

B. Explanation

Article 10 of the Nagoya Protocol calls on Parties "to consider the need for and modalities of a global multilateral benefit-sharing mechanism". The Protocol therefore does not create a global multilateral benefit-sharing mechanism but rather instructs Parties to deliberate on whether such a mechanism would be required and, if so, how it would operate. Issues likely to dominate these discussions, which already surface in an analysis of the text of Article 10, include:[1]

- the need for a global multilateral benefit-sharing mechanism, taking into account that Article 10 refers to transboundary situations and situations where it is not possible to grant or obtain prior informed consent (PIC); and
- modalities of a global multilateral benefit-sharing mechanism, taking into account that Article 10 refers to benefits being shared through this mechanism as a means to support biodiversity conservation and the sustainable use of its components.

It is also relevant to point out that the Article 10 reference to considering the needs and modalities has an important precedent in the CBD context. It was similar language in Article 19(3) of the CBD that instructed Parties to "consider the need for and modalities of a protocol" for the safe transfer, handling, and use of living modified organisms, which resulted in the negotiation and adoption of the Cartagena Protocol on Biosafety. Pursuant to Article 19(3), the Conference of the Parties of the CBD established an Ad Hoc Open-ended Working Group on Biosafety to develop the protocol, which was adopted – after six years of negotiations – in 2000.[2] In the process leading up to the Cartagena Protocol on Biosafety, the working group was given terms of reference on the basis of which to operate. Work to consider the needs and modalities of a global multilateral benefit-sharing mechanism may be launched and directed in a similar manner. Moreover, Article 10 already establishes certain parameters for future discussion, including mentions of the objective of the sharing of benefits and the situations the mechanism would cover. Nevertheless, the text of Article 10 makes clear that the ultimate existence and shape of any multilateral mechanism is open for discussion.

Need for a Global Multilateral Benefit-sharing Mechanism

Regarding the need for a global multilateral benefit-sharing mechanism, Article 10 of the Nagoya Protocol suggests two situations to which such a mechanism could apply: transboundary situations and situations where it is not possible to grant or obtain PIC. The need for a global multilateral benefit-sharing mechanism may be considered in relation to these situations, to other circumstances in which the application of ABS principles to access and utilization of genetic resources need to be facilitated, or to issues such as possible advantages and disadvantages of a multilateral over a bilateral approach.

- Transboundary situations

The first situation is the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations. Biodiversity follows natural rather than political borders. Plant and other species are often, if not regularly, distributed across multiple countries and

1 Executive Secretary of the Convention on Biological Diversity (CBD), *Synthesis of views with respect to the need for and modalities of a global multilateral benefit-sharing mechanism (Article 10),* UNEP/CBD/ICNP/2/7, 2 March 2012.

2 CBD, *Consideration of the Need for and Modalities of a Protocol for the Safe Transfer, Handling and Use of Living Modified Organisms,* Decision II/5 (retired), Second Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, 6 – 17 November 1995 – Jakarta, Indonesia.

regions (see, e.g., UEBT, 2010b). On the basis of the bilateral approach to ABS established by the CBD and the Nagoya Protocol, access to genetic resources for their utilization is subject to the PIC of the country of origin that is in fact providing the genetic resources, not all the countries that possess those genetic resources in *in-situ* conditions. Yet in certain circumstances, the bilateral approach to ABS could raise questions of equity and support for the conservation and sustainable use of biodiversity.

Article 11 of the Nagoya Protocol, on Transboundary Cooperation, provides an approach for dealing with such circumstances. Pursuant to Article 10, Parties will have to determine whether a global multilateral benefit-sharing mechanism is needed as a complementary approach. For example, a global multilateral benefit-sharing mechanism might serve to discharge benefit-sharing obligations in cases in which an individual or organization not involved in the original acquisition of the genetic resources is utilizing them without being able to trace back the provider country among the several countries of origin.

- Situations where it is not possible to grant or obtain PIC

The second situation foreseen in Article 10 involves cases in which it is not possible to grant or obtain PIC. In the view of certain governments and other stakeholders, the entry into force of the Nagoya Protocol should establish procedures for obtaining PIC in all cases in which such consent is legally required. For other governments and stakeholders, there may be several situations where it is not possible to grant or obtain PIC.

For instance, it would not be possible to obtain PIC for the utilization of genetic resources obtained from a country that has decided not to establish access requirements. Another possible instance would be in cases in which there is utilization of genetic resources from *ex-situ* collections with no information on country or countries of origin. Although *ex-situ* collections, such as gene banks and other repositories of biological or genetic material, increasingly maintain information about where and when a sample was collected, such information does not always allow identification of the country of origin of the genetic material utilized or the pertinent PIC to be obtained. In these circumstances, a global multilateral benefit-sharing mechanism would nevertheless allow discharge of benefit-sharing requirements.

Discussion of cases in which it is not possible to grant or obtain PIC is also closely linked to issues certain countries considered unresolved under the Nagoya Protocol – particularly its temporal scope. An international instrument does not apply retroactively – that is, it cannot be binding to acts that took place before or situations that ceased to exist prior to its entry into force. Nevertheless, new benefits arising from prior or ongoing uses could be considered as new situations for benefit-sharing requirements – though access requirements would not apply retroactively. A global multilateral benefit-sharing mechanism could potentially cover these cases, although strongly opposed views endure as to how ABS requirements apply to genetic resources accessed prior to the entry into force of the CBD and the Nagoya Protocol (see also discussion on Article 3).

- Other situations

There are also situations beyond the two sets of circumstances mentioned in Article 10 in which a global multilateral benefit-sharing mechanism could apply. Countries could decide to create a mechanism that applies to cases in which there are no legal obligations to share benefits but users of genetic resources choose to do so for ethical, corporate responsibility, or marketing reasons.

Article 10 discussions could also take into consideration the lack of practicality of obtaining PIC. That is, it could provide a way to comply with relevant Nagoya Protocol requirements in cases in which Parties do not have operational ABS systems or provide no solutions for specific circumstances, such

as, for instance, the use of disseminated traditional knowledge associated with genetic resources. In these circumstances, a multilateral approach would entail advantages such as viable solutions for difficult problems in ABS, more reasonable transaction timelines and costs, and innovative financial mechanisms for conservation and sustainable use of biodiversity. Nevertheless, consideration of the range of circumstances in which there might be a need for a global multilateral benefit-sharing mechanism is likely to prove politically challenging, given the link with broader discussions on interpretation of the objective, scope, and obligations of the Nagoya Protocol.

Modalities of a Global Multilateral Benefit-sharing Mechanism

Article 10 of the Nagoya Protocol furthermore states that Parties shall consider the modalities for a global multilateral benefit-sharing mechanism and that the benefits to be shared by such a mechanism must be used to support the conservation of biological diversity and the sustainable use of its components globally. Indeed, the modalities of a global multilateral benefit-sharing mechanism may be considered in relation to the ultimate goal of the worldwide conservation and sustainable use of biodiversity. The need to advance conservation and sustainable use would provide an important parameter to define the functioning, governance, and accountability of a global multilateral benefit-sharing mechanism.

Discussions on potential modalities may also take into account existing benefit-sharing mechanisms at the multilateral level. In this regard, the most important precedent is the Multilateral System for ABS established by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which entered into force in 2004. The Multilateral System under the ITPGRFA is a global pool of plant genetic resources for food and agriculture, focused on a select group of crop species for which access for research and breeding is facilitated, subject to benefit-sharing in cases in which further research and breeding is restricted. Nevertheless, governments and other stakeholders have pointed out basic differences between this Multilateral System and a global multilateral benefit-sharing mechanism, including:[3]

- Benefit-sharing under the Nagoya Protocol is bilateral and transactional in nature, whereas it is multilateral and non-transactional under the Multilateral System.
- The Multilateral System is a comprehensive system for ABS, of which the benefit-sharing fund is only a part.
- Benefits under the Multilateral System are directed towards conservation of plant genetic resources for food and agriculture in developing countries, whereas under the Nagoya Protocol, Parties are encouraged, but not necessarily required, to direct the benefits to conservation and sustainable use of biodiversity globally.

In this regard, consideration of the modalities of a global multilateral benefit-sharing mechanism would need to look at issues such as the specific nature, objective, and scope of such a mechanism in the context of the Nagoya Protocol. In relation to its nature, for example, Article 10 refers to a “mechanism” for benefit-sharing. As opposed to “fund”, which was the term used in previous discussions about a multilateral approach, “mechanism” emphasizes the intent to capture and allocate both monetary and non-monetary benefits. The benefit-sharing mechanism could be a source of funding for conservation

3 Executive Secretary of the Convention on Biological Diversity (CBD), *Synthesis of views with respect to the need for and modalities of a global multilateral benefit-sharing mechanism (Article 10),* UNEP/CBD/ICNP/2/7, 2 March 2012.

and sustainable use projects. It could also play an important role in tasks such as the monitoring of new uses of genetic resources and in the exchange of experiences and lessons learned. Nevertheless, the nature of the global multilateral benefit-sharing mechanism would need to be coherent with other bodies within the CBD and the Nagoya Protocol, including the ABS Clearing-House.

Article 11
Transboundary Cooperation

1. In instances where the same genetic resources are found *in situ* within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.

2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

A. Background

The Convention on Biological Diversity (CBD) and the Nagoya Protocol establish a bilateral approach to access and benefit-sharing (ABS). Access to genetic resources for their utilization is subject to the prior informed consent of the country of origin that is providing the genetic resources rather than all the countries that possess those genetic resources in *in-situ* conditions. Nevertheless, biodiversity follows natural boundaries and not political borders. In most instances, genetic resources have several countries of origin. Furthermore, different indigenous and local communities (ILCs) based in different countries sometimes hold the same traditional knowledge associated with genetic resources. As a result, co-operation among countries of origin has been identified as important in advancing equitable benefit-sharing as well as in contributing to the conservation of biological diversity and the sustainable use of its components. It is also a way to avoid a "race to the bottom" in which access is sought in countries of origin with no or few ABS requirements rather than in other countries of origin.

Article 11 of the Nagoya Protocol, by seeking to promote transboundary co-operation, is a step towards further defining ways in which ABS principles might be advanced in cases in which countries or ILCs share their genetic resources and/or traditional knowledge associated with genetic resources. But consensus on the importance of co-operation has not converted into strong or clear obligations under the Nagoya Protocol. As negotiations of the Nagoya Protocol made clear, the difficulties are both conceptual and practical. It is seen as fundamental for co-operation requirements to respect the sovereign rights of States over their natural resources and the bilateral approach to ABS. In addition, approaches to ABS differ greatly among countries, which makes co-operation difficult to put into effect.

B. Explanation

1. In instances where the same genetic resources are found *in situ* within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.

Article 11(1) of the Nagoya Protocol addresses situations in which the same genetic resources are found *in-situ* within the territory of more than one Party. This raises the question of when such situations occur, given that they may be the norm in a world in which most species of plants and animals expand beyond national boundaries. It will also be important to determine how the situations foreseen by Article 11 differ from those that could be addressed by the prospective global multilateral benefit-sharing mechanism established by Article 10 of the Protocol.

The term "same genetic resources" could be understood in several ways. One possible yet likely oversimplified perspective would be to take "same genetic resources" to mean "same species", given that species are groups of organisms that have a high level of genetic similarity. With such an understanding, Article 11 would bind all Parties within the geographical range of the species whose genetic resources are utilized. Another, more tenable, approach would be to further pinpoint the same genetic resources. Indeed, the "genetic resources" utilized in research and development are frequently not present in all populations within a species. The same genetic resources within the territory of more than one Party would therefore only exist when the populations of a species in these territories share the specific genetic or biochemical characteristics utilized.

This raises the question of what Parties are obliged to do in these cases. The obligation established by Article 11 is that Parties involved "endeavour to cooperate…with a view to implementing this Protocol". Article 11 thus remains a best endeavours clause, which encourages Parties to co-operate but also recognizes it may not always be possible to achieve such collaboration. Furthermore, the involvement of the ILCs concerned is foreseen, but only "as appropriate" and "where applicable" (see also Box 14 on the term "as appropriate" in the context of Article 5).

The collaboration foreseen in Article 11(1) thus has a broad objective, which is implementing the Nagoya Protocol. It leaves open to the Parties what such collaboration might entail and how it might occur. Examples of existing approaches include Andean Decision 391, which was adopted by the Andean Community in 1996. This established the Andean Community regime on genetic resources and created a Committee 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). Such a collaborative approach would be fully in line with Article 11, which does not preclude countries of origin of genetic resources from entering into ABS agreements that do not include counterparts across the border with the same genetic resources.

2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

As biodiversity, including genetic resources, extends beyond national borders, so does the traditional knowledge associated with these genetic resources. Article 11(2) of the Nagoya Protocol establishes that when traditional knowledge spreads beyond national boundaries, Parties must endeavour to co-operate, with the involvement of ILCs, as may be appropriate.

Article 11(2) refers to situations in which one or more ILCs in several Parties can be said to have the "same traditional knowledge." For example, the African cherry tree *(Prunus africana)* is widespread in African highlands. Its use in traditional medicine also spreads throughout its range, including as treatment for various pains, fevers, and diseases (Stewart, 2003). The existence of traditional knowledge linked to the biochemical composition of the African cherry tree could be seen as the "same traditional knowledge". Another approach would be to understand the "same traditional knowledge" more narrowly, occurring only when it refers to similar properties or applications. In both these cases, it is important to consider that traditional knowledge tends to be part of broader knowledge systems, which include biodiversity, landscapes, spiritual values, and customary laws.[1]

It is important to note that until the adoption of the Nagoya Protocol there have been no legal frameworks in place that address ABS issues linked to transboundary traditional knowledge. Nevertheless, there have been some *ad hoc* solutions to challenges in putting in practice ABS in such contexts. For example, when dealing with benefit-sharing in relation to the Hoodia gordonii and the traditional knowledge of the San peoples, it was the Working Group of Indigenous Minorities in Southern Africa, a regional network that coordinates and represents the interests of San peoples, that mandated and coordinated negotiations.[2]

1 For a perspective on traditional knowledge as a part of the collective bio-cultural heritage of indigenous and local communities, see Swiderska, 2007.

2 Convention on Biological Diversity, *Case Study 7: The Commercial Development of Hoodia,* presented at the sixth meeting of the Open-ended Working Group on Access and Benefit-sharing (WG ABS 6), 21-25 January 2008 - Geneva, Switzerland.

Article 12
Traditional Knowledge Associated with Genetic Resources

1. **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.**

2. **Parties, with the effective participation of indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.**

3. **Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:**

   (a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;

   (b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and

   (c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.

4. **Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.**

A. Background

Until the very end of the negotiations on the Nagoya Protocol, opinions differed on whether the Protocol's provisions on traditional knowledge associated with genetic resources should be confined to one article or, instead, traditional knowledge should be dealt with as a cross-cutting issue. When it was still open which position would prevail, Article 12 was thought of as *the* traditional knowledge provision in the Nagoya Protocol by those favouring the former approach. When eventually delegations opted for dealing with traditional knowledge as a cross-cutting issue, the major regulations on traditional knowledge associated with genetic resources ended up in Articles 5(5), 7, and 16. But the heading of Article 12 was not amended to reflect this change and is thus misleading. What remains in Article 12

is a number of provisions addressing various issues of tangential relevance to the core provisions on access, benefit-sharing, and compliance.

B. Explanation

1. 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 calls on Parties to consider the customary laws, community protocols, and procedures of indigenous and local communities (ILCs). Customary laws and community protocols are two quite different normative systems. What is implied by "procedures" is somewhat unclear.

Customary laws are non-codified norms that have evolved in ILC societies over centuries, constantly responding to changes in these societies and to the surrounding environment. Customary norms continue to develop in these societies. The non-codified aspect of customary norms is essential, as it allows customary laws to gradually and instantly adapt in response to amended societal interests. This is a key feature of customary laws, despite the fact that in more recent times some ILCs have codified their customary laws and may have gained constitutional recognition of such.

The concept of community protocols, on the other hand, is a more recent invention. Even though the idea of community protocols was not necessarily new to all negotiators, it was introduced in concrete terms relatively late in the negotiations by one group and quickly caught many negotiators' interest. It is important to recognize that "community protocols" is neither defined by the Nagoya Protocol nor is it a term of art. Consequently, while the concept of community protocols might be understood as explained during the negotiations on the Nagoya Protocol, other understandings are also possible. Generally speaking, presumably community protocols can be described as written documents adopted by a community holding traditional knowledge where the community internally codifies the terms in which it will agree for access to its traditional knowledge associated with genetic resources. Community protocols can hence in one way be compared with formalized legislative acts enacted by national parliaments, although their origin of course affects their legal status. Furthermore, it is worth noting that community protocols can be, and presumably often are, based on or at least respectful to customary laws of the ILC.

Box 20: Understanding of Bio-Cultural Community Protocols as Presented in the Negotiations on the Nagoya Protocol

When introduced into the negotiations on the Nagoya Protocol, the concept of community protocols was explained as follows. A bio-cultural community protocol (BCP) is a protocol that is developed after a community undertakes a consultative process to outline their 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 natural resources. The process of developing a BCP involves reflection about the interconnectedness of various aspects of ILCs' ways of life (such as between culture, customary laws, practices relating to natural resources management, and traditional knowledge) 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 access and benefit-sharing (ABS). Within the ABS framework, for example, a community may want to evaluate what the community's research priorities are, on what terms it would engage with potential commercial and non-commercial researchers wanting access to their traditional knowledge, what the procedures relating to prior informed consent (PIC) must be, and what types of benefits the community may want to secure.

By articulating the above information in a BCP, communities assert their rights to self-determination and improve their ability to engage with other stakeholders such as government agencies, researchers, and project proponents. These stakeholders are consequently better able to see the community in its entirety, including the extent of their territories and natural resources, their bio-cultural values and customary laws relating to the management of natural resources, their challenges, and their visions of ways forward. By referencing international and national laws, ILCs affirm their rights to manage and benefit from their natural resources. They are also better placed to ensure that any approach to accessing traditional knowledge or any other intended activity on their land occurs according to their customary laws. Overall, BCPs enable communities to affirm their role as the drivers of conservation and sustainable use of biodiversity in ways that support their livelihoods and traditional ways of life.

Source: Adapted from Bavikatte and Jonas, 2009.

As noted, it is somewhat unclear what is understood by "procedures" in Article 12(1), but presumably the term refers to ILC processes for governance of traditional knowledge associated with genetic resources other than customary laws and community protocols. For instance, ways of handling traditional knowledge associated with genetic resources, which are less formalized than community protocols, can be envisioned. "Minimum requirements for mutually agreed terms" referred to in Article 12(3) may also fall under this category.

In conclusion, Article 12(1) proclaims that Parties shall consider a variety of governance mechanisms of ILCs pertaining to traditional knowledge associated with genetic resources, both traditional ones such as customary laws and more recent ones such as community protocols. The provision includes, however, several caveats ("in accordance with domestic law", "take into consideration", and "as

applicable"), rendering it clear that it is up to the Party to determine to what extent it wishes to take such governance mechanisms into account.

2. Parties, with the effective participation of indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.

Article 12(2) calls on Parties, in co-operation with concerned ILCs, to establish mechanisms to inform potential users of traditional knowledge associated with genetic resources of their obligations. It also identifies the ABS Clearing-House as potentially having a particular role in this regard.

The obligation of each Party to establish such mechanisms in co-operation with any concerned ILC is mandatory ("shall establish"). However, it does not go beyond informing potential users of traditional knowledge associated with genetic resources of their obligations under the Nagoya Protocol. Indeed, if the user, thus informed, still fails to comply with its obligations, such non-compliance must be addressed through Article 16 of the Protocol. Notwithstanding this, the fact that potential users of traditional knowledge associated with genetic resources should have been made aware of their obligations vis-à-vis ILCs holding the knowledge – including PIC and approval and involvement requirements – can help make the compliance provision in Article 16 more effective.

3. Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:

(a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;

(b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and

(c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.

Pursuant to Article 12(3) of the Nagoya Protocol, Parties shall endeavour to support ILCs in developing various instruments rendering them better equipped to deal with access procedures with regard to traditional knowledge associated with genetic resources held by them, and to ensure that they receive a fair share in benefits when such knowledge is being used. Particular attention shall be given to women within the communities in this regard. The instruments referred to are of different nature, but with similar functions.

Community protocols are internal norms adopted by an ILC regulating, for example, under what circumstances and on what terms the ILC will agree to access to traditional knowledge associated

with genetic resources held by the community (see explanation of Article 12(1)). Minimum requirements for mutually agreed terms (MAT) presumably have a similar content. The difference between the two may be that community protocols more often, but not necessarily, take a holistic approach, elaborating on the traditional knowledge's role within the community, etc., and thus provide information that is less often found in minimum requirements for MAT. Model contract clauses translate the ILC's position as expressed in community protocols and/or minimum requirements for MAT into explicit contractual language.

It is important to note that, different from Article 12(2), Article 12(3) includes certain qualifiers. Parties are merely obliged to "endeavour" to "support" the ILCs to develop the said instruments, and they should in addition only do so "as appropriate".

The reference to "as appropriate" in this context indicates that not all communities need or desire such assistance. During the negotiations on the Protocol, delegations debated the extent to which Parties should play a role in ABS processes with regard to traditional knowledge associated with genetic resources held by ILCs (see also explanation of Articles 5(5) and 7). Some ILCs lack the capacity to handle such processes and might therefore need state assistance in this regard. Other ILCs are well equipped to deal with potential users themselves. The reference to "as appropriate" can be said to reflect this variety among ILCs. It is not always appropriate that the Party assists in developing community protocols, minimum requirements for MAT, and model contract clauses if the ILC in question is capable of handling, and wishes to handle, these matters by itself. In addition, not all ILCs may wish to develop community protocols, minimum requirements for MAT, and/or model contract clauses. If the ILC opts not to do so, it is also inappropriate for the Party to intervene. Further factors, as identified by the Party, can render support equally inappropriate.

That said, the use of the term "shall" indicates that Parties must, if possible, at least make a serious effort to assist ILCs. This means that when the ILC wishes and needs support, it must reasonably at least endeavour to do so.

Finally, the general reference to "support" indicates that support need not be in monetary terms. Alternative forms of support are envisioned as well.

4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

ILCs have used genetic resources and developed traditional knowledge for centuries, and they continue to do so. Article 12(4) of the Protocol assumes that such use may at times involve exchange of genetic resources and traditional knowledge associated with genetic resources within and among ILCs. Based on this assumption, it confirms that the Protocol does not intend to restrict such use and exchange.

However, Article 12(4) includes two qualifiers. First, the use must be "customary" for the provision to apply. This presumably simply implies that the practice must have been ongoing for a considerable period of time before the Nagoya Protocol entered into force. Second, the provision only applies "as far as possible". It is difficult to imagine what situations could occur that suddenly renders it impossible not to restrict use and/or exchange of genetic resources and traditional knowledge associated with genetic resources within ILCs when such use/exchange have been ongoing for a considerable period of time. But should such a situation occur, the Party is entitled to restrict continued use and/or exchange.

Article 13
National Focal Points and Competent National Authorities

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:

   (a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;

   (b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and

   (c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

The national focal point shall be responsible for liaison with the Secretariat.

2. Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.

5. The Secretariat shall make information received pursuant to paragraph 4 above available through the Access and Benefit-sharing Clearing-House.

A. Background

Under Article 13 of the Nagoya Protocol, each Party is obliged to designate a national focal point (NFP) on access and benefit-sharing (ABS). However, it is up to each Party to decide which national institution will serve in that capacity. According to Paragraph 1, the NFP is responsible for making information on ABS available. It informs potential users of the procedures that are to be followed in applications for access to genetic resources and traditional knowledge associated with genetic resources. The NFP is also responsible for sharing information on competent national authorities (CNAs) and relevant stakeholders. In addition, it is the primary contact between the Party on behalf of which it acts and the Secretariat to the Protocol (Secretariat), which according to Article 28 of the Protocol is the Secretariat of the Convention on Biological Diversity.

Article 13 further obliges each Party to designate at least one competent national authority on ABS. The CNA has the mandate to determine, authorize, and certify access in accordance with national ABS frameworks. Unlike the NFP, which is responsible for sharing information on ABS procedures, the CNA is responsible for giving advice on access procedures and requirements.

However, it is not mandatory to have both an NFP and a CNA (or CNAs). A Party is free to designate only an NFP that will also serve as and carry out the responsibilities of a CNA – or vice versa. Whichever approach a Party opts for, it is important to notify the Secretariat about the designated NFP and CNA(s) as well as their responsibilities, and the information is then made available (by the Secretariat) through the Access and Benefit-sharing Clearing-House (ABS CH), as established under Article 14 of the Protocol.

B. Explanation

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:

According to Article 13(1) of the Nagoya Protocol, the designation of an NFP is a mandatory obligation for each Party. Establishing a national focal point is an important tool in implementation of the Protocol. An NFP, like a CNA, is key in the ABS process as it performs functions relating to the Protocol at the national and local level that help facilitate compliance with the ABS obligations by Parties.

Article 13(1) envisages the NFP as the primary national source of information for a user wishing to access genetic resources and/or traditional knowledge associated with genetic resources. Making relevant information available to users is the key function of an NFP, which thus serves more or less as a “helpdesk” or “information hub”. For instance, a potential user interested in accessing genetic resources from a providing Party would know where to get information, for example, on procedures for prior informed consent (PIC) and mutually agreed terms (MAT), the national authority responsible for granting access permits, relevant stakeholders that must be consulted, etc. In the absence of such a focal point, some of the requirements or procedures can easily be missed, resulting to an unintended breach of national ABS legislation or regulatory requirements. At the same time, the ability to access information easily facilitates access, as it is likely to save on time, costs, and so on.

Subparagraphs (a)-(c) state to whom information is to be made available as well as the kinds of information the NFP is required to make available.

(a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;

The NFP is required to provide information on procedures for obtaining PIC and establishing MAT (see Article 6(3)(b), (c), (g) of the Nagoya Protocol) and benefit-sharing (see Article 5 of the Protocol) to applicants interested in accessing genetic resources. This may encompass the following information, among others:

- documents accompanying an application for access to genetic resources;
- timelines for processing of access applications;
- the State agencies (i.e., CNA(s)) responsible for granting PIC and the genetic resources they are responsible for;
- other stakeholders relevant for access to genetic resources;
- administrative fees charged for processing access applications;
- other consents or licences required prior to access, for instance to enter specific territories as well as access specific genetic resources;
- special procedures for entering specific territories as well as accessing specific genetic resources;
- access conditions on, for example, sample depositing or involvement of local experts or institutions;
- export conditions;
- simplified procedures for non-commercial research;
- permitted uses;
- conditions on third party transfer; and
- types of benefits to be shared and when a benefit-sharing obligation is triggered.

Where indigenous and local communities (ILCs) have the established right to grant access to genetic resources, a Party is obliged in accordance with Article 6(3)(f) of the Nagoya Protocol to set out criteria and/or processes for obtaining their PIC or approval and involvement. It is the task of the NFP to make information available on such criteria and processes to applicants seeking to access genetic resources.

(b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and

Likewise, the NFP is required to give information on procedures for obtaining PIC or approval and involvement of ILCs and establishing MAT and benefit-sharing to applicants interested in accessing traditional knowledge associated with genetic resources (see also Article 12(2) of the Nagoya Protocol). Such procedures may be created under Article 7 of the Protocol, which obliges each Party to take measures, as appropriate, to ensure that ILCs' traditional knowledge associated with genetic resources is accessed with their PIC or approval and involvement and that MAT have been established. It is possible that some of the procedures will emanate directly from customary laws, community protocols, and procedures of ILCs, as Article 12(1) obliges Parties to take them into consideration in

implementing their Protocol obligations. Some of them could also be an amalgamation of these and State administrative procedures.

However, it is important to note that Subparagraph (b) is qualified through the formulation "where possible". Accordingly, the NFP shall provide the respective information only where it is possible.

(c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

Furthermore, the NFP has the function of giving information to potential users on:

- The CNA(s), that is informing them about the relevant institution(s) where they can apply for access. Such information may include information notified to the ABS CH under Paragraph 4, for example, the contact information of CNA(s), and which CNA is responsible for the genetic resource sought. Some of the information to be made available about CNA(s) is covered under Subparagraphs (a) and (b), including their procedures, durations for application processing, fees, etc.
- The relevant ILCs and stakeholders, which means other groups of people that might need to be consulted before access and involved in the decision-making or approval process. Relevant ILCs include communities with the established right to grant access to genetic resources or holding traditional knowledge associated with genetic resources. Relevant stakeholders may include, for example, environmental organizations, research institutes, and universities. With respect to ILCs, a potential user might want to know the community's competent authority, as in many instances this might not be entirely clear.

The national focal point shall be responsible for liaison with the Secretariat.

Finally, the last sentence of Paragraph 1 specifies the NFP as the national institution responsible for communicating as well as maintaining contact with the Secretariat. Thus the NFP is the primary contact point between a Party and the Secretariat.

2. Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

Under Paragraph 2, each Party is furthermore required to designate at least one CNA on ABS. This implies that a Party may also designate more than one CNA. The designation of more than one CNA might be motivated by varying country-specific considerations or differences including institutional structures or division of mandates – based either on the type of genetic resource, its geographic location, or the purpose of access. An example of this approach is South Africa, which has one CNA for access aimed at commercialization and another for access for non-commercial purposes (Cabrera Medaglia et al., 2011). Depending on how the access procedures are organized at the national and local levels (or depending on the relationship between the various ABS-related institutions), the existence

of more than one CNA in a country suggests the need to carefully consider how to make the access procedure as efficient and clear as possible (see Article 6 of the Protocol).

The provision furthermore indicates that a CNA is the State institution that exercises the authority granted under Article 6(1) of the Nagoya Protocol to determine access as well as conditions attached thereto on behalf of the Party that nominates it. The CNA(s) are thus charged with carrying out administrative duties in accordance with national legislation and regulatory requirements. According to Paragraph 2, they perform the following functions:

- grant access – this will include fulfilling the obligations under Article 6(3)(d) of the Protocol;
- issue written evidence that access requirements have been met – for example, that PIC has been granted and MAT have been established – as required under Article 6(3)(e) of the Protocol; and
- Advise on applicable procedures and requirements for obtaining PIC and establishing MAT.

3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

Paragraph 3 indicates that Parties have the discretion to designate a single institution to serve as an NFP and a CNA at the same time. In Costa Rica, for example, the Technical Office of the Comisión Nacional para la Gestión de la Biodiversidad is both the CNA and the ABS NFP (Cabrera Medaglia et al., 2011). Designating a single entity might be prompted by the need to cut down on structural and thereby transaction costs or by efforts to centralize functions within national institutions and thus simplify the access procedure. In such a case, the nominated institution would perform the functions of both the NFP and the CNA as spelled out under Paragraphs 1(a)-(c) and 2.

4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.

Paragraph 4 requires each Party to notify the Secretariat about the contact information of its NFP and CNA(s). If a Party designates more than one CNA, it must notify the Secretariat with the contact information for each one of them and (all) relevant information pertaining to each one's responsibilities. The information on responsibilities of CNAs must indicate which CNA is responsible for which genetic resource, where such division of mandates exists.

A Party must notify all such information on contact(s) and responsibilities to the Secretariat no later than the date the Nagoya Protocol enters into force for that Party (see Article 33 of the Protocol). If any changes occur in regard to notified information on designation of the NFP or contact information or

responsibilities of CNA(s), a Party is required to notify such changes to the Secretariat with immediate effect.

5. The Secretariat shall make information received pursuant to paragraph 4 above available through the Access and Benefit-sharing Clearing-House.

Any information notified to the Secretariat as required under Article 13(4) of the Nagoya Protocol shall be made available on the ABS CH. This is to make it possible for others to use the ABS CH for the purpose of accessing genetic resources and/or traditional knowledge associated with genetic resources. In summary, the information transmitted to the ABS CH should include:

- NFP of the provider country;
- contact(s) of the NFP;
- CNA(s) of the provider country;
- contact(s) of the CNA(s);
- responsibilities of the CNA(s); and
- the CNA responsible for the genetic resources sought if a Party designates more than one.

Article 14
The Access and Benefit-sharing Clearing-House and Information-sharing

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.

2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:

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

   (b) Information on the national focal point and competent national authority or authorities; and

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

3. Additional information, if available and as appropriate, may include:

   (a) Relevant competent authorities of indigenous and local communities, 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.

4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

A. Background

Article 14 of the Nagoya Protocol establishes an Access and Benefit-Sharing Clearing-House (ABS CH), including modalities for information-sharing. The ABS CH is established as part of the clearing-house mechanism (CHM) of the Convention on Biological Diversity (CBD), which was created to "promote and facilitate technical and scientific cooperation" (Article 18(2) and (3) of the CBD) between the Parties to the CBD.

The CHM is key to achieving the three principal objectives of the CBD: conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (Article 1 of the CBD) (MacKenzie et al., 2003, p. 132). It also facilitates access to and the exchange of information on biodiversity around the world. It is a network of Parties and partners working together to facilitate implementation of the CBD, depending on a decentralized process to gather and organize the information that its users need (MacKenzie et al., 2003, p. 132). Driving this process are networks of focal points, international centres, and institutions with expertise that co-ordinate initiatives among themselves on topics of common interest (MacKenzie et al., 2003, p. 132). Each CBD national focal point (NFP) also contributes to the clearing-house information system, which is then made accessible to all users. In this way, focal points encourage networking among government agencies, expert groups, non-governmental organizations, and private enterprises at all levels. The CHM[1] consists of:

- the CBD website, which is its central node;
- the network of national CHMs; and
- various partner institutions.

The ABS CH was modelled after the Biosafety Clearing-House, which was established under Article 20 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, also as part of the CHM of the CBD. Like in the Biosafety Clearing-House, the following elements are visible in the ABS CH:

- It is designed to facilitate access and exchange of information.
- It is meant to assist the Parties in the implementation of the Protocol.
- Its success depends on the active participation of Parties in making information available.

Consequently, the ABS CH might be prone to some of the experiences of the Biosafety Clearing-House that activities directed towards the operationalization of the ABS CH could learn from.

The ABS CH in its most simplistic form could be viewed as a database on ABS information notified by Parties to the Secretariat as required by the Nagoya Protocol. Easy availability of and access to information is meant to facilitate the ABS access and compliance process and the implementation of the Protocol. Based on such information, both providers and users of genetic resources are able to ascertain their rights and obligations before entering into any relationship or before any research or bioprospection activities are undertaken. A potential user, for example, would know beforehand which procedures are foreseen in a providing Party for obtaining prior informed consent (PIC) and establishing mutually agreed terms (MAT), which competent national authority (CNA) is responsible for granting an access permit for the genetic resource sought, which stakeholders must be consulted, and so on. This can help to save on time and costs, minimize the likelihood of unintended breach of national ABS legislation or regulatory requirements, and create a certain level of certainty.

1 See www.cbd.int/chm/ .

B. Explanation

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.

Article 14(1) of the Nagoya Protocol establishes the ABS CH as part of the CHM of the CBD created under Article 18(3) of the CBD. Furthermore, the provision indicates the central task of the Clearing-House: to share information related to ABS.

The idea behind the ABS CH is to ensure that relevant information on ABS is available and accessible to potential users and providers of genetic resources and traditional knowledge associated with genetic resources. As the last sentence of the paragraph suggests ("in particular"), the main source of information in the ABS CH is that provided by Parties. In turn, the ABS CH provides access to that information, which includes information Parties are obliged to notify to the Secretariat of the CBD as providers and users (see Articles 6, 12, 13, 17, and 22 of the Nagoya Protocol). Article 14(2) and (3) contain other types of information to be made available to the ABS CH. It is important to note that in order to facilitate easy access to information for potential users of genetic resources and traditional knowledge associated with genetic resources, a Party may opt to include in the ABS CH more information than specifically required in the Protocol.

In summary, according to Paragraph 1, an ABS CH is established:

- to serve as an information hub or portal;
- to share information related to ABS; and
- to provide information made available by Parties of relevance to the implementation of the Protocol.

2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:

According to Article 14(2) of the Nagoya Protocol, each Party is obliged to make the following information available to the ABS CH:

- any ABS information required by the Nagoya Protocol (first sentence);
- any information required pursuant to the decisions of the Conference of the Parties of the CBD serving as the meeting of the Parties to the Nagoya Protocol (COP/MOP) (first sentence); as well as
- specific information included in a non-exhaustive list (second sentence).

Information Required by the Nagoya Protocol

Since the list provided under Paragraph 2 is not exhaustive, and as the paragraph also states that "any information required by this Protocol" shall be made available to the ABS CH, the following information can likewise be derived from other provisions of the Protocol:

- users' obligations and measures for access to and benefit-sharing from utilization of traditional knowledge associated with genetic resources (see Article 12(2));
- information collected or received at checkpoints, such as on designated checkpoints; relevant information related to PIC; relevant information related to the source of the genetic resource; relevant information related to the establishment of MAT; and relevant information related to the utilization of genetic resources (see Article 17(1)(a)(i) and (iii));
- where available, information from internationally recognized certificates of compliance, without prejudice to the protection of confidential information (see Article 17(2)); and
- information on capacity-building and development initiatives with a view to promoting synergy and coordination on capacity-building and development for ABS (see Article 22(6)).

Information Required by COP/MOP Decisions

Pursuant to the decisions of the COP/MOP, Parties might be required to make more information than currently known available to the ABS CH. The decisions of the COP/MOP will be known following the outcome of its meeting, which will be convened after the Nagoya Protocol has entered into force (see Article 26(6) and Article 33). Therefore, it is still to be seen what kind of information that would be.

Non-exhaustive List of Information

Furthermore, in its second sentence, Paragraph 2 specifically lists some of the information that each Party shall make available to the ABS CH, without providing an exhaustive list.

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

Subparagraph (a) enumerates the ABS measures each Party shall make available to the ABS CH – that is, legislative, administrative, and policy measures. The Subparagraph suggests the measures to be made available are accumulative. However, it is doubtful that it implies an absolute obligation to make all three available. What it likely means is that a Party is to make available any of these measures that it has taken to regulate ABS.

(b) Information on the national focal point and competent national authority or authorities; and

Under Subparagraph (b), each Party is required to make information on the NFP and CNA(s) available to the ABS CH. The kind of information to be made available can be derived from Article 13(4) of the Nagoya Protocol. It includes:

- designated NFP and its contact information;
- designated CNA(s) and relevant contact information;
- responsibilities of each CNA where more than one is designated;

- where applicable, which CNA is responsible for the genetic resource sought;
- any changes in the designation of a Party's NFP; and
- any changes in the contact information or responsibilities of a Party's CNA.

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

Each Party that subjects access to genetic resources to PIC is obliged under Article 6(3)(e) of the Nagoya Protocol to issue a permit or its equivalent as evidence of the decision to grant PIC and of the establishment of MAT. Under the same article, each Party is obliged to notify such information to the ABS CH, in which case it shall constitute an internationally recognized certificate of compliance (see Article 17(2) of the Protocol). Consequently, such information becomes part of the content of Article 14, and therefore Subparagraph (c) requires each Party to make it available to the ABS CH.

Confidential Information

It is important to note that the obligation to provide information under Paragraph 2 is qualified at the beginning by the formulation "without prejudice to the protection of confidential information". However, the Nagoya Protocol does not give an indication as to what kind of information could be regarded as confidential or how such information should be protected. In contrast, the Cartagena Protocol includes a stand-alone article on confidential information (Article 21) in order to do the following: specify the basic procedure for ensuring protection of confidential information provided under the procedures of the Cartagena Protocol; address the situations where parties disagree as to whether particular information should be treated as confidential or not, and where the notifier decides to withdraw a notification; set out a general obligation to protect confidential information received under the Cartagena Protocol; and specify categories of information which shall not be considered confidential (Mackenzie et al., 2003, p. 137ff.).

By not being specific, the Nagoya Protocol gives discretion to the Parties to decide which information is confidential and therefore not under the notification obligation of Article 14(2). Confidential information might be vital for the user's research or business, for instance. In the process of making information available to the ABS CH, the confidentiality (secrecy) of such information could be jeopardized (endangered). Thus, taking such considerations in meeting its notification obligation, a Party should be able to decide, for example, whether partial or full information shall be made available to the ABS CH.

Furthermore, information could also be considered as confidential by another entity that made it available to the Party on condition that it is kept secret – that is, it is not disclosed to a third party. Such information might be contained, for instance, in a permit or its equivalent issued under Article 6 as evidence of the decision to grant PIC and of the establishment of MAT.

3. Additional information, if available and as appropriate, may include:

Paragraph 3 (a)-(c) lists additional information that may be included in the ABS CH. As the paragraph indicates, such information may be provided subject to its availability and as appropriate. The use of the terms "if available", "as appropriate", and "may include" indicates that Parties have discretion to decide whether, when, and which of these types of information to make available. It could also depend

on whether a Party has such information at all and whether the situation requiring certain information or measures applies in its case or not.

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

Subparagraph (a) refers to information on relevant competent authorities of ILCs and information as so decided. It is often hard for users to identify representatives of ILCs as well as establish their authenticity. Thus it might take a potential user quite long as well as cost him or her enormous funds to get such information. That also increases the likelihood of a potential user engaging in deals with imposters – only to be accused of violation of the rights of such communities later. Therefore, the notification according to Subparagraph (a) could be seen as a means of rectifying such a shortcoming in view of facilitating access and fostering certainty as well as compliance.

However, as the term "as appropriate" in the chapeau of Paragraph 3 indicates, this might not apply to every Party – for example, to a Party that does not have ILCs under its jurisdiction, where the ILCs procedures are integrated within the State procedures, or where the State organs (NFP and CNA) represent such communities.

(b) Model contractual clauses;

Under Article 19(1) of the Nagoya Protocol, Parties are required to encourage the development, update, and use of sectoral and cross-sectoral model contractual clauses for MAT. Model contractual clauses were considered in the negotiations as being able to provide practical solutions in the implementation of ABS obligations. Parties having such model contractual clauses may make information about them available to the ABS CH.

(c) Methods and tools developed to monitor genetic resources; and

Methods and tools for monitoring genetic resources are meant to support compliance by users with domestic legislations and regulatory requirements of providing Parties. Such methods and tools may include those named in Article 17(1)(a)(i) and (iii) – checkpoints and internationally recognized certificate(s) of compliance. Concerning internationally recognized certificate(s) of compliance, notification should be without prejudice to the protection of confidential information (see Paragraph 2 above).

(d) Codes of conduct and best practices.

Under Article 20(1) of the Nagoya Protocol, Parties are required to encourage the development, update, and use of voluntary codes of conduct and best practices, among others. Codes of conduct and best practices are norms or rules of non-state actors, such as scientific associations or companies, meant to guide their behaviour and aid them in complying with existing regulations and thus foster compliance, transparency, trust, etc. Examples of such Codes of Conduct and best practices include those of:

- the Swiss Academy of Sciences: Access and Benefit-sharing – Good practice for academic research on genetic resources;
- the German Research Foundation: Funding Regulations within the scope of the CBD; and
- the International Plant Exchange Network: Code of Conduct for botanic gardens governing the acquisition, maintenance, and supply of living plant material.

Parties having such information may make it available to the ABS CH.

It is important to mention in addition that although non-Parties have no obligation whatsoever under the Protocol, Article 24 nonetheless leaves it open for such entities to contribute appropriate information (that is, relevant for ABS) to the ABS CH.

4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 14(4) of the Nagoya Protocol indicates that the first meeting of the COP/MOP will consider how the ABS CH will operate. The COP/MOP will decide on the operation and activities of the ABS CH and keep these under review thereafter.

Table 6: Provisions Indicating the Type of Information to be Made Available through the ABS CH

Article	Information		
	By provider	By user	By all
6(3)(e)	▪ Permits or their equivalents issued at the time of access		
12(2)	▪ Measures in regard to access to traditional knowledge associated with genetic resources and benefit-sharing		
13(4)	▪ Contact information of NFP and CNA(s) ▪ Respective responsibilities of CNAs ▪ CNA responsible for the genetic resources sought ▪ Changes in designation of NFP ▪ Changes in contact information or responsibilities of CNA(s)		
14(2)			▪ Information required pursuant to decisions of COP/MOP ▪ Legislative, administrative, and policy measures on ABS ▪ Information on the NFP and CNA(s) ▪ Information on permits or their equivalent issued at the time of access as evidence of the decision to grant PIC and of the establishment of MAT

Article	Information		
	By provider	By user	By all
14(3)			**If available and as appropriate:** ■ Relevant competent authorities of ILCs ■ Model contractual clauses ■ Methods and tools developed to monitor genetic resources ■ Codes of conduct and best practices
17(1)(a)(i) and (iii)		■ Information on designated checkpoints ■ Relevant information related to PIC ■ Relevant information related to the source of the genetic resource ■ Relevant information related to the establishment of MAT ■ Relevant information related to the utilization of genetic resources ■ Where available, information from internationally recognized certificates of compliance	
22(6)			■ Information on capacity-building and development initiatives at national, regional, and international levels

Article 15
Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing

1. **Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.**
2. **Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.**
3. **Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.**

A. Background

The basis of the set of Articles on compliance in the Nagoya Protocol (Articles 15–18) was the demand of provider countries for international rules that would compel users to comply with the access and benefit-sharing (ABS) regulations in place in the country providing the genetic resources being accessed. Article 15 and subsequent provisions on compliance were the subject of intense negotiations due to the fact that, generally speaking, many developing countries saw these provisions as the cornerstone of the Protocol (Nijar, 2011b, p. 5), while other countries considered the establishment of common standards on access a more important pillar of the treaty and a necessary point of reference for compliance arrangements to be agreed.

The focus of Article 15 is situations where a genetic resource was accessed without observing legislation requiring prior informed consent (PIC) and establishing mutually agreed terms (MAT) in the provider country. Throughout the negotiations, the term “misappropriation” was often used to describe such situations. Though always in brackets, the term appeared in various drafts. The reason it was excluded altogether from the final text of the Protocol may be traced to the fact that if it were used it would have been necessary to define it – an exercise that had encountered opposition from those who argued in favour of being able to regulate freely in their national legislations the terms and conditions that would give rise to a case of so-called misappropriation.

Article 15 sets out an obligation for all Parties to the Protocol. However, it applies only when they are the downstream jurisdiction. It consists of an obligation to take measures (Paragraph 1), an obligation to enforce them (Paragraph 2), and an obligation to co-operate (Paragraph 3). These obligations, which are qualified, shall be implemented to provide that users within the jurisdiction of the Party in which

genetic resources are utilized have followed a PIC procedure and have established MAT as required by the ABS legislation or regulatory requirements of the country providing such resources.

Paragraph 1 refers to compliance by the user with the domestic legislation or regulatory requirements of the provider – that is, compliance with provider country measures. The legislation and the regulatory requirements that need to be complied with have to be specific to ABS. Consequently, it is a condition to apply this provision that the Party that provided the genetic resources has enacted ABS legislation, in the absence of which violation cannot possibly occur. Paragraph 2 again refers to non-compliance with user country measures, and Paragraph 3 calls on Parties to co-operate in cases of alleged violation of ABS legislation or regulatory requirements.

It is important to note that each Party to the Nagoya Protocol has an obligation to implement this provision regardless of whether it decides that its domestic legislation does not require PIC to access genetic resources. Reiterating that requiring PIC is not mandatory, Article 15 implies that States can address PIC and MAT through policy as well as measures that are legislative or administrative in nature or in some other form. In any event, in the absence of legal clarity in relation to PIC and MAT in the country that provides the genetic resources, the obligation to implement this provision will be difficult to apply.

B. Explanation

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

Article 15(1) of the Nagoya Protocol obliges Parties to take what negotiators came to call “user measures”. This is a term that predated the negotiations and that referred to measures that would aim at having the utilization of genetic resources within their jurisdiction comply with the internal ABS legislation in force in the other Party, to the extent that such legislation refers to the granting of PIC and the establishment of MAT.

Party to Take Measures

Paragraph 1 states that “each Party” has an obligation to implement this provision and to take measures as described. This implies that every Party is under this obligation regardless of whether it decides to require PIC for access to its own genetic resources or not. In other words, if a Party grants free access to its genetic resources to all users, it will nevertheless be obliged by the Nagoya Protocol to support measures adopted in another country – that is, the country that provided the genetic resource – irrespective of the fact that it did not take part in the elaboration of such measures.

This characteristic makes the approach adopted in the Nagoya Protocol innovative in nature, but it presents a great challenge in terms of implementation since it will mean a significant change from the existing legal situation in a scenario with no Protocol. In this context, it has to be emphasized that it is generally not possible to directly enforce domestic ABS legislation or regulatory requirements outside

of a country. Instead, only the remedies and sanctions provided for in the law of the country where a genetic resource is used could be enforced, while the remedies and sanctions in the law of the provider country could not be enforced extraterritorially (Chiarolla, 2011, p. 12).

Appropriate, Effective, and Proportionate Legislative, Administrative, or Policy Measures

The obligation is for each Party to "take appropriate, effective and proportionate legislative, administrative or policy measures". When this provision was discussed, different views were expressed on the need to be specific about the type of measures that Parties were bound to take. Whilst some argued that the user measures should be described in detail, others wanted to preserve the sovereignty of the States to adopt measures as they deemed appropriate. The final text of Article 15(1) does not contain specific measures. Instead, it provides Parties with considerable flexibility in relation to the nature of the measures to be taken. Therefore, each Party individually needs to decide whether to adopt legal measures (that is, to enact legislation) or to take administrative (for example, regulations) or policy measures (for instance, adopting a strategy or an action plan).

Nevertheless, Article 15(1) stipulates three qualifiers – appropriate, effective, and proportionate – without setting out criteria for them. Since the qualifiers are not defined in the text of the Nagoya Protocol, this task will also need to be undertaken by each Party individually in its domestic legislation and regulations.

Nonetheless, it is important to note that the obligation to take "appropriate" measures has been understood in another international treaty context to imply a duty of due diligence (Mckenzie et al., 2003, p. 117). In the case of the Nagoya Protocol, it requires each Party to take the necessary legal, administrative, or policy measures to provide that genetic resources used within its jurisdiction have been accessed in accordance with PIC (in case PIC is required by the providing country) and that MAT have been established. At the same time, measures should also fit with the legal, political, social, and economic situation of the country in which they are implemented. This means that a Party should consider avoiding setting up complicated systems that could end up being too bureaucratic.

As to the term "effective", it can be taken in its usual sense – that is to say, something having the desired effect. In this context, that would mean measures that have the potential to be successful in achieving what is intended: that before accessing genetic resources the user will observe the provisions on PIC and MAT of a provider. "Effective" can also be understood as linked to possible sanctions if the measures are not complied with. In the same manner, the term implies that the measures need to have a certain level of deterrence.

The concept of "proportionate" appears here for the first time in the Nagoya Protocol. As with the qualifiers just discussed, it is up to each Party individually to determine what constitutes a proportionate measure. From the standard meaning of the word it is clear that negotiators were aiming at a measure that would be sufficient and would not be unnecessarily burdensome – that is, which corresponds in nature and degree with what needs to be achieved. In this case, keeping in mind that the Protocol gives maximum flexibility to the Parties, determination of whether the measure is proportionate or not can only be made on a case-by-case basis.

Box 21: Principle of Proportionality

The principle of proportionality was initially developed in the German legal system in the late nineteenth century to review actions by the police. It states that no layer of government should take any action that exceeds what is necessary to achieve the objective sought. The principle is also invoked in criminal law, where it conveys the idea that the punishment of an offender should fit the crime. In international humanitarian law it relates the means and ends of an armed attack, so that if either is illegitimate in the context of international humanitarian law, the attack will not be proportionate.

It is also incorporated in European Union legislation, and it aims to control and set boundaries to the exercise of power by the European institutions. Article 5 of the Treaty establishing the European Union regulates that under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.

Some criteria for applying the principle of proportionality have been developed as follows:

- There must be a legitimate aim for a measure.
- The measure should be suitable to achieve the aim.
- The measure must be necessary to achieve the aim, and there should be no less-onerous way of doing it.
- The measure must be reasonable, considering the competing interests of the actors.

Utilization within the Jurisdiction

Furthermore, the obligation of a Party under Article 15(1) of the Nagoya Protocol is to take measures when the genetic resources are “utilized” within its jurisdiction. The reference to utilization links this provision with the definition provided under Article 2. Consequently, the understanding of that provision has an impact on the way Paragraph 1 is ultimately implemented.

Article 2(c) of the Protocol defines utilization of genetic resources as the research and development part of the innovation chain, including the point where an innovation is moved from development to commercialization (see also explanation of Article 2) (Buck and Hamilton, 2011, p. 52). In addition, Article 15(1) of the Protocol makes no reference to subsequent applications and commercialization, something that is made explicit in Article 5 in the context of benefit-sharing. This implies that the measures that a Party shall take in order to comply with this provision do not need to extend to subsequent applications and commercialization, an issue that will be addressed by Parties contractually under MAT, hence falling under the scope of Article 18.

It also needs to be understood that the explicit reference to utilization within “its jurisdiction” refers to a Party’s own territorial jurisdiction over users and is not related to utilization in the jurisdictions of other countries. In other words, situations where the utilization takes place in the jurisdiction of another country are excluded and fall under the jurisdiction of that country.

Domestic ABS Legislation or Regulatory Requirements

The obligation is triggered in relation to the utilization of genetic resources that have already been accessed. The reference to "have been accessed" implies that such resources are already in the hands of the user and that the Party's measures have to verify compliance with the ABS legislation or regulatory requirements of the provider country that were in place at the time of access and not those enacted at a later stage. In this context, it should be kept in mind that the permit referred to in Article 6(3)(e) of the Nagoya Protocol would have been granted when the access occurred.

The measures to be adopted by the Party shall aim at providing that PIC had been obtained and MAT had been established, "as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party". This exact formulation, including the placing of a comma after "established", has particular implications. The reference to "domestic access and benefit-sharing legislation or regulatory requirements of the other Party" specifies that the scope of the obligation does not extend to the whole of the domestic legislation or regulatory requirements of the other Party, but only to those on ABS that require that PIC is obtained when accessing a genetic resource and that MAT is established. The intention is thus not to place an additional burden on user countries, requesting them to undertake a formal check to determine whether specific conditions attached to PIC and MAT have been satisfied. In other words, the measures taken by the Party will have to support the verification of the existence of PIC and MAT but not the actual content of such terms or their enforcement. It is important to note that situations where there is a breach of the contractual terms contained in MAT are addressed under Article 18 of the Protocol.

The obligation is also limited to measures that provide that PIC had been obtained and MAT had been established only "if" this is required by the ABS regime of the provider country. In this regard, it should be noted that during the negotiations, some Parties argued that in the absence of domestic ABS legislation in the country providing a genetic resource, the rules of the Nagoya Protocol and the Convention on Biological Diversity (CBD) should directly apply at the national level, as these would entail a default obligation for users to obtain PIC and establish MAT (Chiarolla, 2011, p. 7). The intention behind this was to avoid situations where access could be legally obtained without PIC in cases where the provider had not enacted specific legislation requiring it. However, what eventually prevailed in the final text of Article 15(1) is that a Party has to enact ABS legislation or regulatory requirements that demand PIC and the establishment of MAT in order for the country where the genetic resource is utilized to be compelled by the provision. This understanding is based on the wording "as required by" that precedes the reference to domestic ABS legislation or regulatory requirements, necessarily implying that PIC and MAT must have been incorporated in the legal system of the other Party for Article 15 to apply. It does not change in any way the reading of Article 6(1) of the Nagoya Protocol, which provides that access to genetic resources for their utilization shall be subject to PIC of the Party providing such resources "unless otherwise determined by that Party". This wording is taken directly from Article 15(5) of the CBD and leaves no doubt that the Nagoya Protocol, in line with the Convention, does not entail a general obligation for Parties to request PIC legally or otherwise.

Finally, Article 15(1) refers to the domestic ABS legislation or regulatory requirements "of the other Party". This formulation does not appear anywhere else in the Nagoya Protocol except for Article 16(1), which mirrors this provision. Other provisions, for instance Articles 5(1), 6(1), and 23, refer to "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", a phrase that can be linked to Article 15(3) of the CBD. Apart from the obvious conclusion that Article 15(1) of the Nagoya Protocol entails only an obligation between Parties to the Protocol, the formulation also circumvents a problem that would

have manifested itself if the text had referred to the country of origin. This would have placed an additional burden on Parties, namely to check whether sovereignty claims of provider countries are well founded.

2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

Article 15(2) of the Nagoya Protocol requires Parties to address situations where a user within its jurisdiction is found to be in non-compliance with the measures taken in accordance with Paragraph 1. When the user does not observe such measures, the Party shall take measures that are qualified as appropriate, effective, and proportionate. Hence, Paragraph 2 is about the range of procedures and actions that a Party shall use to address situations of potential failure to comply with measures taken by itself under Article 15(1). If such measures are legal in nature, then the provision calls for their enforcement.[1]

As in Paragraph 1, Paragraph 2 does not mention specific measures. Therefore, Parties are given the necessary flexibility to decide on the measures that are most appropriate to their own legal system and related social, cultural, and economic circumstances. As an indication of the nature of such measures, it is worth mentioning some examples that were referred to during the negotiations and included fines, but also criminalization of certain acts and the prohibition of using genetic resources when obligations have been violated.

It is important to add that the qualifier "proportionate" can imply both raising the threshold of the measures to be taken (that is, preventing measures that would fall under a certain threshold and therefore fail to be proportional, such as excessively low fines) and aiming at preventing the application of fines or sanctions that are more severe or burdensome than necessary.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Paragraph 3 states that Parties shall co-operate in situations of potential violations of domestic ABS legislation or regulatory requirements. The obligation is thus for Parties to co-operate, which in a broader sense includes, for instance, sharing investigations and exchanging information. It cannot, however, read as including the issue of recognition of foreign judgments, taking into account that it refers to a situation that is still at the stage of "alleged" violation. Indeed, the term "alleged" indicates that there is no requirement to prove there has been an actual violation in order for the Parties to co-operate.

The obligation is qualified by the expression "as far as possible and as appropriate", giving Parties ample flexibility. This formulation can justify a potential refusal where a Party considers that in a particular case the co-operation referred to is either not possible or not appropriate or both. For example, if no

1 The term enforcement has been defined as the range of procedures and actions used by a State and its competent authorities and agencies to ensure that organizations or persons, potentially failing to comply with environmental laws or regulations implementing multilateral environmental agreements, can be brought or returned into compliance and/or punished through civil, administrative, or criminal action (UNEP, 2006, p. 294).

extradition treaty or mutual legal assistance agreement exists with another jurisdiction, such legalistic forms of assistance might not be possible.

Article 15(3) does not include any reference to a potential trigger, for example the request of the country alleging violation. In addition, it does not specify that co-operation is limited to the Parties involved in a potential situation of violation, leaving it open to Parties to request or offer such co-operation as they deem it appropriate. Taking into account that relevant information on illegal access activities is more likely to be available in the Party that provided the genetic resources than in the Party where the genetic resources were used, the co-operation called for in Article 15(3) will be particularly useful in achieving compliance with Article 15 as a whole.

Article 16

Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing for Traditional Knowledge Associated with Genetic Resources

1. **Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.**
2. **Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.**
3. **Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.**

A. Background

Article 16 of the Nagoya Protocol mirrors Article 15, but with a focus on traditional knowledge associated with genetic resources. Hence, the objective of Article 16 is to address situations where traditional knowledge associated with genetic resources was accessed without observing legislation requiring prior informed consent (PIC) or the approval and involvement of indigenous and local communities (ILCs) and establishing mutually agreed terms (MAT) in the country where the ILCs are located.

Parallel to Article 15, Article 16 consists of an obligation to take measures (Paragraph 1), an obligation to enforce them (Paragraph 2), and an obligation to co-operate (Paragraph 3). These obligations, which are qualified, shall be implemented to provide that users within the jurisdiction of the Party in which traditional knowledge associated with genetic resources is used have accessed such knowledge observing the PIC procedure or the approval and involvement of ILCs and have established MAT prior to access, as required by the access and benefit-sharing (ABS) legislation or regulatory requirements of the country where such ILCs are located.

Paragraph 1 refers to compliance by the user with the domestic legislation or regulatory requirements of the Party within which the ILCs providing the traditional knowledge associated with genetic resources are located – that is, compliance with provider country measures. Paragraph 2 refers to non-compliance with user country measures. In addition, Paragraph 3 calls on Parties to co-operate in cases of alleged violation of ABS legislation or regulatory requirements.

Article 16 needs to be read in conjunction with Article 7 of the Nagoya Protocol, which establishes the obligation for each Party to take measures with the aim of ensuring that the traditional knowledge associated with genetic resources that is held by ILCs is accessed with PIC or with the approval and involvement of these ILCs and that MAT have been established. Article 12 also contains certain elements that complement the compliance measures found in this provision.

The question of whether the Protocol should address traditional knowledge associated with genetic resources as a cross-cutting issue or in one single provision was contentious throughout most of the deliberations (see also explanation of Article 12). Disagreement on this issue was particularly visible in the context of compliance. A number of negotiating Parties held the position that the Protocol should not include compliance provisions pertaining to traditional knowledge associated with genetic resources and that it should be left to the World Intellectual Property Organization to address such issues. Other negotiating Parties disagreed, asserting that the Nagoya Protocol would be incomplete if it did not include compliance obligations with regard to traditional knowledge associated with genetic resources. In the end, the latter position prevailed, giving birth to Article 16. The reason compliance with legislation or regulatory requirements on traditional knowledge associated with genetic resources was not treated under Article 15 may be related to the different nature as regards to the ownership of genetic resources on the one hand and traditional knowledge associated with genetic resources on the other hand.

Taking into account the similarities between Articles 15 and 16, explanations made under Article 15 apply to this text as well, in particular in relation to the qualifiers used.

B. Explanation

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.

Article 16(1) of the Nagoya Protocol proclaims that Parties where traditional knowledge associated with genetic resources is being used shall take measures to provide that PIC was obtained or that the ILCs have given approval and have been involved prior to accessing the knowledge and that MAT have been established if required by the ABS legislation or regulatory requirements of the country where the ILCs are situated. This provision follows the approach taken under Article 15(1) of the Nagoya Protocol and thus introduces an obligation for all Parties to take user measures that will support compliance with the domestic ABS legislation or regulatory requirements addressing traditional knowledge associated with genetic resources.

While the wording of Articles 15(1) and 16(1) is almost identical and follows a parallel structure, at least three important differences have to be recognized:

- First, Article 15(1) refers to PIC, whereas Article 16(1) uses language borrowed from Article 7, adding the formulation “approval and involvement” of ILCs (see explanation of Article 7 for a

comprehensive analysis of this formulation). This formulation can also be found in Article 8(j) of the Convention on Biological Diversity (CBD).

- Second, an additional qualifier, "as appropriate", is inserted in Article 16(1) following the main obligation. This is a different approach from the phrasing of Article 15(1), which was done to create further flexibility so that negotiators could achieve consensus on this particularly controversial provision.
- Third, unlike Article 15(1)'s reference only to "the other Party", Article 16(1) specifies that the ABS legislation or regulatory requirements are those of the Party where the ILCs are located.

In order for traditional knowledge to fall under the scope of Article 16(1) it needs to be utilized within the jurisdiction of the Party obliged to take the measures. Such measures are formally aimed at protecting the integrity of the law and regulatory requirements in force in the Party where the respective ILC is located. But provided that the Party where the ILC holding the traditional knowledge associated with genetic resources being used is located has enacted legislation or other regulatory requirements to that effect, such measures have as an additional effect that the ILCs' right to PIC or approval and involvement is complied with. The measures referred to have to be appropriate, effective, and proportionate, and they can include policy as well as measures that are legislative or administrative in nature (see explanation of Article 15(1)).

Article 16(1) indicates that the legislation and the regulatory requirements that need to be complied with have to be specific to ABS. The provision also indicates that the measures that the Party shall take with regard to the requirement of PIC or the approval and involvement of the ILCs as well as the establishment of MAT are contingent on those requirements being reflected in the domestic legislation or regulatory requirements of the Parties in which the ILCs reside. In that regard, it is clear that the Nagoya Protocol does not provide for compliance measures with respect to traditional knowledge associated with genetic resources springing from Parties that do not enact ABS legislation related to traditional knowledge. This can be read as a limitation, in particular taking into account that few countries currently have enacted legislation on rights to traditional knowledge. In addition, from the absence of an explicit reference to customary laws, community protocols, and procedures of ILCs, it is clear that the obligation does not extend to those practices referred to under Article 12 unless they have been incorporated in the ABS legislation or regulatory requirements of the Party. The situation of shared traditional knowledge by two or more ILCs situated in different countries (Parties) was discussed during the negotiations. However, the fact that the word "Party" is used in its singular form in this provision seems to leave that issue unresolved.

Article 16(1) follows the continuing thread of the Nagoya Protocol regarding respect for national sovereignty. However, while States have sovereign rights over genetic resources as stated in Article 15 of the CBD and restated in the Nagoya Protocol, in the case of traditional knowledge associated with genetic resources the State has more of an oversight role, since traditional knowledge is the property of the ILCs that hold it (a difference that could justify the need for two compliance provisions, Articles 15 and 16 of the Nagoya Protocol, and that also underpins the addition of the terms "approval and involvement" of ILCs as an alternative for their PIC).

It should be recognized that the provisions on traditional knowledge associated with genetic resources in the Protocol, including Article 16, go beyond Article 8(j) of the CBD. As stated in the Preamble of the Protocol, the circumstances in which traditional knowledge associated with genetic resources is held or owned by ILCs can differ from country to country. The fact that traditional knowledge is subject to national law also adds to the complexity of the implementation of this particular provision requiring measures that relate to domestic legislation or regulatory requirements addressing a "good" that does

not belong to the State and to which the State is a mere custodian. Moreover, Parties in their role as users will have to comply with a set of rules they did not take part in making and that may even be contrary to their own rules and/or policies.

Finally, the double reference to "appropriate" appears to originate from a text of an earlier draft of the provision that was left in after fairly intense negotiations that ended with the agreement to use the same language as in Article 15(1). One reference qualifies the nature of the measures to be taken, which need to be "appropriate, effective and proportionate", while the other reference qualifies the general obligation to take measures, "as appropriate". As pointed out above, flexibility in implementing this obligation is called for, given the different nature between genetic resources and traditional knowledge associated with these resources, as well as the lack of internationally agreed definitions of the terms "traditional knowledge associated with genetic resources", "utilization of traditional knowledge", and "indigenous and local communities".

However, it is important to note that the double qualification "as appropriate" does not justify a Party not taking measures at all under Article 16(1) unless there are objectively sound reasons for inaction. Indeed, the overall objective of this provision is to provide for compliance measures with regard to traditional knowledge associated with genetic resources. Hence, a Party needs to take effective and proportionate measures in order to comply with the provision if it is not inappropriate for some reason to do so. In other words, Article 16(1) does establish an obligation for Parties to provide for "the good legal status" of traditional knowledge being used within their jurisdictions.

Box 22: Article 8(j) of the CBD and Article 16 of the Nagoya Protocol

Article 8(j) of the CBD establishes an obligation for Parties to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices".

The Conference of the Parties of the CBD has established an Ad Hoc Working Group to discuss issues related to the implementation of this provision, and for years in different fora the question of how to achieve this objective has been discussed. The challenges identified there are of the same nature as the ones that Parties to the Nagoya Protocol are likely to encounter in relation with implementation of the provisions that expressly refer to traditional knowledge associated with genetic resources, such as Article 16.

Notably, one of the difficulties surrounding the implementation of the obligation under Article 16(1) resides in the fact that in order for countries to enact user measures to provide that traditional knowledge has been accessed legally, they have first to be able to identify the particular traditional knowledge that is being used and that was accessed with the genetic resources. The main obstacle is that in every case it will depend on the definition of the concept of traditional knowledge, since the term is not defined in the Nagoya Protocol nor is there a common understanding of its exact meaning.

2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

Paragraph 2 requires each Party to address situations where a user within its jurisdiction is found to be in non-compliance with the measures taken by the Party itself in accordance with Paragraph 1. When a user does not observe such measures, the Party shall take further measures that are qualified as appropriate, effective, and proportionate.

The wording of Article 16(2) is identical to Article 15(2) of the Nagoya Protocol. Consequently, the explanations made under this provision apply here also.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Article 16(3) states that Parties shall co-operate in situations of potential violations of domestic ABS legislation or regulatory requirements of the Party where ILCs are located and that account for obtaining their PIC or approval and involvement and for the establishment of MAT for access to traditional knowledge associated with genetic resources.

Again, the wording of Article 16(3) is identical to Article 15(3) of the Nagoya Protocol. Consequently, the explanations made under this provision apply here also.

Article 17
Monitoring the Utilization of Genetic Resources

1. To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:

   (a) The designation of one or more checkpoints, as follows:

      (i) Designated checkpoints would 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;

      (ii) Each Party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance;

      (iii) Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;

      (iv) Checkpoints must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, *inter alia,* any stage of research, development, innovation, pre-commercialization or commercialization.

   (b) Encouraging users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements; and

   (c) Encouraging the use of cost-effective communication tools and systems.

2. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.

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4. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

(a) Issuing authority;

(b) Date of issuance;

(c) The provider;

(d) Unique identifier of the certificate;

(e) The person or entity to whom prior informed consent was granted;

(f) Subject-matter or genetic resources covered by the certificate;

(g) Confirmation that mutually agreed terms were established;

(h) Confirmation that prior informed consent was obtained; and

(i) Commercial and/or non-commercial use.

A. Background

Article 17 concerns the way in which Parties to the Nagoya Protocol should monitor the utilization of genetic resources. It is intended to support compliance with obligations under the Protocol and to improve transparency about the use of genetic resources by establishing a non-exhaustive list of monitoring tools. The title of the provision, "Monitoring the Utilization of Genetic Resources", presupposes that the obligation to monitor refers only to the utilization of genetic resources as defined in Article 2(c) of the Nagoya Protocol but not to traditional knowledge associated with genetic resources. This understanding is supported by the fact that earlier versions of the draft negotiating text included references to traditional knowledge in the title as well as the operative text of the provision that were left out in the end.

The need for monitoring obligations was close to the heart of a number of Parties during the negotiations. These Parties made it clear that they expected the Nagoya Protocol to reinforce the measures on compliance with specific obligations on monitoring and with the mandatory establishment of predetermined "checkpoints". These would need to be accompanied by an internationally recognized certificate of compliance covering the specific genetic resource under consideration, with standard features to allow international recognition.

Checkpoints were initially proposed as an incentive for users to comply with access and benefit-sharing (ABS) obligations established in the jurisdiction of a provider country. Supporters of the proposal also argued that transactions and uses of genetic resources would need to be verified by authorities in States where genetic resources are utilized.

One issue of serious disagreement between developed and developing countries was the listing of specific checkpoints. During the negotiating process, proposed checkpoints included customs authorities, patent offices, market approval offices, research funding agencies, and indigenous and local community (ILC) representatives. However, there were a variety of views on the value of patent offices and other identified checkpoints to achieve the objective of the provision.

On the one hand, countries argued that Parties should establish effective checkpoints, understood as places where a user would need to go to and provide pertinent information when undertaking research and development on a genetic resource, when claiming a right in relation to the innovation made from such research and development, or when commercializing any resultant product. In the opinion of this group of countries, without such checkpoints compliance could not be achieved effectively.

On the other hand, a number of countries expressed their view that prescribed checkpoints would lack the necessary flexibility to address the different scenarios that could arise in this context. They also expressed their concern that a system that included disclosure obligations in patent applications and patent offices as checkpoints would be costly and ineffective in the fight against misappropriation while at the same time invoking non-compliance with the international patent system and the risk of undermining innovation.

Another concept that was introduced during the negotiating process was that of a so-called certificate of compliance, a term that was later accepted to refer to a specific monitoring tool. The initially proposed concept foresaw the application of such certificates to cases of compliance with domestic ABS regimes, as well as a system of internationally recognized certificates rather than a globally harmonized one. Traditional knowledge associated with genetic resources was excluded from the certification system, possibly reflecting the view that due to its intangible nature, traditional knowledge would pose practical difficulties requiring special consideration before the development of a traditional knowledge certification scheme.

Eventually both concepts – checkpoints and the internationally recognized certificate of compliance – were included in Article 17 of the Nagoya Protocol, with a particular impact on the structure of the provision. Within Article 17, two distinct parts can be identified: Paragraph 1 institutes the obligation to monitor and enhance transparency about the utilization of genetic resources, including the designation of one or more checkpoints. Paragraphs 2, 3 and 4 refer to the internationally recognized certificate of compliance, an issue that is no doubt related, but that perhaps could have benefited from having its own separate provision.

B. Explanation

1. To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:

The objective of Article 17 of the Nagoya Protocol is “to support compliance” as indicated at the beginning of Paragraph 1. There is no specification about whether the provision aims at supporting compliance with a specific provision of the Protocol, with prior informed consent (PIC) and mutually agreed terms (MAT), with the Protocol as a whole, or with domestic ABS legislation and regulatory requirements of the Parties. All these options were at some point on the table during the negotiations. From the explanations of Articles 15, 16, and 18, however, it can be concluded that Article 17 is of a complementary nature and aims at supporting compliance with domestic ABS legislation requiring PIC and the establishment of MAT as well as with user measures. Such understanding is supported by the fact that the internationally recognized certificate of compliance that is regulated in Article 17(2)-(4) serves all these functions.

The use of the term "shall" denotes a mandatory requirement for the Parties to take measures in order to support compliance. Although the obligation is unequivocal, some uncertainty is added by the introduction of the qualifier "as appropriate". In the context of the chapeau of Article 17(1), this qualifier can introduce a certain degree of discretion to each Party when deciding on the nature of the measures or it can be read as indicating that the measures that have to be taken need to be appropriate, meaning fitting or relevant to achieve the intended objective. In the same manner, the aim of the measures is to monitor and enhance transparency about the "utilization of genetic resources", a concept that has to be read as defined in Article 2(c) of the Nagoya Protocol.

Paragraph 1 categorically affirms that for a Party to implement this provision, at a minimum it has to undertake all three measures listed in Subparagraphs (a), (b), and (c). It is important to note that this provides a non-exhaustive list of measures, meaning that additional measures can be taken as well. The non-exhaustive list of measures contains the following:

(a) The designation of one or more checkpoints, as follows:

Paragraph 1(a) calls for the designation of one or more checkpoints. A Party must then nominate at least one entity where monitoring will take place. The provision does not prescribe the use of any particular checkpoint.

At the final stages of the negotiation, when it was clear that developed countries would not accept references to examples of possible checkpoints within the provision, some developing countries proposed that each Party within a certain period of time would be obliged to notify the Secretariat of the checkpoints designated by that Party. The language did not get through the final text, nor did a proposal that invited Parties that had included patent offices as checkpoints in their national laws to designate those as their checkpoints. The compromise text in Paragraph 1(a) leaves Parties with the necessary flexibility to decide on the form of the one or multiple checkpoints that they designate as long as any checkpoint satisfies the characteristics defined in the provisions under (i)-(iv).

(i) Designated checkpoints would 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;

Subparagraph (a)(i) is about the function of the designated checkpoints. The context and the history of the negotiations indicate that despite the use of the term "would", the intention was not to deprive this provision of its binding nature and that the main function of designated checkpoints is to "collect or receive, as appropriate, relevant information". The two verbs used ("collect or receive") imply an active role as well as a passive role for the checkpoint. Parties are given the discretion to decide whether they favour one or the other, thanks to the addition of the formulation "as appropriate". The use of the conjunction "or" instead of "and" should be read as implying that assigning both roles to the same checkpoint is an option, the minimum being that the Party does assign one or the other. However, nothing prevents a Party from implementing this more stringently by requiring both.

The information collected or received by the checkpoints has to be "relevant". This qualification has its origin in the concerns of some negotiators that the obligation could entail an arbitrary capture of activity. The argument was also made that the intention was to avoid a situation where a checkpoint would be submerged by information that will have no relation whatsoever with the objective and scope of the Nagoya Protocol. Furthermore, a list is provided to indicate that the information has to be closely

connected to the PIC procedure (for instance, whether and how it has been requested), the source of the genetic resources (the provenance of the sample of the genetic resources), the establishment of MAT (whether they have been established), and the utilization of genetic resources as defined in Article 2(c) (for instance, information that refers to the research and development phase).

The use of the "and/or" as well as an additional inclusion of the formulation "as appropriate" at the end of the listing in Article 17(1)(a)(i) points to the fact that each Party will have to decide on the suitability of each of these elements. In other words, not necessarily all information listed above has to be revealed.

(ii) Each Party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance;

Subparagraph (a)(ii) acknowledges that for checkpoints to function, each Party shall compel users to supply at a designated checkpoint the information listed in Subparagraph (a)(i). The obligation is subject to the particular characteristics of a designated checkpoint and again to the qualifier "as appropriate", therefore providing flexibility and reaffirming what was said above about the possibility for Parties to decide that a checkpoint would be limited to a passive role.

In such cases, the Party will still be under an obligation to request the user to make the information available. The wording specifying that the subjects of the request for information are the "users" can be read as having the effect of narrowing down the flexibility provided in Subparagraph (a)(i) in relation to the sources from which the information will be received.

An obligation for individual Parties to take measures to address situations of non-compliance with the measures requiring the provision of information is also incorporated in Subparagraph (a)(ii). No examples of possible measures are given. Therefore, they are left at the discretion of the Party as long as they are qualified as being "appropriate, effective and proportionate", qualifiers that have the same meaning as explained under Article 15.

(iii) Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;

Subparagraph (a)(iii) states that the information received or collected by the designated checkpoints has to be provided to three actors:

- relevant national authorities – the relevance in this context will be determined by the legal competence of a public entity on issues related to ABS in accordance with Article 6(1) of the Nagoya Protocol, or to the particular transaction;
- the Party providing PIC – in accordance with Article 6(1), this will be the Party providing the genetic resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention on Biological Diversity (CBD), unless otherwise determined by that Party; and

- the ABS Clearing-House (ABS CH) – established under Article 14 of the Nagoya Protocol, this shall serve as a means for sharing information and will be hosted by the clearing-house mechanism of the CBD.

Furthermore, information is to be provided under two caveats: first, that it is deemed appropriate by the Party providing PIC and, second, that the information is not confidential. Taking into account that the Nagoya Protocol is silent on the matter, confidentiality will be determined by a process in the Party providing the information. The formulation "as appropriate" at the end of the sentence can also be read as relating to the relevant national authorities to which the information is to be sent.

Subparagraph (a)(iii) introduces for the first time in the Nagoya Protocol the term "internationally recognized certificate of compliance". The issue of the legal nature of the certificate then presents itself. The fact that the provision acknowledges that there will be cases where the certificate will not be available indicates that it is not mandatory in all cases, for instance where a Party does not require PIC. Nevertheless a systematic reading of Articles 17(2), 14(2), and 6(3)(e) indicates that when a Party requires PIC pursuant to Article 6(3)(e), a permit or equivalent will be required together with a report of the permit to the ABS CH. This reporting then turns the permit or its equivalent into an internationally recognized certificate of compliance pursuant to Article 17(2). Therefore in this case it will be mandatory to produce such certificate in order to demonstrate compliance.

When seeking to understand this provision and its relation to other articles in the Nagoya Protocol, two different readings may be possible. On the one hand, some argue that the text and the history of the negotiations as well as the outcome from the first meeting of the Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol on ABS indicate that the mere registration of a permit or equivalent does elevate the permit to the status of an internationally recognized certificate of compliance and that no additional action is required. This view implies that Article 17(4) sets out the required elements to be disclosed to the ABS CH to give effect to the intention at Article 17(2) to create certificates of compliance through the interaction of Articles 6 and 17. Moreover, it may be difficult to envisage a situation where a Party requiring PIC would deprive itself of the protections established via certificates of compliance by not providing the information required at Article 17(4).

On the other hand, others see the permit or its equivalent as being different from the internationally recognized certificate of compliance and they question whether the registered information itself constitutes the internationally recognized certificate; if so, there are two different tools. Furthermore, it can also be claimed that the first is mandatory while the second is of a voluntary nature if the notification to the ABS CH does not include the required elements set out at Article 17(4).

(iv) Checkpoints must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, *inter alia,* any stage of research, development, innovation, pre-commercialization or commercialization.

Subparagraph (a)(iv) states that checkpoints must be effective. It is interesting to note that the use of the word "must" instead of "should" or "shall" is unusual, and that the word "relevant" occurs three times. This may be the result of the rush to adopt this provision when consensus was reached on its content. In general, after very difficult negotiations any attempt to change the drafting entails the risk of reopening the discussion.

The Nagoya Protocol does not set criteria to define effectiveness. Therefore, it is up to the Parties to determine whether a designated checkpoint has achieved the desired effect of monitoring and enhancing transparency about the utilization of genetic resources, as established in Paragraph 1.

In addition, checkpoints should have functions relevant to the implementation of Paragraph 1(a). This statement seems redundant considering that the text in (a) is all about checkpoints and their functioning. The same comment applies to the assertion that they should be relevant to the utilization of genetic resources, which has already been made clear in Paragraph 1.

The last part of the sentence refers to the collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization, or commercialization. Arguably, the listing could be surpassing the scope of Article 17, which only refers to the utilization of genetic resources, a term defined under Article 2(c) of the Protocol as to include research and development but not explicitly mentioning other activities such as innovation, pre-commercialization, or commercialization. Following this line of thought, it could be concluded that some of the collected information may indeed be irrelevant for implementing Article 17 of the Nagoya Protocol, and this part of the provision might be inconsistent with the other parts of Article 17(1). Alternatively, innovation, pre-commercialization, or commercialization can be understood as being elements of the concept of development.

It must be recognized that the Latin expression *inter alia* is equivalent to “amongst other things” and leaves no doubt that the list is only of an indicative nature. The preceding preposition allows a checkpoint to operate at any point according to the trail of activities listed.

(b) Encouraging users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements; and

Paragraph 1(b) contains an obligation for each Party to promote that both providers and users include provisions in MAT in order to share information on its implementation. Such provisions can encompass reporting requirements. Parties may consider Paragraph 1(b) as an addition to the list contained in Article 6(3)(g) of what may be included when developing MAT.

It is important to note that the Nagoya Protocol does not go as far as requiring legislation to be developed or for Parties to include the reporting requirement as mandatory, although it does not preclude the possibility of a Party taking such a measure if it so wishes.

(c) Encouraging the use of cost-effective communication tools and systems.

Paragraph 1(c) calls for the use of cost-effective communication tools and systems to monitor and to enhance transparency about the utilization of genetic resources. The first tool that comes into mind is the Internet, as now broadly available and accessible to many. Digital libraries and web registries are examples of possible ways to implement this provision. Although the provision points to a paperless system, it does not preclude a mixture of paper and electronic formats. Such tools and systems are qualified as having to be “cost-effective”, meaning that Parties will need to avoid implementing tools and systems that do not keep a balance between the costs involved and the effectiveness of the measure.

2. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

Article 17(2) of the Nagoya Protocol determines what shall constitute an internationally recognized certificate of compliance. It states that an internationally recognized certificate of compliance is a permit or its equivalent produced as evidence of the decision to grant PIC and of the establishment of MAT. It should be made available to the ABS CH pursuant to Article 6(3)(e) of the Protocol, which indicates its value for monitoring the utilization of genetic resources.

Subsequent Paragraphs 3 and 4 also address the internationally recognized certificate of compliance, a term that was introduced in Article 17(1)(a)(iii) as a potential source of information, amongst others, but that it is not defined under Article 2 of the Nagoya Protocol on the use of terms. In addition, no procedure is found in the Protocol for the issuance of an internationally recognized certificate of compliance, nor is it explicitly mentioned what person or entity will be entitled to produce the certificates. A comprehensive reading of the Protocol, in particular of Articles 6 and 13, can however point out to the competent national authorities to provide the original permit to the ABS CH. If the information criteria under Paragraph 4 are met, the permit then constitutes an internationally recognized certificate of compliance.

It should be recognized that Parties at the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol may decide to consider the need to develop a shared understanding as regards the issue of a common format for the internationally recognized certificate of compliance as well as for a procedure for updating such a certificate.

3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.

The basic role of the certificate, as stated in Article 17(3), is to provide evidence of compliance with domestic ABS legislation or regulatory requirements that require PIC and the establishment of MAT. The certificate can then contribute to addressing eventual conflicts that could arise from the existence of two different jurisdictions: the one of the Party where the genetic resources are accessed and the one of the Party where they are used.

The provision partly mirrors language found in Article 15(1) of the Protocol, which indicates that users of genetic resources who can present an internationally recognized certificate of compliance have sufficient evidence that they accessed the resources in a manner that is in compliance with the ABS legislation or regulatory requirements of the Party that provided the genetic resources. Parties are therefore obliged to acknowledge that fact in their domestic ABS legislation or regulatory requirements.

Furthermore, it is important to note that the Nagoya Protocol is silent on how to address situations where internationally recognized certificates of compliance are not available. Situations where uses of genetic resources are outside of the ABS requirements under the Nagoya Protocol include those related to pre-CBD material, to the high seas and the deep seabed, and to genetic resources from States that do not require PIC.

4. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

Article 17(4) of the Nagoya Protocol provides a list of the minimum information that an internationally recognized certificate of compliance shall contain. Following the explanation under Article 17(2), if that provision is interpreted as meaning that registration at the ABS CH transforms a domestic permit into an internationally recognized certificate of compliance, then the list in Paragraph 4 will result in a global minimum harmonization of domestic permits.

It is important to note that the information listed is to be provided only when it is not confidential. As the Protocol does not define confidentiality, it is left to each Party to decide what information will not be shared. Furthermore, the provision states that the information listed is the minimum, indicating that nothing prevents a Party from including additional data (e.g., information on conditions for third-party transfer).

(a) Issuing authority;

(b) Date of issuance;

(c) The provider;

According to the three items at the top of the list, contact details of the authority that issued the certificate must be submitted together with the date of its issuance as well as the details of the entity that holds the right to provide the genetic resources.

(d) Unique identifier of the certificate;

The intention of providing a unique identifier for each permit or its equivalent as referred to in Subparagraph 4(d) is to facilitate searches. The format of such an identifier has not been determined. Amongst the options discussed for this was the development of guidelines for governments at the time of issuing the permit or for the ABS CH at the time of submission, in order to generate the unique identifier. The combination of a government-issued identifier and a reference code issued by the ABS CH at the time it received the information was also mentioned.

(e) The person or entity to whom prior informed consent was granted;

The data provided under (e) should allow contacting, if needed, the person or entity to which the Party providing the genetic resources granted PIC.

(f) Subject-matter or genetic resources covered by the certificate;

Subparagraph 4(f) requires information on the subject matter or genetic resources covered by the certificate. This could include biota at any taxonomic rank – which may carry a taxonomic name – and might also include a locality where the material was collected. In addition, the genetic resource may be identified through reference to a voucher specimen or field notes held in an identified archive or collection.

(g) Confirmation that mutually agreed terms were established;

Confirmation that MAT were established is included as Subparagraph 4(g) and can be provided in the form of a checkbox. Additional information could even include the identity of the contracting Parties, the date of establishment of MAT, and the full text of the agreement.

(h) Confirmation that prior informed consent was obtained; and

In the same manner, confirmation that PIC was obtained is required under Subparagraph 4(h) and can also be provided in the form of a checkbox. As an option, the purpose of the use of the genetic resources can also be reported.

(i) Commercial and/or non-commercial use.

Finally, a checkbox can also be used to inform on commercial and/or non-commercial use. It is left for the Parties to determine what “commercial use” means, since the Protocol does not define these terms.

Article 18
Compliance with Mutually Agreed Terms

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:

(a) The jurisdiction to which they will subject any dispute resolution processes;

(b) The applicable law; and/or

(c) Options for alternative dispute resolution, such as mediation or arbitration.

2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

3. Each Party shall take effective measures, as appropriate, regarding:

(a) Access to justice; and

(b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.

4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.

A. Background

Article 18 of the Nagoya Protocol, together with Articles 15, 16, and 17, completes the set of provisions covering "user country measures" in the Nagoya Protocol. The title of the article indicates that its content is, once again, addressing compliance. The meaning of the word "compliance" is the same as explained under Articles 15 and 16. This means that it refers to a state of adherence to norms.

However, it is important to understand that Articles 15 and 16 are about the observance of domestic access and benefit-sharing (ABS) legislation or regulatory requirements, including norms for traditional knowledge associated with genetic resources, hence covering situations of what was referred to during negotiations as "misappropriation". In contrast, Article 18 is the result of the concerns expressed by some Parties in relation to situations involving observance of the mutually agreed terms (MAT) reached by a user and a provider. During negotiations, situations where MAT have been breached by a user were often referred to as "misuse".

Domestic ABS arrangements often require prior informed consent (PIC) and MAT. While PIC is a public – that is, a non-contractual act that is not governed by the rules of private international law – MAT are

normally set out in a civil law contract even if it is concluded between a public authority and a private entity. It is commonly understood that relationships of a contractual nature where private parties are involved fall in the domain of private international law when one party resides in a foreign country. They are usually not dealt with through a public international law instrument, such as the Nagoya Protocol, which is deemed to rule relationships between States.

Private international law, also called conflict of laws, refers to the body of domestic principles and rules applicable to transborder cases involving private relationships that contain at least one legally relevant foreign element.[1] It seeks to regulate, first, which jurisdiction applies to a dispute; second, which law applies to the dispute; and third, whether and how eventual decisions or judgments are recognized and may be enforced in another jurisdiction. Private international law is part of the internal law of each State, and in that sense it differs from public international law that regulates the relations among sovereign States and international organizations. Each State has its own national rules on conflict of laws, but some of these may have been harmonized through international agreements, guidelines, and model laws.

The text of Article 18 reflects the legal difficulties associated with the fact that the Nagoya Protocol as an international treaty has limitations in regulating contracts between two parties that may or may not be States.

B. Explanation

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:

Article 18(1) of the Nagoya Protocol addresses the issue of dispute resolution. This provision has its origin in the concerns expressed by some countries regarding their lack of capacity to address situations where there is a breach of MAT. However, the demand for a provision to address such situations encountered resistance from other countries that argued on legal grounds that an international treaty such as the Nagoya Protocol could not regulate a relationship that often involves private persons.

Article 6(3)(g)(i) of the Protocol already refers to the specific element of a dispute settlement clause that may be included in MAT. In addition, according to Article 18(1), each Party is obliged to encourage users and providers to determine the way a dispute would be resolved in case it arises in relation to the implementation of MAT. It is important to note that the provision specifically refers to MAT established in relation to traditional knowledge associated with genetic resources as addressed in Article 7. Furthermore, it uses the formulation to “encourage” and includes the qualifier “where appropriate,” which indicate extensive flexibility of Parties in the implementation of this obligation. However, it should be recognized that even without the Nagoya Protocol it would be common practice for contractual

1 Submission by Canada, Compilation of Submissions by Parties, Governments, International Organizations, Indigenous and Local Communities and Relevant Stakeholders on Compliance in the Context of the International Regime on Access and Benefit-Sharing. Contained in document UNEP/CBD/ABS/GTLE/2/2, p. 5, 19 December 2008.

arrangements, such as MAT, to govern the way in which a dispute should be settled and to include appropriate dispute settlement clauses agreed to by the contracting parties.

Paragraph 1 also contains a list of items related to dispute resolution to be included in MAT. These items are connected by the formulation “and/or”, which means that all of them can be included in MAT or only one of them. While this formulation provides additional flexibility to the Parties in the implementation of the provision, some may not consider it common practice in the drafting of legal instruments.

(a) The jurisdiction to which they will subject any dispute resolution processes;

Subparagraph (a) refers to the jurisdiction to which a dispute resolution process should be subjected – that is, the authority of a particular country and court to administer the dispute resolution process. In this regard, it should be noted that some States have adopted international or regional instruments for co-operating on jurisdictional matters, but common practice is that domestic legislation determines whether the courts of a particular country have jurisdiction over a dispute. In the case of contractual disputes, a general rule is that the defendant shall be prosecuted in the courts of its place of residence.

According to Article 18(1)(a), Parties shall encourage users and providers of genetic resources and traditional knowledge associated with genetic resources to include a so-called express jurisdiction clause in the MAT. Such a clause aims to specify where the contracting parties wish to file a claim in case a dispute arises in relation to the MAT. It should be noted that Parties to the agreement may wish to bring an action for breach of the contract in the jurisdiction of the user, in order to avoid the issue of recognition and enforcement of judgments discussed under Paragraph 3(b).

(b) The applicable law; and/or

Subparagraph (b) refers to the applicable law – the law of a particular country that will govern the dispute. It should be recognized that where the parties of an agreement have not selected a governing law and it cannot be inferred from the circumstances, common law courts will apply the system of law with which the transaction has its closest and most real connection or “the proper law of the contract”. Some facts may influence the determination by the judge of the law that is the most closely connected to the transaction. The court would look, for example, at such factors as the place of performance, the place of residence or business of the parties, and the nature and subject matter of the contract.

It is important to note that in cases where parties fail to include a choice of jurisdiction or a choice of applicable law in their MAT, the Nagoya Protocol does not provide specific guidance on how to determine the jurisdiction and applicable law.

(c) Options for alternative dispute resolution, such as mediation or arbitration.

Finally, Subparagraph (c) concerns alternative dispute resolution – that is, processes and techniques for resolving disputes outside of the judicial (formal litigation) process. Two possible options of alternative dispute resolution are specifically mentioned for users and providers to consider, including when agreeing on the terms of the contract:

- Arbitration: In arbitration, the two disputing parties select an impartial third party, the so-called arbitrator. Both parties usually agree in advance to participate in a hearing at which they can present evidence and testimony. Furthermore, they agree to comply with the arbitrator's

decision, which is usually final and not re-examined by courts. Unlike a mediator, the arbitrator does not actively participate in the discussion.

- Mediation: In mediation, the conflicting parties attempt to settle their dispute through the active participation of a third party, the so-called mediator. The role of the mediator is to find points of agreement that help the disputing parties agree on a fair result. Mediation needs to be distinguished from arbitration, where the arbitrator acts much like a judge but in a less formal.

It is important to note that mediation and arbitration are not the only options for alternative dispute resolution that come into play under Article 18(1)(c). This is also indicated by the use of the formulation "such as". However, both mechanisms are frequently used in private international law for the main reason that they can be expeditious and may entail a less costly and time-consuming procedure than submitting the claim to the judicial system of one of the parties in conflict.

In this context, the 1958 United Nations New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards is relevant, as is has a relatively wide membership (146 Parties as of 2012). Equally pertinent are the 2001 Permanent Court of Arbitration Optional Rules for Arbitration of Disputes relating to Natural Resources and/or the Environment. One important feature of these Rules is that they are available for disputes that involve States, non-governmental organizations, private companies, or individuals – a characteristic well-suited to ABS contractual agreements that, as mentioned before, can involve different types of actors.

2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

Article 18(2) of the Nagoya Protocol establishes an obligation for each Party to ensure at the domestic level that if a dispute arises from MAT, recourse is available under its legal system. This provision arose from the desire of some Parties to get some kind of assurance from the Protocol that remedies (e.g., civil and commercial) could be sought in all jurisdictions independent of the nationality of the claimant.

Paragraph 2 does not mention whether the opportunity to seek resource shall also be granted to foreign citizens. It makes clear, however, that such recourse has to be consistent with applicable jurisdictional requirements of the Party concerned. The availability of recourse to courts will therefore depend in practice on the chosen jurisdiction and applicable law, as established in MAT and accepted by the named court (see Article 18(1)(a) and (b)). In the absence of such contractual clauses, the opportunities to seek resource will be determined by non-contractual private international law rules of the country where the legal action shall be taken.

Paragraph 2 further emphasizes that a Party will not have to run counter its national legislation in order to comply with this obligation. This truism was added because some negotiators where calling for sanctions such as imprisonment if MAT were breached, while others maintained that using criminal provisions to attain civil remedies, such as enforcement of contracts, was not good practice.

It should be noted that in practice, most if not all countries in the world provide an opportunity in their legal systems to seek recourse in cases of breach of contract. Consequently, it could be argued that Article 18(2) is stating the obvious and has little added value. However, Article 18(2) may also be understood as indicating a broader approach to reinforcing the obligations enshrined in Article 18 in relation to jurisdiction and access to justice, as these are two essential components of the requirement

of making available opportunities to seek recourse. The latter approach could imply the establishment of a duty for Parties to provide for judicial remedies, including access to their courts and tribunals to nationals of other Parties. It could also be argued that forum courts, when seized for a dispute arising from MAT, should assert their jurisdiction unless the complaint is apparently based on uncertain jurisdictional grounds (e.g., where none of the parties to the MAT have real connection with the forum) (Chiarolla, 2011, p. 8).

3. Each Party shall take effective measures, as appropriate, regarding:

The chapeau of Article 18(3) of the Nagoya Protocol establishes an obligation for each Party to adopt measures that are related to issues listed in Subparagraphs (a) (on access to justice) and (b) (on the use of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards).

First it is important to note that it is not for the Parties jointly to take the measures referred to, something that would have implied harmonization of jurisdictional requirements between Parties. Instead, it is for "each Party" to enact such measures at the domestic level. Second, the measures shall be taken (only) if it is judged by the Party "appropriate" to do so. Third, the use of the word "regarding", which in its usual sense means concerning or in connection with something, means *stricto sensu* that the measures do not need to be aimed at or shall be undertaken to achieve something specific. Instead, they only have to be related to the issues listed in Subparagraphs (a) and (b). While these three elements seem to limit the scope of the obligation, it must be recognized that the chapeau also refers to "effective" measures.

(a) Access to justice; and

Subparagraph (a) refers to domestic measures regarding access to justice. The term "access to justice" is not defined in the Nagoya Protocol. It is also not self-explanatory, as during the negotiations it was understood in a broad as well as a narrow sense. For example, some Parties considered the notion of access to justice to be underpinned by social equity issues, which look beyond purely procedural matters. This broad understanding was based on some Parties' concerns about the high costs of litigating, especially in developed countries.[2]

In order to determine what the concept of access to justice may entail, its meaning in other international instruments can be taken into consideration. Such international instruments include:

- the 1998 Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus Convention);
- the 1980 Hague Convention on International Access to Justice;
- the 1992 Rio Declaration on Environment and Development;
- the 2002 New Delhi Declaration of Principles of International Law relating to Sustainable Development (adopted by the International Law Association); and

2 Submission by European Community and its Member States, Compilation of Submissions by Parties, Governments, International Organizations, Indigenous and Local Communities and Relevant Stakeholders on Compliance in the Context of the International Regime on Access and Benefit-Sharing. Contained in document UNEP/CBD/ABS/GTLE/2/2, p. 21, 19 December 2008.

- the 2010 Guidelines for the development of national legislation on access to information, public participation and access to justice in environmental matters (adopted by the United Nations Environmental Programme (UNEP)).

It has to be noted, however, that the Rio Declaration, the New Delhi Declaration, and the UNEP Guidelines are only soft-law instruments – that is, they are not legally binding for any country – and that the Aarhus Convention and the 1980 Hague Convention have only limited membership.

Box 23: Relevant International Instruments Pertaining to Access to Justice

Access to justice is addressed by different international instruments that might provide guidance in understanding Article 18(3)(a) of the Nagoya Protocol:

- Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters

The Aarhus Convention was adopted in the framework of the United Nations Economic Commission for Europe in 1998 and entered into force on 30 October 2001. As of February 2012 it had 44 Parties. The Aarhus Convention is open for accession by any other State not member of the European Union that is a Member of the United Nations upon approval by the Meeting of the Parties (Article 19(3)).

The Aarhus Convention establishes a number of rights of the public (individuals and their associations) with regard to the environment. It provides for the right to review procedures to challenge public decisions that have been made without observing the provisions on public participation or environmental law in general. The Aarhus Convention also states that each Party shall ensure that any person who considers that his or her request for information has not been adequately answered will have access to a review procedure before a court of law or another independent and impartial body established by law. The issue of costs is also addressed by requiring that access to an expeditious procedure established by law will be free of charge or inexpensive and that reconsideration by a public authority or review by an independent and impartial body other than a court of law is to be made available as well. The Aarhus Convention includes provisions against discrimination of any person having the nationality of or habitually resident in another Contracting State and grants them the right to obtain information on court decisions.

- New Delhi Declaration of Principles of International Law Relating to Sustainable Development

The International Law Association's Delhi Declaration was adopted on 2 April 2002. Article 5 on the principle of public participation and access to information and justice states in Paragraph 3: "The empowerment of peoples in the context of sustainable development requires access to effective judicial or administrative procedures in the State where the measure has been taken to challenge such measure and to claim compensation. States should ensure that where transboundary harm has been, or is likely to be, caused, individuals and peoples affected have non-discriminatory access to the same judicial and administrative procedures, as would individuals and peoples of the State in which the harm is caused."

▶

- Guidelines for the development of national legislation on access to information, public participation and access to justice in environmental matters

The UNEP Governing Council adopted the Guidelines on 26 February 2010. The instrument aims at providing general guidance on promoting the effective implementation of Principle 10 of the 1992 Rio Declaration on Environment and Development. It seeks to facilitate broad access to information, public participation and access to justice in environmental matters.

Specifically in relation to access to justice, States should ensure that any person who considers that a request for environmental information has been inadequately answered has access to a review procedure before a court of law or other independent and impartial body to challenge such a decision, act, or omission by the public authority in question.

As regards to public participation in decision-making in environmental matters, States should ensure that the members of the public concerned have access to a court of law or other independent and impartial body to challenge the substantive and procedural legality of any decision, act, or omission that affects the environment or allegedly violates the substantive or procedural legal norms of the State related to the environment.

The issue of costs is also addressed, and States should ensure that public access to review procedures relating to the environment is not prohibitively expensive. The establishment of appropriate assistance mechanisms to remove or reduce financial and other barriers to access to justice should be ensured.

(b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.

Subparagraph (b) addresses one of the underlying issues during the negotiating process: the desire of developing countries to ensure that Parties to the Nagoya Protocol would recognize and enforce foreign judgments. This was considered unrealistic by many, taking into account that, as a general rule, countries are reluctant to accept mutual recognition of judgments even in difficult areas such as criminal law.

One mechanism that may be relevant under (b) is the 2005 Convention on Choice of Court Agreements adopted in the framework of The Hague Conference on Private International Law. This Convention regulates when a court must take jurisdiction or refuse to do so where commercial parties have entered into an exclusive choice of court agreement. It also provides for the recognition and enforcement of resulting judgments, with an option for States to agree on a reciprocal basis to recognize judgments based on a choice of court agreement that was not exclusive.

Box 24: Harmonization of Private International Law

Three main organizations are involved in the harmonization of private international law.

The Hague Conference on Private International Law was established in 1893 with the mandate to work for the progressive unification of private international law. It has 69 members that have adopted the following treaties relevant to ABS issues:

- the 1980 Hague Convention on International Access to Justice;
- the Hague Convention on the Recognition and Enforcement of Foreign Judgments in Civil and Commercial Matters;
- the 2005 Hague Convention on Choice of Court Agreements; and
- the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters.

The International Institute for the UN Commission on International Trade Law was established in 1966 by the United Nations General Assembly (UNGA). It has a commission with 60 members selected by UNGA for a six-year period, and its mandate encompasses the progressive harmonization and modernization of the law of international trade by preparing and promoting the use and adoption of legislative and non-legislative instruments in a number of key areas of commercial law. Those areas include dispute resolution, international contract practices, transport, insolvency, electronic commerce and international payments, secured transactions, and the procurement and sale of goods. Relevant instruments for ABS are the UN Convention on Contracts for the International Sale of Goods plus rules on arbitration. It is also in charge of the promotion of the 1958 UN New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards.

The International Institute for Unification of Private Law is an independent intergovernmental organization with 61 members. Its objective is to elaborate harmonized rules of private international law. Rules on conflict of laws are not its main focus. However, the Principles of International Commercial Contracts are relevant in the context of MAT.

4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.

Article 18(4) previews Article 31 of the Nagoya Protocol by stating that this provision has to be reviewed when the Conference of the Parties serving as the meeting of the Parties evaluates the effectiveness of the Nagoya Protocol, which is foreseen four years after its entry into force. This provision departs from good practice in legal drafting, as it repeats something stated elsewhere in the treaty instead of simply referring to the appropriate provision (in this case, Article 31). The rationale behind this duplication might be to ensure that Article 18 is put on the agenda when the assessment under Article 31 is initiated.

Another rationale might be provided by the history of the negotiating process. During the negotiations, some Parties had proposed the creation of an international ombudsman that would provide aid in seeking fair resolution of disputes, including the identification of breaches of the rights of indigenous

and local communities (ILCs).[3] Furthermore, the proposal also intended to empower the international ombudsman to take action on behalf of ILCs. The proposal, however, did not make it to the final text, and therefore the inclusion of a reference to the review clause might have been presented as a compromise solution in the understanding that an international ombudsman could be introduced later in the framework of the review process, if Parties agreed to do so.

3 Contained in document UNEP/CBD/WG-ABS/7/5, p. 45.

Article 19
Model Contractual Clauses

1. **Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.**
2. **The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.**

A. Background

Article 19 of the Nagoya Protocol highlights the importance of sector-specific model clauses for negotiating mutually agreed terms (MAT) in contracts. It places an obligation on Parties to encourage sectors involved in the access and utilization of genetic resources to develop model clauses, to update these clauses, and to use such clauses in the future.

Negotiators of the Nagoya Protocol recognized the significant difficulties faced in implementing the access and benefit-sharing (ABS) provisions of the Convention on Biological Diversity, and this is one of many articles (along with Articles 20–23) designed to put forward some practical solutions for Parties. Through promoting the use of model clauses, Article 19 aims to bring more consistency to the way that the access to and utilization of genetic resources is negotiated. Such consistency would help to bring more legal certainty to users and providers and would reduce transaction costs, thereby supporting fair and equitable benefit-sharing and making compliance across boundaries easier to track and enforce. It also establishes the role of the Conference of the Parties serving as the meeting of the Parties (COP/MOP) in overseeing and reviewing this activity.

B. Explanation

1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.

Article 19(1) creates an obligation for all Parties to encourage the development of model clauses to be used in negotiating contracts for ABS. During negotiations, some Parties pointed out the range of industrial sectors involved in ABS. Each of these sectors has particularities in its utilization of genetic resources and thus is likely to require particular guidance on best practices. For instance, the scientific community, indigenous and local communities, private enterprise, and the public sector will all have different approaches and need different elements to ensure clarity, traceability, and fair and equitable benefit-sharing.

During negotiations, the use of model clauses was much debated. Some Parties felt that general guidelines would be more useful than specific clauses. They felt that model clauses lack flexibility and, more worryingly, can never cover every eventuality (the particular worry being new types of uses and users in the future). Many were worried that a list of model clauses could be seen as a fixed and complete list to pick and choose from. Some sectors feared a "one size fits all" approach, feeling that terms should always be negotiated from scratch, as MAT should be just that – mutually agreed. In the end it was largely accepted that optional model clauses could still provide a useful starting point and help identify best practices, as well as being an important capacity-building tool for those with less experience and saving time and resources when in many cases contracts can be very similar.[1]

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

Article 19(2) obliges the COP/MOP to take stock of the use of model contractual clauses by different sectors. "Taking stock" is likely to mean that the COP/MOP will invite Parties on a periodical basis to submit reports of sectoral reviews they have undertaken and to provide examples of model contractual clauses. The COP/MOP may then choose to synthesise this information and make it available through the ABS Clearing-House.

1 See further discussion on advantages and disadvantages of model contracts in Tvedt and Young, 2007, pp.125–26.

Article 20
Codes of Conduct, Guidelines and Best Practices and/or Standards

1. **Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.**
2. **The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.**

A. Background

Article 20 of the Nagoya Protocol encourages Parties to support development and use of voluntary norms in relation to access and benefit-sharing (ABS). It reflects the recognition that legislation and regulatory requirements do not always suffice in addressing complex global challenges such as ABS. Voluntary norms have emerged to support other legal and policy instruments (Morrison and Roth-Arriza, 2007) and may be particularly valuable in the Nagoya Protocol context, given the complexity of the utilization of genetic resources and therefore the need for additional guidance.

Article 20 highlights the importance of users and providers of genetic resources following voluntary codes of conduct, guidelines, and best practices and/or standards when setting up ABS projects and agreements. As with Article 19, Article 20 places an obligation on Parties to actively encourage the development, update, and use of such tools and also establishes the role of the Conference of the Parties serving as the meeting of the Parties (COP/MOP) in overseeing and reviewing this activity.

B. Explanation

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.

Article 20(1) requires all Parties to encourage, as appropriate, the development, update, and use of voluntary norms. “Voluntary norms” means that such norms are not established or required by governments but they represent expected patterns of behaviour agreed upon by non-state actors such as companies, scientific associations, non-governmental organizations, and multi-stakeholder processes. For example, voluntary norms may aim to maintain excellence in the work of certain institutions or serve to support existing regulations, providing tools and guidelines for the organizations that must comply with these rules. Encouragement of such norms may take place through a range of

mechanisms, from awareness raising and capacity-building through facilitated procedures for requests for organizations working on the basis of their guidance.

Article 20(1) mentions several examples of voluntary norms, including codes of conduct, guidelines, best practices, and standards. The approach and scope of these norms differs, yet all could contribute to raising awareness on and putting into practice ABS. Many sectors have begun to develop voluntary codes and guidelines, as they find it useful for transparency and consistency, as well as a way to build trust.

- Codes of conduct: These are sets of rules outlining the responsibilities or best practices for members of an organization or association. Organizations such as the International Plant Exchange Network have adopted codes of conduct with requirements on the acquisition of living plant material and related benefit-sharing for botanic gardens within the network.[1]
- Guidelines: These generally aim to promote or facilitate particular approaches in order to obtain their objectives. Examples of existing guidelines on ABS include those prepared by the Deutsche Forschungsgemeinschaft, the German research foundation, which require scientists applying for research funding to comply with the ABS principles, and those elaborated by the Swiss Academy of Sciences, which provide researchers with information on the ABS system, case studies, and step-by-step procedures.[2] The International Federation of Pharmaceutical Manufacturers and Associations has also developed guidelines that define certain "best practices" that should be followed by companies that will engage in the acquisition and use of genetic resources.
- Standards: These provide rules, guidelines, or characteristics for products or related processes and production methods (ISO, 2010). ABS issues are slowly emerging in standards dealing with social and environmental issues. For example, the ABS Management Tool, developed by the International Institute for Sustainable Development with Swiss government support and following multi-stakeholder involvement, establishes standards of conduct and provides guidance for providers and users of genetic resources to enable them to meet the requirements of the Convention on Biological Diversity and the 2002 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. The Ethical BioTrade standard, which is managed by the Union for Ethical BioTrade, a full member of the International Social and Environmental Accreditation and Labelling Alliance, includes requirements on ABS for companies working with natural ingredients.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.

Article 20(2) requires the COP/MOP to periodically take stock of the use of voluntary norms on ABS. As under Article 19(2) of the Nagoya Protocol, "taking stock" is likely to mean that the COP/MOP will invite Parties on a periodical basis to submit reports on the use of such codes, guidelines, and best practices and/or standards within their jurisdiction. The COP/MOP may then choose to synthesize

1 The IPEN Code of Conduct is available at www.botgart.uni-bonn.de/ipen/criteria.html.

2 The DFG guidelines are available at www.dfg.de/download/formulare/1_021_e/1_021e_rtf.rtf. The Swiss Academy of Sciences guidelines are available at http://abs.scnat.ch/.

this information and make it available through the ABS Clearing-House. Such occasional assessment of the use of voluntary norms may provide insight into the perceived challenges and gaps, as well as innovative approaches, in relation to ABS among various stakeholder groups.

In addition, Article 20(2) calls on the COP/MOP to consider the adoption of specific codes of conduct, guidelines, best practices, and/or standards. This means that the COP/MOP may develop and adopt specific codes of conduct or other voluntary norms, including guidance on specific issues or for particular groups of stakeholders. Precedents for such guidelines include the 2002 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.

Article 21
Awareness-raising

Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues. Such measures may include, *inter alia:*

(a) Promotion of this Protocol, including its objective;

(b) Organization of meetings of indigenous and local communities and relevant stakeholders;

(c) Establishment and maintenance of a help desk for indigenous and local communities and relevant stakeholders;

(d) Information dissemination through a national clearing-house;

(e) Promotion of voluntary codes of conduct, guidelines and best practices and/or standards in consultation with indigenous and local communities and relevant stakeholders;

(f) Promotion of, as appropriate, domestic, regional and international exchanges of experience;

(g) Education and training of users and providers of genetic resources and traditional knowledge associated with genetic resources about their access and benefit-sharing obligations;

(h) Involvement of indigenous and local communities and relevant stakeholders in the implementation of this Protocol; and

(i) Awareness-raising of community protocols and procedures of indigenous and local communities.

A. Background

Article 21 of the Nagoya Protocol provides for a range of outreach measures to promote awareness of the core objectives of the Protocol, how it functions, and other related issues. Outreach measures are necessary to achieve the obligations found in the Convention on Biological Diversity (CBD) and the Nagoya Protocol. The CBD has a Programme of Work on Communication, Education and Public Awareness based on its Article 13 that aims to support Parties and other stakeholders, including educators, to raise awareness about, among other things, the meaning and importance of biodiversity for achieving sustainable development objectives.

There are also a number of reasons for specifically promoting awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, including their role in supporting the conservation of biological diversity and the sustainable use of its components. The utilization of genetic resources supports a range of different industries, including agriculture, personal and home care, pharmaceuticals, and horticulture. Genetic resources are important for food security, public health, and the mitigation of and adaption to climate change. As such, genetic resources provide an essential and quantifiable ecosystem service. Raising awareness of the environmental, social, and

economic value of genetic resources among various stakeholders is therefore a decisive factor in advancing the objectives of the CBD and the Nagoya Protocol. For example, according to the study on The Economics of Ecosystems and Biodiversity,[1] businesses are beginning to notice the threat posed by biodiversity loss, including the threat to the continued supply of the ingredients and inputs for their products. Public awareness of biodiversity loss is also increasing, leading to changes in consumer preferences and purchasing decisions.[2] Such trends increase pressure on the private sector to review their policies and practices on biodiversity to ensure continued supply and access to markets.

Furthermore, awareness of access and benefit-sharing (ABS) issues is important for the proper functioning of ABS regimes. In particular, awareness raising may support the appropriate implementation of key aspects of an ABS system: the permitting process, prior informed consent (PIC), the establishment of mutually agreed terms (MAT), and the inclusion of fair and equitable benefit-sharing provisions, among others.

Many of the proposed awareness raising measures are participatory in nature and promote the involvement of all ABS stakeholders. Some of the provisions in Article 21 support the implementation of measures increasing the involvement of indigenous and local communities (ILCs). Involving ILCs will be important in raising awareness of traditional knowledge associated with genetic resources. Traditional knowledge and genetic resources are considered to be inseparable by ILCs and form the basis of sustainable livelihoods. Such knowledge is held or owned in diverse circumstances, and ILCs have the right to identify its rightful holders in their communities. It may also exist in various forms that reflect their cultural heritage (see also the explanation of the Preamble and Article 12).

B. Explanation

Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues. Such measures may include, *inter alia:*

Article 21 of the Nagoya Protocol establishes an obligation for Parties to take measures to raise awareness of the importance of genetic resources, traditional knowledge associated with genetic resources, and related ABS issues, and it includes an indicative list of such measures (Tsioumani, 2010, p. 292). It builds upon the obligations found in Article 13 of the CBD on Public Education and Awareness and in Article 17 of the CBD on Exchange of Information, and it will be influenced by the implementation of Article 22 of the Nagoya Protocol on Capacity.

The chapeau of Article 21 indicates that acknowledging the value of genetic resources and traditional knowledge associated with them is an essential field of action for legal and policy frameworks to

1 The Economics of Ecosystems and Biodiversity is a global study supported by the United Nations Environment Programme, initiated by the Group of 8 and five major developing economies, and focusing on the global economic benefit of biological diversity, the costs of the loss of biodiversity, and the failure to take protective measures versus the costs of effective conservation. Online at www.teebweb.org.

2 See, e.g., the results of the annual Union for Ethical BioTrade Biodiversity Barometer, available at www.ethicalbiotrade.org.

implement ABS.[3] If valued and adequately managed, genetic resources and traditional knowledge associated with such resources are a source of growth, prosperity, and well-being – an integral part of a sustainable economy. This requires, however, an assessment and communication of the value of biodiversity to policy-makers, who can fully take genetic resources, traditional knowledge associated with such resources, and ABS into consideration in national rules, strategies, and plans.

Within this context, Article 21 introduces a list of potential awareness-raising measures, which could include:

(a) Promotion of this Protocol, including its objective;

Article 21(a) refers to the promotion of the Nagoya Protocol as well as its objective as a potential awareness-raising measure. The term "promotion" can mean a broad range of activities, such as providing information, training, and education about the Protocol and its objective for all ABS stakeholders, campaigning for their implementation, or advancing such implementation in practice.

The promotion of the Nagoya Protocol may include the promotion of its main concepts, which are included in Articles 5 (Fair and Equitable Benefit-sharing), 6 (Access to Genetic Resources), 7 (Access to Traditional Knowledge Associated with Genetic Resources), 9 (Contribution to Conservation and Sustainable Use), 12 (Traditional Knowledge Associated with Genetic Resources), 15 (Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing), 16 (Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing for Traditional Knowledge Associated with Genetic Resources), 17 (Monitoring the Utilization of Genetic Resources), 18 (Compliance with Mutually Agreed Terms), and 23 (Technology Transfer, Collaboration and Cooperation).

In addition, Article 21(a) refers to the promotion of the objective of the Nagoya Protocol that pursues the implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising from the utilization of genetic resources, within the Convention's framework. The objective, as stated in Article 1 of the Protocol, should be pursued in a manner that includes appropriate access to genetic resources, appropriate transfer of relevant technologies, and appropriate funding, thus contributing to the conservation of biological diversity and the sustainable use of its components.

(b) Organization of meetings of indigenous and local communities and relevant stakeholders;

ILCs that hold genetic resources and traditional knowledge associated with genetic resources receive consideration in this paragraph in order to increase awareness of such resources and knowledge (Kamau, Fedder and Winter, 2010, p. 252). The organization of meetings of ILCs and other stakeholders offers a practical way to facilitate implementation of the Nagoya Protocol. Meetings could help ensure understanding between the ILCs and relevant stakeholders, including requirements for PIC or approval and involvement and MAT. Such meetings could be a part of the mechanisms required by Article 12(2) of the Nagoya Protocol to inform potential users of traditional knowledge associated with genetic resources about their obligations.

3 These fields of action have been identified by stakeholders in the context of the work of the ABS Capacity Development Initiative. More information is available at www.abs-initiative.info.

(c) Establishment and maintenance of a help desk for indigenous and local communities and relevant stakeholders;

Establishing a help desk for ILCs and relevant stakeholders may help users and providers of genetic resources and traditional knowledge associated with genetic resources to access information on the particularities of ABS obligations in specific situations, including when a problem arises. For example, a help desk may provide clarity and certainty in ABS negotiations by addressing the issue of asymmetric information between negotiating parties, which can increase transaction costs and have a negative impact on negotiation outcomes (Richerzhagen, 2011, p. 2,250).

(d) Information dissemination through a national clearing-house;

A national clearing-house mechanism is an important element of a strong institutional infrastructure for ABS. Through such a national clearing-house, a Party can help eliminate information deficiencies and administrative complexities, thereby decreasing transaction costs and facilitating access. It can make national competent authorities and national focal points more accessible and at the same time assist them in the collection, provision, and dissemination of information, as required by Article 13 of the Nagoya Protocol. This means that they play an essential role in raising the level of awareness of ABS (Richerzhagen, 2011, p. 2,254).

(e) Promotion of voluntary codes of conduct, guidelines and best practices and/or standards in consultation with indigenous and local communities and relevant stakeholders;

Article 21(e) complements Article 20 of the Nagoya Protocol, which requests each Party to encourage the development, update, and use of voluntary codes of conduct, guidelines, and best practices and/or standards for ABS. Article 14(3)(c) of the Protocol allows for the sharing of codes of conduct and best practices through the ABS Clearing-House (ABS CH), which is established as part of the clearing-house mechanism of the CBD (Article 18(3) of the CBD).

The 2002 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization are broadly accepted guidelines on best practices for ABS that could be promoted further (see section C of the Introduction). Professional bodies such as the International Federation of Pharmaceutical Manufacturers and Associations and the Biotechnology Industry Organisation responded to the Bonn Guidelines by developing sector-specific recommendations (Harvey and Gericke, 2011, p. 324). Other relevant instruments include the BioTrade Principles and Criteria adopted by the United Nations Conference on Trade and Development[4] and the certification scheme developed by the Union for Ethical BioTrade.[5] Furthermore, instruments adopted by the Conference of the Parties to the CBD relevant to traditional knowledge associated with genetic resources should also be promoted to ensure their use. They include, for example, the Tkarihwaié:ri Code of Ethical Conduct to Ensure Respect for the Cultural and Intellectual Heritage of Indigenous and Local Communities (Decision X/42).

4 UNCTAD BioTrade Initiative, *BioTrade Principles and Criteria,* UNCTAD/DITC/TED/2007.

5 Union for Ethical BioTrade (www.ethicalbiotrade.org/verification), which has as its purpose the "Sourcing with Respect" of ingredients that come from biodiversity.

(f) Promotion of, as appropriate, domestic, regional and international exchanges of experience;

The sharing of and building on existing ABS experiences is key for the implementation of the Nagoya Protocol. According to Article 21(f), Parties may exchange such experiences at different levels. This could be conducted through the ABS CH or capacity development workshops. The ABS Capacity Development Initiative is one example of a project that undertakes awareness raising on ABS issues by promoting exchanges of experience at a domestic, regional, and international level to remedy the lack of awareness of the potential of ABS at the political level (Vernooy and Ruiz, 2011, pp. 21–22).

(g) Education and training of users and providers of genetic resources and traditional knowledge associated with genetic resources about their access and benefit-sharing obligations;

Education and training as spelled out in Article 21(g) may help ensure compliance with PIC and MAT and promote more-equitable ABS contract negotiations. It may also help to ensure that ILCs and relevant stakeholders are aware of requirements regarding PIC or approval and involvement and of MAT for access to genetic resources and traditional knowledge associated with genetic resources. For example, it is important to understand that permission to access genetic resources does not necessarily imply permission to use traditional knowledge associated with such resources, and vice versa (see Paragraph 37 of the Bonn Guidelines).

(h) Involvement of indigenous and local communities and relevant stakeholders in the implementation of this Protocol; and

Full involvement of ILCs and relevant stakeholders is important for the successful implementation of the Nagoya Protocol because of their unique role as stewards of biodiversity and holders of traditional knowledge associated with genetic resources. This involvement could be achieved through consultation processes on matters related to the Protocol, including the participation of ILCs and other relevant stakeholders in commissions or consultative bodies related to its implementation.

(i) Awareness-raising of community protocols and procedures of indigenous and local communities.

Article 12 of the Nagoya Protocol provides context for the awareness-raising measure listed under Article 21(i). Accordingly, Parties are required to take into consideration the customary laws, community protocols, and procedures of ILCs on traditional knowledge associated with genetic resources (Article 12(1)), to establish mechanisms to inform potential users about their obligations (Article 12(2)), and to support the development of community protocols (Article 12(3)(a)). ILCs may establish such community protocols and similar procedures to ensure that users of genetic resources and traditional knowledge associated with genetic resources are familiar with the terms of engagement, including PIC and the negotiation of MAT (see explanation of Article 12 for a comprehensive analysis of the concept of “community protocols”). Consequently, it is important for users to be aware of the existence of community protocols to guarantee the integrity of indigenous governance systems.

Article 22
Capacity

1. The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations. In this context, Parties should facilitate the involvement of indigenous and local communities and relevant stakeholders, including non-governmental organizations and the private sector.
2. The need of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition for financial resources in accordance with the relevant provisions of the Convention shall be taken fully into account for capacity-building and development to implement this Protocol.
3. As a basis for appropriate measures in relation to the implementation of this Protocol, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition should identify their national capacity needs and priorities through national capacity self-assessments. In doing so, such Parties should support the capacity needs and priorities of indigenous and local communities and relevant stakeholders, as identified by them, emphasizing the capacity needs and priorities of women.
4. In support of the implementation of this Protocol, capacity-building and development may address, *inter alia,* the following key areas:
   (a) Capacity to implement, and to comply with the obligations of, this Protocol;
   (b) Capacity to negotiate mutually agreed terms;
   (c) Capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing; and
   (d) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources.
5. Measures in accordance with paragraphs 1 to 4 above may include, *inter alia:*
   (a) Legal and institutional development;
   (b) Promotion of equity and fairness in negotiations, such as training to negotiate mutually agreed terms;
   (c) The monitoring and enforcement of compliance;
   (d) Employment of best available communication tools and Internet-based systems for access and benefit-sharing activities;

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(e) Development and use of valuation methods;

(f) Bioprospecting, associated research and taxonomic studies;

(g) Technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable;

(h) Enhancement of the contribution of access and benefit-sharing activities to the conservation of biological diversity and the sustainable use of its components;

(i) Special measures to increase the capacity of relevant stakeholders in relation to access and benefit-sharing; and

(j) Special measures to increase the capacity of indigenous and local communities with emphasis on enhancing the capacity of women within those communities in relation to access to genetic resources and/or traditional knowledge associated with genetic resources.

6. Information on capacity-building and development initiatives at national, regional and international levels, undertaken in accordance with paragraphs 1 to 5 above, should be provided to the Access and Benefit-sharing Clearing-House with a view to promoting synergy and coordination on capacity-building and development for access and benefit-sharing.

A. Background

Article 22 of the Nagoya Protocol addresses capacity-building, capacity development, and the strengthening of human resources in developing-country Parties, Parties with economies in transition, and small island developing States to effectively implement the Protocol. It is important to note the importance of Articles 21, 23, and 25 of the Protocol in supporting capacity-building and capacity development.

Capacity, in a broad sense, is the ability of individuals, institutions, and societies to perform functions, solve problems, and set and achieve objectives in a sustainable manner. There are three levels at which capacity should be developed: individual (experience, knowledge, technical level), organizational (organizational systems and procedures), and systemic (policies, legislation, social norms).[1]

Capacity for access and benefit-sharing (ABS) has been a frequent and continuing concern of Parties and other stakeholders for many years. Decisions of the Conference of the Parties (COP) of the Convention on Biological Diversity (CBD) and actions by the CBD Secretariat reflect the level of concern about capacity-building and capacity development. The first meeting of the Ad-hoc Open-ended Working Group on ABS considered the issue and called for an expert workshop, which was held in December 2002 and developed an Action Plan on Capacity-building for Access and Benefit-sharing that was adopted by the seventh meeting of the CBD COP in February 2004 (Decision VII/19).

The objective of the Action Plan was to facilitate and support the development and strengthening of capacities of individuals, institutions, and communities for the effective implementation of the provisions of the CBD related to ABS and in particular the 2002 Bonn Guidelines on Access to Genetic

1 UN Public Administration Glossary, at www.unpan.org.

Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. It identifies key areas requiring capacity-building and suggests mechanisms, processes, and measures to implement capacity-building in key areas through actions taken at international, national, regional, and sub-regional levels. It also recognizes the need for co-ordination of activities among different actors and relevant international fora and it encourages Parties, Governments, and relevant international organizations to make available through the CBD clearing-house mechanism steps taken towards the implementation of capacity-building measures. The CBD Secretariat has since developed a database of ABS capacity-building activities.[2] However, the consensus is that effective implementation of ABS requires considerable financial and technical support and that a long time frame is required for results (Vernooy and Ruiz, 2011, p. 20).

B. Explanation

1. The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations. In this context, Parties should facilitate the involvement of indigenous and local communities and relevant stakeholders, including non-governmental organizations and the private sector.

Article 22(1) of the Nagoya Protocol establishes that the Parties shall co-operate in three different areas:

- Capacity-building: Capacity-building is generally needed in situations where there is limited or no capacity to evaluate and address questions related to policy choices and modes of implementation among development options, based on an understanding of environment potentials and limits and of needs perceived by the people of a country. It encompasses human, scientific, technological, organizational, institutional, and resource capabilities.[3]
- Capacity development: Capacity development is the process of long-term development. It is the process through which the ability of individuals, institutions, and societies to perform functions, solve problems, and set and achieve objectives in a sustainable manner is developed and maintained over time.[4]
- Strengthening of human resources and institutional capacities to effectively implement the Nagoya Protocol: Strengthening human resources involves establishing the conditions under which public servants are able to embark on a continuous process of learning and adapting to change by building on existing knowledge and skills and enhancing and using them in new directions. Strengthening institutional capacities involves the modernization of institutional machinery, with a priority on systems and processes. In this process, capacity development

2 Available at www.cbd.int/abs/projects.shtml.

3 UN Public Administration Glossary, at www.unpan.org.

4 Ibid.

for policy support, organizational effectiveness, and revenue and expenditure management is crucial.[5]

Co-operation is to take place with developing countries, notably with least developed countries, small island developing States, and economies in transition, for the effective implementation of the Nagoya Protocol. It might take place through global, regional, and sub-regional institutions and not only in a bilateral manner. This approach maximizes the use of resources for training and other capacity-building activities and builds upon existing experience. Furthermore, Paragraph 1 recognizes that the implementation of the Nagoya Protocol will require the involvement of a wide range of groups at the national level (e.g., governmental staff, private sector, scientific or research community, non-governmental organizations, and indigenous and local communities (ILCs)).

2. The need of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition for financial resources in accordance with the relevant provisions of the Convention shall be taken fully into account for capacity-building and development to implement this Protocol.

Article 22(2) of the Nagoya Protocol provides a clear link between financial resources and the needs of developing countries and indicates that the relevant provisions and mechanisms of the CBD regarding financial resources are relevant here too. These include Article 20 of the CBD on Financial Resources and Article 21 on the Financial Mechanism. The financial mechanism of the CBD is the Global Environment Facility, which is operated jointly by the World Bank, the United Nations Development Programme, and the United Nations Environment Programme. It is important to note that Article 25 of the Nagoya Protocol, in particular in its Paragraphs 3 and 4, gives greater guidance on financial assistance for capacity-building activities.

3. As a basis for appropriate measures in relation to the implementation of this Protocol, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition should identify their national capacity needs and priorities through national capacity self-assessments. In doing so, such Parties should support the capacity needs and priorities of indigenous and local communities and relevant stakeholders, as identified by them, emphasizing the capacity needs and priorities of women.

Paragraph 3 recognizes a fundamental principle in the field of capacity-building and development: any capacity-building measures must be based on the self-assessment and identification of needs and priorities of developing countries. It further emphasizes that capacity-building should be demand-driven and based on the needs and priorities identified through national self-assessments. In practice, this may mean that prior to the development of appropriate national frameworks to meet Parties' obligations under the Nagoya Protocol there is a need to assess, at the national level, the existing measures in place, institutional frameworks, and available resources. This would help to determine

5 Ibid.

the existing gaps as well as the capacities, institutional arrangements, and measures needed to meet Parties' obligations under the Protocol while taking into account national circumstances.

The second sentence of Article 22(3) notes that any national assessment should include and support the capacity needs and priorities of ILCs and other relevant stakeholders, in particular those of women. It is important to mention that other relevant provisions of the Protocol dealing with capacity-building of relevant stakeholders, including ILCs, are found in Article 12.

4. In support of the implementation of this Protocol, capacity-building and development may address, *inter alia,* the following key areas:

(a) Capacity to implement, and to comply with the obligations of, this Protocol;

(b) Capacity to negotiate mutually agreed terms;

(c) Capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing; and

(d) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources.

Article 22(4) of the Nagoya Protocol presents a list of key areas for capacity-building, including areas previously identified in COP decisions. It recognizes in particular the capacities to adopt measures to meet the new obligations of Parties under the Protocol and to develop and implement national ABS measures. For this, some Parties will need to revise their existing legal frameworks and develop them further in light of the Protocol. In other Parties, new legislative, administrative, and policy measures on ABS will need to be adopted, developed, and implemented.

In general, ABS capacity-building projects have supported capacity to develop national or regional measures, including legislative and administrative measures, to implement the CBD's ABS provisions and the Bonn Guidelines, raise awareness, and improve the skills to negotiate both globally at the level of the international regime and locally for ABS contracts. These projects have used a variety of approaches and mechanisms to develop capacity.

Box 25: The ABS Capacity Development Initiative

The ABS Capacity Development Initiative's goal is to contribute, based on business partnerships between South and North on a "level playing field", to poverty reduction, food security, technology transfer, social development, and biodiversity conservation by implementing the Nagoya Protocol and the third CBD objective in its entirety. The Initiative was launched at the eighth meeting of the CBD COP in March 2006 in Curitiba, Brazil, with a view to offer strategic capacity development to African countries regarding the implementation of ABS measures at national and sub-regional levels and the negotiation of the international ABS regime.

Post-Protocol, the focus has shifted to supporting implementation in countries in Africa, the Caribbean, and the Pacific (ACP). It is hosted by the German Federal Ministry for Economic Cooperation and Development (BMZ) and governed by three regional Steering Committees composed of donor and stakeholder representatives. The Secretariat, charged with the Initiative's implementation, is commissioned by BMZ to the Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH.

The implementation of the third objective of the CBD and the Nagoya Protocol is supported by interventions in order to attain the following objectives:

- ACP countries have ratified the Nagoya Protocol and benefit after its entry into force from its compliance mechanisms at the international as well as national levels.
- Transparent and accountable national ABS policies and regulatory frameworks are developed and implemented that allow stakeholders of ACP countries to enter into equitable ABS partnerships with the research community and the private sector.
- Valuation of genetic resources in provider countries is improved and functioning ABS agreements contribute to biodiversity conservation and livelihoods of rural populations.
- National, bilateral, and international partners are supporting ABS implementation at national and (sub-)regional levels.
- Approaches for implementing the Nagoya Protocol are regionally coordinated and harmonized with other processes and fora relevant to ABS in order to increase transboundary co-operation and to address legal gaps.

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Guided by the elevator principle, the Initiative targets its objectives by linking the local level with UN negotiations using regional and sub-regional activities as kick-off platforms. The main activities of the ABS Capacity Development Initiative include:

- design and organization of a platform to initiate and facilitate exchange among and between stakeholders on relevant ABS issues across the regions;
- thematic and/or stakeholder-focused training courses based on needs assessments;
- catalyzing knowledge management by peer-to-peer knowledge transfer;
- development and systematization of ABS best practices with the private sector;
- elaboration of synergetic implementation approaches with other key processes related to land tenure and resource ownership; and
- development of tools to develop, implement, and communicate ABS policies and related matters as defined and agreed upon by Steering Committee(s).

Source: ABS Capacity Development Initiative, online: www.abs-initiative.info.

5. Measures in accordance with paragraphs 1 to 4 above may include, *inter alia:*

Paragraph 5 (a)-(j) presents a non-exhaustive list of measures to support the implementation of the Nagoya Protocol through capacity-building and development activities relevant to the key areas identified in Paragraph 4 and in the rest of the provision.

(a) Legal and institutional development;

According to the CBD database on ABS measures, there are more than 50 ABS measures in place. But some of the measures identified are National Biodiversity Strategies, Plans, or Policies or are enabling provisions facilitating the further development of substantive ABS regimes. At the same time, one critical aspect for the successful implementation of the Nagoya Protocol and the CBD's ABS provisions is the existence of a legal framework regulating ABS as well as the institutional capacity to properly implement it. However, the drafting and enforcement of ABS national or regional legal measures has proved to be a difficult task for several countries.

(b) Promotion of equity and fairness in negotiations, such as training to negotiate mutually agreed terms;

ABS negotiations can be sometimes complex. Therefore, depending on their capacities, it may be a challenge for governmental authorities, ILCs, research institutions and other stakeholders to negotiate properly the different provisions of mutually agreed terms (MAT). In this context, it should be noted that bargaining power and access to legal advice may be different, particularly for ILCs or research organizations. For these reasons, the promotion of equity and fairness in the negotiation of ABS agreements to "level the playing field" is identified as a measure to support capacity.

(c) The monitoring and enforcement of compliance;

Monitoring and enforcement of compliance (for both MAT and contracts or other arrangements and national legislation) is a critical aspect of a functional ABS system. Different stakeholders, however, have raised practical and legal difficulties with the monitoring and enforcement of compliance with national ABS legislation as well as MAT. Identification of innovative mechanisms for the monitoring and enforcement, based on practical experiences and real cases, could be another useful step to increase capacity on ABS issues.

(d) Employment of best available communication tools and Internet-based systems for access and benefit-sharing activities;

The Nagoya Protocol in several provisions envisages the use of communication tools, including Internet-based systems (see, for example, the ABS Clearing-House under Article 14). Therefore, measures on this field may be taken to support the Protocol and its national implementation.

(e) Development and use of valuation methods;

One important aspect of the ABS regimes, especially related to the negotiation of MAT, is the valuation of genetic resources. Giving both users and providers of genetic resources access to information on the value of genetic resources, through the development and use of valuation methods, may facilitate the processes of obtaining prior informed consent and negotiating MAT, among others.

(f) Bioprospecting, associated research and taxonomic studies;

Bioprospecting is sometimes defined as the systematic search of biological material for new sources of compounds, genes, designs, whole organisms, and other products that have potential economic value. Associated research and taxonomic studies may provide useful information and input to support the implementation of ABS agreements and national or regional legal frameworks.

(g) Technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable;

Technology transfer is another key measure relevant for capacity-building and development, including the capacity to make such transfer sustainable. In the context of Paragraph 5(g), the word “sustainable” could be understood not only from an environmental perspective but also as an indication that for this transfer to be successful and sustained over time, infrastructure and technical capacity are also required to take advantage of the technology transferred. It is important to note that the Nagoya Protocol contains a specific provision for technology transfer, collaboration, and co-operation in Article 23.

(h) Enhancement of the contribution of access and benefit-sharing activities to the conservation of biological diversity and the sustainable use of its components;

The relationship and linkage between ABS and the other two objectives of the CBD is now reflected in Articles 1 and 9 of the Nagoya Protocol. Measures to increase the contribution of ABS to the fulfilment of the other two objectives could facilitate the realization of this linkage in practice.

Box 26: Enhancing the Contribution of ABS to Conservation and Sustainable Use

The Millennium Seed Bank Project of the Royal Botanical Gardens at Kew works with over 120 organizations in more than 50 countries. Projects are governed by legally binding ABS agreements negotiated between Kew and partner organizations and governments. These cover legal access to the genetic resources and associated information, terms of use, benefit-sharing clauses, and also a range of capacity-building activities covered by the project. This could include joint fieldwork expeditions, training and enhancement programmes, and – depending on the terms of acquisition – making plant material and seeds available for non-commercial research, conservation, and sustainable use projects.

Source: www.kew.org/science-conservation/save-seed-prosper/millennium-seed-bank/index.htm.

(i) Special measures to increase the capacity of relevant stakeholders in relation to access and benefit-sharing; and

(j) Special measures to increase the capacity of indigenous and local communities with emphasis on enhancing the capacity of women within those communities in relation to access to genetic resources and/or traditional knowledge associated with genetic resources.

Paragraph 5(i) and (j) makes reference to undetermined measures that may be taken by relevant stakeholders, such as the private sector, research institutions, the government, etc. Specific reference is made to the need to increase capacities of ILCs and women in relation to ABS and particularly traditional knowledge associated with genetic resources.

Box 27: Enhancing the ABS Capacity of Relevant Stakeholders

The Royal Botanical Gardens at Kew runs a series of specialist training courses, including regional herbarium techniques courses, a tropical plant identification course, and diplomas in conservation techniques and botanic garden management, with the aim of building capacity and enhancing skills and knowledge. All courses include a module on ABS issues, with discussion and practical training in the development of model agreements and policies.

Source: www.kew.org/learn/specialist-training/courses-a-z/international-diplomas/index.htm.

6. Information on capacity-building and development initiatives at national, regional and international levels, undertaken in accordance with paragraphs 1 to 5 above, should be provided to the Access and Benefit-sharing Clearing-House with a view to promoting synergy and coordination on capacity-building and development for access and benefit-sharing.

This provision stipulates that information should be provided by relevant stakeholders to the ABS Clearing-House with a view to promote synergies and co-ordination. This goal of improving co-ordination, avoiding duplication, and promoting better and targeted provision of capacity-building favouring recipients and the institutions and donors behind them is also considered in other international agreements. The basis for the ABS Clearing-House is found in Article 14 of the Nagoya Protocol.

Box 28: Capacity-Building and Development in Relevant International Agreements

Capacity-building and development is generally relevant for the implementation of international agreements. For example, capacity-building has been an important issue for the implementation of the Cartagena Protocol on Biosafety. At the global level, a number of tools and mechanisms have been developed to facilitate the capacity-building efforts of Parties, including a Capacity-Building Action Plan, a co-ordination mechanism, a set of indicators to evaluate the Action Plan's implementation, and a roster of biosafety experts.

Another interesting example is provided by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Within its context, capacity-building has two dimensions. First, it is one of the mechanisms to share the benefits arising from the use of plant genetic resources for food and agriculture under the Multilateral System of Access and Benefit-sharing.

This aspect is implemented through the Benefit-sharing Fund in accordance with Article 13(2)(c) of the ITPGRFA. Second, Article 19(3) of the ITPGRFA establishes that building capacity is essential for the full implementation of the treaty. Against this background, the Treaty Secretariat, the United Nations Food and Agriculture Organization, and Biodiversity International set up the Joint Capacity Building Programme for Developing Countries in order to provide assistance with implementation of the ITPGRFA. In addition, the Governing Body has created the Capacity Building Coordinating Mechanism to ensure that capacity is built in a coherent, co-ordinated, equitable, and regionally balanced manner, reflecting the actual needs of Contracting Parties and stakeholders and following the guidance of the Governing Body. Additional capacity-building activities are planned within the framework of the Memorandum of Cooperation signed between the Secretariats of the ITPGRFA and the CBD, in particular through joint workshops with a view to supporting the implementation of the Nagoya Protocol and the ITPGRFA in a mutually supportive manner.

Source: UNEP/CBD/ICNP/1/4 Measures to Assist in the Capacity-Building, Capacity Development and Strengthening of Human Resources and Institutional Capacities in Developing Countries and Parties with Economies in Transition.

Article 23
Technology Transfer, Collaboration and Cooperation

In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol. The Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, in order to enable the development and strengthening of a sound and viable technological and scientific base for the attainment of the objectives of the Convention and this Protocol. Where possible and appropriate such collaborative activities shall take place in and with a Party or the Parties providing genetic resources that is the country or are the countries of origin of such resources or a Party or Parties that have acquired the genetic resources in accordance with the Convention.

A. Background

Article 23 of the Nagoya Protocol, building on provisions of the Convention on Biological Diversity (CBD), establishes obligations towards co-operation in research and development as well as towards transfer of technology. In the CBD, the development and transfer of technology has a critical role to play in addressing the continuing loss of biodiversity and ensuring that the use of biodiversity is sustainable and contributes to local livelihoods. In addition, the transfer of technology is considered part of the "grand bargain" in the CBD, an essential counterpart to provisions related to access to genetic resources (Glowka et al., 1994). Biodiversity-rich countries would be providing access to their genetic resources in consideration, *inter alia,* of greater availability of scientific and technological information and access to environmentally sound technology to make use of these resources.

Article 23 confirms the relevance of the topic in the context of access and benefit-sharing (ABS). It provides a platform for Parties to collaborate and co-operate in technical and scientific research and development programmes for the equitable sharing of the benefits derived from its utilization. It also requires Parties to promote and encourage access to technology towards a sound and viable technological and scientific base for conservation, sustainable use, and fair and equitable benefit-sharing.

B. Explanation

There are two main elements in Article 23: technological co-operation and transfer of technology.

The first part of Article 23 focuses on technological co-operation, requiring Parties to "collaborate and cooperate in technical and scientific research and development programmes" as a means to achieve the fair and equitable sharing of the benefits arising from the utilization of genetic resources. Technological co-operation, including active participation in the development and use of technologies prompted by or resulting from the utilization of biodiversity, is seen as one of the paramount benefits in the ABS context. Article 23 builds on CBD provisions addressing technological collaboration, including Article 15(6), which affirms that Parties "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." These CBD provisions remain applicable for Parties of the Nagoya Protocol.

Article 23 is also linked to other provisions in the Nagoya Protocol, including Annex I on possible benefits, which mentions research funding; sharing of research and development results; collaboration, co-operation, and contribution in scientific research and development programmes; and participation in product development. It is important to note that Article 23 approaches technological co-operation in a broad manner, including all types of collaboration leading to the fair and equitable sharing of benefits and involving not only provider and user countries.

The second part of Article 23 focuses on the transfer of technology. It states that Parties "undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition." In negotiations, it was clear that the transfer of technology was not understood as shifting machinery or equipment from one point to another but rather as a flow of goods and knowledge that opens opportunities for learning and capacity-building in developing countries.

Article 23 requires Parties to "undertake" to promote and encourage the transfer of technologies. This best-endeavours clause must be considered in the context of Articles 15(7), 16(3), and 16(4) of the CBD, which establish that Parties "shall take legislative, administrative and policy measures" with the aim of promoting technology transfer and its consideration in fair and equitable benefit-sharing. Thus, the focus of Article 23 is on Parties to the Nagoya Protocol establishing a framework that allows and facilitates technology transfer. For example, the CBD "Strategy for Practical Implementation of the Programme of Work on Technology Transfer and Scientific and Technological Cooperation" mentions possible approaches to establishing such a framework.[1] It refers to assessing priority technology needs; establishing programs that enhance access to capital markets, in particular for small and medium enterprises in recipient countries; and – bearing in mind the critical role of the private sector in technology transfer – establishing incentives such as tax breaks or deferrals, subsidized export credits or loans guarantees, and facilitated access to technologies developed by public research institutions. There is also an important role in technology transfer for information-sharing mechanisms, including the ABS Clearing-House established by Article 14 of the Nagoya Protocol.

1 Convention on Biological Diversity, *Strategy for Practical Implementation of the Programme of Work on Technology Transfer and Scientific and Technological Cooperation,* Decision IX/14: Technology transfer and cooperation, UNEP/CBD/COP/DEC/IX/14, 9 October 2008.

Finally, Article 23 calls for collaborative activities undertaken to take place, where possible and appropriate, in and with the Party or the Parties providing the genetic resources. This clause is important because, as noted by the above-mentioned CBD strategy on technology transfer and scientific and technological co-operation, technology transfer is most effective not as a one-off and one-way activity but as part of an "integrated, long-term scientific and technological cooperation."[2] Arrangements to ensure that research and development based on genetic resources and traditional knowledge associated with genetic resources, among other related activities, takes place in the provider countries aim to promote more pro-active and long-term participation of these countries in research and development, leading to increased capacities, information, and value added at the local level. Nevertheless, this remains a best-endeavour clause, in recognition that it is sometimes not possible or desirable to conduct collaborative activities in the provider country. For example, some arrangements for benefit-sharing establish the possibility of fellowships or traineeships of scientists from the provider country in research and development facilities located abroad. Benefit-sharing is also sometimes conducted at a regional level, whether to avoid national political or logistical problems or to benefit from interaction and synergies in the same region.

Box 29: ABS and Technology Transfer

Article 23 of the Nagoya Protocol reflects technology transfer provisions in other international documents yet also raises distinct issues. Since the Rio Declaration on Environment and Development – adopted at the same time as the CBD in 1992 – there has been widespread recognition that the development, transfer, adaptation, and diffusion of technology and the building of related capacity are crucial for achieving sustainable development. For example, Principle 9 of the Rio Declaration calls upon States to co-operate to strengthen capacity-building for sustainable development through technology transfer. Agenda 21 provides further important guidance on the transfer of environmentally sound technology, co-operation, and capacity-building, including in regards to biotechnology.

In the CBD, Article 16 expressly recognized that access to and transfer of technology among Parties are essential elements for the attainment of the objectives of the Convention. In 2002, in the context of the World Summit on Sustainable Development, countries reaffirmed that a more efficient and coherent implementation of the CBD objectives would require the provision of new and additional financial and technical resources to developing countries. Article 23 of the Nagoya Protocol identifies "a sound and viable technological and scientific base" as a tool for the attainment of the objectives of the CBD. Indeed, as in other multilateral environmental agreements, making scientific and technological developments accessible to a wider range of users in the CBD aims to support the conservation and sustainable use of biodiversity as a shared, limited resource. For instance, facilitating access to remote sensing technologies may support developing country measures to monitor components of biodiversity.

Furthermore, in the CBD, and particularly in the context of ABS, technology transfer is also a way to acknowledge and recompense the contribution of the genetic resources or traditional knowledge ▶

2 Ibid.

associated with those resources – and of countries and communities with rights over these resources – to the development of technologies linked to the utilization of genetic resources. It might include, for example, technologies for screening the genetic and/or biochemical composition of genetic resources for potential commercial applications. Of course, the idea is that technology transfer, as an element of fair and equitable benefit-sharing, promotes and facilitates the conservation and sustainable use of biodiversity. However, Article 16(1) of the CBD uses broader terms, referring to "technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment."

Though not mentioned in Article 23 of the Nagoya Protocol, it is worth recalling that one of the most controversial issues in technology transfer discussions, which is likely to come up once again in the implementation of the Nagoya Protocol, is intellectual property. Article 16(5) of the CBD recognized that patents and other intellectual property rights might influence the implementation of the Convention, and it required Parties to co-operate to ensure that such rights are supportive of and do not run counter to its objectives.

In 2008, a technical study was conducted to explore the role of intellectual property rights in technology transfer in the context of the CBD, as well as to identify potential options to increase synergy and overcome barriers to technology transfer and co-operation. The technical study provides a comprehensive introduction to the subject of technology transfer in the CBD and addresses the benefits and costs of intellectual property rights during the different phases of technology transfer. Among its findings, the study noted that intellectual property should not be seen as a single, stand-alone form of knowledge management, to be adopted or rejected in its entirety or to be used to the exclusion of other forms of innovation promotion and technology diffusion. Rather, the actual effect and operation of intellectual property in the context of the CBD depends on concrete choices, including on the scope of intellectual property protection in the jurisdiction concerned and approaches to licensing and enforcement of intellectual property rights.

Source: Secretariats of the CBD, United Nations Conference on Trade and Development, and World Intellectual Property Organization, *The Role of Intellectual Property Rights in Technology Transfer in the Context of the Convention on Biological Diversity,* UNEP/CBD/COP/INF/7, 3 May 2008.

Article 24
Non-Parties

The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-House.

A. Background

Article 24 of the Nagoya Protocol mirrors Article 24(2) of the Cartagena Protocol on Biosafety, which calls on Parties to that Protocol to encourage non-Parties to adhere to the Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms.

As an international treaty, the Nagoya Protocol cannot create binding obligations for States that choose not to become a Party to the Protocol. Non-Parties to the Nagoya Protocol may include not only States that are not Parties to the Convention on Biological Diversity (CBD) but also CBD Parties that have not ratified or acceded to the Protocol. It should be noted that States that are not Parties to the Nagoya Protocol but that are Parties to the CBD remain bound by relevant access and benefit-sharing (ABS) requirements under the CBD, including those contained in its Articles 15, 8(j), 16, and 19.[1] These are discussed in the Introduction.

In accordance with Article 32 of the CBD, a prerequisite to become a Party to any protocol under the Convention is to be Party to the Convention. It is thus not possible for a State or a regional economic integration organization to be a Party only to a protocol, as it is the Convention that provides the basis for any subsequent protocol under its aegis. Decisions pertaining to a CBD protocol are taken only by its Parties; when the Nagoya Protocol enters into force, decisions under the Protocol will therefore only be taken by the Parties to the Nagoya Protocol. Parties to the CBD that are not Parties to the Nagoya Protocol may nonetheless participate as observers in the meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol, as stated under Article 26(2).

B. Explanation

According to Article 24, Parties to the Nagoya Protocol have the obligation to encourage non-Parties to “adhere” to the Protocol. The word “adhere” means to apply the principles of the Nagoya Protocol or to become a Party to the Protocol. The objective of this provision is therefore to achieve as broad coverage of the Protocol’s provisions as possible. Indeed, there is no provision that would require Parties to the Nagoya Protocol to deny access to countries that have not agreed to be bound by the Protocol. Nor is there anything that would require them to grant such access. Nevertheless, as Parties to the Convention they are still bound by the CBD’s ABS provisions in general and by Article 15 in particular.

1 In this context, it is important to note that as of July 2012 the CBD had 193 Contracting Parties, making it an almost universally accepted international agreement.

While the provision to "encourage non-Parties" is mandatory, Article 24 does not specify what means are to be used. This is left to Parties to determine. The means may include active encouragement, for example by pointing out the advantages of Party status or by providing technical, financial, or institutional support for adherence to the Protocol. Another way to encourage the application of the Protocol's principles might be through the creation of common pools managed through harmonized ABS frameworks.

Furthermore, Article 24 obliges Parties to encourage States that are not Parties to the Nagoya Protocol to provide appropriate information to the Access and Benefit-sharing Clearing-House (ABS CH). The aim here is to gather as much relevant information on ABS frameworks as possible and make it available to all Parties in order to facilitate ABS. According to Article 14(2) and (3) of the Nagoya Protocol, appropriate information to be shared with the ABS CH would include (if available):

- legislative, administrative, and policy measures on ABS;
- information on the national focal point and competent national authority or authorities;
- permits or their equivalent issued at the time of access as evidence of prior informed consent and mutually agreed terms;
- relevant competent authorities of indigenous and local communities, and information as so decided;
- model contractual clauses;
- methods and tools developed to monitor genetic resources; and
- codes of conduct and best practices.

Article 25
Financial Mechanism and Resources

1. **In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.**
2. **The financial mechanism of the Convention shall be the financial mechanism for this Protocol.**
3. **Regarding the capacity-building and development referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need of developing country Parties, in particular the least developed countries and small island developing States among them, and of Parties with economies in transition, for financial resources, as well as the capacity needs and priorities of indigenous and local communities, including women within these communities.**
4. **In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed countries and small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building and development requirements for the purposes of the implementation of this Protocol.**
5. **The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.**
6. **The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and other resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.**

A. Background

Article 25 of the Nagoya Protocol builds the basis to provide financial assistance to developing country Parties and to Parties with economies in transition for the implementation of the Protocol. The underlying rationale of this provision is that Parties with limited capacity need assistance if they are to comply with their obligations under the Protocol. Such compliance is in the interest not only of the Parties concerned but also of the entire community of Parties to the Nagoya Protocol. In order to operationalize the Nagoya Protocol, all Parties need to be in a position to implement it at the national level.

Article 25 addresses two basic issues:

- the provision of financial assistance through the financial mechanism of the Convention on Biological Diversity (CBD), and
- the provision of financial assistance by developed countries through other bilateral, regional, and multilateral channels.

For both sources of financial assistance, developed country Parties assume the role of donors and the developing country Parties and the Parties with economies in transition are designated as recipients. The countries that comprise the category "developed countries" are, for the purposes of financial resources and mechanism in the context of the CBD – and, by implication, its protocols – to be found in a list adopted by the CBD Conference of the Parties (COP) at its first meeting (Decision I/2, Annex II). There are no corresponding lists of "developing countries", "least developed countries", or "economies in transition".

Article 25 is closely linked to the corresponding provisions of the CBD, namely Articles 20 (Financial Resources) and 21 (Financial Mechanism). Article 25 must therefore be read in conjunction with these CBD provisions. Paragraphs 1 and 4 of Article 25 refer to Article 20 of the CBD, and Paragraphs 2, 3, and 5 refer to Article 21. Paragraph 6 reiterates and refines the concept embodied in Article 20(3) of the CBD.[1] In this context, it is worth mentioning that the text in this Article is very similar to Article 28 of the Cartagena Protocol on Biosafety.

B. Explanation

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

Article 25(1) refers to all aspects of Article 20 of the CBD. In seven paragraphs, Article 20 of the CBD sets out a wide range of obligations and guidelines, covering:

- national financing activities;
- the provision of new and additional resources by developed country Parties to developing countries;
- the provision of funds through bilateral or multilateral channels;
- the link between developing countries' implementation of the CBD and the funding received for this purpose;
- consideration of the special dependence of developing countries on biological diversity; and
- the special consideration to be given to the situation of developing countries.

The wording of Article 25(1) is taken verbatim from Article 28(1) of the Cartagena Protocol on Biosafety. Under that Protocol this provision represented a compromise between countries that wanted to include a strong obligation to provide financial resources and those that were disinclined to include a provision of this type.

1 See Glowka et al., 1994, pp. 100–08, for an in-depth analysis of Articles 20 and 21 of the CBD.

Article 25(1) provides that the Parties shall "take into account" the provisions of Article 20 of the CBD in "considering" financial resources for the implementation of the Nagoya Protocol. This wording softens the obligation of potential donor countries in two respects:

- they are not obliged to provide financial resources but to consider the issue of financial resources, and
- although Article 20 of the CBD does not directly apply to the provision of financial resources under the Protocol, it is to be "taken into account" in this context (for example, if a specific issue is not addressed by Article 25).

The open wording of Article 25(1) also takes into account the fact that all provisions of Article 20 of the CBD are not equally relevant to the issue of access and benefit-sharing (ABS), but they should be considered to the extent that they have a bearing on this issue.

As a result of the general reference to Article 20 of the CBD, there is certain repetition of the concepts set out in Article 25 of the Nagoya Protocol. Thus Article 25(6) corresponds to Article 20(3) of the CBD, and Article 25(4) corresponds to Article 20(5) of the CBD, although the provisions of the Nagoya Protocol under these two articles are more detailed.

2. The financial mechanism of the Convention shall be the financial mechanism for this Protocol.

Article 25(2) refers to Article 21 of the CBD, which provides for the establishment and function of the financial mechanism under the CBD. It designates the financial mechanism of the CBD as the financial mechanism of the Nagoya Protocol, through the institutional structure entrusted with its operation. The institutional structure referred to is the Global Environment Facility (GEF), which was designated as the financial mechanism of the CBD in accordance with its Article 39 and relevant decisions of the CBD COP.

Box 30: The Global Environment Facility and the Nagoya Protocol Implementation Fund

The Global Environment Facility is an independent financial organization established in 1991 to address global environmental issues. It provides grants to developing countries and countries with economies in transition for projects related to biodiversity, climate change, international waters, land degradation, the ozone layer, and persistent organic pollutants. These projects benefit the global environment, linking local, national, and global environmental challenges and promoting sustainable livelihoods. The GEF has 182 member governments and co-operates with many international institutions, civil society organizations,the private sector, and several United Nations agencies such as the UN Development Programme, the UN Environment Programme, the World Bank, the UN Food and Agriculture Organization, and the UN Industrial Development Organization. Besides being the financial mechanism for the CBD, the GEF also serves as the mechanism for the United Nations Framework Convention on Climate ▶

Change, the Stockholm Convention on Persistent Organic Pollutants, and the United Nations Convention to Combat Desertification. Furthermore, it provides grants to developing countries and countries with economies in transition for a multitude of environmental projects.

Source: Global Environment Facility. *About GEF.* available at www.thegef.org/gef/whatisgef.

The Nagoya Protocol Implementation Fund (NPIF) is a multidonor trust fund that started operations on May 2011. The World Bank serves as the trustee of the NPIF, in accordance with the Bank's policies and procedures.

The NPIF supports signatory countries and those in the process of signing the Nagoya Protocol that intend to ratify it in order to accelerate its ratification and implementation. It also supports existing opportunities leading to development and implementation of concrete ABS agreements with involvement of the private sector. The projects funded under the NPIF encourage engagement with private sector entities interested in exploring the economic potential of genetic resources and facilitating the transfer of appropriate technologies. Through this type of project, countries should be generating additional information that can help them understand their capacities and needs on ABS, with a focus on the provisions from existing policies, laws, and regulations affecting genetic resources.

Source: www.thegef.org/gef/content/nagoya-protocol-implementation-fund-brochure.

3. Regarding the capacity-building and development referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need of developing country Parties, in particular the least developed countries and small island developing States among them, and of Parties with economies in transition, for financial resources, as well as the capacity needs and priorities of indigenous and local communities, including women within these communities.

Article 25(3) relates again to the financial mechanism of the Nagoya Protocol. It is linked to Article 21 of the CBD under which the CBD COP is assigned the authority of determining the policy of the financial mechanism. Under the Nagoya Protocol, the Conference of the Parties serving as the meeting of the Parties (COP/MOP) will provide guidance with respect to the financial mechanism as it relates to the Protocol. However, this guidance is subject to consideration by the CBD COP. As a consequence, the ultimate authority to determine the guidance to the financial mechanism with respect to the Nagoya Protocol as well as with respect to the CBD rests with the CBD COP. This is a key area of the Nagoya Protocol in which the CBD Conference of the Parties retains competence.

Furthermore, Article 25(3) specifies that in providing guidance to the financial mechanism, as it relates to the Nagoya Protocol, the COP of the CBD – on the recommendation of the COP/MOP – shall take into account the capacity-building and development needs and priorities as set out in Article 22 of the Nagoya Protocol. In this context, attention shall be given by the COP/MOP to the specific capacity-building and development needs of:

- developing country Parties, in particular the least developed countries and small island developing States;
- parties with economies in transition; and
- indigenous and local communities, including women within these communities.

These needs shall be identified in national capacity self-assessments (Article 22(3)). A non-exhaustive list of key areas and measures for capacity-building and development is provided in Articles 22(4) and (5).

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed countries and small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building and development requirements for the purposes of the implementation of this Protocol.

Article 25(4) relates to the financial resources for implementation of the Nagoya Protocol and is linked to Article 20 of the CBD. It recognizes that certain groups of Parties (including Parties with economies in transition) may have specific needs in capacity-building and development that need to be reflected in the provision of financial resources for implementation of the Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis,* to the provisions of this Article.

Article 25(5) relates to the financial mechanism. It refers to the provision of guidance by the CBD COP to the financial mechanism, which is based on Article 21(2) and (3) of the CBD. Article 21(2) of the CBD stipulates that the CBD COP, at its first meeting, "shall determine the policy, strategy and programme priorities, as well as detailed criteria and guidelines for eligibility for access to and utilization of the financial resources" of the mechanism. In accordance with Article 21(3) of the CBD, these criteria and guidelines are reviewed periodically.

At each of the meetings of the CBD COP held since the Convention's entry into force, a decision has been adopted addressing this issue. Thus there already exists a body of guidance to the financial mechanism from the CBD before the adoption of the Nagoya Protocol. Some of this guidance specifically relates to ABS – for instance, Decision X/24 (Review of Guidance to the Financial Mechanism) in Paragraph 4.11(b) of the Annex specifically refers to capacity-building on ABS, while Decision X/25 (Additional Guidance to the Financial Mechanism) in Paragraph 13 "invites the Global Environment Facility to provide financial support to Parties to assist with the early ratification of the Nagoya Protocol (...) and its implementation".

It is important to note that such guidance shall be applied *mutatis mutandis*. This means that the differences between the CBD and the Nagoya Protocol that are relevant to the issue must be taken into consideration when applying the guidance to the financial mechanism. In concrete terms, the guidance may be modified in applying it to the Nagoya Protocol to the extent necessary to adapt it to the specificities of the Protocol.

Future guidance to be developed under Article 25(3) for consideration by the CBD COP will also apply. Article 25(5) thus ensures a strong link between the GEF policies of the CBD COP in relation to the CBD and in relation to the new requirements of the Nagoya Protocol.

Box 31: Meaning of *Mutatis Mutandis*

Mutatis mutandis (also *mutatis mutandi*) is a Latin term meaning "with the necessary changes being made" or "things being changed that are to be changed". In a general sense, *mutatis mutandis* means that the same applies to the subsequent subject, although with any requisite changes made as necessary. It is usually used where a legal provision that normally applies to something else is to be applied to the matter in question by making the relevant changes. As a consequence, it connotes a similarity, not a literal sameness. In a legal context, this can mean that

- rules may be modified in applying them to the Nagoya Protocol, to the extent necessary to adapt them to the specificities of the Protocol; and
- general principles or ideas apply, appropriately adapted to the differing subject matter.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and other resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article 25(6) restates the substance of Article 20(3) of the CBD, according to which financial and technological assistance may be available to developing country Parties and Parties with economies in transition from developed country Parties on a bilateral basis, for example through official development assistance. Such assistance may also be available through regional or multilateral channels – such as regional development banks or the World Bank.

Article 26
Conference of the Parties Serving as the Meeting of the Parties to this Protocol

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

   (a) Make recommendations on any matters necessary for the implementation of this Protocol;

   (b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

   (c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

   (d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 29 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

   (e) Consider and adopt, as required, amendments to this Protocol and its Annex, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

   (f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis,* under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

▶

6. **The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat and held concurrently with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held concurrently with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.**

7. **Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.**

8. **The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.**

A. Background

Multilateral environmental agreements generally establish a governing body known as the Conference of the Parties (COP) or meeting of the Parties (MOP) to steer and supervise the entire process of implementing and further developing the treaty. These bodies consist of representatives of all States that are Party to the treaty in question, and they meet on a periodic basis. In addition, observers – including non-Parties to the treaty and non-governmental organizations – may attend their sessions.

Article 26 of the Nagoya Protocol establishes the highest organ of the Protocol, the Conference of the Parties serving as the meeting of the Parties (COP/MOP). Given the fact that certain issues under the Nagoya Protocol have not yet been fully resolved (for example, the establishment of a potential global multilateral benefit-sharing mechanism under Article 10 or the assessment and review of the Protocol's effectiveness under Article 31), the decision-making role of the governing body will be particularly important. Furthermore, the COP/MOP plays an important role, as it will keep implementation of the Protocol under review (Article 26(4) of the Nagoya Protocol).

As the Nagoya Protocol is established under the Convention on Biological Diversity (CBD), a relationship between the governing body of the Protocol and that of the CBD is a given. As a consequence, the COP to the CBD will also serve as the meeting of the Parties to the Nagoya Protocol. This gives rise to

the use of the convoluted term "Conference of the Parties serving as the meeting of the Parties to this Protocol" used in Article 26 and other provisions of the Nagoya Protocol.

Article 26 and other institutional provisions (see also Articles 27 and 28) assign the functions to be carried out under the Nagoya Protocol to the existing bodies of the CBD in order to:

- achieve greater coherence and efficiency between the two instruments, while ensuring the necessary independence of the work under the Protocol;
- avoid the proliferation of new institutions; and
- minimize operational costs.

Still, the COP serving as the meeting of the Parties is considered a distinct and independent body for all practical purposes, including guidance to the financial mechanism (see Article 25), the costs of Secretariat services to the extent that they cannot be split up between the CBD and the Nagoya Protocol (see Article 28), and the concurrent timing of ordinary meetings of the COP and the COP/MOP to this Protocol (see Article 26(6)).

Since the Nagoya Protocol is a separate legal instrument, the functions of the COP/MOP to the Nagoya Protocol differ to some extent from those of the COP of the CBD. In addition, the membership of the two bodies is not entirely the same: not all Parties to the CBD (who are represented in the COP of the CBD) may necessarily become Parties to the Nagoya Protocol, and those that do not become Parties will not be entitled to participate in the decision-making of the COP/MOP to the Nagoya Protocol (see Article 24).

Finally, it is important to note that the same approach as under Article 26 was already taken by Article 29 of the Cartagena Protocol on Biosafety. In fact both provisions are nearly identical, with an important difference in Paragraph 6 (see below).

B. Explanation

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

Article 26(1) establishes the principle that the CBD COP shall serve as the MOP. Article 26(2)-(8) put this into practice by laying down the mode of operation of the COP/MOP to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

Article 26(2) addresses who is entitled to participate in the COP/MOP to the Nagoya Protocol and thus also participate in the decision-making process regarding the Protocol. In meetings held by the Conference of the Parties in its capacity as COP/MOP to the Nagoya Protocol, States and regional economic integration organizations that are Parties to the CBD but not to the Nagoya Protocol may

participate as observers. Observer status is governed by Rules 6 and 7 of the Rules of Procedure of the CBD COP[1]: it means participation (usually only after Parties have spoken) without the right to vote. Only Parties to the Nagoya Protocol may vote and thus take part in the adoption of the decisions of the COP/MOP to the Nagoya Protocol.[2]

This is a restatement of the principle set out in Article 32(2) of the CBD. Although not entitled to vote, observers may participate in the discussions, make interventions, and submit proposals. In practice, some observers play a very active role in the discussions.

It is also important to note that observer status for States that are not Parties to the CBD is addressed by Article 26(8).

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

Article 26(3) refers to the Bureau of the COP/MOP to the Nagoya Protocol. The "Bureau" performs functions relating to the meetings of the COP/MOP, for example:

- providing guidance to the Secretariat for the preparation and conduct of the meetings of the COP/MOP;
- organizing the work of the meetings; and
- chairing informal negotiations during meetings of the COP/MOP.

Since the COP of the CBD serves as the meeting of the Parties to the Protocol, it follows that the Bureau of the CBD COP serves also as the Bureau of the COP/MOP. This means that as a general rule, the Bureau of the COP/MOP will have the same composition as the Bureau of the CBD COP, as laid down in the Rules of Procedure of the CBD. The Bureau has 11 members: the President and 10 Vice-Presidents (one of whom also acts as Rapporteur), representing the five regions of the United Nations.[3] It is elected at the beginning of each ordinary meeting of the COP. The President then serves from the beginning of that meeting until the beginning of the next ordinary meeting, while the Vice-Presidents serve from the closure of that meeting to the closure of the next meeting. The Bureau also serves at any extraordinary meeting of the COP held during its term of office. No Bureau member may serve for more than two consecutive terms (Rule 21 of the Rules of Procedure of the CBD COP).

In accordance with the overall aim to streamline the institutions and procedures of the CBD and the Nagoya Protocol while ensuring the necessary independence of the Protocol, Article 26(3) provides that if the Bureau of the COP includes one or more members representing States that are not Parties to the Protocol, those members shall be replaced with representatives of Parties to the Protocol when the COP meets as the COP/MOP. In keeping with the Rules of Procedure, which apply *mutatis mutandis* to

1 Rules of Procedure for the Meetings of the Conference of the Parties to the CBD, Annex to CBD COP 1 Decision I/1, as amended by CBD COP 5 Decision V/20.

2 It is important to note that the CBD Parties have not agreed on a voting rule for substantive decision-making and thus such decisions need to be based on consensus.

3 The five UN Regions are Africa, Asia, Eastern Europe, Latin America, and Western Europe and others. Their representation is laid down in Rule 21 of the Rules of Procedure for the Meetings of the Conference of the Parties to the CBD, Annex to CBD COP 1 Decision I/1, as amended by CBD COP 5 Decision V/20.

the Nagoya Protocol, the representation of the five UN regions must be maintained if a replacement is made in accordance with Article 26(3) (see explanation of *mutatis mutandis* under Article 25(5)).

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 29 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its Annex, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

Article 26(4) sets out the functions of the COP/MOP.[4] The following distinctions can be made between:

- the general function of the COP/MOP, which is to keep under regular review the implementation of the Nagoya Protocol and make the necessary decisions to promote its effectiveness (see the introductory sentence of the chapeau of Article 26(4));
- a number of specific functions assigned to it in other Articles of the Nagoya Protocol as well as the functions listed in Article 26(4) (see the second sentence of the chapeau and Subparagraphs (a) – (e)); and
- other functions "as may be required for the implementation of this Protocol" (see Subparagraph (f)).

As a consequence, Article 26(4) ensures that any present and future function needed for the implementation of the Nagoya Protocol may be carried out by the COP/MOP, even where this is not specifically listed.

4 It is interesting to note that the functions of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol as set out in Article 26(4) correspond to those provided in Article 23(4) for the CBD COP, as well as the functions listed in Article 29(4) for the Conference of the Parties serving as the meeting of the Parties of the Cartagena Protocol on Biosafety.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis,* under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

This provision refers to the Rules of Procedure of the COP of the CBD and the Financial Rules of the CBD.[5] The Rules of Procedure govern, for example, the timing and preparation of the CBD COP, the conduct of COP meetings, and the decision-making procedures in the COP. The Financial Rules govern the Trust Fund that is used to finance the administration of the CBD, including the functions of the CBD Secretariat.

Article 26(5) foresees that the Rules of Procedure of the CBD COP and the Financial Rules of the CBD shall be applied *mutatis mutandis* to the COP/MOP to the Nagoya Protocol – that is, with modifications if necessary (see explanation of *mutatis mutandis* under Article 25(5)).

However, the COP/MOP may, by consensus, decide against the application of the Rules in particular instances. Also, in a number of instances, the Nagoya Protocol itself establishes provisions regarding issues addressed by the Rules of Procedure. For example, Article 26 itself addresses the members of the Bureau (Article 26(3)), ordinary and extraordinary meetings of the COP/MOP (Article 26(6) and (7)), and observers (Article 26(2) and (8)). To the extent that such provisions differ from the Rules of Procedure, they take precedence.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat and held concurrently with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held concurrently with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

Article 26(6) clarifies the meeting arrangements of the COP/MOP to the Nagoya Protocol. It aims to harmonize the schedule for these meetings with those of the CBD COP. It therefore reflects again the approach of utilizing the existing rules and bodies of the CBD as far as possible while retaining sufficient independence for the Nagoya Protocol.

It is important to note that the meetings of the COP/MOP to the Nagoya Protocol shall be held concurrently with ordinary meetings of the CBD COP – that is to say, simultaneously – unless otherwise determined by the Parties at the COP/MOP.[6] In this point, the Nagoya Protocol differs considerably from the Cartagena Protocol on Biosafety, which foresees that its meetings will be held in conjunction with ordinary meetings of the CBD COP, so back-to-back rather than simultaneously (see Article 29(6) of the Cartagena Protocol). However, many negotiators of the Nagoya Protocol feared that a further

5 CBD COP 1 Decision I/6, as amended by CBD COP 3 Decision III/1.

6 The same approach is taken by the Kyoto Protocol under the United Nations Framework Convention on Climate Change.

extension of the total period of time spent for the CBD COP[7] would cause serious funding as well as capacity problems amongst Parties as well as observers.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

Article 26(7) is self-explanatory. It provides for the possibility to hold extraordinary meetings of the COP/MOP – that is, outside the schedule foreseen under Article 26(6). An extraordinary meeting can be called by the COP/MOP itself but also by any Party to the Nagoya Protocol. It requires:

- a written request by a Party to the Nagoya Protocol;
- the request is supported by at least one-third of the Parties to the Protocol; and
- the necessary support is obtained within six months of the request being communicated to the Parties by the CBD Secretariat.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 26(8) grants observer status to the United Nations, its specialized agencies, and the International Atomic Energy Agency, as well as to member and observer States of these organizations that are not Parties to the CBD. Thus, States that are not Parties to the CBD may be represented as observers at meetings of the COP/MOP to the Nagoya Protocol. As discussed above, States that are Parties to the CBD but not to the Nagoya Protocol are accorded observer status under Article 26(2). The implications of such observer status are discussed under Article 26(2).

Any governmental or non-governmental body or agency[8] may also apply to the CBD Secretariat for observer status. This is granted if the body in question is qualified in matters covered by the Nagoya

7 Current meetings of the CBD COP including the COP/MOP to the Cartagena Protocol already last three weeks.

8 The terms used in Article 26(8) have been broadly construed in the CBD: nongovernmental agencies or bodies may include environment, consumer, or development organizations; indigenous and local communities' groups; academic or research institutions; industry associations; or individual companies.

Protocol unless one-third of the Parties present at a particular meeting object. The mention of Parties "present" indicates that at each meeting of the COP/MOP, an objection can only be made by Parties attending that meeting and thus only with respect to the presence of a non-governmental body or agency at that meeting. The acceptance or rejection of a body or agency is therefore only valid for that particular meeting. At the next meeting, it is possible that a different decision could be taken with respect to the same body or agency, depending on which Parties are present.

Article 27
Subsidiary Bodies

1. **Any subsidiary body established by or under the Convention may serve this Protocol, including upon a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any such decision shall specify the tasks to be undertaken.**
2. **Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by Parties to this Protocol.**
3. **When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.**

A. Background

Article 27 of the Nagoya Protocol mirrors Article 30 of the Cartagena Protocol on Biosafety, with an exception in Paragraph 1. It addresses:

- the performance of functions by subsidiary bodies of the Convention on Biological Diversity (CBD) in relation to the Nagoya Protocol (Article 27(1));
- which States are entitled to participate in the proceedings of subsidiary bodies when they are performing functions in relation to the Nagoya Protocol (Article 27(2)); and
- who is entitled to act as an officer (or "bureau member") of a subsidiary body when it is performing functions in relation to the Nagoya Protocol (Article 27(3)).

At present there is only one standing subsidiary body established by the CBD: the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), established under Article 25 of the CBD. Other subsidiary bodies have been established by the Conference of the Parties (COP) to deal with specific issues as they arise. These are called "ad hoc open-ended working groups" because they are established for a limited mandate and period of time and because they are open to all Parties as well as to observers. One example is the Ad Hoc Open-ended Working Group on Article 8(j) of the CBD.

B. Explanation

1. Any subsidiary body established by or under the Convention may serve this Protocol, including upon a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any such decision shall specify the tasks to be undertaken.

According to Article 27(1), the subsidiary bodies of the CBD may be assigned functions related to the Nagoya Protocol. Assignments can be made, amongst others, upon decisions of the Conference of the Parties serving as the meeting of the Parties (COP/MOP). It is interesting to note that Article 27(1) uses the formulation "including upon a decision". This seems to indicate that other ways exist in which functions related to the Nagoya Protocol could be assigned to subsidiary bodies, for example through the CBD COP.

Such decisions shall specify the functions that the body shall exercise in the context of the Nagoya Protocol. The bodies that might be affected by this provision are the SBSTTA, the Ad Hoc Open-ended Working Group on Article 8(j), and the Ad Hoc Open-ended Working Group on Review of Implementation.

Box 32: Functions of SBSTTA under Article 25 CBD

The functions of the Subsidiary Body on Scientific, Technical and Technological Advice are contained in Article 25 of the CBD. Accordingly, it will fulfil its mandate under the authority of, and in accordance with, guidance laid down by the CBD COP, and upon its request. Pursuant to Article 25(3) of the CBD, the functions, terms of reference, organization, and operation of the SBSTTA may be further elaborated on and submitted for approval by the COP.

Appendix A of the consolidated *Modus Operandi* of the SBSTTA (included in Decision VIII/10, Annex III) provides a list of its functions:

- provide scientific and technical assessments of the status of biological diversity;
- prepare scientific and technical assessments of the effects of types of measures taken in accordance with the provisions of the CBD;
- identify innovative, efficient, and state-of-the-art technologies and know-how relating to the conservation and sustainable use of biological diversity and advise on the ways and means of promoting development and/or transferring such technologies;
- identify new and emerging issues relating to the conservation and sustainable use of biodiversity;
- provide advice on scientific programmes and international co-operation in research and development related to conservation and sustainable use of biological diversity; and
- respond to scientific, technical, technological, and methodological questions that the COP and its subsidiary bodies may put to the body.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by Parties to this Protocol.

Under Article 27(2), when a subsidiary body of the CBD exercises functions in relation to the Nagoya Protocol, only Parties to this Protocol may take part in the adoption of any decision the subsidiary body reaches. This follows the approach taken in relation to participation in meetings of the COP/MOP under Article 26(2). Parties to the CBD that are not Parties to the Protocol may nonetheless participate as observers.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

The Rules of Procedure of the CBD COP also apply, as appropriate, to its subsidiary bodies. The composition and functions of the Bureau of the CBD COP and the COP/MOP have been described under Article 26(3) above. Accordingly, when a subsidiary body of the CBD carries out functions under the Nagoya Protocol, any member of the Bureau who does not represent a Party to the Nagoya Protocol must be replaced by a representative of a Party to this Protocol.

Article 28
Secretariat

1. **The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.**
2. **Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis,* to this Protocol.**
3. **To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.**

A. Background

Article 28 of the Nagoya Protocol is copied verbatim from Article 31 of the Cartagena Protocol on Biosafety and introduces provisions for the Secretariat to the Nagoya Protocol. Experience has demonstrated that an international treaty can only be implemented satisfactorily if it is serviced by a secretariat carrying out a number of functions, such as administering the treaty and acting as day-to-day contact point for the Parties, international organizations, and others.

B. Explanation

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

Article 28(1) foresees that the Secretariat to the Convention on Biological Diversity (CBD) shall serve as the Secretariat to the Nagoya Protocol. The CBD Secretariat is established under Article 24 of the CBD. In accordance with a decision by the Conference of the Parties (COP) of the CBD, the Secretariat is provided by the United Nations Environment Programme (Decision I/4) and financed by the Parties through their contributions to the Trust Fund. The offices of the CBD Secretariat are located in Montreal, Canada (Decision II/19). Rules 27 and 28 of the Rules of Procedure of the CBD COP, which lay down practical arrangements for the CBD Secretariat, will also apply to the Secretariat to the Nagoya Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis,* to this Protocol.

Article 28(2) refers to Article 24(1) of the CBD, which introduces the functions of the CBD Secretariat. It provides that the functions of the Secretariat to the Nagoya Protocol shall be the same as those of

the CBD Secretariat. The term clarifies that the Secretariat's functions regarding the Nagoya Protocol may, however, be modified in order to meet specific needs and obligations of the Nagoya Protocol (see explanation of under Article 25(5)). Accordingly, the Secretariat's functions shall be:

- to arrange for and service meetings of the Conference of the Parties serving as the meeting of the Parties (COP/MOP);
- to perform the functions assigned to it by the Nagoya Protocol (for example, the establishment and operationalization of the ABS Clearing-House as part of the CBD clearing–house mechanism, Article 14(1));
- to prepare reports on the execution of its functions under the Nagoya Protocol and present them to the COP/MOP;
- to coordinate with other relevant international bodies and, in particular, to enter into such administrative and contractual arrangements as may be required for the effective discharge of its functions; and
- to perform such other functions as may be determined by the COP/MOP.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 28(3) introduces the principle of separate budgets. It clarifies that distinct and specific costs arising from the Secretariat's service to the Nagoya Protocol are to be covered by the Parties to the Protocol only and not by the overall budget of the CBD to which all CBD Parties contribute. The first COP/MOP has to decide on budgetary arrangements.

The same principle of separate budgets is applied with regard to the Cartagena Protocol on Biosafety. While it is not easy to separate and share costs according to CBD and Protocol functions, experience from the Cartagena Protocol proves the practicability of this approach.

In practice, the Secretariat itself therefore decides about the distinction of CBD's Secretariat costs and those arising from the Nagoya Protocol and presents the budget plans to both the CBD COP and the COP/MOP to the Nagoya Protocol. The wording of the first sentence of Article 28(3) indicates that to the extent that the costs are not distinct or cannot be distinguished, they will be met by the CBD Parties rather than only by the Parties to the Nagoya Protocol.

Article 29
Monitoring and Reporting

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals and in the format to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement this Protocol.

A. Background

Article 29 provides a mechanism for the Parties to monitor and report on their implementation of the Nagoya Protocol. The obligation to monitor and prepare reports on implementation for consideration by the governing body of a treaty has become a standard feature of multilateral environmental agreements. However, the formula used in describing the subject of these reports varies from treaty to treaty. Article 29 imposes two obligations on the Parties:

- to monitor their implementation of the Nagoya Protocol, and
- to report regularly to the Conference of the Parties serving as the meeting of the Parties (COP/MOP) on measures taken to implement the Nagoya Protocol.

Monitoring and reporting undertaken under Article 29 will support the review of the effectiveness and collective implementation of the Nagoya Protocol by its Parties, which is foreseen by the COP/MOP (see Articles 18(4), 26(4), and 31). In principle, Article 29 might also support a future compliance mechanism by identifying instances where Parties have not complied with their obligations under the Nagoya Protocol.

B. Explanation

The obligation of Parties to monitor and report on their implementation of the Nagoya Protocol is a logical consequence of the duty of States to implement international obligations that they have accepted by becoming Party to the Protocol. Monitoring is perhaps particularly required in cases, such as the Nagoya Protocol, where many of the obligations are not precise and clear enough but rather conditional and thus require domestic measures of a legislative, administrative, policy and institutional nature.

Under Article 29, the obligations are to collect information on domestic measures taken to implement the Protocol and to share this information with the COP/MOP. The reports will normally be presented through the Secretariat to the Nagoya Protocol to the COP/MOP, where they will be discussed.

The intervals at which reports are to be submitted will be determined by the COP/MOP. For example, it may be decided that the Parties to the Nagoya Protocol are required to submit their reports at each

ordinary meeting of the COP/MOP. The COP/MOP will also determine the format and content of the reports. This will help to ensure that information is provided in a comparable and therefore useful format.

While the obligations of monitoring and reporting are separate, in practice they reinforce one another: Monitoring will provide information needed for the reporting; at the same time, the requirement to submit reports will trigger monitoring activities. As a side effect, reporting may also lead to useful feedback regarding the way monitoring has operated, so that it can be improved in the future.

Article 30
Procedures and Mechanisms to Promote Compliance with this Protocol

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under Article 27 of the Convention.

A. Background

Article 30 addresses the need to develop a mechanism to promote compliance of Parties with their international obligations under the Nagoya Protocol. It provides that procedures and mechanisms to promote compliance will be considered and approved at the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP/MOP).

Pending the entry into force of the Nagoya Protocol (see Article 33) and in preparation for the first COP/MOP, the Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol was mandated to discuss co-operative procedures and institutional mechanisms to promote compliance with the Protocol and to address cases of non-compliance.

B. Explanation

The focus of the compliance mechanism foreseen in Article 30 is on the compliance of individual Parties with their obligations under the Nagoya Protocol (including the ones established under Articles 15 – 18). Therefore it has to be distinguished from other compliance provisions that aim at supporting the observance of domestic access and benefit-sharing (ABS) regimes (Articles 15, 16 and 17) and enforcing ABS contractual arrangements (Article 18).

The compliance mechanism foreseen in Article 30 may help to inform the effectiveness review to be undertaken by the COP/MOP (see Articles 18(4), 26(4), and 31). At the same time, national reports submitted by each Party to the COP/MOP in accordance with Article 29 are likely to provide an important basis for the work of a future compliance mechanism. In principle, such a mechanism may identify instances where Parties have not complied with their obligations under the Protocol. The consequence of a finding of non-compliance will depend upon the content of the compliance mechanism that is adopted.

Article 30 of the Protocol takes the form of a so-called “enabling provision”. This means that it does not yet establish a compliance mechanism, but it provides a basis and framework for its future

establishment by the COP/MOP. This has been a common way of approaching the issue of compliance in multilateral environmental agreements, such as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Article 34), the Kyoto Protocol to the United Nations Framework Convention on Climate Change (Article 18), the Stockholm Convention on Persistent Organic Pollutants (Article 17), the International Treaty on Plant Genetic Resources for Food and Agriculture (Article 21) and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, amongst others.

Box 33: Main Features of Compliance Mechanisms Established under Other Multilateral Environmental Agreements

- Montreal Protocol on Substances that Deplete the Ozone Layer to the Vienna Convention

Among the multilateral environmental agreements that are in force, the most mature compliance mechanism is that of the Montreal Protocol on Substances that Deplete the Ozone Layer. It was developed on the basis of Article 8 of the Montreal Protocol, and it operates independently of, and without prejudice to, the dispute settlement procedure as laid down in Article 11 of the Vienna Convention for the Protection of the Ozone Layer, which is the parent treaty to the Protocol.

The core of the mechanism is the Implementation Committee, consisting of representatives of 10 Parties who are elected by the meeting of the Parties based on equitable geographical distribution. The term of office is two years, with a possibility of serving for two consecutive terms. The Committee meets twice a year. Any Party may, through the Secretariat, bring to the attention of the Committee any reservations regarding another Party's implementation of its obligations under the Protocol, as well as any problems it experiences regarding its own implementation. In addition, the Secretariat may bring to the attention of the Committee cases of possible non-compliance it becomes aware of if it has not received a satisfactory explanation from the Party concerned.

The Implementation Committee considers the matters submitted to it. It identifies possible causes for non-compliance. The Party or Parties concerned are entitled to participate in the deliberations of the Committee. Upon the invitation of the Party concerned, the Committee may gather further information on the matter. Based on its considerations, the Committee makes recommendations for an amicable solution of the problem. It submits a report to the meeting of the Parties, outlining the recommendations made. The report is made publicly available except where it contains confidential information submitted by a Party. The Party or Parties concerned may not participate in the adoption of the recommendations or in the formulation of the report, and they must subsequently inform the meeting of the Parties of any measures adopted to improve the situation, in accordance with the recommendations.

- Kyoto Protocol to the United Nations Framework Convention on Climate Change

The compliance mechanism for the Kyoto Protocol was adopted and established in 2001 through Decision 24/CP7. The Compliance Committee consists of a Facilitative Branch (10 members), an Enforcement Branch (10 members), a Bureau (4 members: President and Vice President of each Branch), and the Plenary (20 members).

▶

The functions of the Facilitative Branch are to provide advice and facilitation to Parties in implementing the Kyoto Protocol, promote compliance by Parties with their commitments, and address certain questions of implementation and facilitation of compliance as specified in the Decision. The Enforcement Branch's function is to determine non-compliance of Annex I Parties with respect to quantified emissions limitation or reduction commitments and methodological and reporting requirements.

The consequences of non-compliance include a declaration of non-compliance, the development of a Compliance Plan, and suspension for the Party found in non-compliance of the right to use the flexibility mechanisms established under the Kyoto Protocol, including the trading of emissions. There is no provision for appeal, except on grounds of procedure.

- Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal

The mechanism for promoting the implementation of and compliance with the obligations set out under the Basel Convention was established in 2002 by Decision VI/12 of the sixth meeting of the Conference of the Parties. Its objective is to facilitate, promote, monitor, and aim to secure the implementation of and compliance with the obligations under the Convention. According to the terms of reference, the nature of the mechanism is non-confrontational, transparent, cost-effective, and preventive in nature, simple, flexible, non-binding, and oriented in the direction of helping Parties to implement the provisions of the Basel Convention. It is also intended to promote co-operation between all Parties.

A Committee for administrating the mechanism is established and consists of 15 members nominated by the Parties and elected by the Conference of the Parties, based on equitable geographical representation of the five regional groups of the United Nations.

Submissions may be made to the Committee by a Party with regards to itself, by a Party that has concerns or is affected by a failure to comply by another Party with whom it is directly involved under the Convention, and finally, only in specific cases, by the Secretariat.

- Cartagena Protocol on Biosafety to the Convention on Biological Diversity

The compliance mechanism of the Cartagena Protocol on Biosafety is based on the enabling provision in Article 34 of the Protocol, corresponding *ad verbatim* to Article 30 of the Nagoya Protocol. It was established in 2004 by Decision BS-I/7 of the first meeting of the Conference of the Parties to the CBD serving as the meeting of the Parties to the Protocol. The mechanism was supplemented in 2010 by Decision BS-V/1 of the COP/MOP.

In conformity with most other compliance mechanisms, the mechanism's objective is to address cases of non-compliance and to provide advice or assistance. Equally, its nature is simple, facilitative, non-adversarial, and co-operative and is guided by the principles of transparency, fairness, expedition, and predictability. It shall pay particular attention to the special needs of developing country Parties and Parties with economies in transition, taking into full consideration the difficulties they face in implementation of the Protocol.

A Committee of 15 members (nominated and elected by the Parties: 3 members from each of the five regional groups of the United Nations) carries out the functions of the mechanism. Members shall have legal or technical expertise and serve objectively and in a personal capacity. The Committee shall receive, through the Secretariat, any submissions relating to compliance either from a Party with respect to itself or from a Party that is affected or likely to be affected with respect to another Party. The Committee may, however, *inter alia,* also review general issues of compliance.

The Committee shall consider relevant information from concerned Parties that are furthermore also entitled to participate in the deliberations of the Committee but not in the elaboration and adoption of recommendations of the Committee. It may also seek or receive relevant information from other sources, e.g. the Biosafety Clearing-House and relevant international organizations, and seek expert advice from the biosafety roster of experts. The Committee shall maintain the confidentiality of any information that is confidential under Article 21 of the Protocol.

- International Treaty on Plant Genetic Resources for Food and Agriculture

The fourth session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture adopted Resolution 2/2011 containing Procedures and Operational Mechanisms to Promote Compliance and Address Issues of Non-Compliance. The objective of the mechanism is to promote compliance with all the provisions of the International Treaty and to address issues of non-compliance. These procedures and mechanisms include monitoring and offering advice or assistance, including legal advice or legal assistance, when needed and requested, in particular to developing countries and countries with economies in transition.

A previously established Compliance Committee (2006) continues to carry out its functions in accordance with the specifications adopted in 2011. Its membership is of maximum of 14 members (up to 2 from each region of the Food and Agriculture Organization (FAO) and not more than 1 from a Contracting Party). The members shall be elected for four years by the Governing Body on the basis of up to two nominations from each of the seven FAO regions. Members of the Committee shall have recognized competence in the field of genetic resource or other fields relevant for the International Treaty, including legal or technical expertise, and they shall serve objectively and in their individual capacity.

The Committee shall receive, through the Secretary, any submissions relating to issues of non-compliance from any Contracting Party with respect to itself, any Contracting Party with respect to another Contracting Party, or the Governing Body. If a Party is found in non-compliance, the Committee may provide advice or facilitate assistance (including legal advice or legal assistance), request or assist the Contracting Party concerned to develop an action plan that addresses the issue of non-compliance within a timeframe to be agreed upon between the Committee and the Contracting Party, and invite the Contracting Party to submit progress reports to the Committee on the efforts it is making to comply with its obligations under the International Treaty. In the same manner, the Governing Body may also, upon the recommendations of the Committee, decide to provide assistance, including legal, financial, and technical assistance, or take any other actions it deems appropriate, including for capacity-building, in accordance with the International Treaty and for the fulfillment of its objectives. ▶

An innovative feature of this mechanism is that a Contracting Party may, through the Secretary, send to the Committee statements and questions concerning implementation of its own obligations under the International Treaty. The Committee shall also consider any questions concerning the implementation of obligations under the International Treaty referred to it by decision of the Governing Body. The Committee may reject consideration of any such statement or question, and if that happens it should give the reasons for any such rejection. In the case of these statements or questions, the Committee may limit itself to making recommendations to the Governing Body unless the Governing Body specifically provides otherwise.

Although the precise nature of the compliance mechanism to be adopted under the Nagoya Protocol must await the decision of the COP/MOP, it may be noted at this stage that the core of a compliance mechanism is often a body to which questions and problems regarding individual compliance by a Party with its obligations under a treaty can be referred to; systemic issues of non-compliance – that is, compliance challenges that affect a whole range of Parties – can also be addressed. Options for triggering the mechanism include the Party in relation to itself and a Party in relation to another Party when it is affected by the other Party's non-compliance. In some specific cases, a limited trigger by the Secretariat has also been included as well as by the compliance body itself or the decision-making body. In any case, existing mechanisms under other multilateral agreements restrict access to the compliance body to the Parties to the treaty concerned.

Box 34: Some Possible Elements and Characteristics to be Considered in Development of a Future Compliance Mechanism

Objective: To promote compliance, to address cases of non-compliance, and to provide advice or assistance to Parties to help them comply.

Nature: The mechanism can be legally binding (an amendment to the treaty) or not legally binding (a decision of the governing body). In existing mechanisms, often the following characteristics appear: cost-effective, non-adversarial, non-judicial, and co-operative.

Institutional Structure: A body usually in the form of a small standing committee composed of relevant experts nominated by governments and elected by the COP/MOP, taking into account equitable geographical representation, that will serve in their personal capacity or, alternatively, as government representatives, serving objectively and in the best interests of the Protocol. Parties will have to agree on the number (usually between 10 and 25), and they will have to determine whether the body should be able to vote in the absence of consensus.

Triggers: Different options could include a Party self-trigger, a Party-to-Party trigger, a decision body trigger, a committee trigger, and a Secretariat trigger (limited to certain situations of non-compliance). Moreover, some advocate that members of the public and indigenous and local communities should also be able to invoke the compliance procedures (which is possible in theory, but not common practice under other existing compliance mechanisms (Koester, 2012, note 60)). ▶

Information for Triggering the Procedure: This can include the information provided by the Party in accordance with Article 29. Discussions on this issue often refer to the need to ensure the reliability of such information.

Measures: Facilitative measures often include technical and financial assistance. In some cases Parties can agree to stronger measures, for instance in cases of persistent non-compliance.

By requiring that the COP/MOP consider and approve mechanisms and procedures to promote compliance and address cases of non-compliance at its first meeting, Article 30 provides both a definite mandate to the COP/MOP and a time frame. This makes it a progressive enabling provision. Article 30 requires that these procedures and mechanisms include provisions on advice and assistance, something that can be achieved by a facilitative branch of the mechanism or by a mechanism that is not punitive but facilitative in nature, meaning a mechanism that will aim at facilitating compliance by Parties, therefore providing for measures, different from sanctions, such as financial and technical assistance.

Article 30 also expressly states that future compliance provisions should be separate from the dispute settlement procedure established under Article 27 of the Convention on Biological Diversity (CBD), which also applies to the Nagoya Protocol. Unlike a dispute settlement procedure, a compliance mechanism is basically a multilateral and non-confrontational instrument that deals with potential situations of non-compliance. In the other hand, a dispute settlement procedure constitutes a legal and institutional framework for solving conflicts or disagreements between two or more Parties in relation with the interpretation of a treaty. It is worth noting that while most multilateral environmental agreements, like the CBD, provide procedures for dispute settlement, in practice they have rarely been used.

Box 35: Dispute Settlement Procedure under Article 27 of the CBD

Article 27 of the CBD provides that in the event of a dispute between Parties concerning the interpretation or application of the Convention (and its Protocols, unless stated otherwise in such instruments), the parties concerned shall seek solution by negotiation. Furthermore, Article 27 refers to the "classical" means of conflict resolution that include binding and non-binding procedures, with a clear priority for non-binding procedures.

Article 30 of the Nagoya Protocol explicitly refers to the application of the dispute settlement mechanisms and procedures under Article 27 of the CBD. Accordingly, in the event of a dispute between Parties to the Nagoya Protocol concerning its interpretation or application, the Parties concerned shall seek solution by negotiation (Article 27(1)). If the Parties concerned cannot reach agreement by negotiation, they may jointly seek the good offices of, or request mediation by, a third party (Article 27(2)).

When ratifying the Nagoya Protocol, a State may declare in writing to the Depositary (the Secretary-General of the United Nations) that for a dispute not resolved in accordance with the above it accepts an arbitration procedure in accordance with Part 1 of Annex II of the CBD and/or submission of the dispute to the International Court of Justice (Article 27(3)). If the parties to the dispute have not accepted the same or any procedure, the dispute shall be submitted to conciliation in accordance with Part 2 of Annex II CBD unless the Parties otherwise agree.

Article 31
Assessment and Review

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, four years after the entry into force of this Protocol and thereafter at intervals determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, an evaluation of the effectiveness of this Protocol.

A. Background

Article 31 establishes the basis for institutional monitoring and supervision of the implementation and effectiveness of the Nagoya Protocol. The provision is linked to Article 26(4) (which describes the mandate of the Conference of the Parties serving as the meeting of the Parties (COP/MOP)) and Article 29 (which requires Parties to monitor the implementation of their obligations and report accordingly). Article 31 resembles Article 35 of the Cartagena Protocol on Biosafety; however, an important difference is the date of the first evaluation, as well as the length of the intervals for consecutive evaluations.

B. Explanation

According to Article 31, the assessment and review of the effectiveness of the Nagoya Protocol will be undertaken on a collective basis through the COP/MOP. Article 26(4) requires the COP/MOP to review the implementation of the Nagoya Protocol and to make decisions necessary to promote its effective implementation. The mechanism and modalities for undertaking the assessment and review will also be decided by the COP/MOP.

The first evaluation is foreseen four years after the entry into force of the Protocol (see Article 33). The intervals for consecutive evaluations will need to be determined by the COP/MOP.[1]

The assessment and review process is likely to be based in part on the information provided by the Parties in their national reports on implementation of the Nagoya Protocol according to Article 29. However, other sources of information, such as submissions by access and benefit-sharing stakeholders, might also play a role in the evaluation.

It is important to note that the objective of the assessment and review process under Article 31 is substantially different from the objective of the compliance mechanism to be established under Article 30. The aim of evaluations under Article 31 is to look at the effectiveness of the Nagoya Protocol, not at the fulfilment of the obligations of individual Parties. However, the results of the assessment and review processes may provide important information for the work of the future compliance mechanism. Conversely, the procedures and mechanisms to promote compliance under Article 30 may also serve as sources of information that contribute to the assessment and review under Article 31.

1 It is interesting to note that the first evaluation under the Cartagena Protocol on Biosafety was undertaken five years after its entry into force, and that a five-year cycle for the consecutive review and assessment process is foreseen by the Cartagena Protocol.

Article 32
Signature

This Protocol shall be open for signature by Parties to the Convention at the United Nations Headquarters in New York, from 2 February 2011 to 1 February 2012.

A. Background

Article 32 specifies which entities may sign the Nagoya Protocol. Furthermore, it lays out the arrangements and timeline for its signature.

Normally, signing an international treaty does not have a binding effect on the State concerned if the treaty requires ratification, acceptance, approval, or accession. However, by signing an international treaty a State sends an important political signal as it declares its intention to become bound by the obligations arising from the treaty.

B. Explanation

According to Article 32, the time period during which the Nagoya Protocol was open for signature was specified to end on 1 February 2012. If States intend to become a Party to the Protocol after this date, they can accede to it by depositing an instrument of accession with the Depositary (see Article 35(1) of the Convention on Biological Diversity (CBD)). The Depositary of the Nagoya Protocol is the Secretary-General of the United Nations (see Article 41 of the CBD).

By 2 February 2012, the Nagoya Protocol had received 92 signatures, including the European Union as a regional economic integration organization being a Party to the CBD. However, in order to become legally bound by the Protocol, States/regional economic integration organizations have to ratify, accept, approve, or accede to the Nagoya Protocol (see Article 33).

After the signature of the Nagoya Protocol, the concerned States/regional economic integration organizations are normally expected to take steps at a national level that would lead to depositing their instruments of ratification, acceptance, or approval. According to the Vienna Convention on the Law of Treaties (Article 18), States/regional economic integration organizations are obliged after signature to refrain from acts that go against the Protocol's objective and intent, in this case as specified in Article 1.

It is interesting to note that in contrast to the Cartagena Protocol on Biosafety, which allowed all States to sign to the Protocol, the Nagoya Protocol only allowed Parties to the CBD to sign. Still, under the Cartagena Protocol only Parties to the CBD could actually become Parties, as is also the case for the Nagoya Protocol (see Article 32(1) of the CBD). Thus, there is no practical difference.

Box 36: Functions of Depositaries

According to Article 77(1) of the Vienna Convention on the Law of Treaties, the functions of a Depositary, unless otherwise provided in the treaty or agreed by the contracting States, consist of, in particular:

- keeping custody of the original text of the treaty and of any full powers delivered to the depositary;
- preparing certified copies of the original text and preparing any further text of the treaty in such additional languages as may be required by the treaty and transmitting them to the parties and to the States entitled to become Parties to the treaty;
- receiving any signatures to the treaty and receiving and keeping custody of any instruments, notifications, and communications relating to it;
- examining whether the signature or any instrument, notification, or communication relating to the treaty is in due and proper form and, if need be, bringing the matter to the attention of the State in question;
- informing the Parties and the States entitled to become Parties to the treaty of acts, notifications, and communications relating to the treaty;
- informing the States entitled to become Parties to the treaty when the number of signatures or of instruments of ratification, acceptance, approval or accession required for the entry into force of the treaty has been received or deposited;
- registering the treaty with the Secretariat of the United Nations; and
- performing the functions specified in other provisions of the present Convention.

Article 33
Entry into Force

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after the deposit of the fiftieth instrument as referred to in paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

A. Background

The Parties to the Nagoya Protocol are not bound by its terms until the Protocol enters into force. Article 24 of the Vienna Convention on the Law of Treaties clarifies that the mode and moment a treaty enters into force depends upon the intention of the Parties. Therefore, most international treaties include clauses that regulate that they will only enter into force after a minimum number of States have ratified, even if other States have not.

Article 33 establishes the formal requirements for the entry into force of the Nagoya Protocol. Procedures for ratification, accession, acceptance, or approval of the Protocol vary according to the domestic requirements of each State. In each case, however, in order to become bound by the Protocol, a State or regional economic integration organization will need to deposit an instrument of ratification, accession, acceptance, or approval with the Depositary of the Protocol. Only when the Protocol has entered into force for a particular State or regional economic integration organization will that State/regional economic integration organization have status as a Party to the Protocol.

Three separate issues are addressed in Article 33:

- when the Protocol itself enters into force as a binding legal instrument (Article 33(1));
- when the Protocol enters into force, or becomes binding, on individual States (Article 33(2)); and
- how instruments deposited by regional economic integration organizations are counted.

B. Explanation

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

Article 33(1) determines the date of entry into force of the Nagoya Protocol. This is 90 days after 50 Parties to the Convention on Biological Diversity (CBD) have deposited their instrument of ratification, acceptance, approval, or accession with the Depositary, which is the Secretary-General of the United Nations (Article 41 of the CBD). In practice, instruments of ratification, accession, acceptance, or approval will be lodged with the Treaty Division of the United Nations Office of Legal Affairs at the United Nations Headquarters in New York.

For the first 50 States that ratify, accept, approve, or accede to the Nagoya Protocol, the Protocol will enter into force in accordance with Article 33(1).

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after the deposit of the fiftieth instrument as referred to in paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

According to Article 33(2), the date of entry into force will vary for States/regional economic integration organizations depositing their instruments of ratification, accession, or approval after the fiftieth instrument was deposited.

If a State/regional economic integration organization is already a CBD Party, the Nagoya Protocol will enter into force 90 days after the deposit of its instrument of ratification, acceptance, approval, or accession to the Protocol. This is also the case if a State/regional economic integration organization becomes a Party to the CBD during this period.

If the State/regional economic integration organization is not already a Party to the CBD, then even if it deposits the required instrument of ratification and so on under the Protocol, the Protocol will only enter into force for it on the date that it becomes bound by the CBD.

As a consequence, in order to become a Party to the Nagoya Protocol, the CBD must also be in force for that State or regional economic integration organization. This follows from the CBD requirement that only a Party to the CBD may become a Party to its Protocols (Article 32(1) of the CBD).

It is interesting to note that Article 37(2) of the Cartagena Protocol on Biosafety does not refer to the deposit of the fiftieth instrument but to the entry into force of the Protocol, which is 90 days after the fiftieth deposit. Consequently, there was a regulatory gap under the Cartagena Protocol with regard to the entry into force for those Parties that ratified, accepted, or approved that Protocol after the fiftieth instrument but before the actual entry into force 90 days afterwards. This regulatory gap is avoided in the Nagoya Protocol by the wording in Article 33(2).

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 33(3) clarifies that an instrument of ratification, acceptance, approval, or accession by a regional economic integration organization does not count for the entry into force if one of its member States has already deposited such an instrument itself. For example, if a European Union member State deposits an instrument of ratification, acceptance, approval, or accession, the instrument deposited by the EU will not be counted as an additional instrument under Article 33(1) and (2).

Article 34
Reservations

No reservations may be made to this Protocol.

A. Background

Article 34 of the Nagoya Protocol is copied verbatim from Article 38 of the Cartagena Protocol on Biosafety, and it is practically the same provision as Article 37 of the Convention on Biological Diversity (CBD). According to Article 2 of the Vienna Convention on the Law of Treaties, a reservation is a unilateral statement made by a State, when signing, ratifying, accepting, approving, or acceding to a treaty, whereby it announces to exclude or to modify the legal effect of certain provisions of the treaty in their application to that State. Reservations must be clearly enunciated and cannot be made at a later date. They may, however, be withdrawn.

B. Explanation

According to Article 19 of the Vienna Convention, a State may formulate a reservation unless the reservation is prohibited by the treaty. Article 34 excludes reservations – as is the case for the CBD and the Cartagena Protocol on Biosafety. States that become Parties to the Nagoya Protocol must therefore accept all its provisions as binding.

The reason behind this strict rule is probably the desire to preserve the balance between the various obligations created by the Nagoya Protocol, which could be threatened if Parties had the right to make reservations. Furthermore, it avoids having Parties pick and choose the obligations that they will comply with.

Article 35
Withdrawal

1. **At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from this Protocol by giving written notification to the Depositary.**
2. **Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.**

A. Background

The text of Article 35 of the Nagoya Protocol is taken verbatim from Article 39 of the Cartagena Protocol on Biosafety and is similar to Article 38(1) and (2) of the Convention on Biological Diversity (CBD). Article 54(a) of the Vienna Convention on the Law of Treaties states that a Party may withdraw from a treaty, provided it is done in conformity with the provisions of the treaty.

B. Explanation

Article 35 regulates the withdrawal from the Nagoya Protocol. According to Article 35(1), a Party may withdraw from the Protocol at any time after two years after the Protocol came into force for it. Furthermore, it foresees that withdrawal is done by notifying the Depositary, in writing, of the decision to withdraw.

Article 35(2) regulates that withdrawal takes effect one year after receipt of notification or on a later date that might be specified in the notification of withdrawal.

Under Article 38 of the CBD, withdrawal from the CBD itself automatically triggers withdrawal from any Protocol to which the State concerned is also a Party. This follows from the requirement under Article 32 of the CBD that only Parties to the CBD may be Parties to the Protocol. It is important to note that this does not apply vice versa. Therefore, withdrawal from the Nagoya Protocol has no impact on the status of a country as a Contracting Party to the CBD.

Article 36
Authentic Texts

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

A. Background

The text of Article 36 of the Nagoya Protocol is taken verbatim from Article 40 of the Cartagena Protocol on Biosafety, and it differs only slightly from Article 42 of the Convention on Biological Diversity (CBD). The provision regulating the authentic texts of an international treaty is a standard clause that is normally put at the end of every international instrument.

B. Explanation

Article 36 foresees that all authentic texts of the Nagoya Protocol are equally authoritative and that the terms of the Protocol are presumed to have the same meaning in each authentic text.

Cases of discrepancies between authentic language versions may, however, happen. In those situations, the discrepancy can only be resolved by negotiation and amendment of one or more versions in accordance with Article 29 of the CBD, which regulates amendments to the CBD and its Protocols.

The Nagoya Protocol was negotiated and adopted in the six official languages of the United Nations and of the CBD. The addition of an authentic version would require the amendment of Article 36.

Box 37: The French Authentic Text

The French version of the original text of the Nagoya Protocol and of the certified true copies that were published on December 14, 2010, by the Secretary-General of the United Nations included several major translation mistakes. The differences between the English and French texts were objected to by several CBD Parties, including the French-speaking African countries, the European Union and its Member States, and Canada as well as others. Correction of the mistakes was required and was made a clear condition for the future signature of the Protocol.

The Vienna Convention on the Law of Treaties regulates the correction of errors in texts or in certified copies of treaties. Article 79(2)-(4) of the Vienna Convention provides:

▶

"2. Where the treaty is one for which there is a depositary, the latter shall notify the signatory States and the contracting States of the error and of the proposal to correct it and shall specify an appropriate time-limit within which objection to the proposed correction may be raised. If, on the expiry of the time-limit:

(a) no objection has been raised, the depositary shall make and initial the correction in the text and shall execute a procès-verbal of the rectification of the text and communicate a copy of it to the parties and to the States entitled to become parties to the treaty;

(b) an objection has been raised, the depositary shall communicate the objection to the signatory States and to the contracting States.

3. The rules in paragraphs 1 and 2 apply also where the text has been authenticated in two or more languages and it appears that there is a lack of concordance which the signatory States and the contracting States agree should be corrected.

4. The corrected text replaces the defective text *ab initio,* unless the signatory States and the contracting States otherwise decide."

Accordingly, the Secretary-General of the United Nations as the Depositary proposed the above-mentioned corrections to the original French version of the Nagoya Protocol and to the certified true copies on March 18, 2011. By 16 June 2011, the expiration date for notification of objection to the proposed corrections, no objection had been notified to the Secretary-General. Consequently, the Secretary-General has made the required corrections to the original text of the Protocol (French version) and to the certified true copies that were circulated by depositary notification. The defective text has been replaced and is therefore irrelevant.

Annex 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 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.
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 utilization 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 related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;

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(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 relevant intellectual property rights.

A. Background

As recognized in Article 5(4) of the Nagoya Protocol, benefits deriving from the utilization of genetic resources and subsequent applications and commercialization may be monetary and non-monetary. Possible monetary and non-monetary benefits are listed in the Annex of the Protocol, which is based on Appendix II of the 2002 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. The list of possible benefits in the Annex is not meant to be exhaustive or to prioritize the approaches included. Rather, this extensive and diverse enumeration aims to highlight the various approaches or conditions that may be considered in negotiations on mutually agreed terms.

B. Explanation

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 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.

The Annex of the Nagoya Protocol presents various types of monetary benefits, which refer to the revenues that may result from research, development, and subsequent applications based on genetic resources. Access fees and up-front payments, for instance, if not too costly, can contribute to financing the implementation of access and benefit-sharing (ABS) systems and ensuring the seriousness of applications, without discouraging applications for access. Milestone payments are linked to specific achievements or reference points in the research and development process. These types of payments have the advantage of recognizing that the likelihood of benefits or the specific benefits that may derive from the utilization of genetic resources are generally unknown at the outset of research and development. Similarly, license fees can be established as benefits in case of commercialization, joint intellectual property for eventual patent and other intellectual property rights, and payment of royalties in case these intellectual property rights are licensed to third parties.

The Annex also mentions monetary benefits that may enhance how providers, users, and their partners work together. For example, if there is ongoing collaboration in research and development or subsequent production or commercialization, preferential salaries and other commercial terms may be important for ensuring long-term relationships with increasing value added and development at the local level. Joint ventures can be a valuable approach to establish fair and equitable commercial relationships. These partnerships sometimes include provisions for joint ownership of intellectual property rights.

Finally, the Annex incorporates suggestions of monetary benefits that could contribute to conservation and sustainable use. For instance, trust funds could be established and research funding could be directed to support activities such as surveys of genetic resources, taxonomy of flora and fauna, nature conservation strategies, and sustainable management plans. More at the local level, community funds may be established to preserve traditional practices or promote good practices for sustainable use and conservation, as well as to support other projects advancing local sustainable development goals and strategies.

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 utilization 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 related 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 relevant intellectual property rights.

Non-monetary benefits include all other outcomes of the utilization of genetic resources that can and should be shared, according to the circumstances, with the Party providing the genetic resources as well as with other relevant stakeholders. These benefits could include results of research and development; technologies that have resulted from or are pertinent for biodiversity-related research and development; information on the conservation, management, and valorization of biodiversity; and other capacities and contributions that could support and incentivize advancing the objectives of the Convention on Biological Diversity. In many cases, these non-monetary benefits could constitute the most valuable consequences of ABS, given that they are more direct, immediately available, and suited to promoting conservation and sustainable use at the local level.

The non-monetary benefits mentioned in the Annex can be loosely structured into four clusters. The first cluster covers the different ways in which the Party providing the genetic resources, or other relevant stakeholders within that Party, can actively participate in and contribute to the utilization of genetic resources. The Nagoya Protocol specifically requires Parties to "collaborate and cooperate in technical and scientific research and development" as a means to achieve the fair and equitable sharing of the benefits arising from the utilization of genetic resources. Modalities for collaboration mentioned in the Annex include organizations cooperating in research and development, as well as conducting such research and development, where possible, within the Party providing the genetic resources. Moreover, collaboration is also mentioned as a way to recognize and promote local expertise, knowledge, and institutions, including through joint ownership of intellectual property rights and the sharing of any subsequent monetary benefits.

The second cluster covers information exchange and technology transfer. One of the main challenges in the conservation of biodiversity and the sustainable use of its components is the lack of knowledge

regarding existing resources in biodiversity-rich developing countries and their potential for scientific or commercial application. In this context, the sharing of research and development results and scientific information – including biological inventories and taxonomic studies, access to facilities and databases dealing with genetic resources, and the institutional and professional relationships that can arise from co-operation in the utilization of genetic resources – are crucial among the non-monetary benefits that may derive from ABS.

Another challenge closely linked to lack of knowledge on biodiversity is the limited access to the technologies that are relevant to the assessment and utilization of genetic resources. The Annex of the Nagoya Protocol thus mentions benefits such as the transfer of technology under prevailing terms in the international market, as well as under concessional and preferential terms, where agreed. The Annex also suggests prioritization of knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity.

The third cluster of non-monetary benefits includes training and capacity development initiatives. The focus on such training as a benefit resulting from the utilization of genetic resources does not imply lack of awareness of existing capacities and skills at the local level. Indeed, the Annex highlights the aim to collaborate on education and training, as to fully engage local stakeholders in training related to genetic resources. Suggestions include initiatives that strengthen capacities for technology transfer, reinforce institutions, and provide the human and material resources to support the implementation of access regulations.

The fourth and final cluster of non-monetary benefits mentioned in the Annex includes efforts to support sustainable development at the local level. As mentioned with regards to monetary benefits, some of the most important benefits linked to the utilization of genetic resources arise only when a product has already been developed and there is continued sourcing of natural ingredients or inputs from biodiversity. In these circumstances, commercial relationships can also be structured in a way that advances the sharing of non-monetary benefits along the supply chain. According to the Annex, these non-monetary benefits include contributions to the local economy, food and livelihood security benefits, and social recognition.

Possible Ways Forward

POSSIBLE WAYS FORWARD

The adoption of the Nagoya Protocol after six years of negotiations was a significant step forward for the implementation of the Convention on Biological Diversity (CBD). It is of strategic importance in a number of ways.

First of all, the Nagoya Protocol attracts the attention of the international community to the third objective of the CBD. Compared with the other two objectives (conservation of biological diversity and sustainable use of its components), access to genetic resources and the fair and equitable sharing of benefits arising out of their utilization (ABS) has often been treated as an "orphan child" within the CBD framework and consequently also in CBD implementation at the country level. The adoption of a CBD Protocol focusing specifically on ABS puts the third objective on equal footing with the others and closes the loop between the three at the international level. However, such awareness also needs to be raised at the national and local level, where the CBD and its Nagoya Protocol are actually implemented in practice.

Second, the Nagoya Protocol also significantly advances the CBD's ABS objective by providing a strong basis for greater legal certainty and transparency for both providers and users of genetic resources. To enter into force, however, the Nagoya Protocol has to be ratified, accepted, approved, or acceded to by at least 50 CBD Parties (Article 33). Only then do the obligations of the Protocol become binding on the Parties. While the entry into force is a key requirement for the implementation of the Nagoya Protocol at the international level, Parties still have to develop the necessary legislative, administrative, and policy measures at the regional, national, and/or local levels to implement it on the ground.

Third, it has to be recognized that as a protocol to the CBD, the Nagoya Protocol is the instrument for the implementation of the ABS provisions of the CBD (Article 4(4)). Therefore, the CBD provides the substantive, institutional, and procedural basis for the Protocol (UEBT, 2010a). But the Protocol also recognizes the special nature and distinctive features of particular genetic resources that might require individually tailored ABS solutions. Consequently, it offers the opportunity to develop other specialized ABS agreements while stressing the importance of implementing the Protocol in a mutually supportive manner with these other instruments. Existing or future specialized ABS agreements thus need to be taken into consideration by the Parties when developing their domestic ABS regimes. In other words, domestic ABS measures will need to be flexible enough to accommodate future specialized agreements.

Furthermore, the Nagoya Protocol enabled the final adoption of the Strategic Plan for Biodiversity for the Period 2011-2020, including the Aichi Targets, as well as the Strategy for Resource Mobilization in Support of the Achievement of the Convention's Three Objectives as a package deal. This close relationship between the implementation of the Nagoya Protocol and the Strategic Plan in particular goes beyond the mere fact that both were part of a negotiation package. Indeed, the Strategic Plan includes under its Strategic Goal D (Enhance the benefits to all from biodiversity and ecosystem services) Aichi Target 16, which specifically deals with ABS and foresees that by 2015 the Nagoya Protocol will be in force and operational, consistent with national legislation.[1] At the same time, under Strategic Goal E (Enhance implementation through participatory planning, knowledge management and capacity-building) Aichi Target 17 envisages that by 2015 each Party will have developed, adopted as a policy, and have recommended the implementation of an effective, participatory, and updated

1 CBD COP 10 Decision X/2, Annex, Strategic Plan for Biodiversity 2011–2020.

National Biodiversity Strategy and Action Plan (NBSAP).[2] When doing so, Parties should ensure that their NBSAP provides an effective and up-to-date national framework for the implementation of all three objectives of the Convention, its relevant provisions, and guidance.[3] Therefore, according to the Strategic Plan, the CBD Parties should provide not only for the entry into force of the Nagoya Protocol but also its implementation in practice. In addition, they should develop new NBSAPs or revise their existing ones in a way that supports the implementation of the Nagoya Protocol.

Against this background, the implementation of the Nagoya Protocol at the domestic level is a challenge for both developing and developed countries. The next section aims to provide some general guidance in this regard, bearing in mind that every State and its particular ABS situation are different. Still, certain commonalities can be identified in view of appropriate ABS policies/strategies, ABS legislation and regulatory requirements, as well as ABS institutions that will facilitate putting the Nagoya Protocol into practice.

A. ABS Policies/Strategies

As just mentioned, implementation of the Nagoya Protocol will be facilitated through appropriate ABS policies or strategies at the national and/or regional level. This approach is underscored by the 2002 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilization, which states that "access and benefit-sharing systems should be based on an overall access and benefit-sharing strategy at the country or regional level" (Paragraph 22). While there is no blueprint regarding the ideal format of such ABS policies, their specific content, or even the development process, the following reflections might serve as general guidance.

Format

ABS policies can be set up as standalone instruments focusing on ABS only but also as integrated parts of broader biodiversity policies, such as NBSAPs. For the latter approach, different arguments can be brought forward for incorporating ABS policies in NBSAPs:

- takes advantage of the greater political attention given to NBSAPs;
- emphasizes that the three CBD objectives (conservation of biodiversity, sustainable use of its components, and ABS) are on equal footing;
- takes into consideration that the three CBD objectives are related and need to be linked to ensure effectiveness;
- promotes a more focused biodiversity-related policy framework at the national level, leading to greater efficiency;
- provides for synergies when meeting Aichi Targets 16 (on operationalization of the Nagoya Protocol) and 17 (on adoption of new ore revision and updating of existing NBSAPs); and
- ensures a more holistic approach in the governance of biological diversity.

2 Ibid.

3 CBD COP 9 Decision IX/8, 8.(a). Review of Implementation of Goals 2 and 3 of the Strategic Plan.

Regardless of the approach taken by a country, it will be important to ensure that a country's ABS policies are mutually supportive with a broader set of policies, including on science and technology, natural resources management, and indigenous and local communities (ILCs).

With regard to the development of NBSAPs, it is interesting to note that countries currently mostly focus on objectives one and two of the CBD only (Prip et al., 2010, p. 48). Conservation tools and mechanisms, in particular protected areas, dominate NBSAPs. Furthermore, the issue of sustainable use is addressed, even though in very general terms. In contrast, ABS – in spite of being the third CBD objective – is often absent or neglected.

Nevertheless, the implementation of the new Strategic Plan – in particular, the development of new or the revision of existing NBSAPs – provides a clear opportunity to revert this "trend" and to adopt ABS policies and practices in harmony with existing frameworks on protected areas, forests, and marine resources, among others. Synergies can be explored and conflicts need to be avoided when addressing complex issues such as ownership of biological and genetic resources, land tenure and ILCs, trade and intellectual property law, industry policies, and the interaction of ABS principles with domestic laws and policies dealing with specialized international obligations, such as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and emerging issues arising out of the World Health Organization (WHO) or the World Intellectual Property Organization (WIPO).

Development Process

The concrete process for the development of ABS policies will depend on the countries' existing legal and political frameworks (e.g., mandatory public information and consultation processes) as well as their specific ABS landscape (e.g., the existence of ILCs in the countries or the interests of the countries' private sectors and scientific communities). However, the following step-wise approach (which has to be further tailored to each individual country) could be taken into consideration when drafting an integrated ABS policy/strategy.

- **Situation analysis**

In a first step, the ABS situation in the country should be analyzed in light of the principles and obligations included in the Nagoya Protocol. The impacts of different instruments that could be adopted to implement the Protocol should be assessed in view of their practicability and cost-effectiveness. In other words, before adopting policy options and concrete proposals, the ABS status quo and the possible effects of all options should be explored.

- **Participatory process**

As part of this situation analysis, a public consultation amongst all ABS stakeholders should be launched in order to explore the possible impacts of the Protocol and to gather concrete ideas on the practical challenges of implementation for different stakeholder groups. In the interest of transparency regarding particular stakeholder interests, such a consultation should not be anonymous. Indeed, participants in the consultation should be invited to provide the public with relevant information about themselves by registering and subscribing to codes of conduct.

- **Provision of information**

In parallel to the situation analysis and participatory process, all ABS stakeholders in the country, including ILCs (if applicable), research, industry, and different governmental sectors (e.g. health, agriculture,

justice, trade, and science) should be informed about the Nagoya Protocol in general, its specific obligations, and particular proposals for implementation. Awareness raising and information sharing could take place through ABS roundtables facilitating multi-stakeholder dialogues. Such dialogues can be helpful as they provide an opportunity to collect further ideas regarding possible options for the implementation of the Protocol. Information sharing could also take place as an integrated part of the public consultation process.

Box 38: Possible Questions for Public Consultation on the Nagoya Protocol

A public consultation on the Nagoya Protocol could raise, among others, the following questions:

- What are the concerns of stakeholders with respect to the new legal situation that will result from the entry into force of the ABS regime established by the Protocol? Do they anticipate any significant changes or problems?
- What implementing measures could be foreseen in order to provide for greater legal certainty and facilitate relations between users and providers?
- Could administrative burdens and costs from implementing the Nagoya Protocol in a specific sector be anticipated? If yes, what approaches could be suggested to minimize such costs?
- What are the problems/challenges for users in ensuring conformity with existing legislation in provider countries establishing a procedure and conditions for prior informed consent?
- Have certain users/providers developed standard clauses or model contracts for mutually agreed terms? If yes, please specify.
- Are there practices and arrangements currently being used for access to and sharing of benefits arising from the utilization of the genetic resources and traditional knowledge associated with these resources in transactions between users and providers? If yes, please specify.
- What are the advantages and challenges for users and providers in the implementation of such arrangements?
- What kind of voluntary checkpoints, if any, are currently used to monitor compliance with ABS provisions?
- Are there existing domestic legislations that might be applicable to the issues covered by the Nagoya Protocol within a specific sector, subject area, and affiliation? If yes, please specify whether that legislation is in need of change.
- Is a harmonized approach at the regional level necessary to effectively implement the Nagoya Protocol and its objectives in the country?
- Would there be advantages in negotiating agreements, within the framework of the Nagoya Protocol, on a bilateral or regional basis with major providers/users, in order to globally facilitate access to genetic resources and traditional knowledge associated with such resources for commercial and/or non-commercial uses?

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- How could the implementation of the Nagoya Protocol affect other international instruments and processes, such as WHO, WIPO, and ITPGRFA?
- Should new institutions or procedures be established specifically for ABS purposes? If so, at what level?
- What features of procedures and checkpoints would ensure that administrative burdens for users and providers as well as public authorities in the country are minimized?

Source: Adapted from a questionnaire used by the European Commission in a European Union public consultation process on ratification and implementation of the Nagoya Protocol.

- **Informed decision-making**

Based on the results of a situation analysis, reasoned decisions should be taken in the development of ABS policies. That is to say, decisions have to strike a balance between fully implementing the Nagoya Protocol on the one hand and not imposing a disproportionate burden on any particular ABS stakeholder group on the other hand. Furthermore, in order to ensure that ABS policies stay up to date and thus relevant, they should be monitored and reviewed on a regular basis. Such reviews should provide additional/new information on the experiences, challenges, and opportunities of implementing the Nagoya Protocol, which again should advise the next round of decision-making.

Content

ABS policies should aim to create a coherent framework for the development of further legal, policy, and administrative measures in order to facilitate environmentally sound access to the genetic resources of the country, clarify access to traditional knowledge associated with these resources (if applicable), ensure the fair and equitable sharing of the benefits arising out of their utilization, and provide for compliance with ABS regimes of other countries. In this context, policy-makers should consider the development of ABS policies not only as an instrument to "protect" their natural resources. In addition, they should see this as an opportunity to become "proactive" and to promote the socio-economic value of a country's biodiversity and its ecosystem services, build an enabling framework for attracting investment in biotechnologies, create strategic partnerships to maximize research and development, and so on.

The concrete content of an ABS policy will again depend on the ABS landscape in a particular country. In any case, it is important to keep the following in mind:

- The Nagoya Protocol includes some obligations that are specifically addressed to providers and others that are only addressed to users. However, each country is a potential provider and user of genetic resources; in other words, providers are not necessarily developing countries, and users are not only industrialized countries.
- Each country has sovereign rights over its genetic resources. Therefore, domestic ABS regimes do not necessarily have to require prior informed consent (PIC) but can also provide free access to genetic resources.
- While some genetic resources and traditional knowledge are endemic to a certain country, others are found in transboundary situations.

- The cultural specificities of a country need to be represented (for example, the status of ILCs and their specific relationship with government authorities).
- Domestic ABS regimes need to build on the obligations included in the Nagoya Protocol, but they also need to be flexible enough to take into account the obligations under specialized ABS agreements (e.g., the ITPGRFA) and ongoing international processes related to ABS (such as those under WIPO, WHO, and the World Trade Organization).

Box 39: Ideas for Designing ABS Policies

ABS policies could be structured according to the following sections.

Vision

The vision of an ABS policy could state the overall, long-term goal that a country aspires to. For example, it could be envisaged that the genetic resources of the country, as well as the traditional knowledge associated with such resources are utilized in a sustainable way and conserved for the benefit of present and future generations.

Goal

A shorter-term goal – in line with this vision – could be the provision of a framework for the development of domestic legal, policy, and administrative measures that build the basis of a successful trading system for the ecologically sustainable use of genetic resources and traditional knowledge associated with such resources as well as for the maximization of economic, social, and environmental benefits.

Principles

A set of general principles could further qualify this goal and guide the development of new and the revision of existing legal, policy, and administrative measures related to ABS. Such measures should, amongst others:

- value the utilization of genetic resources and traditional knowledge associated with such resources for commercial and non-commercial purposes, including the conservation of biodiversity;
- facilitate non-discriminatory and environmentally sound access to the country's genetic resources and traditional knowledge associated with such resources;
- establish a fair and equitable system for sharing benefits arising out of the utilization of the country's genetic resources and traditional knowledge associated with these resources;
- support compliance with ABS regimes of other countries, if their genetic resources or the traditional knowledge associated with these resources are utilized within the national jurisdiction; and
- ensure transparent, clear, and efficient ABS processes in line with other domestic policies and strategies (for example, those related to protected areas, forest and marine resources, or technology transfer).

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Themes, Objectives, and Actions

Furthermore, the implementation of the policy could be directed by clear objectives and concrete action points organized under a number of thematic issues that need to be addressed by the future legal, policy, and administrative ABS measures of the country, such as:

- Theme 1: Access to the country's genetic resources and traditional knowledge associated with such resources
- Theme 2: Fair and equitable sharing of the benefits derived from their utilization
- Theme 3: Compliance with ABS regimes of other countries
- Theme 4: Co-operation with other countries
- Theme 5: Communication, education, and awareness
- Theme 6: Financial mechanisms
- Theme 7: Assessment and review

B. ABS Legislative, Policy, or Administrative Measures

Obligations under an international agreement may be self-executing, depending on whether a Party is a monist or dualist State. Generally speaking, in a pure monist State ratification of an international treaty brings the obligations into domestic law automatically. Dualist States consider national and international law as being different and thus require that international law be translated into national law for it to become a law altogether. It is important to note that regardless of which legal doctrine a State may follow – pure monism, pure dualism, or a mixture of both – ratification of the Nagoya Protocol only marks the beginning of its implementation process (Koester, 2012, p. 31). Indeed, many of the provisions of the Nagoya Protocol oblige countries to take domestic legislative, policy, or administrative measures as appropriate. In practice, this means that they are not concrete enough to be applied directly at the national or local level.

At the same time, the obligation to take such measures provides countries with a great flexibility in implementation of the Protocol. While this may lead to the development of ABS frameworks that differ from country to country, comprehensive ABS regimes in developing as well as developed countries will most likely share some similarities. In particular, they may (Glowka, 1998, p. 24):

- specify principles, objectives, and definitions;
- identify the scope of application and clarify the legal status of genetic resources and traditional knowledge associated with such resources;
- determine whether PIC is required for access to genetic resources or not;
- outline a procedure for determining access (if applicable);
- provide for guidance, rules, and procedures regarding fair and equitable benefit-sharing;
- include monitoring and compliance mechanisms; and

- establish or designate appropriate institutions to share ABS-relevant information (including on ILCs, if applicable), grant access, negotiate and enforce benefit-sharing, as well as monitor and check compliance.

Use of existing public participation processes and standard contract law can complete the necessary domestic regime to implement the ABS concept.

Principles and Objectives

Fundamental principles of ABS that could be highlighted in domestic ABS measures might include, amongst others (Glowka, 1998, p. 27):

- State sovereignty over natural resources in areas within the country's jurisdiction as well as authority to determine access to genetic resources;
- PIC and mutually agreed terms (MAT) of a competent authority as a requirement for access to genetic resources (if the country decides not to grant free access);
- recognition of ILCs' rights over their traditional knowledge associated with genetic resources (if applicable);
- recognition of rights of ILCs over genetic resources held by them (if applicable);
- illegality of using genetic resources and/or traditional knowledge associated with such resources within the country's jurisdiction in violation of PIC and MAT requirements of a provider country;
- conformity of access to genetic resources with conservation or sustainable use legislation;
- application of the precautionary approach;
- goals of benefit-sharing, including conservation and sustainable use of biological diversity, technology transfer, and capacity-building;
- indicative guidance of what benefits could be considered; and
- co-operation with other States to facilitate ABS and ensure compliance.

Objectives to be achieved through the ABS measures could include, amongst others (Glowka, 1998, p. 27):

- implementing the Nagoya Protocol, as well as other specialized ABS instruments in a mutually supportive manner;
- establishing a participatory planning process to address ABS issues;
- promoting transparency in the access determination process (if applicable);
- equitably sharing with providers the benefits derived from the utilization of genetic resources, and the traditional knowledge associated with such resources (if applicable);
- monitoring compliance with ABS legislation of provider countries;
- conserving biological diversity and sustainably using its components;
- directing benefits back to biodiversity conservation;

- stimulating economic, social, scientific, and technological partnerships and development (for example, making protected areas centres of scientific research); and
- providing a legal and institutional framework for international co-operation.

Definitions

Definitions are another important instrument to clarify the agreed specific meaning of certain key terms in the context of ABS. In many cases, drafters will not need to invent new definitions as they will be able to draw on existing documents (Glowka, 1998, p. 28), such as the CBD or the Nagoya Protocol. The definitions contained in the Protocol bring much-needed clarity to those tasked with implementing ABS at the national level.

The Protocol clarifies that derivatives (biochemicals) can be addressed in domestic ABS measures. If a country decides to do so, its ABS framework will be supported by the provisions of the Protocol. While using different definitions (and techniques), several legislative, policy, and administrative measures on ABS have already included derivatives (or biochemicals) in their "scope," leading to the application of the general ABS mechanisms PIC, MAT, and benefit-sharing. This is for instance the case of the Biodiversity Law of Costa Rica (biochemicals), the Philippines Executive Order (by-product and derivatives), the Andean Community Decision 391 (derivatives), the Bhutan Biodiversity Law (biochemicals), and the Australian Environment Protection and Biodiversity Conservation Regulations (biochemicals) (Cabrera Medaglia, 2004).

However, there are criticisms of the lack of clarity of the term "genetic resource" and its implications in determining the scope of access measures. Particularly, the definition included in the CBD has been criticized for its lack of legal precision. It has not always been clear when access to genetic resources occurs, as opposed to access to biological resources, nor when the utilization of genetic resources takes place and if this constitutes a different phase altogether.

From a national point of view, incorporating the term "utilization" in ABS measures and defining it in line with the Nagoya Protocol may provide more clarity and legal certainty on the scope of these measures and improve their implementation. This is because the utilization concept could provide concrete indicators that enable a clear test determining whether a particular activity is covered or governed by the Protocol (or by Article 15 of the CBD) and when the obligation to share benefits is triggered (Cabrera Medaglia, 2004). In other words, it is access for the purpose of utilization of genetic resources that may trigger PIC requirements, and it is utilization of genetic resources that forms the ground for benefit-sharing based on mutually agreed terms. Therefore, the concept of utilization adopted in the Protocol can be seen as the basis for a functional ABS system (Tvedt and Rukundo, 2010).

It is important to note that only a few ABS measures have yet defined the term "utilization" despite its legal relevance for building a functional ABS regime. (On the issue of the role of "utilization" in the drafting and implementation of functional ABS regimes, see Tvedt and Young, 2007; Cabrera Medaglia and López Silva, 2007.) Utilization of genetic resources is now defined in Article 2 of the Protocol as "research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention". The Protocol does not contain a list of types of research and development, as was envisaged in earlier

deliberations.[4] However, the lists resulting from the Group of Technical and Legal Experts on Concepts, Terms, Working Definitions and Sectoral Approaches could be used as indications.

Scope

Properly defining the scope of application of the ABS measures will contribute greatly to its future success. Although the actual text regulating the scope may be very short, it will generally involve determining (Glowka, 1998, p. 29):

- materials (types and sources of genetic resources) and information (traditional knowledge and databases);
- geographical areas (land territory, territorial waters, maritime zones);
- types of utilization (commercial and non-commercial); and
- actors (natural and legal persons, nationals and non-nationals)

to which the ABS measures apply or do not apply.

Article 3 of the Nagoya Protocol will play a guiding role in this regard, as it will assist particularly in establishing the limits of the temporal scope of the measures. That is, it deals with when the measures apply and what implications this may have on the activities and genetic resources covered, with the case of *ex-situ* collections established before the entry into force of the Protocol, and with the issue of non-retroactivity and new utilization of genetic resources.

Access Requirements

It needs to be recalled that it is within the sovereign rights of States over their natural resources to determine if PIC for access to its genetic resources is required or not. However, it is important to understand that if the ABS measures of a providing Party do not mention PIC requirements, such silence does not indicate that the Party does not require PIC. The formulation “unless otherwise determined by that Party” (Article 6(1) of the Nagoya Protocol) suggests that PIC is the norm unless the providing Party decides otherwise. Countries that do not require PIC, including those that traditionally do not regulate access to genetic resources, should therefore give a clear declaration to that effect.

Furthermore, a providing Party is free to decide when PIC for access shall be required or not. For example, it may decide to subject access to PIC for:

- all genetic resources;
- only particular categories of genetic resources (see also Glowka et al., 1994, p. 81) – this may be the case in a number of instances: where the genetic resource to be accessed is found on ILCs’ lands, where the genetic resource to be accessed is found on State-owned land that is under State recognized occupation by an ILC, or where the genetic resource to be accessed is found on land owned by another entity other than the State, such as a private landowner;

4 See Ad Hoc Open-ended Working Group on ABS, official document 7/2, Report of the Meeting of the Group of Technical and Legal Experts on Concepts, Terms, Working Definitions and Sectoral Approaches. UN Doc. UNEP/CBD/WG-ABS/7/2 (2008).

- all purposes of access – that is, both commercial and non-commercial research; or
- some purposes – for example, commercial purposes alone.

The decision on the exemption of non-commercial research from a PIC requirement could be based on the nature of the research to be undertaken. For example, it could differentiate whether the research is purely basic in the sense that its results would barely have a commercial potential or it instead can easily be turned into commercial applications. However, as it is still extremely difficult to draw a clear line between non-commercial and commercial research, it might be advisable for countries requiring PIC to:

- create a simplified procedure for non-commercial research in accordance with Article 8(a) of the Nagoya Protocol;
- tie a possible change of intent (research began with a non-commercial intent) to a come-back clause requiring the renegotiation of PIC and MAT;
- encourage the use of new information technology systems and codes of conduct that enable the tracking of specimens in order to monitor the use of samples by third parties; and
- take short-term and long-term measures in view of research results in the public domain – that is, require that they are given the opportunity to seek proprietary rights to data before they are placed in the public domain as long as they do not alter it or block or delay publication; and
- foresee capacity-building and training so that they can also use the research results in the future.

Access Determination Process

If a country decides to require PIC, an efficient and effective access determination process has to be defined that complies with the international access standards included in Article 6(3) of the Nagoya Protocol. The access determination process could distinguish five primary stages (see also Glowka, 1998, p. 55):

- Application to a competent authority: The specific information that needs to be provided by an applicant has to be decided.
- Review of the access application: The ABS measures need to provide for a transparent and non-arbitrary review process.
- Reaching MAT: It needs to be clear with whom the applicant must negotiate MAT, when MAT should be negotiated, and what minimum criteria (eventually) need to be fulfilled by the agreement.
- Access determination: The ABS measures need to specify against which criteria the application is judged, and they need to determine that a written permit (indicating eventual conditions) or a written denial (indicating the reason(s) leading to the negative decision) is given within a specified and reasonable period of time.
- Appeal: It also has to be decided whether appeals are handled through existing administrative procedures, and on which procedural and/or substantive grounds appeals can be based.

Box 40: Example of Elements for a PIC Application as Listed in Costa Rican Decree 31514

- Aims of research, bioprospection, or economic exploitation.
- Site/sites where research or exploitation will be settled on.
- Number of researchers, bioprospectors, or authorized persons who will enter the site and how they might be identified (if guidance by ILC members is required, these should be duly hired and paid for, if the parties so agree).
- Type of material of interest and approximate quantity.
- Potential destination of genetic and biochemical elements or resources and their subsequent destinations.
- Methods of collection or exploitation of material.
- Initial price of extracted sample, when applicable (price and number of samples is the basis for determining the percentage of project budget to be deposited).
- Approximate time the whole process will last and how many times the access site will be entered.
- Formal commitment by the interested party to provide evidence of the origin of the resources and the related knowledge, in any publication, procedure, or their further use.
- Agreed terms regarding the exchange of knowledge related to characteristics, qualities, uses, procedures, and tending over the genetic and biochemical elements and resources of biodiversity, and how this knowledge will contribute to the conservation of species and ecosystems.
- Agreed terms about any other condition that the practice or the result of the participatory process of the ILCs indicate is required.
- Express manifestation by intellectual property that the protection measures of the related knowledge, practices, and innovations of ILCs will be respected, as established in the national legal system on *sui generis* Communitarian Intellectual Rights.
- Agreed terms on a possible study on cultural impacts of access, if required.
- Agreed terms on the type and ways of transfer of technology or generation of information derived from the research, bioprospection, or economic exploitation towards the national counterparts, ILCs, and provider of the resource.

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- Agreed terms on the equitable distribution of environmental, economic, social, scientific, or spiritual benefits, including possible commercial profits at short, mid, and long term of any product or sub-product derived from the acquired material (the Technical Office will verify the fulfilment of these terms according to the third objective of CBD).
- Approximate terms for the distribution of benefits.
- Special emphasis should be made so that granting of PIC is carried out, as far as possible, with an equitable participation of both genders.
- Signature or fingerprint of the provider and applicant.
- Other terms agreed.

Source: Based on *Decree No. 31514, General Rules for the Access to Genetic and Biochemical Resources and Elements of Biodiversity*, 2003.

There are two possible ways of organizing access procedures that could cut down on costs and duration (Kamau et al., 2010, p. 260).[5]

- Procedural integration – this means the competent agencies coordinate their procedures and conditions of granting access permits to avoid any contradiction of requirements as well as a protracted waiting period. That makes it possible for the applicant to file requests for PIC at the same time and for the agencies to handle them simultaneously and to coordinate the decisions and conditions attached to the permit. This may be done most appropriately by designating one of the agencies with competencies to coordinate and combine the publication of the application, receive comments, hold hearings, and draft decisions.
- Full integration – this involves the integration of licensing procedures by combining the relevant permits into one permit. It implies that the applicant would be required to file only one application with the competent authority, but with the requirement that s/he submits all data and documents necessary for other permits (in line with the relevant agencies' regulations) to the competent authority. In spite of giving the other responsible agencies an opportunity to comment on the application, and respecting the material criteria they would normally apply, the competent authority will have the exclusive competence to take a decision that also includes any other permit.

Guidance, Rules, and Procedures on Benefit-sharing

Article 5 of the Nagoya Protocol contains several provisions that clarify and build on CBD provisions on benefit-sharing, including in relation to the obligation to share benefits, the reach of this obligation to benefits derived from subsequent applications and commercialization of genetic resources, and the recognition of the rights of ILCs over genetic resources and traditional knowledge associated with genetic resources. In this regard, Article 5 is a noteworthy accomplishment within the Nagoya Protocol. However, there are still a number of issues that will benefit from further elucidation and elaboration in domestic ABS measures. Apart from clarifying the process for negotiating MAT and the minimum criteria that need to be fulfilled, ABS measures could include the following features.

5 These approaches are discussed in detail in Kamau and Winter, 2009, pp. 371–73.

- Requirements, procedures, and incentives that ensure and facilitate fair and equitable sharing of benefits

In the case of provider countries, there may be commitments to benefit-sharing, or even requirements for specific benefits, demanded in the context of applications for access to genetic resources. In Brazilian legislation, for example, when access to genetic resources is requested and the probability of commercial use is apparent, authorization will only be granted after signing a contract for use of genetic heritage and benefit-sharing.[6] In Ethiopia, legislation on ABS requires research based on genetic resources, wherever possible, to be carried out in the country and with the participation of local experts.[7] In the case of benefits derived from the utilization of genetic resources or traditional knowledge associated with genetic resources held by ILCs, measures taken by a provider country might include special legislative measures to better enable ILCs to protect and control their knowledge or requiring that certain data are provided to communities in negotiations in order to ensure a fair, equitable, and informed arrangement for benefit-sharing.

Regarding measures in so-called user countries, Article 5 could be considered as part of a group of provisions in the Nagoya Protocol promoting compliance with domestic ABS requirements. Potential measures that could be adopted in user countries to ensure fair and equitable benefit-sharing may include legal, policy, or administrative measures to monitor and enforce that the utilization of genetic resources and/or traditional knowledge associated with such resources in research, development, and commercialization of biodiversity-based products only takes place with fair and equitable sharing of benefits. One example for such measures are disclosure requirements in patent applications. A number of countries have introduced these requirements in various forms, and there is a proposal to amend the Agreement on Trade Related Aspects of Intellectual Property Rights in the World Trade Organization to make the disclosure of the origin of genetic resources and evidence of PIC and MAT obligatory in patent applications.

Furthermore, the obligation of fair and equitable benefit-sharing in Article 5(1) of the Nagoya Protocol could be recognized as a benchmark for good practices in biodiversity-based activities. With growing public awareness of the importance of biodiversity and consumer interest in ethical practices in biodiversity-related activities, such recognition could support discussions on the role of different actors in advancing benefit-sharing in the context of domestic regulatory requirements, as well as the consideration of benefit-sharing in standards, codes of conducts, and practices on the ground.

- A benefit-sharing process for traditional knowledge associated with genetic resources (if applicable), as well as safeguards in that respect

No country has to date taken measures, legislative or otherwise, as foreseen in Article 5(5) of the Nagoya Protocol, to create a system to ensure benefit-sharing with ILCs when their traditional knowledge associated with genetic resources is being used by non-members. Hence, there are presently no model laws or other measures from which to draw inspiration.

The domestic measures most appropriate to implement Article 5(5) will probably to a significant degree depend on how effectively the access provision in Article 7 can be implemented. The successful operationalization of this provision will rely on directing potential users to the relevant point of access –

6 Brazil, Medida Provisoria No. 2.186-16 de 23 de agosto 2001, as clarified by the Genetic Heritage Management Council in their Technical Orientations No 1, 2, 3, 4, 6, and 7, with the exemptions noted by the Genetic Heritage Management Council in Resolutions No 26, 29, and 21 as amended by Resolutions No 28 and 30.

7 Ethiopia, Proclamation No. 482/2006 – Access to Genetic Resources and Community Knowledge and Community Rights Proclamation.

that is, to the relevant authority of the ILC that has developed the traditional knowledge. Such guidance is important, as it might be a challenge sometimes to identify who within an ILC is authorized to provide consent/approval for access. While indigenous peoples will normally have concrete norms, customary or more modern, governing whom the traditional knowledge is vested with and who is entitled to grant access, local communities do not necessarily have defined societal structures making it clear who speaks for the group. Under such circumstances, it will be difficult to identify the relevant point of access. Furthermore, this is also the case with regard to continued use of traditional knowledge associated with genetic resources that has already been widely disseminated outside the relevant community.

To the extent that users can be successfully directed to the relevant point of access – for example, through national registers – their benefit-sharing obligations will normally be outlined in contractual arrangements. In this case, regular administrative and contractual enforcement measures should be sufficient to ensure adherence also to benefit-sharing agreements. If, on the other hand, users are not successfully directed to the relevant point of access, there will presumably be a significant lack of benefit-sharing agreements. To address such cases, legislative measures may require that traditional knowledge can only be accessed following consent/approval by the relevant community.

Another challenge is that the Nagoya Protocol does not define the term "utilization of traditional knowledge". Traditional knowledge associated with genetic resources is used in a variety of ways, which may affect not only how benefits are shared but also whether a benefit-sharing obligation is triggered to begin with. In the CBD, it seems clear that benefit-sharing in relation to traditional knowledge associated with genetic resources aims to recognize and reward the contribution of the knowledge, innovations, and practices of ILCs towards research and development on genetic resources. In practice, however, many laws and stakeholders have different perceptions and approaches – for example, in cases in which the use of a plant in traditional medicine generated a researcher's interest in its biochemical composition, even if the properties found and commercialized do not relate to its traditional uses.

Particular challenges also arise with regard to traditional knowledge associated with genetic resources that is shared among several communities and/or is cross-boundary (when these communities are situated in different countries). Several questions arise in this context: How can a scenario be avoided in which one community receives all the benefits although the traditional knowledge associated with genetic resources is also held by other communities? What can be done if different communities use the same genetic resource in different ways? What should be done if a user is attracted to a genetic resource by the fact that one particular community uses it but ends up using it in a way that mirrors another community's use?[8]

8 The delegations negotiating the Nagoya Protocol were aware of the challenges posed by transboundary traditional knowledge. In the end, however, these issues were simply deemed too technical to address in the otherwise rather generally formulated provisions of the Protocol. It was understood that the complex issues associated with transboundary traditional knowledge had to be resolved via bilateral or plurilateral agreements amongst the countries concerned. Hence, Article 11(2) simply flags that in implementing the Nagoya Protocol, Parties shall co-operate to solve problems associated with transboundary traditional knowledge.

- Direction of benefits towards the conservation of biological diversity and the sustainable use of its components

With regard to the implementation of Article 9, it will be important for Parties to the Nagoya Protocol to consider existing experiences at regional, national, and local levels. For example, in Costa Rica the National Institute of Biodiversity (INBio) is responsible for both the management of biodiversity and bioprospecting processes, which facilitates the operation of ABS as an incentive and a source of financial support for conservation. INBio includes a "conservation overhead" in the budgets of its commercial research partnerships. As a result, 10% of all bioprospecting budgets and 50% of all royalties are donated to the Ministry of Environment and Energy.

Another possibility is the use of trust funds for conservation and sustainable use of biodiversity or broader sustainable development projects. Andean Decision 391, for example, promotes co-operation among Member Countries on matters of mutual interest relating to the conservation and sustainable use of genetic resources, including the Andean Committee on Genetic Resources, which has a mandate on transboundary resources and on a possible Andean Fund for the conservation of genetic resources. In South Africa, an agreement between the National Botanical Institute and the U.S.-based company Ball Horticulture foresees the investment of royalties from successful products in a trust fund to be used for the development of local horticulture and conservation and for rural development projects in collection areas (CBD, 2008).

In the use of funds, however, questions arise as to whether the flow of benefits on a project basis rather than directly linked to the utilization of biodiversity or related knowledge can be an effective incentive for sustainable use or conservation. Similarly, benefits are likely to have much more of an impact on conserving ecosystems, species, or genetic resources, as well as on local development, if they are focused on the areas and communities where these are located. For example, efforts have been undertaken in the South Pacific region of Colombia to promote local sustainable development through value-added biodiversity-based products. These efforts have focused, *inter alia*, on *Morella pubescens*, a tree that plays an important role in protecting watersheds and preventing erosion in the region. The fruit of this tree is used to make a type of wax that – with ongoing work to improve processes, formulate the ingredient, establish the supply chain, and find markets – could be interesting for cosmetic and other applications. Given the involvement and investment of the local communities, along with civil society organizations, in these efforts, it is not difficult to see how ensuring that the benefits flow back to those engaged in the value chain and contribute to the local economy would provide more of an incentive for conservation, as well as have a more significant impact on local development.

More generally, a range of measures could be considered to enhance the link between conservation, sustainable use, and benefit-sharing. For instance, promoting ABS in protected areas has been identified as an opportunity to contribute to conservation and sustainable use. This is because protected areas already play an important role in connecting communities and biodiversity (see, e.g., UNEP, 2011; see also Lausche, 2011). Moreover, protected areas are inherently interesting for bioprospecting, given that they are increasingly repositories of disappearing habitats, species, and genetic resources (UNU–IAS, 2003). An example of measures leading to a link between ABS and protected areas is the development of a biocultural community protocol in the Kruger to Canyons Biosphere Reserve in South Africa, which led to the formation of the Bushbuckridge Traditional Healers Association and negotiations of an ABS agreement.

Other measures could be linked to the non-monetary benefits listed in the Annex to the Nagoya Protocol. ABS agreements or ABS-related projects could be encouraged to consider capacity-building for ILCs to conserve and sustainably use their genetic resources. Promoting access to or exchange of

scientific and technical information relevant to conservation and sustainable use of biological diversity is also important.

- An opportunity to seek legal recourse in cases of disputes arising from MAT concluded within the country's jurisdiction, as well as outside of it

Implementation of Articles 19 and 14(3)(b) of the Nagoya Protocol on the development of model contractual clauses will contribute significantly to the creation of opportunities to seek legal recourse in cases of disputes arising from MAT. Such models can be developed at the multilateral as well as the regional and bilateral levels.

In the same manner, enacting domestic measures in user as well as in provider countries in relation to access to justice, applicable law, and conflict resolution options (Articles 18(1) and 18(3)(a) of the Nagoya Protocol) will support Parties in their endeavours to promote compliance with ABS contractual arrangements. In that regard, Parties can in their domestic measures require ABS contract partners to include specific provisions on jurisdiction and applicable law – even determining the content of such provisions according to what the Party considers most appropriate for a sound resolution of potential conflicts. Parties may also consider that in order to achieve full implementation of Article 18, a common understanding of the concept of access to justice needs to be reached by means of a decision by the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol. Such an endeavour would also promote the definition of specific elements of the concept at the domestic level.

While it is difficult to apply the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to the Nagoya Protocol, since the two treaties address significantly different situations, Parties to the Protocol may get inspired by the Aarhus Convention when implementing the concept of access to justice. In that case, access to justice could be understood as requiring user countries to take effective measures to ensure that provider countries have recourse to their legal system to obtain redress. It could also include an obligation to provide access to administrative or judicial procedures to challenge breaches of national law, and it could envisage giving the right to a wide category of persons to challenge any violation of national law in court or any other independent and impartial body, such as an ombudsman. This could include non-governmental organizations and ILCs. Importantly, it could also oblige a State to ensure that costs for bringing an action are not prohibitively expensive.

Furthermore, to implement Article 18(3)(b) of the Nagoya Protocol, Parties that have not yet done so should consider ratification of the different legally binding instruments developed at the international level to promote harmonization of international private law and to establish rules according to which foreign judgments and arbitral awards would be recognized and enforced.

- Obligation of the country's industry and scientific sectors active in bioprospecting to develop model clauses as well as self-imposed regulations, such as codes of conduct and best practices, that ensure fair and equitable benefit-sharing

Parties may take different approaches to the implementation of Article 19 of the Nagoya Protocol. For example, they may take a pro-active approach to the development of model clauses. This might involve undertaking scoping studies to identify the different sectors involved in access and utilization of genetic resources, including non-commercial research, the pharmaceutical industry, plant breeding, food production and processing, biotechnology, agriculture, fragrance and cosmetics, and pest control. Parties would then need to identify how genetic resources are utilized by each sector and identify both the potential for utilization and the intended utilization in order to develop appropriate model clauses. For instance, in the non-commercial research sector, genetic resources are usually

used simply to create new knowledge, taxonomic systems, and a better understanding of the living world. In other situations, such as with the development of vaccines, the genetic resource may actually make up part of the end product. Similarly, while in some cases all or part of the genetic resource may be used, in others the resource may be used simply as a source of information (e.g., a DNA code or gene sequence), or it may even be synthesized in a model or copy (as with some perfumes). Existing contracts used by sectors could be analyzed and a list of model clauses extracted. Additional model clauses could then be suggested and developed.

Another approach could be described as "bottom-up". Parties would need to encourage sectors to put forward existing model clauses and to develop new ones as may be appropriate. Indeed, sectoral model clauses are likely to be more useful if developed by and with the involvement of the relevant sectors rather than imposed by governments. Parties would need to consider carefully how this is done and may want to give priority to supporting and developing model clauses in sectors where benefit-sharing and compliance have been identified as being most urgent. In addition, Parties need to periodically encourage updating model clauses to reflect scientific developments in the way genetic resources are utilized and to actively assess how they are being used.

Model clauses to be developed could include clauses covering facilitated access for non-commercial use, settlement of disputes, a definition of what constitutes utilization of genetic resources in specific user chains and sectors, clauses covering change of use and/or commercialization, and indicative lists of sector-specific monetary and non-monetary benefit-sharing.[9]

Furthermore, voluntary norms could be valuable tools to support implementation of the Nagoya Protocol.[10] For one thing, further guidance on ABS policies and practices is still clearly needed, even with an international agreement and national implementing legislation. There are a variety of types of genetic resources (such as animals, plants, and microorganisms) used by different types of users (including botanic gardens, academic researchers, and private companies) for different purposes (research or commercialization) in a variety of sectors (such as agriculture, biotechnology, pharmaceutical, and personal care). Voluntary norms that provide more specific ABS guidelines and tools may thus be critical to define, complement, and facilitate the implementation of broader ABS measures. Additionally, given the political differences leading to the Nagoya Protocol and the remaining questions in its compromise text, voluntary norms could provide a useful platform for dialogue, empowering stakeholders to work towards common objectives and enhancing their contribution to policy processes.

As with model clauses, Parties may take different approaches to encouraging the development, use, and update of voluntary norms. They may choose to actively identify the main sectors involved in access and use of genetic resources and undertake a review of standards used in each sector and support the development of appropriate new ones where necessary. Nevertheless, these standard setting tools are again far more likely to be relevant and well-used if developed bottom-up by the individual sectors.

9 The CBD Secretariat is developing a website collecting model clauses and agreements, which is available at www.cbd.int/abs/resources/contracts.

10 A number of sectors have already begun to develop best practice standards and codes of conduct. A list can be found on the CBD website at www.cbd.int/abs/instruments.

Monitoring and Compliance

Compliance with ABS measures is a core issue of the Nagoya Protocol. According to Articles 15 and 16, each Party is obliged to take measures to provide that genetic resources and/or traditional knowledge associated with these resources that are used within its jurisdiction have been accessed in compliance with the provider countries' ABS legislation. This approach has no precedent in international environmental law and entails a great challenge in terms of implementation. This is particularly true since it implies a real change from the legal status quo, in which enforcement is the sole responsibility of the country that enacted the legislation and, hence, the remedies and sanctions provided for in the law of the provider country are not applied extraterritorially.

It is important to recall that every country is both a potential provider and a user of genetic resources. As a consequence, a comprehensive implementation of the Nagoya Protocol will require each Party – regardless of whether it is a developing or a developed country – to take the necessary measures under Articles 5 (on benefit-sharing) and 6 (on access) along with the measures on monitoring and compliance foreseen in Articles 15-18.

With regard to the latter, domestic ABS measures will need to address compliance in two ways: compliance with the country's own ABS regime and with third countries' ABS regimes. Normally, an appropriate ABS framework will regulate the monitoring and enforcement of its legislation. Such monitoring provisions can be targeted on at least three actors: the government, a competent authority overseeing the ABS process, and legal or natural persons seeking an ABS agreement. However, developing appropriate user measures will be one of the greatest challenges in the drafting of ABS measures for both developing and developed countries. Measures to provide for compliance with third countries' ABS legislation could include:

- prohibition of the utilization of genetic resources or traditional knowledge associated with such resources in violation of provider countries' ABS legislation;
- establishment of due diligence obligations for users of genetic resources or traditional knowledge associated with these resources;
- institution of third-party certification;
- development of sector-specific codes of conducts and guidelines, as well as cross-sector guidelines explaining the steps and stakeholders involved in ABS;
- creation of transparent systems for tracking the loan, exchange, and/or utilization of genetic resources, including an obligation to have information on the provider country or country of origin accompany the material when it is used;
- proportionate sanctions and penalties for breaches of third countries' ABS legislation; and
- co-operation in cases of breaches of provider countries' ABS legislation.

Box 41: Understanding a Potential ABS Due Diligence System

The due diligence obligation could build on a general ban on the use of genetic resources or traditional knowledge associated with such resources in breach of a provider country's ABS requirements. To support this prohibition, a due diligence system could establish specific criteria to be met by all users within the jurisdiction at different ABS stages. These criteria would need to be set out in such a way as to ensure a high certainty of compliance with a third country's ABS legislation. At the same time, each user could be obliged to establish an in-house system to gather information about the provider country's ABS legislation and the fulfilment of the compliance criteria, to verify related facts, and to assess risks associated with the utilization of genetic resources or traditional knowledge associated with these resources from the specific provider country.

Monitoring and enforcement in the user country could then mainly focus on checking compliance with the due diligence requirements. The legal responsibility for monitoring the establishment and implementation of due diligence systems could be transferred to specific entities certified to do this job. In the end, the government authorities could concentrate on monitoring these certified entities, as well as undertaking random examinations of users within the jurisdiction.

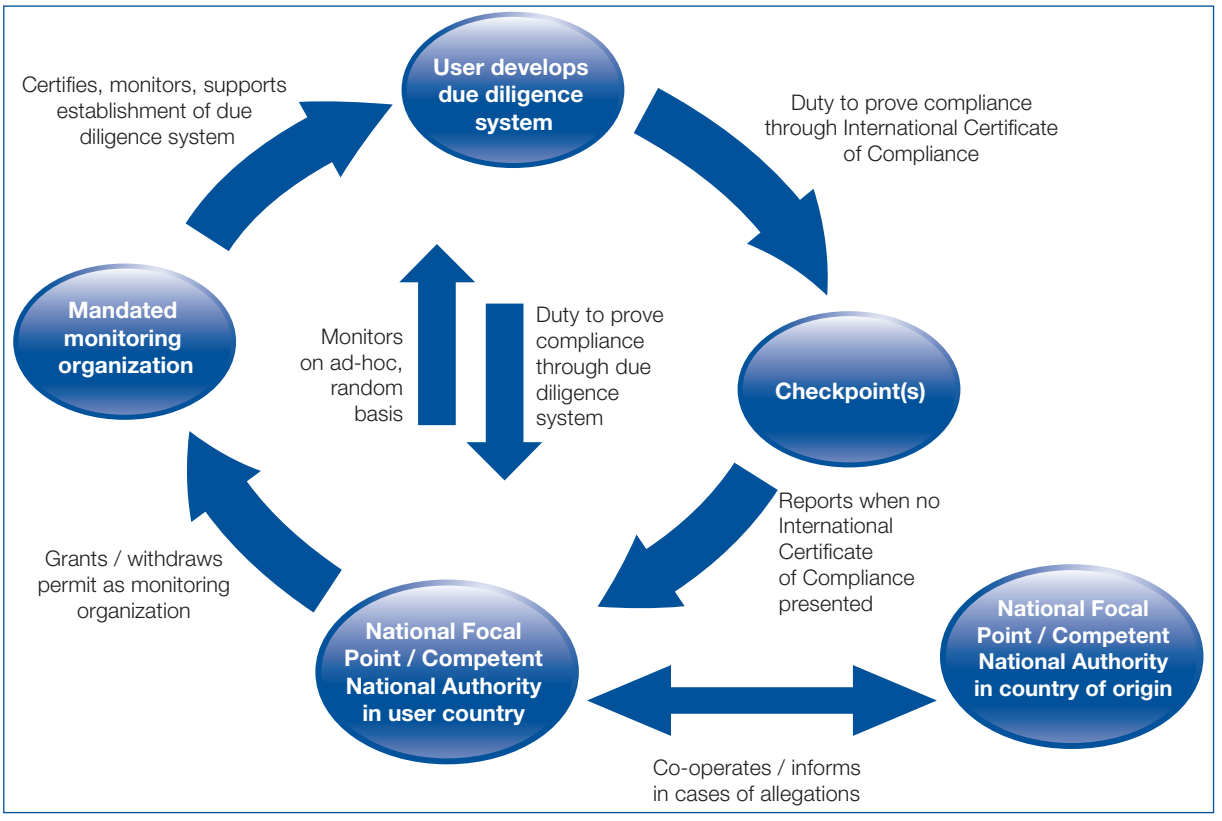
Furthermore, Article 17(1)(a) of the Nagoya Protocol obliges each Party to designate one or more effective checkpoints that will facilitate the monitoring of the utilization of genetic resources. Checkpoints where compliance with third countries' ABS legislation could be monitored may include, amongst others:

- patent application processes;
- product approval processes;
- processes related to the granting of public research funds; and
- standards for academic publication.

In addition to designating checkpoints, domestic user measures should clarify their specific roles and functions. For example, it should be decided whether the import of all genetic resources is subject to monitoring by a designated checkpoint or whether existing inspection agencies are mandated to verify on an ad-hoc basis and at random whether domestic ABS legislation of provider countries' are complied with. Furthermore, domestic measures should define precisely which information has to be provided/disclosed by the user (Article 17(1)(a)(ii)), how it is collected and reviewed by the checkpoint(s) (Article 17(1)(a)(i)), and what the concrete consequences/sanctions would be for not providing the necessary information. Article 17(4) indicates what kind of information this could be, as it lists the minimum information for the internationally recognized certificate of compliance.

It is interesting to note that some countries (developed as well as developing) have already adopted disclosure requirements in their national laws. Examples include Brazil, Costa Rica, Denmark, Egypt, Germany, Norway, New Zealand, Romania, Spain, Sweden, Switzerland, and India. At the regional level, the European Community has opted for voluntary disclosure, while the Andean community has adopted mandatory obligations. However, it seems clear that many of these disclosure requirements will have to be further developed in order to meet all the requirements established under Article 17.

Figure 6: Visualization of a Potential Due Diligence Compliance and Monitoring System



C. ABS Institutions

Since ABS involves issues that cut across sectoral lines, planners need to consider how an integrated institutional framework ensuring a cross-sectoral ABS approach can be created. One way to promote better integration is through the establishment or determination of a national focal point for ABS and/or a competent national ABS authority (or authorities), as foreseen in Article 13 of the Nagoya Protocol, with the responsibilities to share ABS-related information at the national and international level, oversee PIC and MAT processes (if applicable), and provide support to potential users who are interested in accessing genetic resources and/or traditional knowledge associated with these resources, as well as to providers who investigate potential cases of non-compliance.

According to Article 13, Parties have the following obligations:

- The CBD Secretariat must be notified about national focal point and competent national authority(ies). This means an affirmative obligation that Parties must notify, as there is no automatic transfer of information.
- The contact information of the national focal point and competent national authority(ies) must be notified no later than the date of entry into force of the Protocol for the Party.
- If a Party designates more than one competent national authority, it must provide the information on the respective responsibilities of each authority to the Secretariat at the time of notification.

- As a standing responsibility, a Party must always notify the Secretariat of any changes regarding the designation of the national focal point and competent national authority(ies), their contact information, and their responsibilities.

Furthermore, the jurisdictional competencies, powers, and functions of the specific authority or authorities need to be clarified vis-à-vis other institutions. Important functions may include:

- gathering information and coordinating with potentially affected parties inside and outside the government;
- identifying and informing potential users of national or sub-national access rules;
- liaising with ILCs (if applicable);
- deciding on access applications;
- negotiating terms of ABS and reaching MAT for access;
- tracking utilization of genetic resources and monitoring and enforcing compliance;
- collecting and disbursing benefits (fees, royalties, other financial returns);
- reporting to the ABS Clearing-House Mechanism;
- collaborating with other Parties to the Nagoya Protocol;
- co-ordinating identification and characterization of genetic resources and traditional knowledge associated with such resources to ascertain their potential use or value; and
- assessing whether further legislation in the area is needed.

While Article 13 seems to indicate that obligations thereunder are to be undertaken by Parties acting predominantly in their capacity as providers, it is important to recall that a country can be both a provider and a user. Therefore, it is advisable for each Party to reflect both situations in the processes of designating competencies and notifying the CBD Secretariat accordingly.

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Supplementary Materials

Supplementary Materials

A. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the Convention, and recognizing that this Protocol pursues the implementation of this objective within the Convention,

Reaffirming the sovereign rights of States over their natural resources and according to the provisions of the Convention,

Recalling further Article 15 of the Convention,

Recognizing the important contribution to sustainable development made by technology transfer and cooperation to build research and innovation capacities for adding value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention,

Recognizing that public awareness of the economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components,

Acknowledging the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability and thereby contributing to achieving the Millennium Development Goals,

Acknowledging the linkage between access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources,

Recognizing the importance of providing legal certainty with respect to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization,

Further recognizing the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources,

Recognizing also the vital role that women play in access and benefit-sharing and affirming the need for the full participation of women at all levels of policy-making and implementation for biodiversity conservation,

Determined to further support the effective implementation of the access and benefit-sharing provisions of the Convention,

Recognizing that an innovative solution is required 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,

Recognizing the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaptation to climate change,

Recognizing the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions,

Recognizing the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard,

Mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes,

Acknowledging ongoing work in other international forums relating to access and benefit-sharing,

Recalling the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture developed in harmony with the Convention,

Recognizing that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention,

Recalling the relevance of Article 8(j) of the Convention as it relates to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising from the utilization of such knowledge,

Noting the interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities, the importance of the traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities,

Recognizing the diversity of circumstances in which traditional knowledge associated with genetic resources is held or owned by indigenous and local communities,

Mindful that it is the right of indigenous and local communities to identify the rightful holders of their traditional knowledge associated with genetic resources, within their communities,

Further recognizing the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity,

Noting the United Nations Declaration on the Rights of Indigenous Peoples, and

Affirming that nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities,

Have agreed as follows:

Article 1 OBJECTIVE

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

Article 2 USE OF TERMS

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Convention" means the Convention on Biological Diversity;

(c) "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;

(d) "Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

(e) "Derivative" means 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.

Article 3 SCOPE

This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

Article 4 RELATIONSHIP WITH INTERNATIONAL AGREEMENTS AND INSTRUMENTS

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.

2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

Article 5 FAIR AND EQUITABLE BENEFIT-SHARING

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with 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. Such sharing shall be upon mutually agreed terms.

2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.

3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.

4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.

5. Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

Article 6 ACCESS TO GENETIC RESOURCES

1. 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 utilization 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.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

   (a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;

   (b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;

   (c) Provide information on how to apply for prior informed consent;

   (d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;

   (e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefitsharing Clearing-House accordingly;

   (f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

   (g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia:*

      (i) A dispute settlement clause;

      (ii) Terms on benefit-sharing, including in relation to intellectual property rights;

      (iii) Terms on subsequent third-party use, if any; and

      (iv) Terms on changes of intent, where applicable.

Article 7 ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

Article 8 SPECIAL CONSIDERATIONS

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

   (a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, 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 for such research;

   (b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and

equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;

(c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

Article 9 CONTRIBUTION TO CONSERVATION AND SUSTAINABLE USE

The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

Article 10 GLOBAL MULTILATERAL BENEFIT-SHARING MECHANISM

Parties shall consider the need for and modalities of a global multilateral benefitsharing mechanism 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. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

Article 11 TRANSBOUNDARY COOPERATION

1. In instances where the same genetic resources are found *in situ* within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.

2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

Article 12 TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

1. 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.

2. Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.

3. Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:

(a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;

(b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and

(c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.

4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

Article 13 NATIONAL FOCAL POINTS AND COMPETENT NATIONAL AUTHORITIES

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:

(a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;

(b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and

(c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

The national focal point shall be responsible for liaison with the Secretariat.

2. Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.

5. The Secretariat shall make information received pursuant to paragraph 4 above available through the Access and Benefit-sharing Clearing-House.

Article 14 THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE AND INFORMATION-SHARING

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefitsharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.

2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:

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

   (b) Information on the national focal point and competent national authority or authorities; and

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

3. Additional information, if available and as appropriate, may include:

   (a) Relevant competent authorities of indigenous and local communities, 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.

4. The modalities of the operation of the Access and Benefit-sharing Clearing- House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 15 COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Article 16 COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING FOR TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.

2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Article 17 MONITORING THE UTILIZATION OF GENETIC RESOURCES

1. To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:

   (a) The designation of one or more checkpoints, as follows:

      (i) Designated checkpoints would 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;

      (ii) Each Party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance;

      (iii) Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;

      (iv) Checkpoints must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, inter alia, any stage of research, development, innovation, pre-commercialization or commercialization.

(b) Encouraging users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements; and

(c) Encouraging the use of cost-effective communication tools and systems.

2. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.

4. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

(a) Issuing authority;

(b) Date of issuance;

(c) The provider;

(d) Unique identifier of the certificate;

(e) The person or entity to whom prior informed consent was granted;

(f) Subject-matter or genetic resources covered by the certificate;

(g) Confirmation that mutually agreed terms were established;

(h) Confirmation that prior informed consent was obtained; and

(i) Commercial and/or non-commercial use.

Article 18 COMPLIANCE WITH MUTUALLY AGREED TERMS

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:

(a) The jurisdiction to which they will subject any dispute resolution processes;

(b) The applicable law; and/or

(c) Options for alternative dispute resolution, such as mediation or arbitration.

2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

3. Each Party shall take effective measures, as appropriate, regarding:

(a) Access to justice; and

(b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.

4. The effectiveness of this Article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.

Article 19 MODEL CONTRACTUAL CLAUSES

1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

Article 20 CODES OF CONDUCT, GUIDELINES AND BEST PRACTICES AND/OR STANDARDS

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.

Article 21 AWARENESS-RAISING

Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues. Such measures may include, inter alia:

(a) Promotion of this Protocol, including its objective;

(b) Organization of meetings of indigenous and local communities and relevant stakeholders;

(c) Establishment and maintenance of a help desk for indigenous and local communities and relevant stakeholders;

(d) Information dissemination through a national clearing-house;

(e) Promotion of voluntary codes of conduct, guidelines and best practices and/or standards in consultation with indigenous and local communities and relevant stakeholders;

(f) Promotion of, as appropriate, domestic, regional and international exchanges of experience;

(g) Education and training of users and providers of genetic resources and traditional knowledge associated with genetic resources about their access and benefit-sharing obligations;

(h) Involvement of indigenous and local communities and relevant stakeholders in the implementation of this Protocol; and

(i) Awareness-raising of community protocols and procedures of indigenous and local communities.

Article 22 CAPACITY

1. The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations. In this context, Parties should facilitate the involvement of indigenous and local communities and relevant stakeholders, including non-governmental organizations and the private sector.

2. The need of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition for financial resources in accordance with the relevant provisions of the Convention shall be taken fully into account for capacity-building and development to implement this Protocol.

3. As a basis for appropriate measures in relation to the implementation of this Protocol, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition should identify their national capacity needs and priorities through national capacity self-assessments. In doing so, such Parties should support the capacity needs and priorities of indigenous and local communities and relevant stakeholders, as identified by them, emphasizing the capacity needs and priorities of women.

4. In support of the implementation of this Protocol, capacity-building and development may address, *inter alia*, the following key areas:

   (a) Capacity to implement, and to comply with the obligations of, this Protocol;

   (b) Capacity to negotiate mutually agreed terms;

   (c) Capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing; and

   (d) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources.

5. Measures in accordance with paragraphs 1 to 4 above may include, *inter alia:*

   (a) Legal and institutional development;

   (b) Promotion of equity and fairness in negotiations, such as training to negotiate mutually agreed terms;

   (c) The monitoring and enforcement of compliance;

   (d) Employment of best available communication tools and Internet-based systems for access and benefit-sharing activities;

   (e) Development and use of valuation methods;

   (f) Bioprospecting, associated research and taxonomic studies;

(g) Technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable;

(h) Enhancement of the contribution of access and benefit-sharing activities to the conservation of biological diversity and the sustainable use of its components;

(i) Special measures to increase the capacity of relevant stakeholders in relation to access and benefit-sharing; and

(j) Special measures to increase the capacity of indigenous and local communities with emphasis on enhancing the capacity of women within those communities in relation to access to genetic resources and/or traditional knowledge associated with genetic resources.

6. Information on capacity-building and development initiatives at national, regional and international levels, undertaken in accordance with paragraphs 1 to 5 above, should be provided to the Access and Benefit-sharing Clearing-House with a view to promoting synergy and coordination on capacity-building and development for access and benefit-sharing.

Article 23 TECHNOLOGY TRANSFER, COLLABORATION AND COOPERATION

In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol. The Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, in order to enable the development and strengthening of a sound and viable technological and scientific base for the attainment of the objectives of the Convention and this Protocol. Where possible and appropriate such collaborative activities shall take place in and with a Party or the Parties providing genetic resources that is the country or are the countries of origin of such resources or a Party or Parties that have acquired the genetic resources in accordance with the Convention.

Article 24 NON-PARTIES

The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-House.

Article 25 FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism of the Convention shall be the financial mechanism for this Protocol.

3. Regarding the capacity-building and development referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need of developing country Parties, in particular the least developed countries and small island developing States among them, and of

Parties with economies in transition, for financial resources, as well as the capacity needs and priorities of indigenous and local communities, including women within these communities.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed countries and small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building and development requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and other resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article 26 CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

   (a) Make recommendations on any matters necessary for the implementation of this Protocol;

   (b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

   (c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

   (d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 29 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its Annex, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat and held concurrently with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held concurrently with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 27 SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may serve this Protocol, including upon a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any such decision shall specify the tasks to be undertaken.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by Parties to this Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

Article 28 SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 29 MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals and in the format to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement this Protocol.

Article 30 PROCEDURES AND MECHANISMS TO PROMOTE COMPLIANCE WITH THIS PROTOCOL

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under Article 27 of the Convention.

Article 31 ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, four years after the entry into force of this Protocol and thereafter at intervals determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, an evaluation of the effectiveness of this Protocol.

Article 32 SIGNATURE

This Protocol shall be open for signature by Parties to the Convention at the United Nations Headquarters in New York, from 2 February 2011 to 1 February 2012.

Article 33 ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after the deposit of the fiftieth instrument as referred to in paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 34 RESERVATIONS

No reservations may be made to this Protocol.

Article 35 WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from this Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article 36 AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary- General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol on the dates indicated.

DONE at Nagoya on this twenty-ninth day of October, two thousand and ten.

Annex 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 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.

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 utilization 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 related 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 relevant intellectual property rights.

B. Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising from their Utilization

I. GENERAL PROVISIONS

A. Key features

1. These Guidelines may serve as inputs when developing and drafting legislative, administrative or policy measures on access and benefit-sharing with particular reference to provisions under Articles 8(j), 10 (c), 15, 16 and 19; and contracts and other arrangements under mutually agreed terms for access and benefit-sharing.

2. Nothing in these Guidelines shall be construed as changing the rights and obligations of Parties under the Convention on Biological Diversity.

3. Nothing in these Guidelines is intended to substitute for relevant national legislation.

4. Nothing in these Guidelines should be interpreted to affect the sovereign rights of States over their natural resources;

5. Nothing in these Guidelines, including the use of terms such as “provider”, “user”, and “stakeholder”, should be interpreted to assign any rights over genetic resources beyond those provided in accordance with the Convention;

6. Nothing in these Guidelines should be interpreted as affecting the rights and obligations relating to genetic resources arising out of the mutually agreed terms under which the resources were obtained from the country of origin.

7. The present Guidelines are voluntary and were prepared with a view to ensuring their:

   (a) *Voluntary nature:* they are intended to guide both users and providers of genetic resources on a voluntary basis;

   (b) *Ease of use:* to maximize their utility and to accommodate a range of applications, the Guidelines are simple;

   (c) *Practicality:* the elements contained in the guidelines are practical and are aimed at reducing transaction costs;

   (d) *Acceptability:* the Guidelines are intended to gain the support of users and providers;

   (e) *Complementarity:* the Guidelines and other international instruments are mutually supportive;

   (f) *Evolutionary approach:* the Guidelines are intended to be reviewed and accordingly revised and improved as experience is gained in access and benefit-sharing;

   (g) *Flexibility:* to be useful across a range of sectors, users and national circumstances and jurisdictions,guidelines should be flexible;

   (h) *Transparency:* they are intended to promote transparency in the negotiation and implementation of access and benefit-sharing arrangements.

B. Use of terms

8. The terms as defined in Article 2 of the Convention shall apply to these Guidelines.These include: biological diversity,biological resources,biotechnology, country of origin of genetic resources, country providing genetic resources,ex situ conservation, in situ conservation, genetic material,genetic resources, and in situ conditions.

C. Scope

9. All genetic resources and associated traditional knowledge, innovations and practices covered by the Convention on Biological Diversity and benefits arising from the commercial and other utilization of such resources should be covered by the guidelines, with the exclusion of human genetic resources.

D. Relationship with relevant international regimes

10. The guidelines should be applied in a manner that is coherent and mutually supportive of the work of relevant international agreements and institutions. The guidelines are without prejudice to the access and benefit-sharing provisions of the FAO International Treaty for Plant Genetic Resources for Food and Agriculture. Furthermore, the work of the World Intellectual Property Organization (WIPO) on issues of relevance to access and benefit-sharing should be taken into account. The application of the guidelines should also take into account existing regional legislation and agreements on access and benefit-sharing.

E. Objectives

11. The objectives of the Guidelines are the following:

    (a) To contribute to the conservation and sustainable use of biological diversity;

    (b) To provide Parties and stakeholders with a transparent framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits;

    (c) To provide guidance to Parties in the development of access and benefitsharing regimes;

    (d) To inform the practices and approaches of stakeholders (users and providers) in access and benefit-sharing arrangements;

    (e) To provide capacity-building to guarantee the effective negotiation and implementation of access and benefit-sharing arrangements, especially to developing countries, in particular least developed countries and small island developing States among them;

    (f) To promote awareness on implementation of relevant provisions of the Convention on Biological Diversity;

    (g) To promote the adequate and effective transfer of appropriate technology to providing Parties, especially developing countries, in particular least developed countries and small island developing States among them, stakeholders and indigenous and local communities;

    (h) To promote the provision of necessary financial resources to providing countries that are developing countries, in particular least developed countries and small island developing

States among them, or countries with economies in transition with a view to contributing to the achievement of the objectives mentioned above;

(i) To strengthen the clearing-house mechanism as a mechanism for cooperation among Parties in access and benefit-sharing;

(j) To contribute to the development by Parties of mechanisms and access and benefit-sharing regimes that recognize the protection of traditional knowledge, innovations and practices of indigenous and local communities, in accordance with domestic laws and relevant international instruments;

(k) To contribute to poverty alleviation and be supportive to the realization of human food security, health and cultural integrity, especially in developing countries, in particular least developed countries and small island developing States among them;

(l) Taxonomic research, as specified in the Global Taxonomy Initiative, should not be prevented, and providers should facilitate acquisition of material for systematic use and users should make available all information associated with the specimens thus obtained.

12. The Guidelines are intended to assist Parties in developing an overall access and benefit-sharing strategy, which may be part of their national biodiversity strategy and action plan, and in identifying the steps involved in the process of obtaining access to genetic resources and sharing benefits.

II. ROLES AND RESPONSIBILITIES IN ACCESS AND BENEFIT-SHARING PURSUANT TO ARTICLE 15 OF THE CONVENTION ON BIOLOGICAL DIVERSITY

A. National focal point

13. Each Party should designate one national focal point for access and benefitsharing and make such information available through the clearing-house mechanism. The national focal point should inform applicants for access to genetic resources on procedures for acquiring prior informed consent and mutually agreed terms, including benefit-sharing, and on competent national authorities, relevant indigenous and local communities and relevant stakeholders, through the clearing-house mechanism.

B. Competent national authority(ies)

14. Competent national authorities, where they are established, may, in accordance with applicable national legislative,administrative or policy measures, be responsible for granting access and be responsible for advising on:

(a) The negotiating process;

(b) Requirements for obtaining prior informed consent and entering into mutually agreed terms;

(c) Monitoring and evaluation of access and benefit-sharing agreements;

(d) Implementation/enforcement of access and benefit-sharing agreements;

(e) Processing of applications and approval of agreements;

(f) The conservation and sustainable use of the genetic resources accessed;

(g) Mechanisms for the effective participation of different stakeholders, as appropriate for the different steps in the process of access and benefitsharing, in particular, indigenous and local communities;

(h) Mechanisms for the effective participation of indigenous and local communities while promoting the objective of having decisions and processes available in a language understandable to relevant indigenous and local communities.

15. The competent national authority(ies) that have the legal power to grant prior informed consent may delegate this power to other entities, as appropriate.

C. Responsibilities

16. Recognizing that Parties and stakeholders may be both users and providers, the following balanced list of roles and responsibilities provides key elements to be acted upon:

(a) Contracting Parties which are countries of origin of genetic resources, or other Parties which have acquired the genetic resources in accordance with the Convention, should:

(i) Be encouraged to review their policy, administrative and legislative measures to ensure they are fully complying with Article 15 of the Convention;

(ii) Be encouraged to report on access applications through the clearing-house mechanism and other reporting channels of the Convention;

(iii) Seek to ensure that the commercialization and any other use of genetic resources should not prevent traditional use of genetic resources;

(iv) Ensure that they fulfil their roles and responsibilities in a clear, objective and transparent manner;

(v) Ensure that all stakeholders take into consideration the environmental consequences of the access activities;

(vi) Establish mechanisms to ensure that their decisions are made available to relevant indigenous and local communities and relevant stakeholders, particularly indigenous and local communities;

(vii) Support measures, as appropriate, to enhance indigenous and local communities' capacity to represent their interests fully at negotiations;

(b) In the implementation of mutually agreed terms, users should:

(i) Seek informed consent prior to access to genetic resources, in conformity with Article 15,paragraph 5,of the Convention;

(ii) Respect customs, traditions, values and customary practices of indigenous and local communities,

(iii) Respond to requests for information from indigenous and local communities;

(iv) Only use genetic resources for purposes consistent with the terms and conditions under which they were acquired;

(v) Ensure that uses of genetic resources for purposes other than those for which they were acquired, only take place after new prior informed consent and mutually agreed terms are given;

(vi) Maintain all relevant data regarding the genetic resources, especially documentary evidence of the prior informed consent and information concerning the origin and the use of genetic resources and the benefits arising from such use;

(vii) As much as possible endeavour to carry out their use of the genetic resources in, and with the participation of, the providing country;

(viii) When supplying genetic resources to third parties, honour any terms and conditions regarding the acquired material. They should provide this third party with relevant data on their acquisition, including prior informed consent and conditions of use and record and maintain data on their supply to third parties. Special terms and conditions should be established under mutually agreed terms to facilitate taxonomic research for non-commercial purposes;

(ix) Ensure the fair and equitable sharing of benefits, including technology transfer to providing countries, pursuant to Article 16 of the Convention arising from the commercialization or other use of genetic resources, in conformity with the mutually agreed terms they established with the indigenous and local communities or stakeholders involved;

(c) Providers should:

(i) Only supply genetic resources and/or traditional knowledge when they are entitled to do so;

(ii) Strive to avoid imposition of arbitrary restrictions on access to genetic resources.

(d) Contracting Parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted. These countries could consider, inter alia, the following measures:

(i) Mechanisms to provide information to potential users on their obligations regarding access to genetic resources;

(ii) Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights;

(iii) Measures aimed at preventing the use of genetic resources obtained without the prior informed consent of the Contracting Party providing such resources;

(iv) Cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements;

(v) Voluntary certification schemes for institutions abiding by rules on access and benefit-sharing;

(vi) Measures discouraging unfair trade practices;

(vii) Other measures that encourage users to comply with provisions under subparagraph 16 (b) above.

III. PARTICIPATION OF STAKEHOLDERS

17. Involvement of relevant stakeholders is essential to ensure the adequate development and implementation of access and benefit-sharing arrangements. However, due to the diversity of stakeholders and their diverging interests, their appropriate involvement can only be determined on a case-by-case basis.

18. Relevant stakeholders should be consulted and their views taken into consideration in each step of the process, including:

(a) When determining access, negotiating and implementing mutually agreed terms, and in the sharing of benefits;

(b) In the development of a national strategy, policies or regimes on access and benefit-sharing.

19. To facilitate the involvement of relevant stakeholders, including indigenous and local communities, appropriate consultative arrangements, such as national consultative committees, comprising relevant stakeholder representatives, should be made.

20. The involvement of relevant stakeholders should be promoted by:

(a) Providing information, especially regarding scientific and legal advice, in order for them to be able to participate effectively;

(b) Providing support for capacity-building, in order for them to be actively engaged in various stages of access and benefit-sharing arrangements, such as in the development and implementation of mutually agreed terms and contractual arrangements.

21. The stakeholders involved in access to genetic resources and benefit-sharing may wish to seek the support of a mediator or facilitator when negotiating mutually agreed terms.

IV. STEPS IN THE ACCESS AND BENEFIT-SHARING PROCESS

A. Overall strategy

22. Access and benefit-sharing systems should be based on an overall access and benefit-sharing strategy at the country or regional level. This access and benefit-sharing strategy should aim at the conservation and sustainable use of biological diversity, and may be part of a national biodiversity strategy and action plan and promote the equitable sharing of benefits.

B. Identification of steps

23. The steps involved in the process of obtaining access to genetic resources and sharing of benefits may include activities prior to access, research and development conducted on the genetic resources, as well as their commercialization and other uses, including benefit-sharing.

C. Prior informed consent

24. As provided for in Article 15 of the Convention on Biological Diversity, which recognizes the sovereign rights of States over their natural resources, each Contracting Party to the Convention shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and fair and equitable sharing of benefits arising from such uses. In accordance with Article 15, paragraph 5, of the Convention on Biological Diversity, access to genetic resources shall be subject to prior informed consent of the contracting Party providing such resources, unless otherwise determined by that Party.

25. gainst this background, the Guidelines are intended to assist Parties in the establishment of a system of prior informed consent, in accordance with Article 15, paragraph 5, of the Convention.

1. Basic principles of a prior informed consent system

26. The basic principles of a prior informed consent system should include:

(a) Legal certainty and clarity;

(b) Access to genetic resources should be facilitated at minimum cost;

(c) Restrictions on access to genetic resources should be transparent, based on legal grounds, and not run counter to the objectives of the Convention;

(d) Consent of the relevant competent national authority(ies) in the provider country. The consent of relevant stakeholders, such as indigenous and local communities, as appropriate to the circumstances and subject to domestic law, should also be obtained.

2. Elements of a prior informed consent system

27. Elements of a prior informed consent system may include:

(a) Competent authority(ies) granting or providing for evidence of prior informed consent;

(b) Timing and deadlines;

(c) Specification of use;

(d) Procedures for obtaining prior informed consent;

(e) Mechanism for consultation of relevant stakeholders;

(f) Process.

Competent authority(ies) granting prior informed consent

28. Prior informed consent for access to in situ genetic resources shall be obtained from the Contracting Party providing such resources, through its competent national authority(ies), unless otherwise determined by that Party.

29. In accordance with national legislation, prior informed consent may be required from different levels of Government. Requirements for obtaining prior informed consent (national/provincial/local) in the provider country should therefore be specified.

30. National procedures should facilitate the involvement of all relevant stakeholders from the community to the government level, aiming at simplicity and clarity.

31. Respecting established legal rights of indigenous and local communities associated with the genetic resources being accessed or where traditional knowledge associated with these genetic resources is being accessed, the prior informed consent of indigenous and local communities and the approval and involvement of the holders of traditional knowledge, innovations and practices should be obtained, in accordance with their traditional practices, national access policies and subject to domestic laws.

32. For ex situ collections, prior informed consent should be obtained from the competent national authority(ies) and/or the body governing the ex situ collection concerned as appropriate.

Timing and deadlines

33. Prior informed consent is to be sought adequately in advance to be meaningful both for those seeking and for those granting access. Decisions on applications for access to genetic resources should also be taken within a reasonable period of time.

Specification of use

34. Prior informed consent should be based on the specific uses for which consent has been granted. While prior informed consent may be granted initially for specific use(s),any change of use including transfer to third parties may require a new application for prior informed consent. Permitted uses should be clearly stipulated and further prior informed consent for changes or unforeseen uses should be required. Specific needs of taxonomic and systematic research as specified by the Global Taxonomy Initiative should be taken into consideration.

35. Prior informed consent is linked to the requirement of mutually agreed terms.

Procedures for obtaining prior informed consent

36. An application for access could require the following information to be provided, in order for the competent authority to determine whether or not access to a genetic resource should be granted. This list is indicative and should be adapted to national circumstances:

    (a) Legal entity and affiliation of the applicant and/or collector and contact person when the applicant is an institution;

    (b) Type and quantity of genetic resources to which access is sought;

    (c) Starting date and duration of the activity;

    (d) Geographical prospecting area;

    (e) Evaluation of how the access activity may impact on conservation and sustainable use of biodiversity, to determine the relative costs and benefits of granting access;

    (f) Accurate information regarding intended use (e.g.: taxonomy, collection, research, commercialization);

(g) Identification of where the research and development will take place;

(h) Information on how the research and development is to be carried out;

(i) Identification of local bodies for collaboration in research and development;

(j) Possible third party involvement;

(k) Purpose of the collection, research and expected results;

(l) Kinds/types of benefits that could come from obtaining access to the resource, including benefits from derivatives and products arising from the commercial and other utilization of the genetic resource;

(m) Indication of benefit-sharing arrangements;

(n) Budget;

(o) Treatment of confidential information.

37. Permission to access genetic resources does not necessarily imply permission to use associated knowledge and vice versa.

Process

38. Applications for access to genetic resources through prior informed consent and decisions by the competent authority(ies) to grant access to genetic resources or not shall be documented in written form.

39. The competent authority could grant access by issuing a permit or licence or following other appropriate procedures. A national registration system could be used to record the issuance of all permits or licences, on the basis of duly completed application forms.

40. The procedures for obtaining an access permit/licence should be transparent and accessible by any interested party.

D. Mutually agreed terms

41. In accordance with Article 15,paragraph 7,of the Convention on Biological Diversity, each Contracting Party shall "take legislative, administrative or policy measures, as appropriate (...) 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 utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms". Thus, guidelines should assist Parties and stakeholders in the development of mutually agreed terms to ensure the fair and equitable sharing of benefits.

1. Basic requirements for mutually agreed terms

42. The following principles or basic requirements could be considered for the development of mutually agreed terms:

(a) Legal certainty and clarity;

(b) Minimization of transaction costs, by, for example:

(i) Establishing and promoting awareness of the Government's and relevant stakeholders' requirements for prior informed consent and contractual arrangements;

(ii) Ensuring awareness of existing mechanisms for applying for access, entering into arrangements and ensuring the sharing of benefits;

(iii) Developing framework agreements, under which repeat access under expedited arrangements can be made;

(iv) Developing standardized material transfer agreements and benefitsharing arrangements for similar resources and similar uses (see appendix I for suggested elements of such an agreement);

(c) Inclusion of provisions on user and provider obligations;

(d) Development of different contractual arrangements for different resources and for different uses and development of model agreements;

(e) Different uses may include, inter alia, taxonomy, collection, research, commercialization;

(f) Mutually agreed terms should be negotiated efficiently and within a reasonable period of time;

(g) Mutually agreed terms should be set out in a written agreement.

43. The following elements could be considered as guiding parameters in contractual agreements. These elements could also be considered as basic requirements for mutually agreed terms:

(a) Regulating the use of resources in order to take into account ethical concerns of the particular Parties and stakeholders, in particular indigenous and local communities concerned;

(b) Making provision to ensure the continued customary use of genetic resources and related knowledge;

(c) Provision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained and to provide licences by common consent;

(d) The possibility of joint ownership of intellectual property rights according to the degree of contribution.

2. Indicative list of typical mutually agreed terms

44. The following provides an indicative list of typical mutually agreed terms:

(a) Type and quantity of genetic resources, and the geographical/ecological area of activity;

(b) Any limitations on the possible use of the material;

(c) Recognition of the sovereign rights of the country of origin;

(d) Capacity-building in various areas to be identified in the agreement;

(e) A clause on whether the terms of the agreement in certain circumstances (e.g. change of use) can be renegotiated;

(f) Whether the genetic resources can be transferred to third parties and conditions to be imposed in such cases, e.g. whether or not to pass genetic resources to third parties without ensuring that the third parties enter into similar agreements except for taxonomic and systematic research that is not related to commercialization;

(g) Whether the knowledge, innovations and practices of indigenous and local communities have been respected, preserved and maintained, and whether the customary use of biological resources in accordance with traditional practices has been protected and encouraged;

(h) Treatment of confidential information;

(i) Provisions regarding the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products.

3. Benefit-sharing

45. Mutually agreed terms could cover the conditions, obligations, procedures, types, timing, distribution and mechanisms of benefits to be shared. These will vary depending on what is regarded as fair and equitable in light of the circumstances.

Types of benefits

46. Examples of monetary and non-monetary benefits are provided in appendix II to these Guidelines.

Timing of benefits

47. Near-term, medium-term and long-term benefits should be considered, including up-front payments, milestone payments and royalties. The time-frame of benefit-sharing should be definitely stipulated. Furthermore, the balance among near-term, medium-term and long-term benefit should be considered on a case-by-case basis.

Distribution of benefits

48. Pursuant to mutually agreed terms established following prior informed consent, benefits should be shared fairly and equitably with all those who have been identified as having contributed to the resource management, scientific and/or commercial process. The latter may include governmental, non-governmental or academic institutions and indigenous and local communities. Benefits should be directed in such a way as to promote conservation and sustainable use of biological diversity.

Mechanisms for benefit-sharing

49. Mechanisms for benefit-sharing may vary depending upon the type of benefits, the specific conditions in the country and the stakeholders involved. The benefit-sharing mechanism should be flexible as it should be determined by the partners involved in benefit-sharing and will vary on a case-by-case basis.

50. Mechanisms for sharing benefits should include full cooperation in scientific research and technology development, as well as those that derive from commercial products including trust funds, joint ventures and licences with preferential terms.

V. OTHER PROVISIONS

A. Incentives

51. The following incentive measures exemplify measures which could be used in the implementation of the guidelines:

    (a) The identification and mitigation or removal of perverse incentives, that may act as obstacles for conservation and sustainable use of biological diversity through access and benefit-sharing, should be considered;

    (b) The use of well-designed economic and regulatory instruments, directly or indirectly related to access and benefit-sharing, should be considered to foster equitable and efficient allocation of benefits;

    (c) The use of valuation methods should be considered as a tool to inform users and providers involved in access and benefit-sharing;

    (d) The creation and use of markets should be considered as a way of efficiently achieving conservation and sustainable use of biological diversity.

B. Accountability in implementing access and benefit-sharing arrangements

52. Parties should endeavour to establish mechanisms to promote accountability by all stakeholders involved in access and benefit-sharing arrangements.

53. To promote accountability, Parties may consider establishing requirements regarding:

    (a) Reporting; and

    (b) Disclosure of information.

54. The individual collector or institution on whose behalf the collector is operating should, where appropriate, be responsible and accountable for the compliance of the collector.

C. National monitoring and reporting

55. Depending on the terms of access and benefit-sharing, national monitoring may include:

    (a) Whether the use of genetic resources is in compliance with the terms of access and benefit-sharing;

    (b) Research and development process;

    (c) Applications for intellectual property rights relating to the material supplied.

56. The involvement of relevant stakeholders, in particular, indigenous and local communities, in the various stages of development and implementation of access and benefit-sharing arrangements can play an important role in facilitating the monitoring of compliance.

D. Means for verification

57. Voluntary verification mechanisms could be developed at the national level to ensure compliance with the access and benefit-sharing provisions of the Convention on Biological Diversity and national legal instruments of the country of origin providing the genetic resources.

58. A system of voluntary certification could serve as a means to verify the transparency of the process of access and benefit-sharing. Such a system could certify that the access and benefit-sharing provisions of the Convention on Biological Diversity have been complied with.

E. Settlement of disputes

59. As most obligations arising under mutually agreed arrangements will be between providers and users, disputes arising in these arrangements should be solved in accordance with the relevant contractual arrangements on access and benefitsharing and the applicable law and practices.

60. In cases where the access and benefit-sharing agreements consistent with the Convention on Biological Diversity and national legal instruments of the country of origin of genetic resources have not been complied with, the use of sanctions could be considered, such as penalty fees set out in contractual agreements.

F. Remedies

61. Parties may take appropriate effective and proportionate measures for violations of national legislative, administrative or policy measures implementing the access and benefit-sharing provisions of the Convention on Biological Diversity, including requirements related to prior informed consent and mutually agreed terms.

Appendix I

SUGGESTED ELEMENTS FOR MATERIAL TRANSFER AGREEMENTS

Material transfer agreements may contain wording on the following elements:

A. Introductory provisions

1. Preambular reference to the Convention on Biological Diversity

2. Legal status of the provider and user of genetic resources

3. Mandate and/or general objectives of provider and, where appropriate, user of genetic resources

B. Access and benefit-sharing provisions

1. Description of genetic resources covered by the material transfer agreements, including accompanying information

2. Permitted uses, bearing in mind the potential uses, of the genetic resources, their products or derivatives under the material transfer agreement (e.g. research, breeding, commercialization)
3. Statement that any change of use would require new prior informed consent and material transfer agreement
4. Whether intellectual property rights may be sought and if so under what conditions
5. Terms of benefit-sharing arrangements, including commitment to share monetary and non-monetary benefits
6. No warranties guaranteed by provider on identity and/or quality of the provided material
7. Whether the genetic resources and/or accompanying information may be transferred to third parties and if so conditions that should apply
8. Definitions
9. Duty to minimize environmental impacts of collecting activities

C. Legal provisions

1. Obligation to comply with the material transfer agreement
2. Duration of agreement
3. Notice to terminate the agreement
4. Fact that the obligations in certain clauses survive the termination of the agreement
5. Independent enforceability of individual clauses in the agreement
6. Events limiting the liability of either party (such as act of God, fire, flood, etc.)
7. Dispute settlement arrangements
8. Assignment or transfer of rights
9. Assignment, transfer or exclusion of the right to claim any property rights, including intellectual property rights, over the genetic resources received through the material transfer agreement
10. Choice of law
11. Confidentiality clause
12. Guarantee

Appendix II

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 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.

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 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 utilization 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;

(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.

C. Convention on Biological Diversity

Preamble

The Contracting Parties,

Conscious of the intrinsic value of biological diversity and of the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components,

Conscious also of the importance of biological diversity for evolution and for maintaining life-sustaining systems of the biosphere,

Affirming that the conservation of biological diversity is a common concern of humankind,

Reaffirming that States have sovereign rights over their own biological resources,

Reaffirming also that States are responsible for conserving their biological diversity and for using their biological resources in a sustainable manner,

Concerned that biological diversity is being significantly reduced by certain human activities,

Aware of the general lack of information and knowledge regarding biological diversity and of the urgent need to develop scientific, technical and institutional capacities to provide the basic understanding upon which to plan and implement appropriate measures,

Noting that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity at source,

Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat,

Noting further that the fundamental requirement for the conservation of biological diversity is the in-situ conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings,

Noting further that *ex-situ* measures, preferably in the country of origin, also have an important role to play,

Recognizing the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components,

Recognizing also the vital role that women play in the conservation and sustainable use of biological diversity and affirming the need for the full participation of women at all levels of policy-making and implementation for biological diversity conservation,

Stressing the importance of, and the need to promote, international, regional and global cooperation among States and intergovernmental organizations and the non-governmental sector for the conservation of biological diversity and the sustainable use of its components,

Acknowledging that the provision of new and additional financial resources and appropriate access to relevant technologies can be expected to make a substantial difference in the world's ability to address the loss of biological diversity,

Acknowledging further that special provision is required to meet the needs of developing countries, including the provision of new and additional financial resources and appropriate access to relevant technologies,

Noting in this regard the special conditions of the least developed countries and small island States,

Acknowledging that substantial investments are required to conserve biological diversity and that there is the expectation of a broad range of environmental, economic and social benefits from those investments,

Recognizing that economic and social development and poverty eradication are the first and overriding priorities of developing countries,

Aware that conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technologies are essential,

Noting that, ultimately, the conservation and sustainable use of biological diversity will strengthen friendly relations among States and contribute to peace for humankind,

Desiring to enhance and complement existing international arrangements for the conservation of biological diversity and sustainable use of its components, and

Determined to conserve and sustainably use biological diversity for the benefit of present and future generations,

Have agreed as follows:

Article 1. OBJECTIVES

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Article 2. USE OF TERMS

For the purposes of this Convention:

"Biological diversity" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

"Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

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

"Country of origin of genetic resources" means the country which possesses those genetic resources in in-situ conditions.

"Country providing genetic resources" means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.

"Domesticated or cultivated species" means species in which the evolutionary process has been influenced by humans to meet their needs.

"Ecosystem" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.

"Ex-situ conservation" means the conservation of components of biological diversity outside their natural habitats.

"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.

"Habitat" means the place or type of site where an organism or population naturally occurs.

"In-situ conditions" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"In-situ conservation" means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"Protected area" means a geographically defined area which is designated or regulated and managed to achieve specific conservation objectives.

"Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Convention and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it.

"Sustainable use" means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

"Technology" includes biotechnology.

Article 3. PRINCIPLE

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and

the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Article 4. JURISDICTIONAL SCOPE

Subject to the rights of other States, and except as otherwise expressly provided in this Convention, the provisions of this Convention apply, in relation to each Contracting Party:

(a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and

(b) In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

Article 5. COOPERATION

Each Contracting Party shall, as far as possible and as appropriate, cooperate with other Contracting Parties, directly or, where appropriate, through competent international organizations, in respect of areas beyond national jurisdiction and on other matters of mutual interest, for the conservation and sustainable use of biological diversity.

Article 6. GENERAL MEASURES FOR CONSERVATION AND SUSTAINBLE USE

Each Contracting Party shall, in accordance with its particular conditions and capabilities:

(a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned; and

(b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies.

Article 7. IDENTIFICATION AND MONITORING

Each Contracting Party shall, as far as possible and as appropriate, in particular for the purposes of Articles 8 to 10:

(a) Identify components of biological diversity important for its conservation and sustainable use having regard to the indicative list of categories set down in Annex I;

(b) Monitor, through sampling and other techniques, the components of biological diversity identified pursuant to subparagraph (a) above, paying particular attention to those requiring urgent conservation measures and those which offer the greatest potential for sustainable use;

(c) Identify processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity, and monitor their effects through sampling and other techniques; and

(d) Maintain and organize, by any mechanism data, derived from identification and monitoring activities pursuant to subparagraphs (a), (b) and (c) above.

Article 8. *IN-SITU* CONSERVATION

Each Contracting Party shall, as far as possible and as appropriate:

(a) Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity;

(b) Develop, where necessary, guidelines for the selection, establishment and management of protected areas or areas where special measures need to be taken to conserve biological diversity;

(c) Regulate or manage biological resources important for the conservation of biological diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use;

(d) Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings;

(e) Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas;

(f) Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species, *inter alia*, through the development and implementation of plans or other management strategies;

(g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;

(h) Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species;

(i) Endeavour to provide the conditions needed for compatibility between present uses and the conservation of biological diversity and the sustainable use of its components;

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

(k) Develop or maintain necessary legislation and/or other regulatory provisions for the protection of threatened species and populations;

(l) Where a significant adverse effect on biological diversity has been determined pursuant to Article 7, regulate or manage the relevant processes and categories of activities; and

(m) Cooperate in providing financial and other support for in-situ conservation outlined in subparagraphs (a) to (l) above, particularly to developing countries.

Article 9. *EX-SITU* CONSERVATION

Each Contracting Party shall, as far as possible and as appropriate, and predominantly for the purpose of complementing *in-situ* measures:

(a) Adopt measures for the *ex-situ* conservation of components of biological diversity, preferably in the country of origin of such components;

(b) Establish and maintain facilities for *ex-situ* conservation of and research on plants, animals and micro-organisms, preferably in the country of origin of genetic resources;

(c) Adopt measures for the recovery and rehabilitation of threatened species and for their reintroduction into their natural habitats under appropriate conditions;

(d) Regulate and manage collection of biological resources from natural habitats for *ex-situ* conservation purposes so as not to threaten ecosystems and in-situ populations of species, except where special temporary *ex-situ* measures are required under subparagraph (c) above; and

(e) Cooperate in providing financial and other support for *ex-situ* conservation outlined in subparagraphs (a) to (d) above and in the establishment and maintenance of *ex-situ* conservation facilities in developing countries.

Article 10. SUSTAINABLE USE OF COMPONENTS OF BIOLOGICAL DIVERSITY

Each Contracting Party shall, as far as possible and as appropriate:

(a) Integrate consideration of the conservation and sustainable use of biological resources into national decision-making;

(b) Adopt measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity;

(c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;

(d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced; and

(e) Encourage cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources.

Article 11. INCENTIVE MEASURES

Each Contracting Party shall, as far as possible and as appropriate, adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity.

Article 12. RESEARCH AND TRAINING

The Contracting Parties, taking into account the special needs of developing countries, shall:

(a) Establish and maintain programmes for scientific and technical education and training in measures for the identification, conservation and sustainable use of biological diversity and its components and provide support for such education and training for the specific needs of developing countries;

(b) Promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, *inter alia*, in accordance with decisions of the Conference of the Parties taken in consequence of recommendations of the Subsidiary Body on Scientific, Technical and Technological Advice; and

(c) In keeping with the provisions of Articles 16, 18 and 20, promote and cooperate in the use of scientific advances in biological diversity research in developing methods for conservation and sustainable use of biological resources.

Article 13. PUBLIC EDUCATION AND AWARENESS

The Contracting Parties shall:

(a) Promote and encourage understanding of the importance of, and the measures required for, the conservation of biological diversity, as well as its propagation through media, and the inclusion of these topics in educational programmes; and

(b) Cooperate, as appropriate, with other States and international organizations in developing educational and public awareness programmes, with respect to conservation and sustainable use of biological diversity.

Article 14. IMPACT ASSESSMENT AND MINIMIZING ADVERSE IMPACTS

1. Each Contracting Party, as far as possible and as appropriate, shall:

(a) Introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects and, where appropriate, allow for public participation in such procedures;

(b) Introduce appropriate arrangements to ensure that the environmental consequences of its programmes and policies that are likely to have significant adverse impacts on biological diversity are duly taken into account;

(c) Promote, on the basis of reciprocity, notification, exchange of information and consultation on activities under their jurisdiction or control which are likely to significantly affect adversely the biological diversity of other States or areas beyond the limits of national jurisdiction, by encouraging the conclusion of bilateral, regional or multilateral arrangements, as appropriate;

(d) In the case of imminent or grave danger or damage, originating under its jurisdiction or control, to biological diversity within the area under jurisdiction of other States or in areas beyond the

limits of national jurisdiction, notify immediately the potentially affected States of such danger or damage, as well as initiate action to prevent or minimize such danger or damage; and

(e) Promote national arrangements for emergency responses to activities or events, whether caused naturally or otherwise, which present a grave and imminent danger to biological diversity and encourage international cooperation to supplement such national efforts and, where appropriate and agreed by the States or regional economic integration organizations concerned, to establish joint contingency plans.

2. The Conference of the Parties shall examine, on the basis of studies to be carried out, the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter.

Article 15. ACCESS TO GENETIC RESOURCES

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. 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.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 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 utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16. ACCESS TO AND TRANSFER OF TECHNOLOGY

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are

relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Article 17. EXCHANGE OF INFORMATION

1. The Contracting Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries.

2. Such exchange of information shall include exchange of results of technical, scientific and socioeconomic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1. It shall also, where feasible, include repatriation of information.

Article 18. TECHNICAL AND SCIENTIFIC COOPERATION

1. The Contracting Parties shall promote international technical and scientific cooperation in the field of conservation and sustainable use of biological diversity, where necessary, through the appropriate international and national institutions.

2. Each Contracting Party shall promote technical and scientific cooperation with other Contracting Parties, in particular developing countries, in implementing this Convention, *inter alia*, through the development and implementation of national policies. In promoting such cooperation, special

attention should be given to the development and strengthening of national capabilities, by means of human resources development and institution building.

3. The Conference of the Parties, at its first meeting, shall determine how to establish a clearing-house mechanism to promote and facilitate technical and scientific cooperation.

4. The Contracting Parties shall, in accordance with national legislation and policies, encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies, in pursuance of the objectives of this Convention. For this purpose, the Contracting Parties shall also promote cooperation in the training of personnel and exchange of experts.

5. The Contracting Parties shall, subject to mutual agreement, promote the establishment of joint research programmes and joint ventures for the development of technologies relevant to the objectives of this Convention.

Article 19. HANDLING OF BIOTECHNOLOGY AND DISTRIBUTION OF ITS BENEFITS

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

Article 20. FINANCIAL RESOURCES

1. Each Contracting Party undertakes to provide, in accordance with its capabilities, financial support and incentives in respect of those national activities which are intended to achieve the objectives of this Convention, in accordance with its national plans, priorities and programmes.

2. The developed country Parties shall provide new and additional financial resources to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures which fulfil the obligations of this Convention and to benefit from its provisions and which costs are agreed between a developing country Party and the institutional structure referred

to in Article 21, in accordance with policy, strategy, programme priorities and eligibility criteria and an indicative list of incremental costs established by the Conference of the Parties. Other Parties, including countries undergoing the process of transition to a market economy, may voluntarily assume the obligations of the developed country Parties. For the purpose of this Article, the Conference of the Parties, shall at its first meeting establish a list of developed country Parties and other Parties which voluntarily assume the obligations of the developed country Parties. The Conference of the Parties shall periodically review and if necessary amend the list. Contributions from other countries and sources on a voluntary basis would also be encouraged. The implementation of these commitments shall take into account the need for adequacy, predictability and timely flow of funds and the importance of burden-sharing among the contributing Parties included in the list.

3. The developed country Parties may also provide, and developing country Parties avail themselves of, financial resources related to the implementation of this Convention through bilateral, regional and other multilateral channels.

4. The extent to which developing country Parties will effectively implement their commitments under this Convention will depend on the effective implementation by developed country Parties of their commitments under this Convention related to financial resources and transfer of technology and will take fully into account the fact that economic and social development and eradication of poverty are the first and overriding priorities of the developing country Parties.

5. The Parties shall take full account of the specific needs and special situation of least developed countries in their actions with regard to funding and transfer of technology.

6. The Contracting Parties shall also take into consideration the special conditions resulting from the dependence on, distribution and location of, biological diversity within developing country Parties, in particular small island States.

7. Consideration shall also be given to the special situation of developing countries, including those that are most environmentally vulnerable, such as those with arid and semi- arid zones, coastal and mountainous areas.

Article 21. FINANCIAL MECHANISM

1. There shall be a mechanism for the provision of financial resources to developing country Parties for purposes of this Convention on a grant or concessional basis the essential elements of which are described in this Article. The mechanism shall function under the authority and guidance of, and be accountable to, the Conference of the Parties for purposes of this Convention. The operations of the mechanism shall be carried out by such institutional structure as may be decided upon by the Conference of the Parties at its first meeting. For purposes of this Convention, the Conference of the Parties shall determine the policy, strategy, programme priorities and eligibility criteria relating to the access to and utilization of such resources. The contributions shall be such as to take into account the need for predictability, adequacy and timely flow of funds referred to in Article 20 in accordance with the amount of resources needed to be decided periodically by the Conference of the Parties and the importance of burden-sharing among the contributing Parties included in the list referred to in Article 20, paragraph 2. Voluntary contributions may also be made by the developed country Parties and by other countries and sources. The mechanism shall operate within a democratic and transparent system of governance.

2. Pursuant to the objectives of this Convention, the Conference of the Parties shall at its first meeting determine the policy, strategy and programme priorities, as well as detailed criteria and guidelines for eligibility for access to and utilization of the financial resources including monitoring and evaluation on a regular basis of such utilization. The Conference of the Parties shall decide on the arrangements to give effect to paragraph 1 above after consultation with the institutional structure entrusted with the operation of the financial mechanism.

3. The Conference of the Parties shall review the effectiveness of the mechanism established under this Article, including the criteria and guidelines referred to in paragraph 2 above, not less than two years after the entry into force of this Convention and thereafter on a regular basis. Based on such review, it shall take appropriate action to improve the effectiveness of the mechanism if necessary.

4. The Contracting Parties shall consider strengthening existing financial institutions to provide financial resources for the conservation and sustainable use of biological diversity.

Article 22. RELATIONSHIP WITH OTHER INTERNATIONAL CONVENTIONS

1. The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.

2. Contracting Parties shall implement this Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the sea.

Article 23. CONFERENCE OF THE PARTIES

1. A Conference of the Parties is hereby established. The first meeting of the Conference of the Parties shall be convened by the Executive Director of the United Nations Environment Programme not later than one year after the entry into force of this Convention. Thereafter, ordinary meetings of the Conference of the Parties shall be held at regular intervals to be determined by the Conference at its first meeting.

2. Extraordinary meetings of the Conference of the Parties shall be held at such other times as may be deemed necessary by the Conference, or at the written request of any Party, provided that, within six months of the request being communicated to them by the Secretariat, it is supported by at least one third of the Parties.

3. The Conference of the Parties shall by consensus agree upon and adopt rules of procedure for itself and for any subsidiary body it may establish, as well as financial rules governing the funding of the Secretariat. At each ordinary meeting, it shall adopt a budget for the financial period until the next ordinary meeting.

4. The Conference of the Parties shall keep under review the implementation of this Convention, and, for this purpose, shall:

   (a) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 26 and consider such information as well as reports submitted by any subsidiary body;

   (b) Review scientific, technical and technological advice on biological diversity provided in accordance with Article 25;

(c) Consider and adopt, as required, protocols in accordance with Article 28;

(d) Consider and adopt, as required, in accordance with Articles 29 and 30, amendments to this Convention and its annexes;

(e) Consider amendments to any protocol, as well as to any annexes thereto, and, if so decided, recommend their adoption to the parties to the protocol concerned;

(f) Consider and adopt, as required, in accordance with Article 30, additional annexes to this Convention;

(g) Establish such subsidiary bodies, particularly to provide scientific and technical advice, as are deemed necessary for the implementation of this Convention;

(h) Contact, through the Secretariat, the executive bodies of conventions dealing with matters covered by this Convention with a view to establishing appropriate forms of cooperation with them; and

(i) Consider and undertake any additional action that may be required for the achievement of the purposes of this Convention in the light of experience gained in its operation.

5. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State not Party to this Convention, may be represented as observers at meetings of the Conference of the Parties. Any other body or agency, whether governmental or non-governmental, qualified in fields relating to conservation and sustainable use of biological diversity, which has informed the Secretariat of its wish to be represented as an observer at a meeting of the Conference of the Parties, may be admitted unless at least one third of the Parties present object. The admission and participation of observers shall be subject to the rules of procedure adopted by the Conference of the Parties.

Article 24. SECRETARIAT

1. A secretariat is hereby established. Its functions shall be:

(a) To arrange for and service meetings of the Conference of the Parties provided for in Article 23;

(b) To perform the functions assigned to it by any protocol;

(c) To prepare reports on the execution of its functions under this Convention and present them to the Conference of the Parties;

(d) To coordinate with other relevant international bodies and, in particular to enter into such administrative and contractual arrangements as may be required for the effective discharge of its functions; and

(e) To perform such other functions as may be determined by the Conference of the Parties.

2. At its first ordinary meeting, the Conference of the Parties shall designate the secretariat from amongst those existing competent international organizations which have signified their willingness to carry out the secretariat functions under this Convention.

Article 25. SUBSIDIARY BODY ON SCIENTIFIC, TECHNICAL AND TECHNOLOGICAL ADVICE

1. A subsidiary body for the provision of scientific, technical and technological advice is hereby established to provide the Conference of the Parties and, as appropriate, its other subsidiary bodies with timely advice relating to the implementation of this Convention. This body shall be open to participation by all Parties and shall be multidisciplinary. It shall comprise government representatives competent in the relevant field of expertise. It shall report regularly to the Conference of the Parties on all aspects of its work.

2. Under the authority of and in accordance with guidelines laid down by the Conference of the Parties, and upon its request, this body shall:

   (a) Provide scientific and technical assessments of the status of biological diversity;

   (b) Prepare scientific and technical assessments of the effects of types of measures taken in accordance with the provisions of this Convention;

   (c) Identify innovative, efficient and state-of-the-art technologies and know-how relating to the conservation and sustainable use of biological diversity and advise on the ways and means of promoting development and/or transferring such technologies;

   (d) Provide advice on scientific programmes and international cooperation in research and development related to conservation and sustainable use of biological diversity; and

   (e) Respond to scientific, technical, technological and methodological questions that the Conference of the Parties and its subsidiary bodies may put to the body.

3. The functions, terms of reference, organization and operation of this body may be further elaborated by the Conference of the Parties.

Article 26. REPORTS

Each Contracting Party shall, at intervals to be determined by the Conference of the Parties, present to the Conference of the Parties, reports on measures which it has taken for the implementation of the provisions of this Convention and their effectiveness in meeting the objectives of this Convention.

Article 27. SETTLEMENT OF DISPUTES

1. In the event of a dispute between Contracting Parties concerning the interpretation or application of this Convention, the parties concerned shall seek solution by negotiation.

2. If the parties concerned cannot reach agreement by negotiation, they may jointly seek the good offices of, or request mediation by, a third party.

3. When ratifying, accepting, approving or acceding to this Convention, or at any time thereafter, a State or regional economic integration organization may declare in writing to the Depositary that for a dispute not resolved in accordance with paragraph 1 or paragraph 2 above, it accepts one or both of the following means of dispute settlement as compulsory:

   (a) Arbitration in accordance with the procedure laid down in Part 1 of Annex II;

(b) Submission of the dispute to the International Court of Justice.

4. If the parties to the dispute have not, in accordance with paragraph 3 above, accepted the same or any procedure, the dispute shall be submitted to conciliation in accordance with Part 2 of Annex II unless the parties otherwise agree.

5. The provisions of this Article shall apply with respect to any protocol except as otherwise provided in the protocol concerned.

Article 28. ADOPTION OF PROTOCOLS

1. The Contracting Parties shall cooperate in the formulation and adoption of protocols to this Convention.

2. Protocols shall be adopted at a meeting of the Conference of the Parties.

3. The text of any proposed protocol shall be communicated to the Contracting Parties by the Secretariat at least six months before such a meeting.

Article 29. AMENDMENT OF THE CONVENTION OR PROTOCOLS

1. Amendments to this Convention may be proposed by any Contracting Party. Amendments to any protocol may be proposed by any Party to that protocol.

2. Amendments to this Convention shall be adopted at a meeting of the Conference of the Parties. Amendments to any protocol shall be adopted at a meeting of the Parties to the Protocol in question. The text of any proposed amendment to this Convention or to any protocol, except as may otherwise be provided in such protocol, shall be communicated to the Parties to the instrument in question by the secretariat at least six months before the meeting at which it is proposed for adoption. The secretariat shall also communicate proposed amendments to the signatories to this Convention for information.

3. The Parties shall make every effort to reach agreement on any proposed amendment to this Convention or to any protocol by consensus. If all efforts at consensus have been exhausted, and no agreement reached, the amendment shall as a last resort be adopted by a two-third majority vote of the Parties to the instrument in question present and voting at the meeting, and shall be submitted by the Depositary to all Parties for ratification, acceptance or approval.

4. Ratification, acceptance or approval of amendments shall be notified to the Depositary in writing. Amendments adopted in accordance with paragraph 3 above shall enter into force among Parties having accepted them on the ninetieth day after the deposit of instruments of ratification, acceptance or approval by at least two thirds of the Contracting Parties to this Convention or of the Parties to the protocol concerned, except as may otherwise be provided in such protocol. Thereafter the amendments shall enter into force for any other Party on the ninetieth day after that Party deposits its instrument of ratification, acceptance or approval of the amendments.

5. For the purposes of this Article, “Parties present and voting” means Parties present and casting an affirmative or negative vote.

Article 30. ADOPTION AND AMENDMENT OF ANNEXES

1. The annexes to this Convention or to any protocol shall form an integral part of the Convention or of such protocol, as the case may be, and, unless expressly provided otherwise, a reference to this Convention or its protocols constitutes at the same time a reference to any annexes thereto. Such annexes shall be restricted to procedural, scientific, technical and administrative matters.

2. Except as may be otherwise provided in any protocol with respect to its annexes, the following procedure shall apply to the proposal, adoption and entry into force of additional annexes to this Convention or of annexes to any protocol:

   (a) Annexes to this Convention or to any protocol shall be proposed and adopted according to the procedure laid down in Article 29;

   (b) Any Party that is unable to approve an additional annex to this Convention or an annex to any protocol to which it is Party shall so notify the Depositary, in writing, within one year from the date of the communication of the adoption by the Depositary. The Depositary shall without delay notify all Parties of any such notification received. A Party may at any time withdraw a previous declaration of objection and the annexes shall thereupon enter into force for that Party subject to subparagraph (c) below;

   (c) On the expiry of one year from the date of the communication of the adoption by the Depositary, the annex shall enter into force for all Parties to this Convention or to any protocol concerned which have not submitted a notification in accordance with the provisions of subparagraph (b) above.

3. The proposal, adoption and entry into force of amendments to annexes to this Convention or to any protocol shall be subject to the same procedure as for the proposal, adoption and entry into force of annexes to the Convention or annexes to any protocol.

4. If an additional annex or an amendment to an annex is related to an amendment to this Convention or to any protocol, the additional annex or amendment shall not enter into force until such time as the amendment to the Convention or to the protocol concerned enters into force.

Article 31. RIGHT TO VOTE

1. Except as provided for in paragraph 2 below, each Contracting Party to this Convention or to any protocol shall have one vote.

2. Regional economic integration organizations, in matters within their competence, shall exercise their right to vote with a number of votes equal to the number of their member States which are Contracting Parties to this Convention or the relevant protocol. Such organizations shall not exercise their right to vote if their member States exercise theirs, and vice versa.

Article 32. RELATIONSHIP BETWEEN THIS CONVENTION AND ITS PROTOCOLS

1. A State or a regional economic integration organization may not become a Party to a protocol unless it is, or becomes at the same time, a Contracting Party to this Convention.

2. Decisions under any protocol shall be taken only by the Parties to the protocol concerned. Any Contracting Party that has not ratified, accepted or approved a protocol may participate as an observer in any meeting of the parties to that protocol.

Article 33. SIGNATURE

This Convention shall be open for signature at Rio de Janeiro by all States and any regional economic integration organization from 5 June 1992 until 14 June 1992, and at the United Nations Headquarters in New York from 15 June 1992 to 4 June 1993.

Article 34. RATIFICATION, ACCEPTANCE OR APPROVAL

1. This Convention and any protocol shall be subject to ratification, acceptance or approval by States and by regional economic integration organizations. Instruments of ratification, acceptance or approval shall be deposited with the Depositary.

2. Any organization referred to in paragraph 1 above which becomes a Contracting Party to this Convention or any protocol without any of its member States being a Contracting Party shall be bound by all the obligations under the Convention or the protocol, as the case may be. In the case of such organizations, one or more of whose member States is a Contracting Party to this Convention or relevant protocol, the organization and its member States shall decide on their respective responsibilities for the performance of their obligations under the Convention or protocol, as the case may be. In such cases, the organization and the member States shall not be entitled to exercise rights under the Convention or relevant protocol concurrently.

3. In their instruments of ratification, acceptance or approval, the organizations referred to in paragraph 1 above shall declare the extent of their competence with respect to the matters governed by the Convention or the relevant protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.

Article 35. ACCESSION

1. This Convention and any protocol shall be open for accession by States and by regional economic integration organizations from the date on which the Convention or the protocol concerned is closed for signature. The instruments of accession shall be deposited with the Depositary.

2. In their instruments of accession, the organizations referred to in paragraph 1 above shall declare the extent of their competence with respect to the matters governed by the Convention or the relevant protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.

3. The provisions of Article 34, paragraph 2, shall apply to regional economic integration organizations which accede to this Convention or any protocol.

Article 36. ENTRY INTO FORCE

1. This Convention shall enter into force on the ninetieth day after the date of deposit of the thirtieth instrument of ratification, acceptance, approval or accession.

2. Any protocol shall enter into force on the ninetieth day after the date of deposit of the number of instruments of ratification, acceptance, approval or accession, specified in that protocol, has been deposited.

3. For each Contracting Party which ratifies, accepts or approves this Convention or accedes thereto after the deposit of the thirtieth instrument of ratification, acceptance, approval or accession, it shall enter into force on the ninetieth day after the date of deposit by such Contracting Party of its instrument of ratification, acceptance, approval or accession.

4. Any protocol, except as otherwise provided in such protocol, shall enter into force for a Contracting Party that ratifies, accepts or approves that protocol or accedes thereto after its entry into force pursuant to paragraph 2 above, on the ninetieth day after the date on which that Contracting Party deposits its instrument of ratification, acceptance, approval or accession, or on the date on which this Convention enters into force for that Contracting Party, whichever shall be the later.

5. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 37. RESERVATIONS

No reservations may be made to this Convention.

Article 38. WITHDRAWALS

1. At any time after two years from the date on which this Convention has entered into force for a Contracting Party, that Contracting Party may withdraw from the Convention by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

3. Any Contracting Party which withdraws from this Convention shall be considered as also having withdrawn from any protocol to which it is party.

Article 39. FINANCIAL INTERIM ARRANGEMENTS

Provided that it has been fully restructured in accordance with the requirements of Article 21, the Global Environment Facility of the United Nations Development Programme, the United Nations Environment Programme and the International Bank for Reconstruction and Development shall be the institutional structure referred to in Article 21 on an interim basis, for the period between the entry into force of this Convention and the first meeting of the Conference of the Parties or until the Conference of the Parties decides which institutional structure will be designated in accordance with Article 21.

Article 40. SECRETARIAT INTERIM ARRANGEMENTS

The secretariat to be provided by the Executive Director of the United Nations Environment Programme shall be the secretariat referred to in Article 24, paragraph 2, on an interim basis for the period between the entry into force of this Convention and the first meeting of the Conference of the Parties.

Article 41. DEPOSITARY

The Secretary-General of the United Nations shall assume the functions of Depositary of this Convention and any protocols.

Article 42. AUTHENTIC TEXTS

The original of this Convention, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary- General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Convention.

Done at Rio de Janeiro on this fifth day of June, one thousand nine hundred and ninety-two.

Annex I – IDENTIFICATION AND MONITORING

1. Ecosystems and habitats: containing high diversity, large numbers of endemic or threatened species, or wilderness; required by migratory species; of social, economic, cultural or scientific importance; or, which are representative, unique or associated with key evolutionary or other biological processes;

2. Species and communities which are: threatened; wild relatives of domesticated or cultivated species; of medicinal, agricultural or other economic value; or social, scientific or cultural importance; or importance for research into the conservation and sustainable use of biological diversity, such as indicator species; and

3. Described genomes and genes of social, scientific or economic importance.

Annex II – PART 1. ARBITRATION

Article 1

The claimant party shall notify the secretariat that the parties are referring a dispute to arbitration pursuant to Article 27. The notification shall state the subject-matter of arbitration and include, in particular, the Articles of the Convention or the protocol, the interpretation or application of which are at issue. If the parties do not agree on the subject matter of the dispute before the President of the tribunal is designated, the arbitral tribunal shall determine the subject matter. The secretariat shall forward the information thus received to all Contracting Parties to this Convention or to the protocol concerned.

Article 2

1. In disputes between two parties, the arbitral tribunal shall consist of three members. Each of the parties to the dispute shall appoint an arbitrator and the two arbitrators so appointed shall designate by common agreement the third arbitrator who shall be the President of the tribunal. The latter shall not be a national of one of the parties to the dispute, nor have his or her usual place of residence in the territory of one of these parties, nor be employed by any of them, nor have dealt with the case in any other capacity.

2. In disputes between more than two parties, parties in the same interest shall appoint one arbitrator jointly by agreement.

3. Any vacancy shall be filled in the manner prescribed for the initial appointment.

Article 3

1. If the President of the arbitral tribunal has not been designated within two months of the appointment of the second arbitrator, the Secretary-General of the United Nations shall, at the request of a party, designate the President within a further two-month period.

2. If one of the parties to the dispute does not appoint an arbitrator within two months of receipt of the request, the other party may inform the Secretary-General who shall make the designation within a further two-month period.

Article 4

The arbitral tribunal shall render its decisions in accordance with the provisions of this Convention, any protocols concerned, and international law.

Article 5

Unless the parties to the dispute otherwise agree, the arbitral tribunal shall determine its own rules of procedure.

Article 6

The arbitral tribunal may, at the request of one of the parties, recommend essential interim measures of protection.

Article 7

The parties to the dispute shall facilitate the work of the arbitral tribunal and, in particular, using all means at their disposal, shall:

(a) Provide it with all relevant documents, information and facilities; and

(b) Enable it, when necessary, to call witnesses or experts and receive their evidence.

Article 8

The parties and the arbitrators are under an obligation to protect the confidentiality of any information they receive in confidence during the proceedings of the arbitral tribunal.

Article 9

Unless the arbitral tribunal determines otherwise because of the particular circumstances of the case, the costs of the tribunal shall be borne by the parties to the dispute in equal shares. The tribunal shall keep a record of all its costs, and shall furnish a final statement thereof to the parties.

Article 10

Any Contracting Party that has an interest of a legal nature in the subject-matter of the dispute which may be affected by the decision in the case, may intervene in the proceedings with the consent of the tribunal.

Article 11

The tribunal may hear and determine counterclaims arising directly out of the subject-matter of the dispute.

Article 12

Decisions both on procedure and substance of the arbitral tribunal shall be taken by a majority vote of its members.

Article 13

If one of the parties to the dispute does not appear before the arbitral tribunal or fails to defend its case, the other party may request the tribunal to continue the proceedings and to make its award. Absence of a party or a failure of a party to defend its case shall not constitute a bar to the proceedings. Before rendering its final decision, the arbitral tribunal must satisfy itself that the claim is well founded in fact and law.

Article 14

The tribunal shall render its final decision within five months of the date on which it is fully constituted unless it finds it necessary to extend the time-limit for a period which should not exceed five more months.

Article 15

The final decision of the arbitral tribunal shall be confined to the subject-matter of the dispute and shall state the reasons on which it is based. It shall contain the names of the members who have participated and the date of the final decision. Anymember of the tribunal may attach a separate or dissenting opinion to the final decision.

Article 16

The award shall be binding on the parties to the dispute. It shall be without appeal unless the parties to the dispute have agreed in advance to an appellate procedure.

Article 17

Any controversy which may arise between the parties to the dispute as regards the interpretation or manner of implementation of the final decision may be submitted by either party for decision to the arbitral tribunal which rendered it.

Annex II – PART 2. CONCILIATION

Article 1

A conciliation commission shall be created upon the request of one of the parties to the dispute. The commission shall, unless the parties otherwise agree, be composed of five members, two appointed by each Party concerned and a President chosen jointly by those members.

Article 2

In disputes between more than two parties, parties in the same interest shall appoint their members of the commission jointly by agreement. Where two or more parties have separate interests or there is a disagreement as to whether they are of the same interest, they shall appoint their members separately.

Article 3

If any appointments by the parties are not made within two months of the date of the request to create a conciliation commission, the Secretary-General of the United Nations shall, if asked to do so by the party that made the request, make those appointments within a further two-month period.

Article 4

If a President of the conciliation commission has not been chosen within two months of the last of the members of the commission being appointed, the Secretary-General of the United Nations shall, if asked to do so by a party, designate a President within a further two-month period.

Article 5

The conciliation commission shall take its decisions by majority vote of its members. It shall, unless the parties to the dispute otherwise agree, determine its own procedure. It shall render a proposal for resolution of the dispute, which the parties shall consider in good faith.

Article 6

A disagreement as to whether the conciliation commission has competence shall be decided by the commission.

D. Conference of the Parties to the Convention on Biological Diversity: Decision X/1 *Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization*

The Conference of the Parties,

Recalling that the fair and equitable sharing of the benefits arising from the utilization of genetic resources is one of the three objectives of the Convention on Biological Diversity,

Recalling also Article 15 of the Convention on access to genetic resources and the sharing of the benefits arising from their utilization,

Further recalling its decision V/24 A adopting the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising out of their Utilization,

Further recalling the Plan of Implementation adopted by the World Summit on Sustainable Development held in Johannesburg in September 2002, which called for action to negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources 1,

Recalling decision VII/19 D, in which the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (the Working Group) was mandated with the collaboration of the Ad Hoc Open-ended Intersessional Working Group on Article 8(j) and Related Provisions, to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions of Article 15 and Article 8(j) of the Convention and the three objectives of the Convention,

Recognizing that the International Regime 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 Utilization 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 Utilization,

Further recalling decision IX/12,

Noting with appreciation the work carried out by the Working Group,

Noting the valuable work carried out by the Co-Chairs of the Working Group, Mr. Fernando Casas (Colombia) and Mr. Timothy Hodges (Canada), in steering the process through both formal and informal ways,

Noting also with appreciation the participation of indigenous and local communities and stakeholders including industry, research, and civil society representatives in the Working Group,

Recognizing that the objectives of the International Treaty on Plant Genetic Resources for Food and Agriculture are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security,

Recognizing further the progress made by many intergovernmental forums in addressing access and benefit-sharing related issues,

Considering the need for interim arrangements pending the entry into force of 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 to prepare for its effective implementation once it enters into force,

Noting with appreciation resolution 18/2009 of the Conference of the Food and Agriculture Organization of the United Nations on policies and arrangements for access and benefit-sharing for genetic resources for food and agriculture,

Recognizing the importance of communication, education and public awareness for the successful implementation of 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,

I. ADOPTION OF THE NAGOYA PROTOCOL

1. *Decides* to adopt the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the Protocol) as set out in annex I to the present decision;

2. *Requests* the Secretary-General of the United Nations to be the Depositary of the Protocol and to open it for signature at the United Nations Headquarters in New York from 2 February 2011 to 1 February 2012;

3. *Calls upon* the Parties to the Convention on Biological Diversity to sign the Protocol at the earliest opportunity and to deposit instruments of ratification, acceptance or approval or instruments of accession, as appropriate, with a view to ensuring its entry into force as soon as possible;

4. *Invites* States that are not Parties to the Convention to ratify, accept, approve or accede to it, as appropriate, thereby enabling them also to become Parties to the Protocol;

5. *Agrees,* bearing in mind decision II/11, paragraph 2, and without prejudice to the further consideration of this issue by the Conference of the Parties serving as the meeting of the Parties to the Protocol, that human genetic resources are not included within the framework of the Protocol;

6. *Decides* that the first review under Article 31 of the Protocol shall assess the implementation of Article 16 in light of developments in other relevant international organizations, including, inter alia, the World Intellectual Property Organization, provided that they do not run counter to the objectives of the Convention and the Protocol;

II. INTERGOVERNMENTAL COMMITTEE FOR THE NAGOYA PROTOCOL

7. *Decides* to establish an Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the Intergovernmental Committee);

8. *Decides* that the Intergovernmental Committee shall undertake, with the support of the Executive Secretary, the preparations necessary for the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, at which time it will cease to exist, taking into account the budgetary provisions adopted by the Conference of the Parties;

9. *Notes* that the rules of procedure for the Conference of the Parties to the Convention shall apply, *mutatis mutandis*, to meetings of the Intergovernmental Committee;

10. *Decides* that the Intergovernmental Committee shall hold its first meeting from 6 to 10 June 2011 and the second meeting from 23 to 27 April 2012;

11. *Also decides* that the Co-Chairs of the Intergovernmental Committee shall be Mr. Fernando Casas (Colombia) and Mr. Timothy Hodges (Canada) and that the first Intergovernmental Committee will be preceded by a one-day meeting to elect its Bureau and agree on other organizational matters. To that effect, the President is mandated to undertake the necessary consultations;

12. *Endorses* the work plan for the Intergovernmental Committee as contained in annex II to the present decision;

13. *Requests* the Executive Secretary to provide technical assistance to Parties, subject to the availability of financial resources, with a view to supporting the early ratification and implementation of the Protocol;

14. *Invites* the Global Environment Facility to provide financial support to Parties to assist with the early ratification of the Protocol and its implementation;

15. *Requests* the Executive Secretary, in collaboration with relevant organizations, as appropriate, to carry out awareness-raising activities among relevant stakeholder groups, including the business community, the scientific community and others, to support the implementation of the Protocol;

16. *Invites* Parties and relevant organizations to provide financial and technical assistance, as appropriate, to support the implementation of the Protocol;

17. *Invites* Parties that are developing countries, in particular the least developed countries and small island developing States, as well as Parties with economies in transition, to make an initial identification of their needs in relation to capacity-building, capacity development and strengthening of human resources and institutional capacities in order to effectively implement the Protocol and to make this information available to the Executive Secretary no later than two months prior to the first meeting of the Intergovernmental Committee;

18. *Requests* the Executive Secretary to collect and make available on the clearing-house mechanism sectoral and cross-sectoral model contractual clauses for mutually agreed terms;

19. *Also requests* the Executive Secretary to collect and make available on the clearing-house mechanism existing guidelines and codes of conduct related to access and benefit-sharing;

20. *Urges* the Parties to the Convention and other States and regional economic integration organizations to designate, as soon as possible and no later than 31 March 2011, a focal point for the Intergovernmental Committee and to inform the Executive Secretary accordingly;

III. ADMINISTRATIVE AND BUDGETARY MATTERS

21. *Decides* that, pending the entry into force of the Protocol and the convening of the first Conference of the Parties serving as the meeting of the Parties to the Protocol, the financial costs of the interim mechanisms shall be borne by the Trust Fund for the Convention on Biological Diversity (BY);

22. *Takes note* of the amounts supplementary to the funding estimates for the Special Voluntary Trust Fund (BE) for Additional Voluntary Contributions in Support of Approved Activities for the biennium 2011-2012 specified by the Executive Secretary and invites Parties and other States to make contributions to that Fund.

ANNEX I 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 *(see Supplementary Materials A. above)*

ANNEX II WORK PLAN FOR THE INTERGOVERNMENTAL COMMITTEE FOR THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING OUT OF THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY

A. Issues for consideration by the Intergovernmental Committee at its first meeting

1. The modalities of operation of the Access and Benefit-sharing Clearing-House, including reports on its activities (Article 14, paragraph 4).

2. Measures to assist in the capacity-building, capacity development and strengthening of human resources and institutional capacities in developing countries, in particular the least developed countries and small island developing States amongst them, and Parties with economies in transition, taking into account the needs identified by the Parties concerned for the implementation of the Protocol (Article 22).

3. Measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues (Article 21).

4. Cooperative procedures and institutional mechanisms to promote compliance with the Protocol and to address cases of non-compliance, including procedures and mechanisms to offer advice or assistance, where appropriate (Article 30).

B. Issues for consideration by the Intergovernmental Committee at its second meeting

5. Development of a programme budget for the biennium following the entry into force of the Protocol.

6. Elaboration of guidance for the financial mechanism (Article 25).

7. Elaboration of guidance for resource mobilization for the implementation of the Protocol.

8. Consideration of rules of procedure for the Conference of the Parties serving as the meeting of the Parties to the Protocol (Article 26, paragraph 5).

9. Elaboration of a draft provisional agenda for the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (Article 26, paragraph 6).

10. The need for and modalities of a global multilateral benefit-sharing mechanism (Article 10).

11. Continued consideration of items taken up at the first meeting of the Intergovernmental Committee, as needed.

...

E. Conference of the Parties to the Convention on Biological Diversity: Decision VII/19 *Access and Benefit-sharing as Related to Genetic Resources (Article 15)*

...

D. INTERNATIONAL REGIME ON ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

The Conference of the Parties,

Reaffirming that the fair and equitable sharing of the benefits arising out of the utilization of genetic resources is one of the objectives of the Convention on Biological Diversity, in accordance with Article 1 of the Convention,

Reaffirming the sovereign rights of States over their natural resources and that the authority to determine access to genetic resources rests with the national Governments and is subject to national legislation, in accordance with Article 3 and Article 15, paragraph 1, of the Convention,

Reaffirming the commitment of Parties in Article 15, paragraph 2 of the Convention to "endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention",

Recalling paragraph 44 (o) of the Plan of Implementation of the World Summit on Sustainable Development, which calls for action to "negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources",

Further recalling resolution 57/260 of 20 December 2002, adopted by the United Nations General Assembly at its fifty-seventh session, inviting the Conference of the Parties to take appropriate steps with regard to the commitment made at the World Summit on Sustainable Development "to negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources",

Recalling the recommendation of the Inter-Sessional Meeting on the Multi-Year Programme of Work of the Conference of the Parties up to 2010 inviting the Ad Hoc Open-ended Working Group on Access and Benefit-sharing "to consider the process, nature, scope, elements and modalities of an international regime on access to genetic resources and benefit-sharing and to provide advice to the Conference of the Parties at its seventh meeting on this issue",

Noting the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, adopted at the sixth meeting of the Conference of the Parties, "as a useful first step of an evolutionary process in the implementation of relevant provisions of the Convention related to access to genetic resources and benefit-sharing",

Recalling also paragraph 44 (n) of the Plan of Implementation of the World Summit on Sustainable Development which calls for action to promote the wide implementation of and continued work on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization, as an input to assist the Parties when developing and drafting legislative,

administrative or policy measures on access and benefit sharing as well as contract and other arrangements under mutually agreed terms for access and benefit-sharing",

Recalling further the Millennium Development Goals and the potential role of access and benefit-sharing in poverty eradication and environmental sustainability,

Taking into account Articles 8(j), 15, 16, 17, 18, 19, paragraphs 1 and 2, 20, 21 and 22 of the Convention on Biological Diversity,

Reaffirming the commitment by Parties, subject to national legislation, to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from their utilization,

Noting the work being carried out under the framework of the Convention by the Working Group on Article 8(j) and Related Provisions of the Convention,

Recognizing that the Convention is the key instrument for the conservation, sustainable use and fair and equitable sharing of benefits arising out of the utilization of genetic resources and bearing in mind the work related to access to genetic resources and benefit sharing carried out in other relevant international interGovernmental organizations,

Recognizing also the important contribution of the FAO International Treaty for Plant Genetic Resources for Food and Agriculture that was negotiated in harmony with the Convention on Biological Diversity,

Recognizing that Parties that are countries of origin of genetic resources may be both users and providers and that Parties that have acquired these genetic resources in accordance with the Convention on Biological Diversity may also be both users and providers,

Recalling that the Bonn Guidelines indicate that Parties and stakeholders may be both users and providers, noting that these terms may still need to be examined and clarified,

Recognizing that the regime should be practicable, transparent, and efficient and avoid arbitrary treatment, consistent with the provisions of the Convention,

Recalling that the international regime should recognize and shall respect the rights of indigenous and local communities,

Noting that there is a need for further analysis of existing national, regional and international legal instruments and regimes relating to access and benefit-sharing and experience gained in their implementation, including gaps and their consequences,

Noting that the Ad Hoc Open-ended Working Group on Access and Benefit-sharing has identified possible components of an international regime, without prejudging the outcome,

1. *Decides* to mandate the Ad Hoc Open-ended Working Group on Access and Benefit-sharing with the collaboration of the Ad Hoc Open ended Inter-Sessional Working Group on Article 8(j) and Related Provisions, ensuring the participation of indigenous and local communities, non-Governmental organizations, industry and scientific and academic institutions, as well as interGovernmental organizations, to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument\instruments to

effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention;

2. *Recommends* that the Ad Hoc Open-ended Working Group on Access and Benefit-sharing should operate in accordance with the terms of reference contained in the annex to this decision;

3. *Request* the Executive Secretary to make the necessary arrangements for the Ad Hoc Open-ended Working Group on Access and Benefit-sharing to be convened twice before the eighth meeting of the Conference of the Parties with one meeting from the core budget back to back with the Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions and the other from voluntary contributions;

4. *Requests* the Ad Hoc Open-ended Working Group on ABS to report on progress to the Conference of the Parties at its eighth meeting;

5. *Invites* the United Nations Environment Programme, the Food and Agriculture Organization of the United Nations, the World Trade Organization, the World Intellectual Property Organization, the International Union for the Protection of New Varieties of Plants, to cooperate with the Ad Hoc Open-ended Working Group on Access and Benefit-sharing in elaborating the international regime;

6. *Encourages* Parties, Governments, international organizations and all relevant stakeholders to provide the ways and means to allow for sufficient preparation and to facilitate effective participation of indigenous and local communities in the process of the negotiation and elaboration of an international regime;

7. *Recommends* the promotion of the participation of all relevant stakeholders, including non Governmental organizations and the private sector, and indigenous and local communities;

8. *Invites* Parties, Governments, international organizations, indigenous and local communities and all relevant stakeholders, to submit to the Executive Secretary their views, information and analysis on the elements of the international regime as soon as possible;

9. *Requests* the Executive Secretary to compile the submissions received and to make them available through the clearing-house mechanism and other means for the Ad Hoc Open-ended Working Group on Access and Benefit-sharing.

Annex TERMS OF REFERENCE FOR THE AD HOC OPEN-ENDED WORKING GROUP ON ACCESS AND BENEFIT-SHARING

(a) **Process:**

(i) To elaborate and negotiate the nature, scope and elements of an international regime on access and benefit-sharing within the framework of the Convention on Biological Diversity, as contained in paragraphs (b), (c) and (d) below, drawing on *inter alia* an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing, including: access contracts; experiences with their implementation; compliance and enforcement mechanisms; and any other options.

(ii) As part of the work, the Ad Hoc Open-ended Working Group on Access and Benefit-sharing will examine whether and to what extent possible elements as contained in

paragraph (d) below are part of these instruments and determine how to address the gaps.

(b) **Nature:** The international regime could be composed of one or more instruments within a set of principles, norms, rules and decision-making procedures, legally-binding and/or non-binding.

(c) **Scope:**

(i) Access to genetic resources and promotion and safeguarding of fair and equitable sharing of the benefits arising out of the utilization of genetic resources in accordance with relevant provisions of the Convention on Biological Diversity;

(ii) Traditional knowledge, innovations and practices in accordance with Article 8(j).

(d) **Elements:** The following elements shall be considered by the Ad Hoc Open ended Working Group on Access and Benefit-sharing for inclusion in the international regime, *inter alia:*

(i) Measures to promote and encourage collaborative scientific research, as well as research for commercial purposes and commercialization, consistent with Articles 8(j), 10, 15, paragraph 6, paragraph 7 and Articles 16, 18 and 19 of the Convention;

(ii) Measures to ensure the fair and equitable sharing of benefits from the results of research and development and the benefits arising from the commercial and other utilization of genetic resources in accordance with Articles 15.7, 16, 19.1, 19.2. of the Convention;

(iii) Measures for benefit-sharing including, *inter alia*, monetary and non-monetary benefits, and effective technology transfer and cooperation so as to support the generation of social, economic and environmental benefits;

(iv) Measures to promote facilitated access to genetic resources for environmentally sound uses according to Article 15.2 of the Convention on Biological Diversity;

(v) Measures to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources;

(vi) Measures to ensure the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products, in the context of mutually agreed terms;

(vii) Measures to promote access and benefit-sharing arrangements that contribute to the achievement of the Millennium Development Goals, in particular on poverty eradication and environmental sustainability;

(viii) Measures to facilitate the functioning of the regime at the local, national, subregional, regional and international levels, bearing in mind the transboundary nature of the distribution of some *in situ* genetic resources and associated traditional knowledge;

(ix) Measures to ensure compliance with national legislations on access and benefit-sharing, prior informed consent and mutually agreed terms, consistent with the Convention on Biological Diversity;

(x) Measures to ensure compliance with prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with Article 8(j);

(xi) Measures to ensure compliance with the mutually agreed terms on which genetic resources were granted and to prevent the unauthorized access and use of genetic resources consistent with the Convention on Biological Diversity;

(xii) Addressing the issue of derivatives;

(xiii) Internationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge;

(xiv) Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights;

(xv) Recognition and protection of the rights of indigenous and local communities over their traditional knowledge associated to genetic resources subject to the national legislation of the countries where these communities are located;

(xvi) Customary law and traditional cultural practices of indigenous and local communities;

(xvii) Capacity-building measures based on country needs;

(xviii) Code of ethics/Code of conduct/Models of prior informed consent or other instruments in order to ensure fair and equitable sharing of benefits with indigenous and local communities;

(xix) Means to support the implementation of the international regime within the framework of the Convention;

(xx) Monitoring, compliance and enforcement;

(xxi) Dispute settlement, and/or arbitration, if and when necessary;

(xxii) Institutional issues to support the implementation of the international regime within the framework of the Convention;

(xxiii) Relevant elements of existing instruments and processes, including:

- Convention on Biological Diversity;
- Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization;
- The International Treaty on Plant Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations;
- The Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations;
- Current national legislative, administrative and policy measures implementing Article 15 of the Convention on Biological Diversity;
- The United Nations Permanent Forum on Indigenous Issues;

- Outcomes of Working Group on Article 8(j);
- The Agreement on Trade-related Aspects of Intellectual Property Rights and other World Trade Organization agreements;
- World Intellectual Property Organization conventions and treaties;
- International Convention for the Protection of New Varieties of Plants;
- Regional agreements;
- Codes of conduct and other approaches developed by specific user groups or for specific genetic resources, including model contractual agreements;
- African Model Law on the Rights of Communities, Farmers, Breeders, and on Access to Biological Resources;
- Decision 391 of the Andean Community;
- Decision 486 of the Andean Community;
- United Nations Convention on the Law of the Sea;
- Agenda 21;
- Rio Declaration;
- CITES;
- Antarctic Treaty;
- The Universal Declaration of Human Rights;
- The International Covenant on Civil and Political Rights;
- The International Covenant on Economic, Social and Cultural Rights.

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