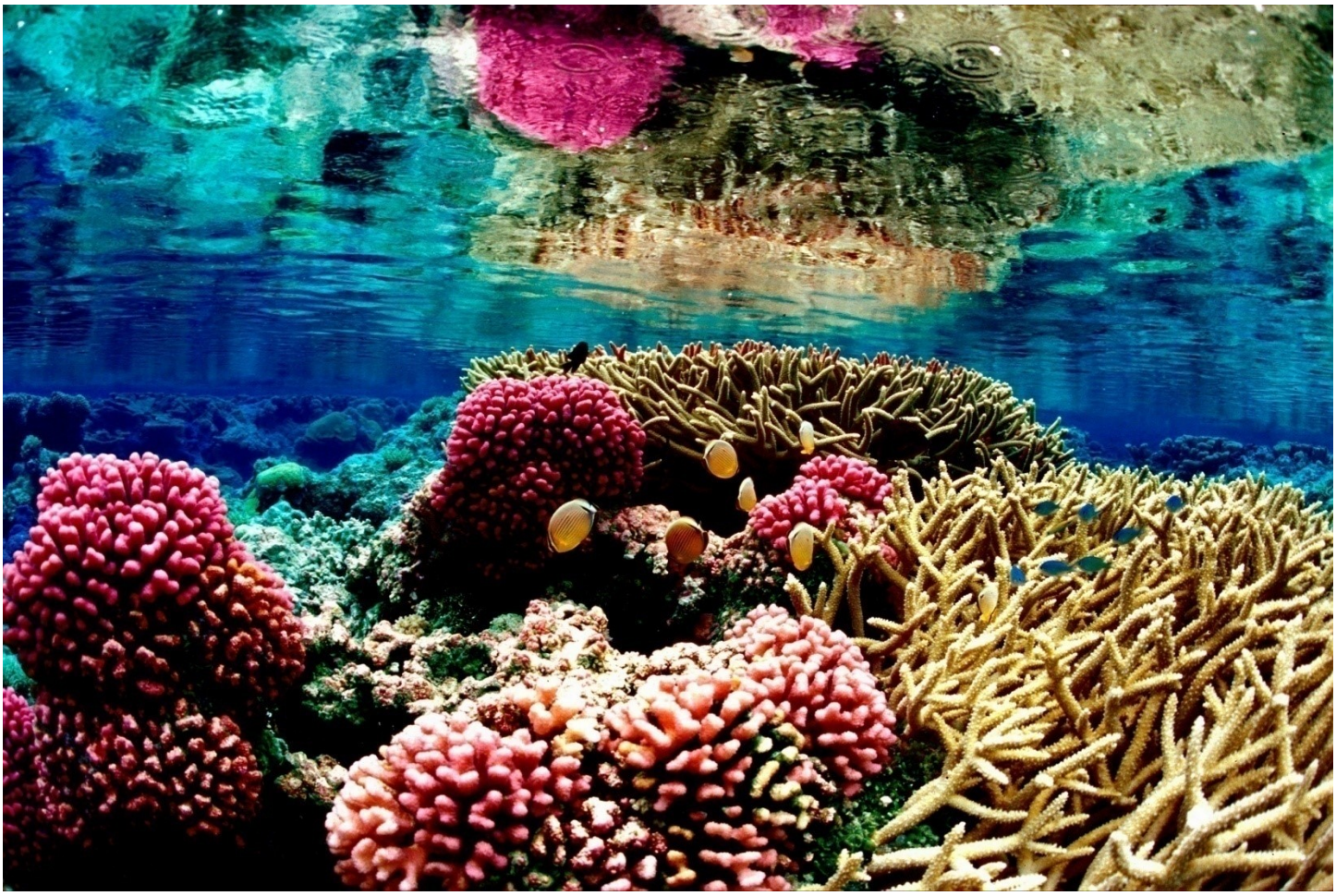

OVERVIEW OF NATIONAL AND REGIONAL MEASURES ON ACCESS AND BENEFIT SHARING

CHALLENGES AND OPPORTUNITIES IN IMPLEMENTING THE NAGOYA PROTOCOL

Third Edition

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ACRONYMS AND ABBREVIATIONS

ABS	Access and Benefit-Sharing
ABS Initiative	Access and Benefit-Sharing Capacity Development Initiative
ABRAPI	Association of Biotechnology Companies (Brazil)
AU	African Union
BL	Biodiversity Law (Costa Rica)
BS	Benefit-Sharing
CAFTA	United States-Dominican Republic-Central America Free Trade Agreement
CBD	Convention on Biological Diversity
CDI	National Commission for the Development of Indigenous Peoples
CGRFA	Food and Agriculture Organization Commission on Genetic Resources for Food and Agriculture
CISDL	Centre for International Sustainable Development Law
CGEN	Conselho de Gestao do Patrimonio Genetico (Brazil)
CHM	Clearing-House Mechanism
CNA	Competent National Authority/Authorities
CNPq	National Council for Scientific and Technological Development (Brazil)
CONABIO	National Commission for Knowledge and Use of Biodiversity (Mexico)
CONAGEBIO	National Biodiversity Administration Committee (Costa Rica)
COP	Conference of the Parties to the Convention on Biological Diversity
COP-MOP	Conference of the Parties serving as the meeting of the Parties to 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
CSIC	Consejo Superior de Investigaciones Científicas de España
DEFRA	Department for Environment, Food and Rural Affairs (UK)
DIGERPI	Collective Register for Intellectual Property (Panama)
EEZ	Exclusive economic zone
Embrapa	Agricultural Research Corporation (Brazil)
EU	European Union
FOEN	Federal Ministry for the Environment (Switzerland)
FPIC	Free prior informed consent
Funai	National Foundation for Indigenous People (Brazil)
General Act	Ecological Equilibrium and Environmental Protection General Act (Mexico)
GR	Genetic resources
IBAMA	Institute for the Environment and Renewable Natural Resources (Brazil)
ICBG	International Cooperative Biodiversity Group
ICNP	Intergovernmental Committee on the Nagoya Protocol
IDLO	International Development Law Organization
ILC	Indigenous and local communities
IGC	World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IMPI	Mexican Institute of Industrial Property
INBio	National Biodiversity Institute (Costa Rica)

INDECOPI	National Institute for the Protection of Intellectual Property
INPI	National Industrial Property Institute (Brazil)
IPR	Intellectual Property Rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN	International Union for the Conservation of Nature
JBA	Japan Bioindustry Association
KRIBB	Korean Research Institute of Bioscience and Biotechnology
LMMC	Like-Minded Megadiverse Countries
LRGCT	Draft General Law on Access to Genetic Resources and the Protection of the Traditional Associated Knowledge (Mexico)
MAT	Mutually agreed terms
MEE	Ministry of Environment and Energy (Costa Rica)
MMV	Medicine for Malaria Venture
MP	Provisional Measure (Brazil)
MTA	Material Transfer Agreements
NBSAP	National Biodiversity Strategy and Action Plan
NCDDG	National Cooperative Drugs Discovery Group
NP	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
PAN	National Action Party (Mexico)
PIC	Prior informed consent
PRI	Institutional Revolutionary Party (Mexico)
SAGARPA	Ministry of Environment and Natural Resources (Mexico)
SBPC	Society for the Advancement of Science (Brazil)
SEMARNAT	Ministry of Agriculture, Livestock, Rural Development, Fishing and Food (Mexico)
SINAREFI	National System of Plant Genetic Resources for Food and Agriculture (Mexico)
SRE	Ministry of Foreign Affairs (Mexico)
TK	Traditional Knowledge
TO	Technical Office (Costa Rica)
UNARGEN	Unit for Access to Genetic Resources (Panama)
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNU	United Nations University
WG-ABS	Ad Hoc Open-ended Working Group on Access and Benefit-Sharing
WIPO	World Intellectual Property Organization

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[1] [α] Post Nagoya Protocol Measure [β] Pre Nagoya Protocol Measure

EXECUTIVE SUMMARY

The third objective of the *Convention on Biological Diversity* (CBD) is the fair and equitable sharing of the benefits derived from the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.[2] To further implement this objective, 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*[3] (Protocol) was adopted by the tenth meeting of the Conference of the Parties to the CBD (COP) held in Nagoya, Japan in 2010. The Strategic Plan for Biodiversity 2011-2020, also adopted at COP 10, aims for the Protocol to enter into force and be operational in accordance with national legislation by 2015.[4]

Since the entry into force of the CBD in 1993, many countries and several regions have established provisions on access and benefit-sharing (ABS) for biological and genetic resources through laws, regulations, policies or administrative measures. A wide range of mechanisms exist to regulate access to biological and genetic resources and for benefit-sharing at the national level. These systems are important to analyse because they put the broad terms of the CBD into practice. Drawing lessons from the implementation of laws and policies on ABS is crucial in identifying the different options and approaches that are available. The Parties recognized the significance of experience with ABS systems in the terms of reference they set for the negotiation of the Protocol, which drew on an analysis of existing legal and other instruments at national, regional and international levels relating to ABS, including access contracts, experiences with their implementation, and compliance and enforcement mechanisms.[5]

In light of the Protocol's adoption, it is important to learn lessons from countries that have, or are in the process of putting in place, national ABS measures. Drawing on practical experiences with ABS will highlight where regulatory gaps exist; the strengths and weaknesses of different approaches to ABS; and where further measures need to be developed by the COP-MOP or by other international fora, such as the World Intellectual Property Organisation (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), or the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA).

This **third edition** of the CISDL study reviews the ABS measures in countries from Latin America and the Caribbean, Asia, the South Pacific, Africa, Europe, and North America as well as the regional measures of the Andean Community, the Association of South-East Asian Nations (ASEAN), the African Union (AU), the European Union (EU), and the Nordic countries. It examines relevant laws and policies, and their provisions on scope, prior informed consent, mutually agreed terms on benefit-sharing, compliance, and monitoring and enforcement, as well as any access agreements that have been granted, or relevant experience gained in the implementation of ABS measures. It also presents a discussion and conclusions on the main legislative challenges to implementing the Protocol.

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[2] *Convention on Biological Diversity*, 5 June 1992, 1760 U.N.T.S. 79, at Article 1 [CBD].

[3] *2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the 1992 Convention on Biological Diversity*, 29 October 2010 [Nagoya Protocol].

[4] *Convention on Biological Diversity, Strategic Plan for Biodiversity 2011-2020*, Aichi Biodiversity Target 16.

[5] *Convention on Biological* Diversity, COP Decision VII/19 at Part D, Annex, para. (a)(i).

INTRODUCTION

The main objectives of the CBD are the conservation of biodiversity, the sustainable use of its components, and the fair and equitable sharing of the benefits derived from the utilisation of genetic resources. The objective of fairly and equitably sharing the benefits derived from the access to and use of biodiversity requires regulating access to genetic resources (and associated knowledge) and subjecting it to the laws of the country, and ensuring a fair and equitable sharing of the benefits with the country providing the genetic resources.[6] Since the Convention's entry into force on December 29, 1993, one of the most controversial regulatory and public policy issues both in the international and national contexts has been access to genetic resources and the equitable sharing of the benefits arising therefrom (ABS). Article 15 of the CBD sets out the related principles and obligations of the Parties relating to access to genetic resources and the fair and equitable sharing of benefits arising from use, on the basis of prior informed consent (PIC) and mutually agreed terms (MAT).

Since the first specific national legislation on ABS – the Philippines Executive Order in 1995 – and the first regional framework – Decision 391 of the Andean Community, "The Common Regime for Access to Genetic Resources" – many studies, seminars, publications, laws and draft laws have been produced and undertaken on this subject. A number of countries and regions around the world have established provisions on ABS for biological and genetic resources in their laws, regulations or administrative structures. The countries that do have national ABS frameworks in place have chosen a wide range of mechanisms to regulate access to biological and genetic resources and benefit-sharing at the national level. Some countries have developed new stand-alone laws on ABS and others have amended, revised or updated existing general biodiversity-related laws to introduce and give effect to ABS components. Still others have promulgated administrative guidelines as they are in the process of considering legislative options, and a number have only adopted policies.

Following the adoption of the Bonn Guidelines at the 6th Conference of the Parties (COP) to the CBD in 2002, and the call for continued negotiation of an international framework for ABS issued at the World Summit for Sustainable Development, negotiations concluded at COP 10 in October 2010 with the adoption of the Nagoya Protocol.[7] As part of the Strategic Plan for Biodiversity 2011-2020, Aichi Biodiversity Target 16 was adopted as a driver to promote the Protocol's rapid entry into force, its implementation and its operationalization. Target 16 calls on at least 50 Parties to the CBD to ratify or accede to the Protocol so that it enters into force by 2015 and is operationalized, consistent with national legislation. Over 20 years after the entry into force of the CBD, and three years after the adoption of the Protocol, many CBD Parties continue to face challenges in the adoption and implementation of functional national ABS laws and measures. According to the CBD Secretariat ABS Measures Database, to date, only 57 countries have some type of law, measures or instruments to regulate access to their genetic resources and the fair and equitable sharing of benefits arising from their utilization. Yet, if the Protocol enters into force by 2015, various components of the Protocol must be swiftly operationalized at the national level and lessons must be learned from efforts already undertaken.

[6] CBD, *supra* note 2, at Articles 1, 8(j), 15, 16, and 19.
[7] Nagoya Protocol, *supra* note 3.

RATIONALE

In light of the adoption of the Nagoya Protocol and the goals set out in the Strategic Plan for Biodiversity 2011-2020, notably Aichi Target 16, it is important for countries that have or are in the process of putting in place national administrative, legislative or policy measures on ABS to share their experiences in relation to implementation. This will be instrumental in appraising and illustrating the different options and approaches that countries have selected in their efforts towards implementation. As Parties to the CBD endeavour to implement Target 16, these practical national experiences will greatly assist in highlighting where regulatory gaps exist, what the strengths and weaknesses of different approaches to ABS are, and where supplementary international rules could be useful.

The CISDL published its first global research findings on National and Regional Measures on ABS in 2005, in preparation for the fourth meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (WG-ABS) in January-February 2006. Following the adoption of the Protocol at COP 10, the CISDL periodically reviewed and revised its research findings with the financial support of the Swiss Federal Ministry for Environment (FOEN) to reflect ongoing changes in the international legal regime, and advances in implementation made at the national and regional levels. These findings were presented at the first Intergovernmental Committee on the Nagoya Protocol (ICNP) in Montreal, Canada in 2011 and the second ICNP in New Delhi, India in 2012. After COP 11 decided to reconvene the ICNP to review outstanding issues prior to the entry into force of the Nagoya Protocol, CISDL has again partnered with FOEN to expand and refine the study in order to provide an updated report on the state of implementation of the Protocol to delegates at ICNP 3 and WGRI 5. This **third edition** focuses on expanding and enhancing the review of national and regional experiences to include newly developed ABS measures, while improving and updating current measures found in the study specifically incorporating: (a) amendments, new regulations, new drafts, and new relevant information; (b) practical measures taken by Parties towards implementation, including permits and contracts; (c) measures taken to ratify and/or implement the Protocol, including draft legislation; and (d) relevant experience from the legal development and ratification process.

There are now 38 Parties to the Nagoya Protocol and many others developing measures to prepare for ratification. Operationalization of the Protocol will require decisions on whether and how to regulate access to genetic resources, how to implement the fair and equitable sharing of benefits resulting from the utilization of genetic resources (GR) and traditional knowledge associated with GR, and which measures to implement to support the legislation of provider countries for the purposes of compliance, among others. Existing national and regional experiences in the implementation of access and benefit-sharing measures – both positive and negative – can inform global stakeholders on available legislative and policy frameworks, potential risks and mitigation measures, and practical experiences including contracts and permits. In light of this, the interface between the Nagoya Protocol and national ABS laws and related measures must be further explored to identify opportunities, challenges, and key considerations for the implementation of ABS-related measures and legislation.

To date, a number of different studies on the efforts of promulgating and implementing legal frameworks on ABS at the national and regional levels have been completed.[8] These studies can, on

[8] For example, even though the scope, methodology, objectives and geographic range of the studies vary, the following documents can be mentioned to guide the design of ABS legislation: Glowka, et al, 1994; Glowka, 1998; Mugabe, et al (eds) 1997. From other perspectives it is also possible to mention: Sheiler and Dutfield 2001; Bass and Ruiz (eds),

the basis of the approaches they adopt, be grouped into four broad thematic categories: (1) the design of laws and regulations; (2) the participation of stakeholders in the national or regional processes of drafting ABS laws and policies, and eventually, in the negotiation of contractual agreements and other arrangements related to ABS; (3) contracts, agreements and other arrangements on ABS; and (4) aspects relating to the implementation of the legal provisions.

Before undertaking detailed analysis of the selected ABS laws, it is useful to provide a brief overview of the status of the implementation of ABS legislation and measures to better situate the overall context. Although scant research and very few analytic studies have been done on the state of implementation of ABS at the national level, it is widely recognized that the level of national ABS implementation is low and often incomplete.[9] Countries have reached different levels of implementation and have adopted different approaches to regulation, reflecting their national administrative structures, priorities, and cultural and social realities. Some countries have only adopted one measure – generally legislation – while others have adopted a package of measures such as a national strategy, legislation or regulations and guidelines. However, many countries do not have a complete system because legislative or administrative developments at different levels of government (e.g., regional, national/federal and state/provincial level) are ongoing.[10]

Most countries with measures listed on the Database on ABS Measures on the CBD website[11] (Clearing-House Mechanism - CHM) can be divided into three categories: (1) countries that refer to ABS in their national biodiversity strategy and action plan (NBSAP) or their environmental or biodiversity legislation, but have not yet regulated ABS in detail (these measures generally provide for the development of ABS regulations and include some general elements to be addressed); (2) countries that have a biodiversity or environmental law with some general provisions on ABS or access to biological resources, which may include a provision for the establishment of a regulation on ABS; and (3) countries that have addressed ABS in greater detail. This latter group of countries have established competent national authorities, procedures for prior informed consent, procedures for the development of mutually agreed terms, including benefit-sharing, and compliance measures. The issue of intellectual property rights (IPR) over products of genetic resources is also generally addressed in varying degrees of detail.[12]

In the past 10 years, capacity building and awareness-raising activities have been carried out by governments, UN agencies (e.g. UNDP, UNEP, UNU), development-aid organizations (e.g. ABS

2000; Caillaux, Ruiz, and Tobin, 1999; Swiderska, 2001; Columbia University School of International Affairs, 1999; Crucible Group II 2001; Secretariat of the Convention on Biological Diversity, Case studies on benefit sharing arrangements, distributed at the Fourth meeting of the Conference of the Parties, Bratislavia, 4-15 May, 1998; UNEP-WIPO, 2000; Laird, S.(ed), 2002; and Svarstad, H., and Dhillion, S. eds, 2000; Garforth et al (2005); Carrizosa et al, *supra* note.; Cabrera, 2004; IUCN ABS Project books, particularly Cabrera Medaglia & Lopez Silva, *supra* note. And Tvedt and Young 2007; Dross and Wolff, 2005; Nnadozie et al 2003; Kamau and Winter 2009; UNU, 2008; among others.

[9] The information available indicates that the development of national measures has proven difficult for many countries due to a number of factors including a lack of technical expertise, budgetary constraints, weak government structures and political support, local social conflict and conflict over ownership of genetic resources, see: CBD, *Analysis of Existing National, Regional and International Legal Instruments Relating to Access and Benefit-Sharing and Experience Gained in their Implementation, Including Identification of Gaps*. Note by the Executive Secretary. UNEP/CBD/WG-ABS/3/2, Convention on Biological Diversity, Montreal, 2005.

[10] Valerie Normand, *Level of National Implementation of ABS*, paper presented to the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca, Mexico, October 2004 [Normand].

[11] CBD, Database on ABS Measures, online: http://www.cbd.int/abs/measures/default.shtml

[12] Based on Normand, *supra* note 10.

Capacity Development Initiative[13]), intergovernmental organizations (e.g. IDLO, IUCN), and civil society organisations (e.g. CISDL, ETC Group, Frijol Nansen Institute, Third World Network[14]), but progress on the operationalization of the ABS provisions of the CBD has been slow. Nevertheless, the adoption of the Nagoya Protocol has provided new impetus for the implementation of ABS measures, and a number of laws have been adopted and draft measures discussed since 2010.

Box 1 - General Structure of ABS Measures

The main features of ABS frameworks vary from one national system to another, but some of the underlying elements include:

Competent National Authority (CNA): In some cases the CAN may be an organization already in existence, while in other cases a new organization is created by the ABS measure.[15]

Prior Informed Consent (PIC): In each country, some type of application for access has to be made in order to obtain access to genetic resources. Provisions on PIC also provide indications regarding the specific information that an application should contain, and the procedure leading to approval or refusal. The majority of measures also require the PIC of the relevant authority/resource provider in the geographical area where the GR are to be accessed. Specificities of some measures include different requirements for access depending on the type of applicant, and different requirements depending on whether access is granted for commercial or non-commercial purposes.[16]

Mutually Agreed Terms (MAT): A majority of existing national systems provide that mutually agreed terms are to be set out in an agreement. Some measures also provide for different types of agreements depending on whether the genetic resources are being accessed for research or commercial purposes. The measures generally provide that the agreement is also to be approved by the National Competent Authority. Measures also generally provide for benefit sharing with the competent authority or with Indigenous peoples and local communities or the resources provider, and in most cases for both. Indications regarding the types of benefits to be shared vary depending on the measures.[17]

Compliance measures: The measures examined generally include provisions for compliance. Although few countries address monitoring and enforcement to ensure compliance with ABS measures, they generally provide penalties or sanctions for infractions or offences, such as infractions to the provisions of the legislation, regulation or guideline. These sanctions include fines, seizure of samples, revocation and cancellation of the permission to access, revocation of the agreement, a ban on future bioprospecting, and imprisonment.[18]

[13] The ABS Capacity Development Initiative, online: http://www.abs-initiative.info
[14] Third World Network, online: http://www.twnside.org.sg/access.htm
[15] Required by Article 13 of the Nagoya Protocol (National Focal Points and Competent National Authorities).
[16] Required by Article 6 of the Nagoya Protocol (Access to Genetic Resources).
[17] Required by Article 6(3)(g) of the Nagoya Protocol.
[18] Framework established by Articles 15, 16, 17, and 18 of Nagoya Protocol (*supra* note 3).

METHODOLOGY

In the first two editions of this study (released at ICNP 1 and ICNP 2), CISDL chose to review ABS laws based on their level of detail and guidance, degree of implementation, relevance of ABS for the country considering its significance in terms of biodiversity or ability to support implementation in other jurisdictions, and capacity to support compliance with foreign legislation through user measures. In this **third edition**, the CISDL has decided to look more deeply at existing ABS laws (pre- or post-Nagoya Protocol), and also to expand the scope of inquiry to include draft frameworks, initiatives and draft legislation developed after the adoption of the Nagoya Protocol for the purpose of its ratification and/or implementation. When conducting this inquiry, we will focus on the relevance of ABS laws and practices for other countries (e.g. whether the laws under analysis could be used as a model for the development of other ABS measures, or could provide valuable lessons to the international and regional legal community), and whether they have any innovative approaches (e.g. to what extent the norms contain innovative approaches or mechanisms that could be replicated for use elsewhere). The CISDL reviewed different sources of information in order to select ABS laws. The complete references are provided below, including ABS databases, reports and studies on ABS laws (design and implementation), CBD documents and papers, and book chapters. As of 25 April 2014, the ABS Measures Database listed 57 Countries and 7 regions with ABS measures. However, in a number of cases, the measures described consist of a strategy or plan, not necessarily a legally binding measure (e.g. a law, regulation or guideline). Furthermore, other legislation may be relevant to ABS in countries that do not appear on the CBD website. This study attempts to use the broadest possible information base through additional research by the authors and other CISDL members.

1. OVERVIEW OF NAGOYA PROTOCOL OBLIGATIONS

The Protocol contains a series of provisions that create a number of obligations for both user and provider countries. First, the Protocol generally requires all Parties to establish "appropriate, effective and proportionate" measures to ensure that genetic resources and traditional knowledge utilized within their jurisdiction have been accessed with PIC and in accordance with MAT, as stipulated by the rules in the providing country.

A. CORE LEGAL REQUIREMENTS

Access to Genetic Resources

In keeping with the CBD, the Protocol reaffirms the sovereign rights of States over GR, as well as their authority to determine access in accordance with PIC and MAT.[19] Going further, the Protocol obliges Parties to provide for legal certainty, clarity and transparency, fair and non-arbitrary rules and procedures, and clear rules and procedures for PIC and MAT if rules on access to GR are established.[20] The Protocol also creates a number of other obligations for providing countries. It requires the issuance of a permit or its equivalent at the time of access as evidence of the decision to grant PIC and of the establishment of MAT. This could be in the form of a certificate, in which case the providing country would be required to transmit relevant information through this certificate. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the ABS Clearing-House, constitutes an internationally recognized certificate of compliance.[21] Furthermore, the Protocol requires countries to take appropriate and non-arbitrary measures with a

[19] Nagoya Protocol, *supra* note 3 at Art. 6(1).
[20] *Ibid.* at Art 6(3).
[21] *Ibid.* at Art 17(2)

view to enhancing legal certainty, clarity and transparency of access rules and procedures. The Protocol goes further than article 8(j) of the CBD in that it establishes an obligation to take measures in accordance with domestic law for obtaining PIC or prior approval and involvement of Indigenous and local communities (ILCs) for access to genetic resources where they have the established rights to grant access to those resources.[22]

Fair and Equitable Sharing of Benefits

Parties to the Protocol are called upon to take measures relating to benefits arising from the utilization of genetic resources, as well as subsequent applications and commercialization, so that they are shared with the provider country. The Protocol reiterates the fact that benefits shared on MAT may be monetary and/or non-monetary. Those benefits should be shared with the Indigenous and local communities that are holders of GR under domestic legislation.[23] Similarly, benefit-sharing measures should be developed in order that benefits from the utilization of TK are shared fairly and equitably.[24]

Traditional Knowledge Associated with Genetic Resources

The Protocol calls on countries to take measures, in accordance with domestic law, aimed at ensuring that TK held by Indigenous and local communities is accessed with PIC or prior approval and involvement of ILCs, and that MAT are established. The Protocol also requires countries to establish mechanisms to inform potential users of TK associated with genetic resources about their obligations. Furthermore, countries are requested to support the development by ILCs of community protocols, minimum requirements for MAT, and model contractual clauses for benefit-sharing arising from the utilization of TK associated with genetic resources. The Protocol also contains a specific obligation requesting countries to take into consideration the customary laws, community protocols, and procedures of Indigenous and local communities.

Compliance

The compliance measures under the Nagoya Protocol require Parties to take appropriate, effective and proportionate measures to ensure that GR and associated TK are accessed in accordance with PIC and that MAT have been established, as required by the domestic ABS legislative, regulatory or administrative requirements of the provider jurisdiction.[25] These measures are one of the innovative mechanisms set by the Protocol. The Protocol leaves a great degree of discretion to parties as to the types of measures they may adopt to meet this obligation, only requiring that countries designate one or more checkpoints to monitor and enhance transparency on the utilization of GR. There is no specificity or explicit obligation to designate a specific type of checkpoint, nor does the Protocol prescribe any specific obligation as to the type of information that would be collected or received by the designated checkpoint. Rather, the Protocol states in an indicative manner that relevant information related to PIC, to the source of the GR, to the establishment of MAT, and/or to the utilization of GR, could as appropriate, be collected or received by a designated checkpoint. Hence, the Protocol makes it the prerogative of each Party to determine which measures they may wish to adopt to meet their compliance obligations. Nevertheless, the Protocol does require the checkpoint(s) to be effective and possess functions relevant to collecting designated information.[26] Countries must therefore put adequate compliance mechanisms into place within the framework of

[22] *Ibid.* at Art 6(2).
[23] *Ibid.* at Art 5(2).
[24] *Ibid.* at Art 5(5).
[25] *Ibid.* at Arts. 15 and 16.
[26] *Ibid.* at Art. 17(1)(a)(iv).

their national measures, in order to give effect to the compliance provisions of the Protocol. The compliance provisions of the Protocol will thus be largely informed by the type of measures that countries adopt at the national level.

B. OBLIGATIONS TO SUPPORT IMPLEMENTATION

Designation of ABS focal point, national competent authorities
On the institutional front, Parties are required to designate national institutions to perform functions relating to the Protocol. Each Party needs to designate one NFP to be responsible on its behalf for liaising with the Secretariat of the Protocol. The liaison functions of the NFP include notification requirements in relation to the issuance of access permits and certificates. Each Party is also required to designate one or more CNA, which are responsible for undertaking the various administrative functions required by the Protocol, and which shall be sanctioned to act on its behalf with respect to those functions. According to the Protocol, a Party may designate a single entity to fulfil the functions of both focal point and CNA.

ABS Clearing House Mechanism
The Protocol requires that information required pursuant to COP decisions be made available to the ABS CHM. The information must include legislative, administrative and policy measures on ABS; information on the NFP and CNA or authorities; and permits or their equivalent issued at the time of access as evidence of the decision to grant PIC and establish MAT. Additional information, if available and as appropriate, may also include: relevant competent authorities of ILCs, and information so decided; model contractual clauses; methods and tools developed to monitor genetic resources; codes of conduct; and best practices. The new ABS Clearing House (ABS-CH) is in the pilot phase of development, but is not yet fully operational.[27]

2. NATIONAL AND REGIONAL IMPLEMENTATION OF ABS

A. LATIN AMERICA AND THE CARIBBEAN

Latin America and the Caribbean is an area of high biological and cultural diversity, and similarly high activity on ABS. At the regional level, both the Andean Community and the Central American countries have ABS measures, although the latter are still in draft form. In addition to the countries discussed below, several other Latin American countries are in various stages of creating and implementing ABS measures, including Argentina (at the provincial level), El Salvador, and Guyana. At least 2 countries have adopted ABS laws after Nagoya, but not all the new requirements of the Nagoya Protocol have yet been incorporated, perhaps because these laws/regulations were discussed – including in Parliament – for many years before the Nagoya Protocol adoption, and were therefore not drafted in full consideration of the innovations and new provisions of this international instrument.

Andean Community[βα]
In 1993, the Andean Community of countries[28] (Bolivia, Colombia, Ecuador, Peru, and Venezuela – which later withdrew from the Andean Community Agreement) issued Decision 345 on a *Common Regime on Plant Breeder's Rights*. The Decision first expressed the commitment to establish a common regime on ABS in the region. This commitment came to fruition when the Andean Community

[27] Access and Benefit-Sharing Clearing-House, online: https://absch.cbd.int/
[28] The Andean Community of countries has its origins in the 1969 *Andean Subregional Integration Agreement* (Cartagena Agreement).

created the first regional approach to a common access regime in the form of Decision 391, a *Common Regime on Access to Genetic Resources*[29], in 1996. Once approved, the Decision was directly applicable in the Member States of the Andean Community, but different factors such as social protests, technical ambiguities, legal differences, and institutional limitations forced the Andean countries to develop national policies and regulations to facilitate the implementation of Decision 391 at the national level.[30]

Decision 391 establishes both general principles and concrete access rules. Among the principles, it recognizes national sovereignty over genetic resources, the right of Indigenous, Afro-American, and local communities to exercise decision-making authority over their traditional knowledge (TK), the importance of regional cooperation among Andean countries, and the precautionary principle. The access regulations apply to genetic resources, their by-products, their intangible compounds (TK, innovations and practices), and the genetic resources of migratory species found within the national territory for natural reasons. The access procedure includes an application, a contract, an official resolution, and registration in a public list.

The access contract is signed by the National Authority and the applicant, but Decision 391 also requires the contract to take into account the rights and interests of the providers of the genetic resources, by-products of the resources, biological resources containing them, and their intangible compounds.[31] In any case, the applicant might be required to sign accessory contracts with other agents involved in providing access: the landowner where the genetic resource is sought, the entity responsible for *ex situ* conservation, and the owner of the biological resource containing the genetic information. When accessing TK, innovations and practices, the contract for access must include an annex on the equitable sharing of benefits between the provider of the knowledge and the user.

Applications and contracts may include elements such as the following:

- Participation of local people in research activities;
- Support for research inside the country;
- Transfer of environmentally-friendly technology and knowledge (including biotechnology);
- Supplying information about antecedents, state of the science about resources, and products;
- Capacity-building measures;
- Depositing collected materials in national institutions;
- Mention of the country of origin in publications;
- Communicating results of the research to national authorities;
- Conditions of transfer of accessed material to third parties.

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[29] *Common Regime on Access to Genetic Resources*, Decision 391, 2 July 1996, Official Gazette 17 July 1996 [Decision 391].

[30] Santiago Carrizosa, "Diversity of Policies in Place and in Progress" in Santiago Carrizosa *et al.*, eds., *Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity,* IUCN Environmental Policy and Law Paper No. 54 (Gland, Switzerland & Cambridge: IUCN, 2004) at 10, online: IUCN http://www.iucn.org/themes/law/pdfdocuments/EPLP54EN.pdf. For instance Peru, Bolivia and Ecuador have developed detailed ABS measures based on Decision 391.

[31] Decision 391, *supra* note 22 at Art. 34.

Following the provisions in Decision 391, the Board of the Cartagena Agreement approved Resolutions 414 and 415[32], which establish an application form and a model contract containing the elements necessary to regulate access to genetic resources and benefit-sharing.

According to the Complementary Provisions of Decision 391, intellectual property rights applications could operate as a tracking mechanism. National patent offices of the Andean countries must ask the applicants to submit the access contract when the product or process they want to protect might have been developed from genetic resources or the by-products thereof. Intellectual property rights already granted will be void when the access has not observed the legal provisions.[33]

Furthermore, in 2000, the Cartagena Agreement issued Decision 486 on Industrial Property, which developed certain compliance provisions anticipated in provisional stipulations of Decision 391. According to Article 26 of Decision 486, applications to patent inventions including genetic material or TK originating in countries of the Andean region should present the corresponding access contract or the respective license or authorization of use of TK. These provisions, however, do not limit patenting in other jurisdictions.

In July 2002, the Andean Community adopted a Regional Biodiversity Strategy (Decision 523[34]), which addresses the legal and institutional difficulties found by Andean countries in implementing Decision 391. The Strategy proposes, among other measures, to specify the subject matter under Decision 391, consolidate the administrative mechanisms, build scientific capacity, establish financial support, and create an information system. To date, member countries have each been interpreting the Decision in a different manner.[35] This situation makes it difficult to apply the regulation in a uniform way. Lapeña and Ruiz Müller highlight that one of the main concerns is how to interpret and apply Decision 391 in order to foster research and add value to genetic resources in the Andean Region.[36]

Several initiatives and projects have been developed to support the national implementation of Decision 391, including the capacity building activities and the draft of a Manual or Guide to the Decision. Some experts[37] suggested the need for a review of the Decision based on the difficulties experienced in its implementation at the national level, but no decision was taken until 2012, based on the consideration that it was more appropriate to support implementation rather than a revision of the text of the Decision. After many years of hesitation, in 2012 the Andean Community Body

[32] Cartagena Agreement Resolutions 414 & 415, 22 July 1996.

[33] However, the implementing legislation of the Agreement on Commercial Promotion between Peru and the United States (Law No. 29316, published on January 14 in the Official Peruvian Diary) has amended the substantive requirement of having an access contract for genetic resources with the Peruvian State or a license contract with the Indigenous communities for the use of their traditional knowledge, as a condition for being able to obtain a patent that uses GR or TK. In the case that there is no contract, a sanction exists to penalize the applicant, but this is not a cause for annulment or invalidity of the patent. Decision 486 is modified at two fundamental moments of the IP process: the patent application and the declaration of annulment of a patent that has already been granted.

[34] *Regional Biodiversity Strategy*, Decision 523, 7 July 2002, online: Andean Community http://www.comunidadandina.org/ingles/treaties/dec/D523e.htm

[35] See Isabel Lapeña and Manuel Ruiz Müller, eds., *Acceso a Recursos Genéticos, Propuestas e Instrumentos Jurídicos*, SPDA, Peru, 2004.

[36] *Ibid.*

[37] Gabriel Nemogá et al., *La Investigación sobre Biodiversidad en Colombia. Propuesa de ajustes al Régimen de Acceso a Recursos Genéticos y Productos Derivados y a la Decisión Andina 391 de 1996* (Bogotá: Universidad Nacional de Colombia, 2010,.

for ABS (Comité de Recursos Genéticos) decided to begin a formal process for the revision of the decision in the light of the new international developments, including the NP.[38]

Bolivia[β]

Bolivia has implemented a national regimen on ABS through a regulation to the Decision 391 (Decreto Supremo No. 24676 del 21 de junio de 1997). It was the first country in the Andean Community to provide a specific regulation to implement the Decision.[39]

Most of the features of the measure closely follow the text of Decision 391, including the regulation of the contract for access to genetic resources (article 15); the limitations for access (article 16); the content of the applications (article 17); the procedures set for handling access requests, including the publication of the request and the participation of an Advisory Committee (arts 18-25); and the minimum content of the contract (article 37-43). It also requires the subscription of annex contracts and accessory contracts for access and utilization with other stakeholders such as the National Support Institution, the owner or possessor of the land where the GR is located, the ex situ Conservation Center, the owner of possessor of the biological resources within the GR is contained and the Protect Area Director. It creates a national system for genetic resources (Article 55), and a separate chapter for sanctions and penalties (including fines, suspension, revocation and resolution of the contract, and seizure of the samples).

The National Competent Authority is the Ministry of Sustainable Development (the Biodiversity Office), and a Technical Advisory Body was created with representatives from the different Ministries and universities. The "Prefacturas" (a regional body) are entitled to receive the applications and have some functions regarding the monitoring of access activities and compliance with the terms of the contracts. Among the few contracts that have been signed, two were for commercial research (one for the improvement of a variety of potato, signed in 2004, and the other related to camelids), and several more were for basic research (around 10). The current National ABS authority is also working on a regimen for the protection of TK.

Brazil[β]

Brazil is a megadiverse country and one of the richest countries of the world in terms of its biodiversity and associated TK. It has also developed considerable technological capacities in the field of biotechnology. The legal ABS developments in Brazil have attracted a lot of attention from outside the country. The ABS legal system has evolved over the time and covers many additional aspects through resolutions and decrees. Since 1994, there have been several initiatives[40] to regulate access to Brazilian genetic resources, but no law has yet been approved. Currently, different proposals are being evaluated by commissions under the Congress. In the meantime, the States of Amapa and Acre have passed their own laws regulating access to genetic resources.

A project between Bioamazonia and Novartis to access, research and develop the genetic heritage of Brazil, disclosed in June 2000, provoked very strong opposition from some sectors. At that time, the federal government did not consider the benefit-sharing to be fair or equitable, and the

[38] Jimena Nieto, personal communication.

[39] Bolivia's Constitution also includes several provisions of relevance for ABS and the protection of TK associated with GR.

[40] Bill No 306/95, introduced by Senator Marina Silva and amended by Senator Osmar Dias. Bill No 4579/98, introduced by Deputy Jacques Wagner. The Executive power formulated a third bill in response to Senator Marina's bill. It proposes an amendment to the Constitution.

environmental authorities were very concerned about the piracy of Brazilian biodiversity.[41] To mitigate this concern, the federal government passed a Provisional Measure[42] (MP) addressing elements involved in access to genetic resources. The MP establishes a council for managing Brazilian genetic heritage, the *Conselho de Gestao do Patrimonio Genetico* (CGEN). Its main tasks are to implement national policies on access to genetic resources and TK, and develop technical and administrative activities for providing or denying access. It has been difficult to implement the original MP, making it necessary to draft complementary legal measures clarifying the original terms and scope.

These changes have created controversy and drawn negative reactions from some sectors, including the research sector and private companies, which complain about the lack of clarity on the requirements to be met for each type of permit, the scope of the legislation, and the overly bureaucratic and time-consuming procedures in place. The system has improved over the last few years, but the nature of the MP (in principle a "provisional" legal solution that has been in place 13 years), and the difficulties encountered in its implementation, make it difficult to undertake ABS agreements in Brazil.

Access to genetic heritage requires prior authorization from the CGEN. Depending where the resources are expected to be collected (Indigenous territory, protected area, private land, land indispensable for national security, or jurisdictional waters, continental shelf or exclusive economic zone [EEZ]), different agents are called to take part in the authorization granting or denying prior informed consent (Indigenous communities, a competent authority within the protected area, the landowner, or the Brazilian maritime authority, respectively). Expeditions for accessing genetic resources must be coordinated by a national institution. Foreign institutions or persons are not allowed to develop such activities by themselves.

If the access is for commercial purposes, Article 16 of the MP establishes that the applicant, besides obtaining authorization, must sign a contract that sets out how the benefits arising from the commercialization of the resources are to be distributed. Article 25 indicates some ways for sharing the benefits: royalties, technology transfer, free licenses to products or process, and human capacity building. The contract must include, among other elements, the resources accessed, benefit-sharing provisions, rights and obligations, intellectual property rights, contract cancellation clauses, and jurisdiction in Brazil for dispute settlement.

According to Chapter 8 of the MP, non-compliance may be punished with different types of penalties such as fines, confiscation of samples and products, suspension of the sale of products, closing down establishments, suspension or cancellation of the registry, patent, license or authorization, prohibition of contracting with the public administration, and restriction of tax incentives.

The IPR application procedure in Brazil may work as a monitoring mechanism. Article 31 of the Provisional Measure requires that the origin of the genetic material and the associated TK be specified when applying for IPR for a process or product obtained using samples of components of genetic heritage. However, this requirement only applies to GR from Brazil, which is not sufficient

[41] Marco Abreu Torres, *Brief on the Brazilian Act about Access to Genetic Resources and Benefit Sharing Target 16 – Ratification of Nagoya Protocol. Provisional Measure No. 2.186-16/2001* (Rome: IDLO, 2014).

[42] Medida provisoria Nº 2186-16.23.8.2001. Regulamenta o inciso II do §1º e o §4º do art. 225 da Constituição o, os arts. 1º, 8º, alínea "j", 10, alínea "c", 15 e 16, alíneas 3 e 4 da Convenção sobre Diversidade Biológica [MP].

to fulfil the compliance obligations set out in the Nagoya Protocol (regulated in CGEN Resolution 39 of 2009).

The Brazilian legal framework enshrining the principles of PIC, MAT, and ABS includes the following pieces of legislation:

a) Law 9.279/96 "Industrial Property Law";
b) Provisional Measure 2.186-16, of 2001;
c) Decisions by the National Industrial Property Institute (INPI) and by the CGEN.

The executive bodies of the system are the INPI itself - which is the Brazilian patent office - as well as the CGEN. The CGEN's main tasks are to implement national policies on access to genetic resources and TK, and to develop technical and administrative activities for providing or denying access.

The CGEN is, in turn, a collective inter-ministerial body that holds monthly meetings, and is chaired by the Ministry of Environment. Its membership includes representatives of 19 other bodies or entities of the Federal Administration, each of which holds the right to vote. These bodies are: the Ministry of Environment; the Ministry of Science and Technology; the Ministry of Health; the Ministry of Justice; the Ministry of Agriculture, Livestock and Supply; the Ministry of Defence; the Ministry of Culture; the Ministry of External Relations; the Ministry of Development, Industry and Foreign Trade; the Brazilian Institute for the Environment and Renewable Natural Resources (IBAMA); the Research Institute Botanical Garden of Rio de Janeiro; the National Council for Scientific and Technological Development (CNPq); the National Institute for Amazon Research; the Emílio Goeldi Museum of Pará; the Brazilian Agricultural Research Corporation (Embrapa); the Oswaldo Cruz Foundation; the National Foundation for Indigenous People (Funai); the INPI and the Palmares Cultural Foundation. The INPI, therefore, takes part in all CGEN deliberations. Other than these regular members, some representatives of civil society hold a standing invitation to CGEN meetings with the right to speak, such as the Brazilian Association of Biotechnology Companies (ABRABI) and the Brazilian Society for the Advancement of Science (SBPC).

The MP created a legal regime based on two main instruments: authorization to access to GR and associated TK, and benefit-sharing contracts. IBAMA is the responsible authority for authorizing access to GR for the purpose of scientific research with no potential for economic use, and which does not involve access to associated TK. The CGEN is responsible when access to GR is aimed at research with the potential for commercialization or economic use, or if it involves access to associated TK. If access to TK held by Indigenous peoples or traditional communities is involved, the authorization of access depends on their previous acquiescence, without which the Council cannot grant authorization. When there is a prospect of commercial use, a benefit-sharing agreement contract must be signed with the Indigenous peoples or local communities.

CGEN Resolution No. 21 of 2006 established that certain types of research and scientific activities are not subject to the access legislation, including the evaluation of the evolutionary history of species or taxonomic groups; studies on the relationship/interactions of living beings among themselves or the environment, or on the genetic diversity of populations; chromosomal or DNA analysis aimed at identifying species; activities aimed at creating collections of DNA, tissue, germplasm or blood, among others.

The Brazilian legislation defines access to associated TK as the "acquisition of information on individual or collective knowledge or practice associated to the genetic heritage, from an indigenous community or local community for the purpose of scientific research, technological development or bioprospecting with a view to its industrial or other application."[43] The MP defines local community as a "human group, including descendants of Quilombo communities, differentiated by its cultural conditions, which is traditionally organized along successive generations and having its own customs and preserves its social and economic institutions."[44] A broader version of the concept is provided by Decree 6040/2007, which institutes the National Policy for Sustainable Development of Traditional Peoples and Communities and whose definition is identical to the draft ABS law: "Traditional Peoples and Communities are culturally differentiated groups, who identify themselves as such, possess their own forms of social organization, occupy and use territories and natural resources as a condition for their cultural, social, religious, ancestral and economic reproduction, using knowledge, innovations and practices that are generated and transmitted through tradition."[45]

Under the current law, benefit-sharing contracts are only required when authorization is requested for access to GR and TK for the purposes of commercial or economic use. The MP provides that authorization for access to GR for bioprospecting purposes requires that a benefit-sharing contract be signed in advance. A Presidential Decree (6159-2007) stipulates that, if the provider agrees, the benefit-sharing contract could be drawn up and signed at a later date as long as it is prior to the development of any commercial product or patent application. The CGEN has granted authorization of access to TK for the purpose of scientific research with the prior consent of communities or Indigenous peoples organizations. Benefit sharing is required however, once a possibility of economic exploitation has been identified. In 2006, the Council approved Resolution 21, which exempts four kinds of research and scientific activity from the need for authorization.

On 15 September 2009, the Ministry of Environment and the Ministry of Science and Technology signed a Technical Cooperation Agreement, which grants the CNPq the competence to authorize access to Brazil's genetic patrimony for research purposes. The partnership between the two Ministries aims at accelerating the administrative procedures for those requests that do not involve access to associated TK.

The revision of Brazil's ABS legislation is still underway, and stakeholders have discussed several draft bills. Considering the need to improve regulations, the CGEN initiated a public consultation in 2006 involving the broad participation of local and traditional communities, academics, and governmental sectors. The results will be used to define the current legislation project that will replace MP 2.186-16.

To improve the current system, the Brazilian Government is currently discussing a draft law that will establish a specific procedure to regularize access that occurred without prior authorization by the CGEN. Presently, administrative fines are levied when access occurs without authorization. In the project under discussion, such fines would not apply or would be reduced when applicants voluntarily filed a request to regularize the research. Patent requests pending the regularization of access are suspended until the publication of the Decree establishing the specific procedure before CGEN.

[43] *Ibid.* at Article 7(V).
[44] *Ibid.* at Article 7(III).
[45] *Ibid.* at Article 3(I).

The MP is complemented with a number of Decrees (around 4), Resolutions (more than 20), and Technical Guidelines (8). Of the Technical Guidelines, No. 07-2009 regulates access to genetic resources for the specific purpose of plant breeding, and No. 8-2012 clarifies the application ABS provisions to the species listed in Annex I of the International Treaty. As a result of these decrees, resolutions and technical guidelines, the legal framework in Brazil is very complex.[46]

In terms of implementation, a growing number of permits have been granted, particularly for non-commercial research, as well as for commercial research or commercial research utilizing TK.[47] Finally, the MP sets penalties for the use of genetic resources or traditional knowledge in disagreement with its rules. Products developed in contravention of the components of the MP are liable to pay a minimum of twenty five percent of the gross sales or royalties if developed by a third party.[48]

Other sections of the MP include the confiscation of samples and products developed; a partial or total ban on activities, including the suspension or cancelation of patent, licensee or authorization; additional civil sanctions where necessary;[49] and fines ranging from USD $100 to 25,000,000, depending upon the gravity of the offence and the infringing party.[50] A new policy on monitoring and enforcement was developed that led to fines for national and international companies; some of which amounted to millions of US dollars (some of them are pending appeal under the Courts in Brazil.)

Box 2. Some lessons learned in the implementation of the Provisional Measure

A number of lessons could be taken from the implementation of the MP since it was issued 12 years ago. Firstly, the institutional framework established for access and benefit-sharing was not sufficient to meet the opportunities offered by the sustainable use of Brazilian biological diversity. Although Brazil is a large nation where the power related to environmental issues is given by the Constitution to all levels of competence (Union, States and Municipalities), the mandate to manage genetic resources and associated traditional knowledge is concentrated within the federal government. According to the Supplementary Law n. 140/2011, the Union can delegate powers from CGEN to States and Municipalities, as long as they have an institutional framework qualified to perform the actions delegated. So far, there has not been any experience of such delegation, demonstrating the impetus of the Union to concentrate powers. In addition, the CGEN is a council composed solely of representatives of the government, which means that the private sector, academics, and Indigenous peoples and local communities are excluded from the deliberation of the main issues related to the management of genetic resources and the associated traditional knowledge.

Another lesson arising with the MP is that strict rules on access to genetic resources and to the associated traditional knowledge can dissuade researchers and business from its utilization and,

[46] For further information see http://www.mma.gov.br/patrimonio-genetico/conselho-de-gestao-do-patrimonio-genetico

[47] See http://www.mma.gov.br/patrimonio-genetico/conselho-de-gestao-do-patrimonio-genetico

[48] MP, *supra* note 35 at Article 26.

[49] *Ibid.* at Article 30(1).

[50] *Ibid.* at Article 30(4)-(5). Article 30(4) states that "fines […] shall be determined by the competent authority according to the gravity of the offense […] and may vary from R$200 to R$100,000 in the case of a natural person." Article 30(5) states that "[i] f the offense was committed by a legal entity or with its consent, the fine shall be from R$10,000 to R$50,000,000.

therefore, may not result in benefits that ensure conservation or sustainable use of biodiversity.

Obtaining the permit from CGEN is not an easy process. More than ten procedures are required, such as the need to deposit a representative sub-sample of the accessed genetic resource in *ex situ* condition at an institution accredited as a trustee by CGEN. In addition, CGEN meets to deliberate permits required by researches and companies only once a month, delaying the requirements and jeopardizing the user's schedules.

Besides being complex, the rules contained in the MP are also obscure. It is not uncommon to find researchers and entrepreneurs who are not sure whether such rules apply to their activities. The lack of clear rules has forced CGEN to approve 48 regulatory provisions so far, and many more issues still need to be regulated. Hundreds of fines have been given by the National Environmental Agency[51], and researchers and companies are becoming reluctant to use Brazilian biodiversity.

Finally, the implementation of the MP has shown that the proposed rules related to benefit-sharing do not ensure legal certainty. As mentioned, if there is the possibility of commercial use arising from the access to genetic resources or to the associated traditional knowledge, the user has to present an agreement with the provider to CGEN. However, the high transaction costs of the agreement often prevent its signing. Moreover, CGEN usually interferes in the terms of the agreement in order to rule what is or should be fair and equitable in each specific case.

The institutional framework and the administrative mechanisms of the MP have also failed to ensure the achievement of the CBD goals. The MP also suffers from a lack of legitimacy, as it has never been approved by the Congress and has been criticized as being excessively bureaucratic.

Since 2003 several attempts have been made to review the MP. In 2007, a draft bill was sent to the Chief of Staff, who opened it for public consultation. Due to the diversity of opinions and interests, the process was concluded with no outcomes. Since 2011 some key players have been working on another draft to improve the MP, but this has gained little traction.

The main proposal is a change in the requirements for the permit, allowing on-line registration containing the essential data of the research, without the need for previous approval by CGEN. In terms of benefit-sharing, the proposal is to retain the need for mutual agreement between user and provider if the access is related to associated traditional knowledge. When access to the genetic resource does not involve associated traditional knowledge, the parties can choose whether the benefit to be shared is non-monetary or monetary. In the first case, the provider shall implement projects related to the conservation of the biological diversity, while in the case of monetary benefits, the provider must allocate an amount that ranges from 0.1 to 0.5% of the profits obtained by the commercial use of the product derived from the access to a proposed National Fund of Benefit-Sharing.

Brazil regulated access and benefit sharing more than a decade ago in order to tackle a concrete issue related to benefit-sharing between a governmental institution and an international company. The rules issued were hastily developed, have yet to receive Congressional approval, and are widely criticized by stakeholders and civil society.

A revised MP would help provide the research and investor communities with the stability needed

[51] In just two operations of the Agency – New Directions I and II – 355 research institutions and companies were fined, at a total amount around US$ 100 million.

to avoid capital flight in pursuit of better conditions to work with biodiversity assets. The revised MP should also prepare the country to ratify and implement the Nagoya Protocol, which will promote significant changes in international commercial relations.

Brazil requires new legislation on access to genetic resources and benefit-sharing that increases legal certainty at the same time that it stimulates research and the development of new products derived from the local biodiversity. A new framework should be consistent with Brazil's potential as home to an immense wealth of biodiversity resources that must be sustainably and equitably accessed.

Source: Abreu Torres, Marco, "Brief on the Brazilian act about access to genetic resources and benefit sharing Target 16 – ratification of Nagoya Protocol. Provisional Measure No. 2.186-16/2001", IDLO, Rome, 2014.

Colombia[β]

The 1991 Colombian Constitution established that the State has responsibility for the movement of genetic resources into and out of the country, and that only the State is authorized to provide genetic resources.[52] Additionally, the Constitution establishes that the exploitation of natural resources in Indigenous territories should only take place if the cultural, social and economic integrity of communities is respected. The Law No. 99 of 1993 made the Ministry of Environment the responsible body for the protection and management of biological and genetic resources. In addition to the commitment in Decision 345 of the Andean Community, discussed above, Colombia's commitment to regulate access to genetic resources was reinforced by the ratification of the CBD in 1994.

In implementing the general provisions of Andean Community Decision 391, the Colombian government identified the Ministry of Environment, through the 1997 Resolution No. 620, as the national authority entitled to grant access to genetic resources. In 2007, Resolution No. 1393 established that the Direction of Permits and Environmental Licenses will be the competent body for the approval or rejection of ABS applications, as well as for the signature of the ABS agreements.[53] Subsequently, the responsibility of the approval or rejection of ABS permits was allocated to the Unit of Genetic Resources of the Ministry of Sustainable Development (under the Division of Forest, Biodiversity and Ecosystem Services). The main steps for access include: the filing of an application, its study and approval or rejection by the national authority, and, in the case of approval, the access contract. The entire process is public, although the state may grant confidentiality for information susceptible to unfair competition. The procedure is intended to guarantee transparency and to facilitate civil society participation.

The application must specify the genetic resources to be researched, the access activities required, the proposed geographical area, the identification of the supplier of the biological and genetic resources, the state of the art regarding the genetic material and its application, the résumé of the lead scientist of the project, and a copy of the research project. If the research project includes access to TK, the application must identify the provider. The application must also identify a national institution as a research partner. The national authority then considers the technical, economic and legal viability of the proposal. The approval of an application is communicated through an administrative resolution and the process moves to a negotiation phase.

[52] The exclusive right of the Colombian state as a legitimate holder of the genetic resources has been affirmed through judicial decisions of the highest tribunals: Sentence C-137 de 1996 by the Constitutional Court, and Concept August 8 of 1977 by the High Administrative Council.

[53] The Order 309 of 2000 introduced a more flexible regime to grant research permits on biological diversity.

Decree 309 of 2000 also regulates the research on biological resources for scientific purposes of some particular institutions. The relation of this specific decree to Colombia's other ABS procedures has not been clarified, resulting in some confusion.

Pursuant to Decision 391 and Resolutions 414 and 415 of the Andean Community, an access contract in Colombia establishes the conditions for access to genetic resources, their derivatives, and TK. It also sets up the distribution of monetary and non-monetary benefits. If bioprospecting activities imply access to TK, the contract must include an annex containing the provisions for benefit-sharing that have been previously approved by the provider. Depending on the resources to be accessed and their location, the applicant may also be required to sign additional agreements with the steward, landowner and provider of the biological resources where the genetic resources are found, and if necessary, with *ex situ* conservation institutions. A national research partner must be identified as part of the mechanism for technology transfer.

The application of a legal regime on access to genetic resources in Colombia has not been free of difficulties. The low policy profile of genetic resources and the lack of technical expertise are limiting factors. Although the state and international agencies have sponsored at least two technical and comprehensive assessments,[54] the government has yet to take decisive steps to implement the recommendations. Legal measures are emphasized but a substantial redefinition of the institutional framework and capacity building continue to be postponed. As a result, only two applications had been concluded by the end of 2004. In 1997, one application by BioAndes of Colombia S.A. to study plants, animals and microorganisms in national parks with commercial purposes was rejected, while in 2004 another application to access the genetic resources of the South American dolphin *Sotalia fluviatilis* for academic purposes was accepted. No ABS application was submitted in 2004 or 2005. From 2007 to 2013, approximately 89 ABS contracts were signed, most of them for basic research. Several applications are currently under review.

Due to the difficulties experienced in the implementation of the Decision 391 and the local measures put in place, a process to amend the current system was initiated with the support of the National University of Colombia (under request of the Ministry of Environment), which not only includes amendments to the national measures, but also a proposal to amend Decision 391.[55] One of the main criticisms to the proposed amendments has come from the research sector in Colombia, including national universities. Responding to these concerns in June 2013, two new decrees were approved in Colombia. The first decree (No 1376 of June 2013) regulates permits for the collection of wildlife species for non-commercial research purposes. It creates a simplified system for access with a different national competent authority. In particular, article 2, paragraph 5 stipulates that basic research involving activities of molecular systems, molecular ecology, evolution and biogeography do not qualify as access to genetic resources and are not subject to the ABS procedures under Decision 391. Access for bioprospecting, commercial or industrial purposes of material collected for non-commercial purposes obliges the applicant to enter into an access contract in accordance to the national legislation (case of change of intent). The second decree (No. 1375 of June 2013) regulates biological collections, including the register and conditions for their operation, but not specifically

[54] See: "Access to Genetic Resources: Technical and Legal Proposal" (Bogotá: National University of Colombia, Institute of Socio-Legal Research – UNIJUS, 2003), and "Technical Proposal for Policy on Access and Sustainable Use of Genetic Resources in Colombia" (Bogotá: Institute Alexander von Humboldt, 2004).

[55] Gabriel Nemoga *et al.*, *La Investigación sobre Biodiversidad en Colombia* (Bogotá: Universidad Nacional de Colombia, 2010).

for access purposes. Regarding TK, the document (CONPES 3533 of July 2008) recommends the elaboration of a *sui generis* system for the protection and recognition of TK[56].

A draft regulation to implement the Decision is now under consultation, but no further details are known.

One of the reasons mentioned for the lack of ratification of the ITPGRFA in Colombia has been the apparent contradiction between the ITPGRFA ABS provisions and Decision 391, which is part of the communal law of the Andean Community. However, no written legal opinion stating these concerns and providing an explanation for the interpretation of the alleged conflict between the instruments was identified.

Costa Rica[β]

Costa Rica's Biodiversity Law (BL) of May 27, 1998 applies to the components of biodiversity that are under the sovereignty of the State, as well as to the processes and activities carried out under its jurisdiction or control. The BL specifically regulates the use and management of the components of biodiversity, as well as the associated knowledge, benefit-sharing and derived costs from this utilization.

Article 6 establishes that the biochemical and genetic properties of the components of wild or domesticated biodiversity are part of the public domain. The State authorizes exploration, research, bioprospecting, and use of biodiversity components that constitute part of public domain, as well as the use of all genetic and biochemical resources, through access standards established in Chapter V of the Law.

Likewise, in accordance with Articles 62 and 69, all research or bioprospecting programs on the genetic or biochemical material of biodiversity that are to be carried out in Costa Rican territory require an access permit, unless they fall into one of the exceptions provided by Article 4 of the Law. These exceptions include access to human genetic resources; the non-profit exchange of genetic and biochemical resources and the traditional associated knowledge resulting from the traditional practices of Indigenous peoples and local communities; and research by public universities, which had one year (until May 7, 1999) to establish their own controls and regulations for research that implies non-profit access to biodiversity (just one university, the University of Costa Rica, has developed its own ABS regulations). If none of these exceptions apply, all sectors (pharmaceuticals, agriculture, crop protection, biotechnology, ornamental, herbal, etc.) that wish to access genetic components are subject to the Law and must follow the access procedures. The definitions of access and bioprospecting in the Law also restrict its scope.

The access regulations apply to genetic resources in public or private lands, terrestrial or marine environments, under *ex situ* or *in situ* conditions, and in Indigenous territories. In addition, the rules of Indigenous people should be taken into account for access in their territories, as should their *sui generis* community intellectual property rights. Similarly, communities and Indigenous peoples have a recognized right to oppose access to their resources and associated knowledge for cultural, spiritual, economic or other reasons.

The access procedure is set out in two chapters of the BL. The competent body that initially grants access is the Technical Office (TO) of the recently created National Biodiversity Administration

[56] One example of a community experience regulating TK is a provision of the Guambiano Indigenous Peoples, which, among other issues, regulates the access and used of genetic resources and TK in the territory of the Guambianos.

Committee (CONAGEBIO) within the Ministry of Environment and Energy (MEE). CONAGEBIO is entrusted with preparing ABS policies and can revoke the rulings of the TO on access issues. The main duty of the TO is to process, reject, and audit applications to access biodiversity, and to coordinate with the Conservation Areas, the private sector, Indigenous peoples, and peasant communities on actions that relate to access. It is responsible for organizing and updating a register of applications for access to the components of biodiversity, *ex situ* collections, and of individuals and corporations who work on genetic manipulations. The TO is expected to collect and update regulations related to the fulfilment of treaties and guidelines on biodiversity issues.

Chapter V defines the requirements and procedures relating to the access of genetic and biochemical components and the protection of the associated knowledge. CONAGEBIO is expected to act as the mandatory consultative body for all application procedures for the protection of intellectual rights related to biodiversity. The BL regulates the basic requirements for access, which include prior informed consent (PIC), benefit-sharing, the protection of associated knowledge, and the ways in which the activities will contribute to conservation. Chapter V also establishes the legal procedures to be followed, the Registry of access rights, and the protection of confidential information.

The BL also regulates the terms of access permits, including their limitations and characteristics, the information required in a permit application, the authorization of agreements with individuals seeking access to genetic and biochemical components by the TO, and the possibility of agreements with universities and other duly registered centres. It stipulates that up to 10 percent of royalties must go to the conservation area, private owner, or Indigenous territory, in addition to the payment of administrative expenses. The TO must also always be consulted in processes where IPR are granted for components of biodiversity, and its decision on these matters is binding.

Lastly, the BL establishes the grounds for the protection of traditional, Indigenous, and community knowledge, and for the establishment of a participatory process for the determination and registration of these *sui generis* intellectual community rights. Article 112 establishes a system of fines for illegal access, and there is also a section on the framework for sanctions. A draft proposal for the implementation of sanctions has been developed and it is currently under discussion at the CONAGEBIO.

To date, the National Biodiversity Institute (INBio) has conducted most of the bioprospecting in the country. INBio was created in 1989 as a non-governmental, non-profit association and it has been declared of public good. Its mission is to promote new awareness of the value of biodiversity, and to thereby achieve the conservation and use of biodiversity to improve quality of life. In 1991, INBio developed the concept and practice of "bioprospecting" as one answer to the need for sustainable use of Costa Rican biodiversity to benefit society.

Table 1: Most significant Collaborative Research Agreements with industry and academia from 1991-2013

Industry or academic partner	Natural resources accessed or main goal	Application fields	Research activities in Costa Rica
Cornell University	INBio's capacity building	Chemical prospecting	1990-1992
Merck & Co	Plants, insects, microorganisms	Human health; Veterinary medicine	1991-1999
British Technology Group ECOS	*Lonchocarpus felipei*, source of DMDP	Agriculture	1992-2005
Cornell University, Bristol Myers and NIH International Cooperative Biodiversity Group (ICBG)	Insects	Human health	1993-1999
Givaudan Roure	Plants	Fragrances and essences	1995-1998
University of Massachusetts	Plants and insects	Agriculture	1995-1998
Diversa (Now VERENIUM)	DNA from non-cultivable bacteria	Industrial applications	1995-present
INDENA SPA	Plants	Human health	1996-2005
Phytera Inc.	Plants	Human health	1998-2000
Strathclyde University	Plants	Human health	1997-2000
Eli Lilly	Plants	Human health; Agriculture	1999-2000
Akkadix Corporation	Bacteria	Agriculture	1999-2001
Follajes Ticos	Palms	Ornamental applications	2000-2004
La Gavilana S.A.	Microorganisms	Agriculture	2000-present
Laboratorios Lisan S.A.	Plants	Human health	2000-2004
Bouganvillea S.A.	Quassiaamara	Agriculture	2000-2004
Agrobiot S.A.	Plants	Ornamental applications	2000-2004
Guelph University	Plants	Agriculture; Conservation	2000-2003
Chagaspace Project	Plants, fungi, marine organisms	Human health	2001-2011
SACRO	Orchids	Conservation	2002-2008
Merck Sharp &Dohme	Training and education	IPR; Bioprospecting	2002-2006
Industrias El Caraíto S.A.	Nutraceutics	Human health	2001-2004
Harvard Medical School- International Cooperative Biodiversity Group R21	Endophytic fungi	Human health	2003-2005
Universidad de Panamá-OEA	Plants	Human health	2003-2004

Harvard Medical School- National Cooperative Drugs Discovery Group (NCDDG)	Endophytic fungi	Human health	2005-2008
Ehime Women College	Plants	Human health	2005-2008
Laboratorios Vaco S.A.	Microorganisms	Industrial applications	2005-present
Harvard Medical School - International Cooperative Biodiversity Group (ICBG)	Endophytic fungi-microorganisms, lichens and marine organisms	Human health	2005-present
Instituto Pfizer	Microorganisms	Human health	2005-2006
PNUD-BIOTRADE-UNCTAD-CAF	Implementation of the National Program of Biotrade	Biotrade	2005-2006
CONICIT	Spiders (DNA)	Molecular taxonomy	2004-2005
CONICIT	Plants	Human health	2005-2006
Korean Research Institute of Bioscience and Biotechnology (KRIBB)	Plants	Human health	2008
Harvard Medical School - Medicine for Malaria Venture (MMV)	Endophytic fungi	Human health	2007-2009
CONICIT	Microorganisms	Industrial applications	2008
CONICIT	Establishment of *Aedes aegypti* bioassay	Human health	2007-2009
Consejo Superior de Investigaciones Científicas de España (CSIC) Fundación CR USA	Microorganisms	Enzymes for industrial applications	2008
Consejo Superior de Investigaciones Científicas de España (CSIC) Fundación CR USA	Microorganisms	Human health	2008
BID-Fondo Chileno Universidad Adolfo Ibañez/Octantis	INBio's Capacity Building	Entrepreneurship	2008
International Cooperative Biodiversity Groups Michigan (lead), Harvard and INBio	Endophytic fungi-microorganisms, lichens and marine organisms, including for energy research	Human health; Energy	2009-2014
EISAI	Fractions (from research on Endophytic fungi-microorganisms)	Human health	2008-present
DistribuidoraFlorex S.A	Enzymes, others	Industrial products for	2010-2011

(national company)		the cleaning sector	
CONICIT	Endophytic fungi	Human Health	2010-2011
CR-USA-CSIC	Microorganisms	Human Health	2010-2012
CONICIT	Plants	Human Health	2012-2014
Pharmamar	Marine organisms	Human Health	2012-2017
Ciris	Microorganisms	Energy	2013-present

Source: *INBio's Bioprospecting Unit*

These agreements involve a significant amount of technical and scientific support from INBio. As a result of these agreements, many benefits have been generated, including the following:

- Monetary benefits from direct payments;
- Payment for samples supplied;
- Research budgets covered;
- Transfer of important technology, which has enabled the development of the infrastructure at the Institute (biotechnology lab, etc.), and which can be used for the investigation and generation of their own products;
- Training of scientists and experts in state-of-the-art technology;
- Negotiating experience and knowledge of the market and the probabilities of searching for intellectual uses for biodiversity resources;
- Support of conservation through payments made to the Ministry of the Environment for strengthening of the National System of Conservation Areas;
- Transfer of equipment to other institutions, such as to the University of Costa Rica;
- Donation of equipment from partners;
- Funding of publications and for the dissemination of scientific literature;
- Future royalties and milestone payments to be shared 50:50 with the Ministry of the Environment;
- Establishment of national capabilities for assessing the value of biodiversity resources;
- Royalties received from two products: a phytomedicine generated from the collaboration with Lisan (a national company) and an industrial enzyme (Cottonase) for textile processing of cotton (an environmental friendly alternative for chemical scouring in cotton preparation) arising from the Diversa (now Verinium) collaboration. The enzyme cleans better than chemical scouring agents and also greatly reduces the need for extensive waste, waste treatment and energy consumption. A fluorescent protein has also been developed (with Diversa) and royalties have accrued to INBio;
- Access to drugs developed from collaboration on a non-commercial and more favorable basis.

INBio has a formal agreement with the MEE that allows it to carry out specific national inventory activities and grants it use of the biodiversity in the country's protected areas. Research is carried out in collaboration with investigation centres, universities and national and international private companies by means of investigation agreements that include key elements, such as:

- Access: limited in time and quantity;
- Equity and compensation: research budget, benefit-sharing (royalties and milestone payments, etc.), technology transfer, training;
- Non-destructive activities; and

- Up-front payment for conservation.

The agreements specify that 10 percent of the research budgets and 50 percent of the future royalties must be donated to the MEE to be reinvested in conservation. The research budget supports the scientific infrastructure in the country, as well as added-value activities for the conservation and sustainable use of biodiversity. INBio has signed over more than 60 bioprospecting agreements. Several permits have been granted for the TO of CONAGEBIO. Between 2005 and February 2014, 348 permits were granted, mostly for basic non-commercial research, as well as for some commercial research or bioprospecting.[57]

Number of access permits granted during 2004 - February 2014.

Permission Type	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Total
Basic Research	2	25	26	24	38	32	41	25	37	46	4	300
Bioprospecting	2	4	4	6	4	1	10	5	1	10	1	48
Total	4	29	30	30	42	33	51	30	38	56	5	348

The Costa Rican experience has provided some of the most relevant examples in terms of obstacles and achievements relating to the regulation of access to genetic resources, intellectual property, and TK.

Some relevant lessons learned include:

- In Costa Rica the income contributed by the biodiversity prospecting program reaches several million U.S. dollars overall and makes important contributions to technology, capacity-building, scientific equipment, the National System of Conservation Areas, as well as to the creation of national capacities and negotiation capacities. Although this last aspect stands out as the most important in relation to acquired benefits, it is important to point out that ecological tourism contributed around $700 USD million in just one year, making monetary returns from bioprospecting seem relatively small with respect to the amount of money obtained.

- The strict ABS regulations of some countries can result in a lack of compliance with the objectives of the CBD. In this respect, some regulations to date have concentrated more on controlling than promoting access. These types of laws create high transaction costs and complicated bureaucratic procedures, deterring access applications, without which it is not possible to speak of benefit-sharing. The BL has created the necessary legal guarantees and an ABS regime that is sufficiently flexible and transparent.

[57] See *La Comisión Nacional para la Gestión de la Biodiversidad de Costa Rica*, online: <http://www.conagebio.go.cr>.

- Many national rules on ABS were developed separately from the national policies on the conservation and sustainable use of biological diversity. As a result, the contribution of monetary and non-monetary benefits to the conservation process is often minimal. However, the BL has been able to make a connection between ABS and conservation. The regulations on access are based on the idea of conserving biological diversity, its sustainable use and the fair distribution of its benefits.

- Participatory processes are important in the regulation of areas of great national importance, such as biological diversity. The process for the development of the BL has been highly participatory, as it will be explained later.

- The changes in the IPR/Biodiversity section due to the implementing laws (on IPR) of the Free Trade Agreement between Central America, Dominican Republic and the United States (CAFTA) required the emission of two decrees: one regulating the consultation process for IP in cases where access to national genetic resources is involved (Decreto No. 34958-MINAET-COMEX of 2008), and another defining when an invention is considered to have been derived from TK (Decreto No. 34959-MINAET-COMEX of 2008). After a legal challenge in the Constitutional Court, both of these decrees were declared unconstitutional and annulled. However, how the process of consultation between the IPR authorities and the TO will take place is still unclear in practice.

- Almost all the ABS initiatives so far have focused on the collection of genetic resources in protected or private areas, as well as marine portions of the country. Almost no ABS initiatives have been proposed or carried out in Indigenous territories, and a result, no benefits have accrued directly to this population.

The implementing decrees (regulations) for the BL are now under revision in order to: (a) facilitate procedures, including through on-line applications, and to create a clearer differentiation between different categories of basic research; and (b) comply with the NP provisions.

Ecuador[β]

The new Ecuadorian Constitution recognizes in several provisions the duty to conserve and preserve the genetic resources of the country, as well as the associated TK (articles 74, 313, 322, 400 402, 408, among others). Activities related to genetic resources are declared to be of public interest and a strategic sector of the nation. Furthermore, the Constitution outlines several limitations and prohibitions in relation to the appropriation, including through IPR, of the genetic resources or the collective knowledge of the people.

Ecuador has implemented Decision 391 of the Andean Community through its own Regulation, enacted after the adoption of the NP, the *Reglamento Nacional al Régimen Común sobre Acceso a Recursos Genéticos en Aplicación de la Decisión Andina 391*, *No. 905 del 2012* (the Regulation).

Most of the features of the Regulation closely follow the text of Decision 391, including the scope (article 2); general norms (article 3); and definitions (article 6). The Regulation designates a National Competent Authority, which is the Ministry of Environment (Biological Diversity Unit, article 7), whose functions are described in detail (article 8), including regarding the signature of ABS contracts. The Regulation also creates a system of "entidades evaluadoras" (assessment entities), including different Ministries with the responsibility to issue a technical report for each access request. Every assessment entity has a specific field of work in accordance to the type of genetic

resources for which access is sought (agriculture, fisheries, wildlife, associated TK, etc). A detailed procedure is established under Title IV, and the negotiation and signature of the access contract is regulated in Title V, including minimum requirements, mandatory access clauses, and economic guarantees (a percentage of the budget of the proposal). It also regulates limitations for access (articles 32-33), access to intangible components (TK), framework contracts (articles 39-41), and other contracts (article 42).

It is worth noting that there is a provision for the development of a Protocol for PIC (final provision 4), as well as an exemption from application of the law for uses of biological material for systematic, taxonomy, conservation, evolution, biology of populations, biogeography and phylogeography for which the support of the accredited university, museum, herbaria or research center is required, as well as a framework contract (article 2). A specific exception is also provided for the species and varieties included in Annex I of the IT.

To date, no contract has been signed, but several applications are pending, including for commercial purposes.

México[βα]

Despite being considered a priority area for many people, Mexico lacks a specific and comprehensive regulatory framework for genetic resources. While there are legal initiatives pending in Congress that aim to fill this gap, they have not yet been finally approved. The current rules regulating access to genetic resources are found in different federal laws. The *Ecological Equilibrium and Environmental Protection General Act* (General Act) recognizes that the use of genetic resources is considered of public interest. Due to this recognition, the State can regulate individual actions on behalf of the greater interests of society. According to Article 87 of the General Act, scientific collection of biological resources (including genetic resources) for non-biotechnological purposes requires authorization by the Secretariat of Environment and Natural Resources. Research results must be made available to the public. When the resources are to be used for the purposes of biotechnology, Article 87bis conditions authorization on the prior consent of the landowner where the resource is sought. The benefits arising from the use of the resources must be shared with such owner.

The prior consent of the landowner is also required by the *Wildlife General Act* when collecting activities are for scientific purposes. This regulation asks users to submit reports about their activities and to deposit samples of biological materials in national research institutions. The regulations of Wildlife General Act published in 2006 establish 5 modalities of scientific research (article 123), and require the preservation (and sharing of benefits) of TK of rural communities when carrying out activities of conservation and sustainable use of wildlife (article 124). The collectors must also present a results report (article 124 and 125).[58]

In order to complete article 87 of the General Act, the *Official Mexican Standard Nom-126-ecol-2000* specifies the requirements for scientific collections. If the user changes his purpose from scientific to biotechnological applications, he must submit a new declaration stating the new purpose and setting the stage for new consent and benefit-sharing agreements. Under this law or regulation many

[58] Mexico, *Reglamento de la Ley General de Vida Silvestre*, http://www.profepa.gob.mx/innovaportal/file/429/1/reg_lgvs.pdf.

scientific permits have been granted. In one case a change of intent has occurred, but no specific provisions are set to deal with this situation.[59]

The provisions of the *Sustainable Forestry Development Act* regulating collection for scientific, commercial and biotechnological purposes follow the access scheme in the General Act. The former adds a simplified procedure in case of collections done by the owner of the land or by public agencies. The novel element in this Act is that it recognizes the rights of Indigenous people over local varieties and related TK. This regulation declares void any registration, including, patents that does not acknowledge the right of Indigenous people to the ownership, knowledge and use of local varieties. If TK is to be used, there must be recognition of the ownership on behalf of the communities, an access agreement, and proof of prior informed consent.

The Mexican Criminal Code explicitly includes the illegal collection and traffic of genetic resources, which is punishable by imprisonment and a fine. Additional punishment will be applied when the activities are executed with a commercial purpose".

Conflicts of land tenure and resource use in rural areas are also important factors that have hindered the establishment and enforcement of an efficient ABS regime in Mexico. Due to uncertainty and distrust felt by some social sectors, bioprospecting activities have been difficult to carry out on some occasions.

Finally, the Mexican Intellectual Property Right Law or the Plant Varieties Federal Law does not contain a disclosure of origin requirement.

Box 3. Summary of the main content of the Mexican Draft Law[60]

As part of the implementation of the CBD, Mexico signed the Nagoya Protocol on 25 February 2011, ratifying the document on 16 May 2012 as the fifth country to do so. Nevertheless, in order to implement the Nagoya Protocol, several pending tasks need to be addressed at the national level.

In the process of implementing the CBD in Mexico, two draft laws were filed in the Federal Congress in 2001 and 2002, one submitted by Federal Senator Jorge Nordhausen (National Action Party (PAN)) and the other by Federal Representative Alejandro Cruz Gutierrez (Institutional Revolutionary Party (PRI))[61]. Although the Nordhausen draft law, the "Access and Use of the Genetic Resources Law", is officially still pending in the Chamber of Review, no action has been taken in relation to it since 2005. On the other hand, the draft law filed by the PRI, the "Biotechnology Development and Biosecurity Law", was rejected in the Chamber of Origin on 2007.

After the Nagoya Protocol was negotiated and adopted, Federal Representative Teofilo Manuel Garcia Corpus filed another draft law to the Federal Congress in November 2011: the Draft General Law on Access to Genetic Resources and the Protection of the Traditional Associated Knowledge (LRGCT). This draft law constitutes the latest attempt to regulate access to genetic resources and traditional knowledge. However the draft was officially rejected on August 2012 in the Chamber of

[59] See Valeria Souza Saldíva, "Case Study: Biotechnology for Conservation in Cuatro Cienégas Coahuila, México" in *Case Studies: Access and Benefit-Sharing for Non Commercial Research in LAC*, 2013.

[60] Denisse Blanck, "Mexico's Framework Regarding the Implementation of the Nagoya Protocol into National Legislation" (Rome: IDLO, 2014).

[61] J. Larson-Guerra *et al.*, "Mexico: Between Legality and Legitimacy" in International Union for Conservation of Nature and Natural Resources, ed., *Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity* (2004) 123 at 144.

Origin, based not on any substantial discussion, but on a rule establishing a deadline for revision. Despite the current absence of an *ad hoc* legal instrument, there are other laws that address specific issues in relation to ABS. Nevertheless, these are dispersed, they are not systematically integrated, and since they predate the Nagoya Protocol, they do not necessarily reflect its new spirit.

The definition of access provided in the LRGCT is: "the obtaining and use of the genetic resources in *in situ* and *ex situ* conditions, its derivatives, with investigation or bio-prospecting purposes".[62] Access to genetic resources and associated traditional knowledge is only permitted when SEMARNAT or SAGARPA (as defined below) give permission, and after the conclusion of the Access Agreement where the PIC and ABS is guaranteed. The permission granted might be in 2 modalities: (a) for teaching purposes, or (b) for bio-prospecting purposes.[63]

Competent Authorities
The draft establishes five Mexican competent authorities regarding access to genetic resources and associated traditional knowledge, namely: the Ministry of Environment and Natural Resources (SEMARNAT); the Ministry of Agriculture, Livestock, Rural Development, Fishing and Food (SAGARPA); the National Commission for the Development of Indigenous Peoples (CDI); the Mexican Institute of the Industrial Property (IMPI); and the National Commission for Knowledge and Use of Biodiversity (CONABIO). Each one of these authorities has its own sphere of competence,[64] with collaboration among multiple competent national authorities occurring intermittently.

Prior Informed Consent
Obtaining PIC is mandatory for any access to genetic resources and associated traditional knowledge. It must be contained in the Access Agreement (as defined below), and include the following information: purposes of the scientific information, places of access and uses, number of researchers and authorized persons, required material, recollection mechanism, term, potential destination of the genetic resources obtained, mutual agreed terms, and signature.[65] A special emphasis is placed on obtaining the PIC from Indigenous peoples. The petitioner is required to discuss the meaning and scope of the access, the required terms of the protection of the Traditional Knowledge, and the practical, economical and logistical aspects of the access with the community representative.

Access Agreement
In order to access genetic resources, the parties involved must execute an Access Agreement. This document establishes the terms and conditions of the access, and additionally, when the access involves Traditional Knowledge, it must contain an Annex establishing very clearly the terms for the fair and equitable sharing of benefits of the Agreement.[66] The parties involved in the Agreement are the Indigenous populations where the genetic resources and/or the Traditional Associated Knowledge is located, as well as the access petitioner.

Protection of Traditional Knowledge
The TK of Indigenous populations is strongly protected in the draft law. Access to the land and

[62] Mexico, Draft General Law on Access to Genetic Resources and the Protection of the Traditional Associated Knowledge, at section 5
[63] *Ibid.* at section 35.
[64] *Ibid.* at section 14.
[65] *Ibid.* at section 22.
[66] *Ibid.* at section 30.

territories of Indigenous populations requires authorization and PIC from the competent authorities and the owners or representatives of the land or territory. Native communities have the right to create, develop, preserve and transfer their TK associated with genetic resources.[67] Individuals who obtain permission to access the TK must also guarantee that they will not transfer or surrogate the rights arising from the permission; that they will not disclose information related to the TK; and, that they will not obtain economic benefits from the TK without the PIC of the native communities, acquired pursuant the legal requirements.[68]

The government acknowledges and protects the knowledge, practices and innovations of the Indigenous populations related to biodiversity and TK.[69] The IMPI must protect the intellectual property rights through the National Inventory of Traditional Knowledge, and the registry to the Inventory must be voluntary and free. The IMPI will deny any third parties' application involving intellectual property rights over TK and GR contained in the Inventory, and shall address defense actions against acts of biopiracy. In addition, IMPI will not grant patents or register commercial secrets without fulfilling the national and international regulations related to Indigenous TK and access to genetic resources and associated traditional knowledge.[70]

In situ and _ex situ_ access conditions

Access to *in situ* genetic resources will be permitted only to research institutions (public or private). Access to foreign institutions will only be granted if the research is conducted with a national institution.[71] When genetic resources are located within a natural protected area or an area considered risky, access will be permitted only for conservation purposes.[72] There is no regulation regarding access for commercial purposes. *Ex situ* genetic resources include systematized collections and genetic and biochemical resources held *ex situ* by individuals or institutions. In order to access *ex situ* resources, an access permit must be obtained by the interested party.[73]

Fair and Equitable Sharing of Benefits

If the access to genetic resources and associated traditional knowledge involves Indigenous populations and their territories, the sharing of benefits must be fair and equitable. If the access to genetic resources and associated traditional knowledge is done in National Territory, the sharing of benefits must be allocated to the conservation of genetic resources.[74] There is no provision regarding non-monetary benefits.

National System of Genetic Resources Information[75]

The CONABIO must develop a System of Genetic Resources Information that will organize, update and disseminate information on genetic resources. Such authority will gather relevant reports and documents arising from investigations, access and the conservation of genetic resources. Additionally, the System will also contain: (i) laws, regulations and guidelines; (ii) regional, bilateral and multilateral agreements, (iii) permission applications, (iv) social and economic effects of the access to genetic resources and associated traditional knowledge, as well as the cultural and

[67] *Ibid.* at section 53.
[68] *Ibid.* at section 54.
[69] *Ibid.* at section 55.
[70] *Ibid.* at section 56.
[71] *Ibid.* at section 57.
[72] *Ibid.* at section 58.
[73] *Ibid.* at section 61.
[74] *Ibid.* at sections 68 and 69.
[75] *Ibid.* at section 71.

environmental impacts, and (v) reports on compliance with the Nagoya Protocol.

Registry of Genetic Resources[76]
The Registry will be in charge of SEMARNAT and the National System of Plant Genetic Resources for Food and Agriculture[77] (SINAREFI), according to their respective competences and will be public. The objective of the Registry is the registration of relevant information regarding access to genetic resources and associated traditional knowledge.

Because Mexico has ratified the NP, a detailed plan for its implementation exists,[78] but only limited actions have been initiated so far. An Inter-ministerial Group was created for the Implementation of the NP including CONABIO, SEMARNAT, SAGARPA, IMPI, and the Ministry of Foreign Affairs (SRE). Because current applicable laws were enacted prior the ratification of the NP, adjustment is needed based on a strategic planning in the short, medium and long term. Experts have suggested that in the short-term, legislative changes need to be made to address the provisions of the NP, particularly those that are not covered by national laws.

The modifications for implementation must be directed toward the 11 laws affected and meet the requirements of the Mexican Constitution on participation of the Federation, States and Municipalities. The modifications would be temporary until a framework law developed is enacted.

Mexico's priorities or key areas for capacity building and development are:

a) Legal and institutional development;
b) Special measures to increase capacity of ILC;
c) Mobilising new and innovative financial resources to implement the NP;
d) Establishing a mechanism for interagency coordination;
e) Promoting equity and fairness in negotiations;
f) Supporting the development of model contractual clauses;
g) Developing and implementing pilot access and benefit-sharing agreements;
h) Developing a policy framework on ABS;
i) Taking stock of domestic measures relevant to ABS in light of the obligations of the NP;
j) Setting up new or amended ABS measures with a view to implementing the NP;
k) Developing minimum requirements for MAT in the case of associated TK;
l) Developing community protocols.

Nicaragua[α]
The 1996 General Law for the Environment mandated the development of the 2012 Biodiversity Law.[79] The first draft was submitted to Parliament in 2006 and it entered into force in 2012.[80] Civil society representatives were invited to participate in the long consultation and negotiation process through a multi-stakeholder Technical Commission, which included representatives from the

[76] *Ibid.* at section 72.
[77] SINAREFI is a mechanism coordinated by SAGARPA that aims to implementation a regime similar to that created under the ITPGRFA, to which Mexico is not yet a Party.
[78] Norma Mungía, PowerPoint Presentation, Lima, November 2013.
[79] *Ley 217 General del Medio Ambiente y los Recursos Naturales*, 1996 at Article 70 [Ley 217].
[80] *Ley Nº 807 de Conservacion y Utilizacion sostenible de la diversidad biologica*, published in La Gaceta – Diario Oficial nº 200, 19 October 2012 at 8368-8380 [Biodiversity Law].

government and civil society organizations gathered under the "Alliance for the Protection of Biodiversity."[81]

The Biodiversity Law comprises 105 articles organized in 19 Chapters. It covers all aspects related to the conservation and sustainable use of biological diversity, including access to genetic resources and benefit-sharing arising from its utilization. It pays special attention to the protection of Indigenous and Afro-descendant communities, as well as the respect and recognition of intellectual property rights, traditional knowledge, and customary use of local communities.[82]

Biodiversity and its components are under the sovereignty of the state and its components (ecosystems, species, genes and derivatives) are part of the public domain.[83] The Biodiversity Law articulates among its objectives the establishment of procedures for the access and use of genetic resources and the promotion of fair and equitable benefit-sharing arising from the use of biodiversity.[84] The general scope of the law is broader than the scope of the Nagoya Protocol, since it covers all benefits derived from the use of biodiversity and all traditional knowledge, not only those associated to the use of genetic resources.

While the Nagoya Protocol excludes illegally acquired genetic resources,[85] the Biodiversity Law aims at the repatriation of domestic genetic resources that have been removed in breach of the requirements of national standards. Nonetheless, there is only mention of this in the items to be funded by the Biological Diversity Account, not any direct action required.[86]

Institutional Framework

The competent authority is Ministry of Environment and Natural Resources through the Natural Heritage Direction General. Through the general framework of the Biodiversity Law, new institutions with competencies related to ABS were created, including:

- The Biological Diversity Technical Committee[87] is a multi-stakeholder advisory board
- The Biological Diversity Account formalises existing practices of financing conservation activities from fees and revenues derive from use of biological diversity
- The National Research Centre for Biological Diversity is only mentioned in the transitory provision[88]

Non-commercial research

All access to genetic resources and bio-prospecting activities are subject to the issuance of a permit by the National System of Licences and Permits, and to the publication and registration of the

[81] *Dictamen de Proyecto de Ley de Conservación de Utilización Sostenible de la Diversidad Biológica*, Comisión de Medio Ambiente y Recursos Naturales Asamblea Nacional, CMARM-AN-FSGP-044-06-2012, 28 June 2012, Nicaragua at 3.
[82] Biodiversity Law, *supra* note 77 at Article 2.
[83] *Ibid.* at Articles 3 and 4.
[84] *Ibid.* at Article 5.
[85] Nagoya Protocol, *supra* note 3 at Article 1; Convention on Biological Diversity, *supra* note 2 at Article 15(3); see also, Thomas Greiber *et al. An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing* (Gland, Switzerland: IUCN, 2012) at 86 [IUCN Explanatory Guide].
[86] Biodiversity Law, *supra* note 77 at Article 30.8.
[87] *Ibid.* at Article 13-16.
[88] *Ibid.* at Article 101.

mutually agreed terms.[89] Non-commercial research is not explicitly included in the Law, which defines bio-prospecting as the systematic search for, classification of, and commercial research into new sources of chemical compounds, genes, proteins, microorganisms and other products with actual or potential economic value found in biological diversity.

Derivatives

The regulation of the benefits arising from the utilization of derivatives (naturally occurring chemical compounds resulting from the genetic expression or metabolism of biological or genetic resources, even if they do not contain the functional units of heredity) are included in the Nagoya Protocol,[90] but experts disagree regarding access to the derivative on its own, for example, from an *in situ* conservation centre under the scope of the NP.

The Nicaraguan Biodiversity Law expands and provides clarity by also regulating access to derivatives,[91] in line with the practice observed by other Latin American countries.[92] According to the Biodiversity Law, derivatives are part of biodiversity.[93] The same procedure established to access genetic resources and traditional knowledge applies in the case of accessing derivatives.

Procedure to access genetic resources and/or traditional knowledge

The Biodiversity Law distinguishes between access to genetic resources and access to traditional knowledge. Access is defined as the adequate and authorized acquisition of genetic and biological resources, or associated knowledge, innovations and practices.[94] In that light, independent authorisations for access are required to access the genetic resource and the associated traditional knowledge.[95]

Prior informed consent

A public consultation with the community, representatives and local authorities is the starting point of the process. Prior informed consent should be given in writing (ie. a letter of prior informed consent) for access to either genetic resources or their associate traditional knowledge.[96] The state will ensure throughout the process that the PIC was obtained according to the law.[97] PIC is required from Indigenous peoples, ethnic groups, and local or municipal authorities.[98]

Submission of the application

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[89] *Ibid.* at Article 56 and 57.
[90] For the interpretation of Article 2 of the Nagoya Protocol on Use of Terms, see IUCN Explanatory Guide, *supra* note 82 at 61-69.
[91] Biodiversity Law, *supra* note 77 at Articles 10.7, 10.8, 56, 63, 76, 81
[92] J. Cabrera Medaglia, "El Protocolo de Nagoya: Opciones de Politica para su Implementacion en America Latina, Consultoría "Acceso y Distribución de Beneficios: estudios técnicos y análisis de casos de bioprospección y biopiratería" Proyecto GEF sobre Acceso a Recursos Genéticos y Distribución de Beneficios para América Latina y del Caribe (Colombia, Costa Rica, Cuba, Ecuador, Guyana, Panamá, Perú y Republica Dominicana – GEF ABS LAC), Quito, marzo 2013. Pages 24-30.
[93] Biodiversity Law, *supra* note 77 at Article 4.
[94] *Ibid.* at Article 10.1.
[95] *Ibid.* at Article 64.
[96] *Ibid.* at Article 60.
[97] *Ibid.* at Art. 61 and 62.
[98] *Ibid.* at Article 62.

Once PIC is granted, the applicant can submit the application together with a set of documentation, which includes a project proposal. When the competent authority verifies that the dossier is complete, it will inform the applicant of any cost of further measures necessary to emit a resolution.[99]

Mutually agreed terms and the sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge

Article 5 of the NP regulates the sharing of benefits in three cases. Parties shall take the appropriate measures to ensure that:

- The Party providing such resources participates in the benefits arising from the utilization of genetic resources, as well as subsequent application and commercialisation;
- Benefits arising from utilization of genetic resources held by ILC are shared based on mutually agreed terms and according to the rights over genetic resources established in the domestic legislation[100]; and
- Benefits arising from utilization of traditional knowledge associated with genetic resources are shared with the ILC holding such knowledge based on mutually agreed terms.

Once the applicant obtains a permit for access, the State of Nicaragua and the applicant will enter into negotiations for a Permit of Access Agreement (the Agreement) that should include a clause on the fair and equitable sharing of benefits.[101] It applies to both genetic resources and traditional knowledge.

While the protocol only envisions benefit-sharing with ILCs in the context of traditional knowledge associated with genetic resources and not with Parties,[102] the law does not stipulate either the degree of participation of ILCs in the negotiation of the Agreement, or the benefits the ILC should receive from the utilization of their TK.

Determining the sharing of benefits with the ILC is left to the negotiation of a Complementary Agreement to the Permit of Access Agreement (Complementary Agreement), which, according to the use of terms, "shall include provisions regarding the equitable participation and fair sharing of benefits arising from biological diversity"[103], without further guidance. The applicant and the owner, community or manager of the *in situ* conservation are may enter into a Complementary Agreement with the purposes of the development of activities related to the access and use of genetic resources or their derivatives.[104] The Complementary Agreement can only be entered into once the Agreement has been signed.[105]

Protection of TK: *Sui Generis* Community Intellectual Rights

[99] *Ibid.* at Article 66.
[100] Indigenous peoples are holders of rights internationally acknowledge while the rights of local communities shall be determined by domestic legislation. See: IUCN Explanatory Guide, *supra* note 82.
[101] Biodiversity Law, *supra* note 77 at Article 70 and 71.
[102] IUCN Explanatory Guide, *supra* note 82 at 88.
[103] Biodiversity Law, *supra* note 77 at Article 10.8.
[104] *Ibid.* at Article 10.8 and 75.
[105] *Ibid.* at Article 76.

The Biodiversity Law offers strong protection for TK, which is defined as all knowledge, innovation and practice, individual or collective, with actual or potential value associated with biological resources, which could be tangible or intangible expressions.[106] A second definition of TK adds a time qualifier (developed through centuries), and the fact that TK is transmitted from generation to generation.[107]

Nicaragua recognises and protects TK related to conservation and the sustainable use of biodiversity and its sub-products under the name of *Sui Generis* Community Intellectual Rights. According to the Biodiversity Law, Indigenous peoples, and ethnic and local communities have the right to decide upon their intellectual property rights.[108] TK is considered to be part of the cultural heritage of the ILC, and it can only be utilized after the person entitled, according to the law, grants PIC.[109] Consultation, the PIC procedure, and any protection of TK must also respect the ILC's traditional forms of organization,[110] and Indigenous peoples' systems,[111] in order to prevent interference and restriction on TK.

The *sui generis* system for the protection of TK is established in Article 86: "The *sui generis* intellectual community property rights exist and are recognized with the mere existence of the cultural practice or knowledge related to genetic resources and it will not require prior declaration, explicit recognition nor official record, which can include practices which in the future acquire such status."

Disclosure of origin

Formerly, the Government decreed that all germplasm and every native species, especially species endemic to Nicaragua, were registered and patented in favour of the state and people of Nicaragua for their own or exclusive use.[112] The current Patent Law overruled this provision,[113] stating that only natural processes obtained with human intervention are considered inventions.[114]

The Biodiversity Law establishes the obligation to submit a certificate of disclosure of origin issued by the Biodiversity and Natural Resources Directorate to apply for the registration of domestic intellectual property rights. In the case of intellectual property rights granted outside Nicaragua, documentation issued by the competent authority from the country of origin of the resource must be submitted.[115]

Compliance and monitoring

The mechanisms for monitoring the implementation of the obligations of informing and requesting authorization to change certain conditions of the Permit, such as the transfer of the access rights to

[106] *Ibid.* at Article 10.3.
[107] *Ibid.* at Article 10.9.
[108] *Ibid.* at Article 80.
[109] *Ibid.* at Article 82.
[110] *Ibid.* at Article 60.
[111] *Ibid.* at Article 83.
[112] Ley 217, *supra* note 76 at Article 64.
[113] *Ley Nº 354 de Patentes de Invención, Modelo de Utilidad y Diseños Industriales*, 2000, Art. 6.c and 6.d.
[114] Grethel Aguilar, "Conocimiento Tradicional sobre la Biodiversidad en el Proyecto Manejo Integrado de Ecosistemas por Pueblos Indígenas y Comunidades", Proyecto Regional de Manejo Integrado de Ecosistemas por Pueblos Indígenas y Comunidades en Centroamerica, GEF-PPG-No.TF 051362, 2003 at 45.
[115] Biodiversity Law, *supra* note 77 at Article 84.

a third party, must be determined in the Permit itself.[116] The Directorate for Biodiversity and Natural Resources can revoke the Permit if the applicant does not fulfil its obligations.[117]

Infringement of the ABS provisions of the Biodiversity Law or of the terms of the Permit of Access Agreement would result in very serious offenses,[118] which can be sanctioned with fines, revocation or suspension of the permit, or the requirement to pay compensatory damages. In case of the provision of misleading or wrongful information for the registration of intellectual property rights, the Law establishes that administrative, civil and criminal sanctions apply.[119]

[116] *Ibid.* at Article 73.
[117] *Ibid.* at Article 78.
[118] *Ibid.* at Article 78, 85 and 94.
[119] *Ibid.* at Article 85.

Technology Transfer and Capacity Building

The transfer of knowledge and technology, and the development of the capacity of Indigenous, local and scientific communities, is considered in the granting of Permits of Access.[120] The Biodiversity Law describes the specific components of such transfer, including the participation of a Nicaraguan scientist in the research, the designation of a research centre to deposit the samples, and the transfer of technology and biotechnology resulting from the use of the genetic resource.[121] This provision may narrow the opportunities for technology transfer and capacity building, however, since the knowledge transferred could be of application to other areas of conservation and sustainable use.[122] The emphasis of the Biodiversity Law on the development of national scientific capacity is the best alternative to transfer in order to add value to the rich biodiversity of Nicaragua.[123]

Panamá[§124]

The General Environment Law No. 41 from July 1, 1998 establishes the National Environmental Authority as the body competent to dictate norms, and regulate and control the access and use of biogenetic resources in general (with the exception of human species) in a manner that respects intellectual property rights. In order to fulfil this function, the National Environmental Authority will develop and introduce legal tools and/or economic mechanisms. The Unit for Access to Genetic Resources (Unidad de Acceso al Recurso Genético -UNARGEN) was created as a part of the National Office for Protected Areas and Wildlife of the National Environmental Authority.

According to Article 72 of the Law No. 41, the right to use natural resources does not grant its users the right to use the genetic resources contained in them. This article forms the starting point for subsequent ABS regulation. Article 2 of Law No. 41 defines genetic resources as "a set of hereditary molecules within organisms whose primary function is the generational transfer of the information on natural heredity of live organisms. Its expression is the collection of cells and tissues that form the live organism". Similarly, it defines biological surveying as "[t]he exploration of wild natural areas in the search of species, genes or chemical substances derived from biological resources with the goal of obtaining medicinal, biotechnological and other products."

In Article 62, Law No. 41 indicates that natural resources are part of the public domain and are of social interest, without infringing upon the rights legitimately acquired by individuals. Article 63 of Law No. 41 stipulates that "indigenous territories (*comarcas*) and the municipalities where natural resources exist and are used or extracted have the responsibility of contributing to their protection and conservation according to the parameters established by the National Environmental Authority together with the indigenous authorities, in conformity with applicable law."

Executive Decree No. 257 of October 16, 2006 regulates Article 71 of Law 41 and governs access to genetic resources. This decree was subsequently amended by Executive Decree No. 25 of April 29,

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[120] *Ibid.* at Article 57.

[121] *Ibid.* at Article 72.

[122] *Ibid.* at Article 72.

[123] J. Cabrera Medaglia, "El Protocolo de Nagoya: Opciones de Politica para su Implementacion en America Latina, Consultoría "Acceso y Distribución de Beneficios: estudios técnicos y análisis de casos de bioprospección y biopiratería" Proyecto GEF sobre Acceso a Recursos Genéticos y Distribución de Beneficios para América Latina y del Caribe (Colombia, Costa Rica, Cuba, Ecuador, Guyana, Panamá, Perú y República Dominicana – GEF ABS LAC), Quito, marzo 2013 at 66.

[124] Cfr. Elia Guerra's study, *Acceso a recursos genéticos y distribución de beneficios,* prepared for the Natural Patrimony Office of the ANAM, dated March 11, 2004.

2009. The Decree contains two issues of interest. Firstly, it defines the certificate of origin or provenance as "the legal recognition on the part of the National Environmental Authority of the origin or provenance of the genetic or biological resource whose genetic heredity makes up the genetic materials where processes or other products are derived."[125] Secondly, it provides that access contracts should include the obligation of the applicant to declare the origin and provenance of genetic resources in all publications or summaries that incorporate the genetic or biological resource collected.[126] In the same manner, the certificate of origin and provenance of the genetic and/or biological resource or material used in the development of the invention should be presented in all invention patent applications that are taken to the General Office of Intellectual Property and/or any patent office of WIPO member countries.[127] No access permit was granted in accordance with Decree No. 257[128], although several have been issued under the new regulations of 2009.

Lastly, Law No. 20 from June 26, 2000 on the "Special regimen of collective rights for indigenous communities" and its regulation (Executive Decree No 12 from March 20, 2001) creates a *sui generis* system for the protection of TK, which is limited to Indigenous communities and targeted fundamentally at folklore and other traditional cultural expressions. This system protects and regulates intellectual property rights and the TK of Indigenous communities relating to creations such as dress, work instruments, drawings, designs, figures and graphics, as well as other cultural elements such as music and dance. This protection is implemented through a registry system, as well as through the promotion and commercialization of their rights.[129] The Law also contains a chapter on prohibitions and sanctions. The 2007 Penal Code of Panama includes a section on crimes against the collective rights of Indigenous communities and their TK, with punishments of four to six years in prison for those who violate these registered collective rights.

Box 4: Summary of the ABS Regulation in force in Panamá.

Objectives - Executive decree No. 25 of April 2009 (ED 25) sets out several objectives, which encompass procedural matters, as well as the promotion of research, the strengthening of capacities, and conservation objectives.[130] It is interesting to note that although the objectives set out in this regulation are identical to the objectives of the Bonn Guidelines, ED 25 does not include important objectives related to the protection of traditional knowledge, innovations and practices of indigenous and local communities and to contribute to poverty alleviation and human food security, health and cultural integrity.[131]

Scope – ED 25 covers all genetic and/or biological resources (with the exception of human genetic resources), whose origin or provenance is the territory of Panama, including both wild and domesticated resources, those found *in situ* and *ex situ*, derivatives of the resources, and the genetic resources of migratory species found within the country for natural reasons. It also deals with the access to knowledge, innovations and traditional practices associated with the use of these resources, as well as the benefits arising from their commercial and non-commercial utilization.[132]

[125] Executive decree No. 25 of April 2009, Article 3.
[126] *Ibid.* at Article 19(e).
[127] *Ibid.* at Article 19(g).
[128] Darío Luque and Leonardo Uribe, personal communications.
[129] From 2002 to 2009, 10 registries have been granted. The protected material includes designs or textiles of molas, bags, necklaces, traditional dress, wood works, baskets, hammocks and musical instruments.
[130] Executive decree No. 25 of April 2009, Article 1.
[131] *Ibid.*
[132] *Ibid.* at Article 2.

Institutional Framework – ED 25 designates the National Environment Authority as the Competent National Authority,[133] and creates the Unit for Access to Genetic Resources (UNARGEN)[134] under the Directorate of Protected Areas and Wildlife, conferring important responsibilities regarding the process of petition for access to genetic resources, reporting, monitoring, negotiation of access contracts, and support to local and Indigenous communities in negotiations in transfer agreements, FPIC and benefits contracts.[135] Although the regulation does not formally designate a focal point, in the practice this role has been carried out by UNARGEN.

ED 25 also creates, within this Unit, a "single processing window" for handling access petitions,[136] and establishes a Technical Advisory Group in order to provide support in the process of evaluating access petitions using scientific criteria.[137] Nonetheless, it needs further regulation in order to establish its memberships and working procedure.

Procedure to Access Genetic Resources and/or Traditional Knowledge - ED 25 establishes that all petitions shall be presented to the single processing window for UNARGEN's evaluation.[138] It does not formally differentiate the procedure depending on the access purpose, although it mentions that basic research petitions for non-commercial or industrial purposes, carried out by students or research staff, shall be evaluated and processed by UNARGEN. Throughout other documents, however, no distinction is made among petitions or purposes.[139] The regulation makes clear that authorizations are not transferable, and are limited to the territory or area authorized for the collection, and to the resource covered under the terms of the Access Contract.[140]

Access Contract - ED 25 establishes the parties to the Access Contract,[141] and the obligations that shall be included in the Contract. Special obligations are also incorporated for applications for commercial, industrial and bioprospecting purposes, such as the incorporation of national researchers in the activities, and reporting to the scientific community on the progress of research.[142] Finally, it is required to communicate to UNARGEN any agreement reached between petitioner and genetic resource provider prior to the signing of the Access Contract.[143]

Free Prior Informed Consent (FPIC) - ED 25 also addresses FPIC from providers of genetic and/or biological resources found within private areas, local communities, and Indigenous communities, as well as those under special regimen, or those involving traditional knowledge.[144] FPIC is recognized as an accessory contract, which contains the obligations and rights agreed between the petitioner and the provider of the genetic resource or TK. In the case of TK, the FPIC must include aspects related to Intellectual Property Rights.[145]

[133] *Ibid.* at Article 4.
[134] *Ibid.* at Article 5.
[135] *Ibid.* at Article 6.
[136] *Ibid.* at Article 7.
[137] *Ibid.* at Article 11.
[138] *Ibid.* at Article 14.
[139] *Ibid.* at Article 15.
[140] *Ibid.* at Article 16.
[141] *Ibid.* at Article 18.
[142] *Ibid.* at Articles 19-20.
[143] *Ibid.* at Articles 21.
[144] *Ibid*, at Article 23
[145] *Ibid.* at Article 24.

FPIC is formalized between the petitioner and either the owner or possessor of the resource. In the case of TK, FPIC must be obtained from the representatives of the local communities or Indigenous communities that possess the TK.[146] FPIC, together with the Letters of Commitment and Benefits Contracts derived from FPIC, must be communicated to the UNARGEN, including the certification of authority, which establishes the competence of the provider to provide FPIC.[147] Finally, it establishes that FPIC must be limited to the specific uses for which it is granted, and any change in the use or transfer to third parties requires additional FPIC.[148]

Genetic Resource Transfer – ED 25 establishes that any individual or legal entity holding a genetic or biological resource in *ex situ* conditions must declare it to the UNARGEN and establish an agreement of responsibility for appropriate care and management.[149] It outlines conditions regarding the issuance of the transfer permit and signing of the Transfer Agreement;[150] but does not establish the procedure for requesting the transfer permit – this makes declaring the resource at the UNARGEN mandatory to obtain a permit.

Traditional Knowledge - ED 25 establishes that the UNARGEN will collaborate with the authorities of local and Indigenous communities in the classification and registration of knowledge, innovations and traditional practices.[151] This regulation does not mention how this process must be carried out; nevertheless, the Special Regime for Intellectual Property over Collective Knowledge of Indigenous Peoples regulated by the Law No. 20 of 2000, as well as Executive Decree 12 of 2001, creates a Collective Register for Intellectual Property (DIGERPI)[152] under the Department of Collective Rights and Expressions of Folklore of the Industrial Property Office of the Ministry of Commerce and Industry, and establishes the requirements for registration of a collective right.[153] With regards to the use of the traditional knowledge registered, the regulation establishes that the registration request must include a *use regulation* for the traditional knowledge.[154]

Benefit Contract - In addition to FPIC, a Benefit Contract must be part of the Access Contract. These benefits shall include economic and non-economic benefits to the Panamanian State, as well as intellectual property rights, royalties and any other benefits considered among the parties.[155] In case of commercial and industrial purposes, the benefits contract must include an annual royalty of not less than one percent (1%) of the net sales, a payment at the onset of the project for a sum agreed upon by the parties, and periodic or non-periodic payments.[156]

[146] *Ibid.* at Article 25.
[147] *Ibid.* at Article 26.
[148] *Ibid.* at Article 27.
[149] *Ibid.* at Article 29.
[150] *Ibid.* at Articles 30-31.
[151] *Ibid.* at Article 34.
[152] Executive Decree 12 of 2001 at Article 7.
[153] Executive Decree 25 of 2009 at Articles 5 and 6.
[154] *Ibid.* at Articles 6-7.
[155] *Ibid.* at Article 39.
[156] *Ibid.* at Article 41.

The Benefits Contract agreed to by the provider of genetic resources or traditional knowledge must be communicated to UNARGEN and incorporate benefits to the Panamanian State, as established in the regulation.[157]

Compliance - ED 25 establishes prohibitions such as petitions of access to areas used by Indigenous communities for sacred or religious purposes, and petitions of access to genetic resources with foreseen uses in environmentally harmful biological warfare, or which might seriously endanger human health.[158]

ED 25 also regulates the causes of contract cancellation[159] and infractions to the genetic patrimony.[160] These infringements have sanctions ranging from written warnings to fines and cancellation of contract.[161] Since the regulation has not established a specific procedure for the imposition of sanctions for breaches of this regulation, the general administrative procedure under Law 38 of 2000 should be used.

Institutional Framework – ED 25 creates a specialized department, which deals exclusively with ABS. This entity – the Unit of Access to Genetic Resources – is responsible for all procedures, monitoring and reporting related to ABS.

Administrative Procedures – ED 25 has established the instruments and conditions for accessing genetic resources and traditional knowledge, including PIC and MAT for assuring benefit sharing and compliance measures.

Coordination among Institutions – The National Environmental Authority as Competent National Authority and the Ministry of Commerce and Industry, through the Directorate of Industrial Property, are working together in the creation of the first national Checkpoint under article 17 of the Nagoya Protocol, in order to ensure compliance with regulations.

Strengthening National Capacities - There is a Cooperation Agreement between the Ministry of Commerce and Industry and the National Environment Authority to strengthen institutional capacities in ABS.[162]

Consistency in Domestic Legislation - The Ministry of Commerce is in the process of reviewing Panamanian regulation on patent registration in order to include the communication of the source of origin of a genetic or biological resource as a requirement for patent applications.[163] To date, no modification to domestic regulation has been carried out, but on April 27 of 2012, Panama ratified the Patent Cooperation Treaty.[164] In 2012, Panama also ratified and became a Party to the International Convention for the Protection of New Varieties of Plants.[165]

The Registration of Traditional Knowledge and Practices - The Directorate of Industrial Property is working with representatives of the Guna Yala community (one of the Indigenous groups in

[157] *Ibid.* at Article 44.
[158] *Ibid.* at Articles 45-47.
[159] *Ibid.* at Article 28.
[160] *Ibid.* at Article 49.
[161] *Ibid.* at Article 50.
[162] D Luque Interview, *supra* note 132.
[163] *Ibid.*
[164] Panama, Law 21 of 2012
[165] Law 25 of 2012

Panama) in order to establish a TK registry. Because this registry relates to only one Indigenous community in Panama, authorities must work with other Indigenous and local communities in order to create equal registers for them. This is a huge challenge since each Indigenous community has its own regulations and procedures.

Promotion of Projects for Research and Capacity Building relating to Genetic Resources – Bioprospecting projects have been carried out in Panama for the discovery of nature-based products for the pharmaceutical and agrochemical industries, as well as benefit-sharing to increase the scientific capacity of the Protected Areas System of Panama,[166] to increase capacities for the implementation of the NP, and to adapt ABS regulation to NP clauses and objectives.[167]

Source: Patricia Parez, "ABS Legal Framework of the Republic of Panama: Taking Actions for Biodiversity Conservation and Sustainable Use", IDLO, Rome, 2014.

Perú[β]

Since the CBD came into force in Peru in 1993, the issue of ABS has been part of the legislative and policy agenda. Even before Decision 391 of the Andean Community was adopted, the Ministry of Agriculture and the National Institute for the Protection of Intellectual Property (INDECOPI) established a multidisciplinary working group to assess alternatives for implementing the ABS regimen in Peru. After Decision 391 was adopted, several proposals for implementing this Decision were made.

In 1997, Peru enacted the Law on the Conservation and Sustainable Utilization of Genetic Resources. The Law addresses, in a general way, Indigenous peoples' rights and scientific research. However, it lacked detailed provisions regarding ABS. In the access discussions, the protection of TK has been a top priority on the political and legal agenda. In August 2002, the Law Introducing a Protection Regimen for the Collective Knowledge of Indigenous Peoples Related to Biological Resources was published.[168] This legislation establishes a *sui generis* protection regimen covering only the collective TK related to biodiversity. Prior informed consent is the main condition to be fulfilled to obtain access to collective TK, and must be obtained from the representative organizations of the Indigenous peoples involved. Indigenous peoples may refuse access. It is also necessary in cases of commercial and industrial applications to sign an agreement that ensures benefit-sharing. The license must be in written form and registered with the National Institute for the Protection of Intellectual Property. The Law specifies some clauses that the license agreement must include, without which the Institute must refuse to register the license.

The Law also provides for three types of registry for collective TK: (a) the National Public Register; (b) the National Confidential Register; and (c) local registers of collective knowledge. Indigenous peoples possess rights over their knowledge whether in a register or not. A fund for the development of Indigenous peoples is created to compensate all Indigenous peoples for their contribution to the preservation of this knowledge.

[166] UNDP-GEF NPIF Project entitled "Promoting the application of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing in Panama."

[167] UNEP/GEF ABS-LAC IUCN-South, "Strengthening the implementation of Access to Genetic Resources and Benefit Sharing regimes in Latin America and the Caribbean."

[168] See also the CONADIB, *National Report of Peru on the Progress Reached in the National Implementation of Article 8(j) and Related Provisions Programme of Work,* submitted to the CBD, Lima, September 2013.

There is also a Law for the Protection of Access to Peruvian Biological Diversity and to Collective Indigenous Knowledge (the Anti-Biopiracy Law). This Law creates a National Commission for the Prevention of Biopiracy, and one of its main objectives is to prevent illegal access and appropriation of the biological resources and TK. The Commission is fully operational and has been very active in searching for foreign patent applications involving or using national genetic resources or TK.

Finally, in 2008, ABS regulations for Peru were issued through Ministerial Resolution 087-2008-MINAM (later on converted into National Decree No. 003-2009-MINAM). These regulations closely follow the main provisions of the Decision 391 (including the definitions which are the same as those contained in article 1 of the Decision). Its scope is broad, covering all genetic resources for which Peru is the country of origin, as well as their derivative products, their intangible components and the migratory species found for natural reasons in Peruvian territory.[169]

Excluded from the regulations are human genetic resources and their derivative products; the traditional and customary use of genetic resources by Indigenous peoples and local communities; the species included in Annex I of the ITPGRFA; the use of genetic resources for cultivation purposes within Peru; and activities that involve the economic use of non-timber natural resources to produce natural products (nutraceuticals and functional foods).[170]

The regulations recognize and protect the rights of Indigenous peoples to make decisions concerning their innovations, practices and knowledge associated to genetic resources.[171]

The Ministry of Environment is the national competent authority on ABS; it approves the national policy and the guidelines and norms for the management of genetic resources. It also establishes the strategy for international negotiations in coordination with other bodies and holds the registry of access contracts and national research entities,.[172] However, the permitting process and the signature of access contracts is the responsibility of the Administrative and Execution Authorities[173] (so far the agricultural, fisheries and protected areas authorities).

Following Decision 391, the regulations provide for access contracts, accessory contracts, and framework contracts and Material Transfer Agreements (MTA) to be signed by *ex situ* conservation centres (the model of the MTA must be approved in advance by the Ministry). The access contracts and the accessory contracts must include some provisions,[174] including: the prohibition of claiming ownership over the material *per se* or its derivatives; the obligation not to transfer the material without the authorization of the competent authority; recognition of the origin of the material; training and infrastructure; information exchange; technology transfer; economic benefits; and research reports. Framework agreements with universities, research centres and researchers are also regulated only for non-commercial purposes.[175]

The transfer of material from *ex situ* conservation facilities located in the country for research purposes is to be done using an MTA, establishing the conditions for the transfer of the materials to third parties as well as the recognition of origin. The transfer of materials for commercial purposes

[169] National Decree No. 003-2009-MINAM at Article 4.
[170] *Ibid.* at Article 5.
[171] *Ibid.* at Article 6.
[172] *Ibid.* at Article 13.
[173] *Ibid.* at Article 14.
[174] *Ibid.* at Article 23.
[175] *Ibid.* at Article 24.

must be done using an access contract.[176] The Administrative authorities, in coordination with the Ministry, are tasked with establishing a standardized MTA, which must include minimum conditions including the prohibition against claiming ownership over the material *per se*, and against transferring the material without prior authorization.[177]

A list of sanctions is provided, including cancellation, suspension of the permit, fines, seizure of the material, and cancellation of the register. The regulations also create a national system for the monitoring of genetic resources.[178]

In addition, a regional ordinance on access to genetic resources and to associated traditional knowledge in the territories of the farmer and native communities of Cusco[179] establishes an institutional mechanism to prevent and address cases of biopiracy in the region. It also promotes the conservation of and research on genetic resources.[180]

Despite all the legislative effort, few ABS initiatives exist within the country. One well know initiative was the International Cooperative Biodiversity Group (ICBG) between Searle Pharmaceuticals, the Araguana Peoples, Washington University, the Universidad Cayetano Heredia and the Museo de Historia Natural of Peru. Nevertheless, it appears that most of ABS activity is conducted in the country through other legal channels, and does not use the ABS legal framework.

In practice, only one formal ABS contract has been concluded, with the Korean Institute of Biosciences and Biotechnology (KRIBB), which aims to conduct research on the medicinal plants traditionally used in the Amazonian Region. This contract implied the development of complex institutional arrangements with the participation of three different Peruvian entities.[181]

More than 20 contracts for research purposes have been signed between the Ministry of Environment and different applicants,[182] and a number of MTA have been also signed between the National Agriculture Research Institution and applicants in the case of agricultural genetic resources.

Venezuela[β]

A new Constitution was adopted in Venezuela in 1999 providing some general rules on the treatment to biodiversity, as well as more specific rules on contracts involving natural resources. Articles 127 and 129 of the Constitution state:[183]

> Article 127. It is the right and duty of each generation to protect and maintain the environment for the benefit of itself and the world to come. Everyone has the right, individually and collectively, to enjoy life and a safe, healthy and ecologically balanced. The

[176] *Ibid.* at Article 29.
[177] *Ibid.* at Article 33.
[178] *Ibid.* at Articles 37 and 38.
[179] Ordenanza Regional No. 048-2008-CR/genetic resources published in the Official Gazette "El Peruano" January 14, 2009.
[180] Other relevant norms include Law No. 28477, which declares, as natural heritage of the Peruvian nation a list of 35 native crops and wild fauna species, and the National Directorial Resolution No. 1986/INC dated December 23, 2009 which declares that as national cultural heritage, the knowledge, practices and technologies associated to the traditional cultivation of maize in the Sacred Valley of Incas in the Andes of Peru.
[181] See Isabel Lapeña *et al*, *Incentivos y Desincentivos para la participación de Perú en el Sistema Multilateral de Acceso del Tratado Internacional Sobre Recursos Fitogenéticos para la Alimentación y la Agricultura*, Biodiversity International, 2010.
[182] See http://dgffs.minag.gob.pe/index.php/recursos-genetico
[183] See: Astudillo Francisco, Legal Brief on Venezuela´s Biodiversity Law (Rome: IDLO, 2014).

> State shall protect the environment, biodiversity, genetics, ecological processes, national parks and natural monuments and other areas of special ecological importance. The genome of living organisms cannot be patented, and the law relating to bioethical principles will regulate this matter.
>
> Article 129. In contracts signed by the Republic with individuals or corporations, domestic or foreign, or permits to be granted, involving natural resources shall be counted even if not expressed, the obligation to preserve the ecological balance, to allow access to technology and transfer of the same on mutually agreed terms and to restore the environment to its natural state if it is altered, in the terms established by law.

ABS in Venezuela was initially carried out in conformity with Decision 391 of the Andean Community with the Biodiversity Law of 2000,[184] but now takes place in conformity with Chapter VII of the *Biological Management Act of 2008*, as well as other relevant legislation. According to the 2008 Act, all persons seeking access to genetic resources must follow the proper administrative procedure, which includes an application, a contract, a public resolution and a registration of the process. Some factors such as the conservation of endemic species, ecosystem preservation, and human health protection, *inter alia*, can be used to justify limitations to access. Concerning the use of TK associated with genetic resources, the State commits itself to promoting and protecting the collective rights of Indigenous peoples and local communities.

The 2008 Act provides for a specific chapter on the regulation of access to genetic resources, which permits the national environmental authority to allow access to these resources, as well as their products, derivatives and associated intangible components, provided they do not cause damage to biological diversity and its components.[185]

The CNA of Venezuela in the regulation of access to genetic resources is the Ministry of Popular Power for the Environment, which in 2010 issued a policy document called the National Strategy for the Conservation of Biodiversity.[186]

Authorizations for research or science-based institutions require an agreement for the purposes and possible uses of the given resources in the research. This agreement covers access to genetic resources, their derivatives and intangible components, involving the generation of information and scientific knowledge.[187]

Access contracts must be concluded with each person or institution conducting research involving access to GR/TK or their derivatives,[188] with the limitations on access being the possible danger of genetic erosion, the declaration of strategic importance, or as established by law.[189]

The National Environmental Authority may, if requested, provide confidential treatment to information submitted during proceedings,[190] and is empowered to establish requirements and procedures for processing access applications.[191]

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[184] Ley 4.780, de 24 de mayo de 2000, Official Gazette No. 5468.
[185] Venezuela, *Biodiversity Management Act* (2008).
[186] National strategy for the conservation of biological diversity of the Bolivarian Republic of Venezuela (2010), online: <http://issuu.com/diversidad_biologica/docs/encdb_ingles>.
[187] *Ibid.* at Article 97.
[188] *Ibid.* at Article 98.
[189] *Ibid.* at Article 99.

Where access to genetic resources, traditional knowledge or derivatives, is to be done on the land of, or will involve, Indigenous communities, the National Environmental Authority requires obtaining the prior informed consent of the communities. The prior informed consent contract must include terms providing for the fair and equitable distribution of benefits deriving from such use.[192]

Traditional knowledge, or the "intangible components" of biological diversity, is recognized for its value in understanding, applying, and preserving genetic resources – the knowledge, innovations and practices of ILCs. The right of these communities to collectively benefit from use of this knowledge is explicitly reaffirmed in the act.[193]

Venezuela has granted access to different projects and has signed several framework agreements with national universities and research centres to carry out bioprospecting activities for non-commercial purposes.[194] Under prior legislation (the Biodiversity Law of 2000) more than 50 permits were granted, while under the current legislation, more than 20 permits have been granted.

In addition to the Biodiversity Law, there are two other pieces of legislation of relevance for TK protection: the *Ley de Patrimonio Cultural de los Pueblos Indígenas*, No 39.115 of 2009, and the *Ley Orgánica de Pueblos y Comunidades Indígenas*. These instruments –which sometimes address the rights of Indigenous peoples in general and are not specifically targeted at the protection of TK or genetic resources – provide for the recognition of Indigenous rights over the TK and their lands; the requirement of PIC; the requirement to provide benefit-sharing; the limitations to applying for IPR on TK; and the voluntary register of intangible heritage.

Other Developments

- **Cuba.** There is no specific ABS legislation in Cuba. However, under regulation No.R-111-96 of 1996 (Regulations on Biological Diversity), the Ministry of Science, Technology and Environment is designated as the agency responsible for the issuance of collection permits, including requests for the signature of benefit-sharing contracts. No information was obtained about the practical application of this provision in the light of the legal Cuban system. In many cases, the collection and use of GR is made only by the National Research Institutions (of a public nature) of Cuba, which have different legal mandates and institutional frameworks. A 2012 amendment of patent law includes a disclosure of origin and source requirement (in cases of utilization of foreign genetic resources), and requires proof of the legality of the access of the material (an authorization) for national use of genetic resources in patents and plant variety rights (Laws 290-2012 and Law 291-2012 in force since April 2012, respectively).

- **Dominica.** A draft ABS law exists. In **Saint Lucia,** as part of a comprehensive biodiversity law, a detailed chapter on ABS has been drafted.

- **Guyana**. Draft regulations on ABS have been developed and are under revision. A national policy on this issue and several ABS agreements are reported between the Iwokama International Center and some ILCs of that country.[195]

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[190] *Ibid.* at Article 102.
[191] *Ibid.* at Article 103.
[192] *Ibid.* at Article 100.
[193] *Ibid.* at Article 101.
[194] Santiago Carrizosa, "Diversity of Policies in Place and in Progress" in Carrizosa, et al, eds, *Accessing Biodiversity and Sharing the Benefits : Lessons from Implementing the Convention on Biological Diversity* (IUCN, 2004)
[195] See GENIVAR, Thematic Report on ABS, UNDP, EPA, GEF, 2009, submitted to the SCBD.

- **El Salvador.** Article 66 of the general environmental law contains an enabling clause providing for the future development of specific ABS regulations (to be developed by the different authorities in charge of the management of natural resources). Administrative procedures have been adopted, along with a detailed ABS Law (which has not formally been submitted to Parliament, although it was developed several years ago).

- **The Central America Draft Protocol on ABS** is still in draft form. However, the Draft Protocol lacks many components and elements to be fully in line with recent ABS developments at the national level, as well as with the Nagoya Protocol. No initiative to revise and update the text has been undertaken in the context of the Central American Commission of Environment and Development (CCAD).[196]

- **Guatemala** is currently in the process of developing a comprehensive ABS regimen with the support of a GEF project (a medium size Project "ABS and Protection of Traditional Knowledge to Promote Biodiversity Conservation and Sustainable Use" with UNEP as the implementing Agency). The objective of the project is to develop policies, regulatory frameworks and institutional mechanisms for ABS. In addition to supporting the basic measures of the Nagoya Protocol, the project aims at protecting traditional knowledge associated with the sustainable use of biodiversity in an effort to catalyze rural development.

- **Argentina**. ABS measures are in place in Argentina at the state level.

- **Chile.** There is no specific ABS framework, but several proposals have been developed (some of them drafted by the agriculture sector), and few ABS agreements have been concluded based on general legal clauses.[197]

B. NORTH AMERICA

Neither Canada nor the United States have implemented a comprehensive ABS system. Furthermore, the United States is a signatory but not a party to the CBD, so it does not have the same international obligations on ABS.

Canada[β]

There are no national laws specifically devoted to ABS, and jurisdiction in this area is shared with provincial and territorial governments, as well as with Aboriginal communities. On October 15, 2010, just before CBD COP 10, the Government of Canada released a draft policy statement called *Managing Genetic Resources in the 21st Century: Domestic Policy Guidance for Canada*.[198] This guidance document was developed to form the basis of ABS policies at the federal, provincial and territorial levels but is not binding in any manner.

The federal government has a permitting system in place for research and collection in national parks.[199] One existing project explores how the commitment of Aboriginal groups, academics,

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[196] Personal communication of CCAD officer.
[197] Teresa Agüero, personal communication.
[198] Government of Canada, Managing Genetic Resources in the 21st Century: Domestic Policy Guidance for Canada, online: <http://cisdl.org/biodiversity-biosafety/public/policies/Canada_2010_Domestic_Policy_Guidance_on_ABS.pdf>
[199] Parks Canada, *Research and Collection Permit System*, online: <http://www.pc.gc.ca/apps/RPS/page1_e.asp>.

government and non-governmental organizations to using or integrating traditional ecological knowledge into the decision-making process is affecting resource management – namely, how aboriginal systems of management and knowledge are shaping management structures, as well as the use of terminology, concepts and procedures in the decision making-process.[200]

Scientists and landowners do contract directly for the collection of specimens. Furthermore, agreements exist to transfer material between academic institutions, researchers and private business. Various industry sectors also have policies or practices regarding ABS, and in those cases ABS is mostly governed by the policies and practices of the institutions directly involved, or by day-to-day practices.

Canada's three northern territories – the Yukon, the Northwest Territories (NWT), and Nunavut – have gone the furthest in implementing access systems that accord with ABS. Each territory has research licensing legislation that serves as a form of access system. The licensing of research in the NWT and Nunavut is governed by the *Scientists Act,*[201] which requires anyone conducting scientific research or collecting specimens for scientific research in the jurisdictions of the territories to obtain a license.[202] Research on wildlife or the collection of wildlife specimens is exempt, as is archaeological work, although these activities require permits under other legislation.[203] Research in the Yukon is licensed by the *Scientists and Explorers Act,* [204]which restricts scientific and exploration activities to persons holding a valid license issued under the Act.[205]

Applications for licenses under the *Scientists Act* are made to the Aurora Research Institute in the NWT and to the Nunavut Research Institute in Nunavut. The Aurora Research Institute is part of Aurora College and its mandate is to improve the quality of life for the NWT's residents by applying scientific, technological and Indigenous knowledge to solve northern problems and advance social and economic goals.[206] The mission of the Nunavut Research Institute is to provide leadership in the development, facilitation and promotion of Inuit Qaujimanituqangit,[207] science, research and technology as a resource for the well-being of the people of Nunavut.[208]

The *Scientists Act* makes no distinction between scientific and commercial research. The Aurora Institute interprets this to mean that "[w]ithout exception, all research in the Northwest Territories must be licensed. This includes work in indigenous knowledge as well as in the physical, social and biological sciences."[209] The Act also makes no mention of prior informed consent, but the application process requires written confirmation that the researcher has discussed their plans with the agencies and/or communities affected, and that they provide support to proceed.[210] The Department of Environment and Natural Resources, Forest Management Division also reviews all forest-related research proposals, which means that research related to trees and/or plants may

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[200] Parks Canada, *Research in Parks*, online: <http://www.pc.gc.ca/progs/np-pn/recherche_research/index_e.asp>.
[201] *Scientists Act*, R.S.N.W.T. 1988, c. S-4, as duplicated by s. 29 of the Nunavut Act, S.C. 1993, c. 28 [*Scientists Act*].
[202] *Ibid.* at section 2.
[203] *Ibid.* at section 1 & 2(b).
[204] *Scientists and Explorers Act*, R.S.Y. 2002, c. 200.
[205] *Ibid.* at section 3
[206]Aurora Research Institute, *Guide to Research in the Northwest Territories*, online: <http://wiki.nwtresearch.com/ResearchGuide.ashx>.
[207] Traditional Inuit knowledge.
[208] Nunavut Research Institute, *Compendium of Research Undertaken in Nunavut 2008* (Iqaluit, Canada: Nunavut Research Institute, 2008) at 2 [*Compendium*].
[209] *Guide to Research in the Northwest Territories*, *supra* note 210, "Licensing your Research."
[210] *Ibid.* at "Community Consultation."

require a Forest Research Licence under the *Forest Management Act* and Regulations.[211] Obligations for benefit-sharing are largely limited to reporting and sharing research results.[212]

The NWT and Nunavut research licensing systems are frequently used. The Aurora Research Institute, headquartered in the NWT, documents hundreds of licenses issued under the *Scientists Act* in the year 2007 in areas including ethnography, biology, protected areas, and traditional knowledge.[213] The Nunavut Research Institute counts over one hundred research projects undertaken in the territory in 2002 under the *Scientists Act* in the areas of health, physical sciences, and social sciences and traditional knowledge.[214]

The Development and Future of the ABS regime in Canada

There are no national laws specifically targeted at the issue of ABS. Legislative jurisdiction over the subjects that constitute ABS law is shared between the federal Parliament, provincial and territorial governments and Aboriginal communities.[215] In general, Parliament has the authority to legislate over genetic resources found on federal crown lands,[216] or in federal government possession (e.g. plant material held in a federal plant research centre). Parliament also has legislative authority over patents[217] and copyright,[218] as well as interprovincial and international trade,[219] and aboriginal peoples and their lands.[220] Lastly, relevant regulations on biotechnological innovations have been made by the Federal government's environmental law power under the Canadian Environmental Protection Act.[221]

On the other hand, the provinces and territories have authority over public lands within their area of jurisdiction and associated forest resources (forest genetic resources being a part thereof).[222] They have jurisdiction over the law of property (real and personal) and its derivatives, such as laws governing access to privately-owned lands and land-use planning. They also have jurisdiction over the laws of contract and tort.[223]

Between 2004 and 2006, a series of awareness-building activities were organized under the leadership of Environment Canada in order to better define and understand Canada's interests in ABS. These activities involved the federal government, the provinces and the territories in different workshops whose main goal was to inform Canadian stakeholders of the policy process and gather their views.

In 2005, federal, provincial and territorial governments agreed on the following policy objectives and core principles to guide Canadian approaches to managing genetic resources:

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211 *Ibid.* at "Forestry-related Research."
212 *Scientists Act*, *supra* note 199 at section 5(1).
213 Aurora Research Institute, *Compendium of Research in the Northwest Territories 2007* (Inuvik: Aurora Research Institute, 2007).
214 *Compendium*, *supra* note 206.
215 Kathryn Garforth *et al.*, *Overview of the National and Regional Implementation of Access to Genetic Resources and Benefit-Sharing Measures, Third Edition* (Montreal: Centre for International Sustainable Development Law, 2005).
216 *Constitution Act, 1867 (U.K.)*, 30& 31 Victoria, c. 3 at s. 91(1A).
217 *Ibid.* at s. 91(22).
218 *Ibid.* at s. 91(23).
219 *Ibid.* at s. 91(2).
220 *Ibid.* at s. 91(24).
221 *New Substances Notification Regulations (Chemicals and Polymers)*, SOR/2005-247 and *New Substances Notification Regulations (Organisms)*, SOR/2005-248.
222 *Ibid.* at s. 92A(1) and s. 92(5).
223 *Ibid.* at s. 92(13).

- Environment-focused: contributing to the conservation and sustainable use of biodiversity;
- Practical and Economically Supportive: generating and sharing economic benefits of the utilization of genetic resources among both providers and users as a means of contributing to sustainable development;
- Simple, Efficient and Adaptable: taking into account different sectors and allowing for different approaches in different jurisdictions;
- Supportive of current governmental policies, and building on and respecting Canada's existing international commitments;
- Balanced, equitable and transparent: balancing responsibilities between users and providers of genetic resources in a manner that is clear and whose rationale makes sense to all concerned; and
- Inclusive: developed and implemented with the appropriate involvement of Aboriginal groups and communities.[224]

Despite the progress made between 2004 and 2006, the arrival of a new Federal Government in 2006 led to a delay in the ABS policy-making process. In the spring of 2009, a Federal/Provincial/Territorial Task Group led by Environment Canada, with guidance from the Canadian Council of Resource Ministers, including the Canadian Council of Forest Ministers, Canadian Parks Council and Canadian Endangered Species Conservation Council,[225] was established to examine the issue of ABS policy in Canada and to develop options for consideration by Canadians.[226] The process was based on a discussion paper, *Access to Genetic Resources and Sharing the Benefits of Their Use in Canada: Opportunities for a New Policy Direction*, which presented options for a domestic policy on ABS and how traditional knowledge could be addressed in that policy. The main caveat is that the Government is not committed to adopting a policy on ABS at all.[227] There has still been no decision as to how Canada's policy will be developed in response to the comments received, or whether a policy will be developed at all.

United States of America[β]

In the U.S., as in Canada, there is no one overarching piece of legislation that governs ABS in the country. Instead, jurisdiction is divided among different federal and state departments and agencies, as well as private landowners.[228] That being said, a system of ABS has been created for the national parks system. The U.S. Code of Federal Regulations prohibits the "sale or commercial use of natural products" collected from national parks.[229] It also forbids the taking of plants, fish, wildlife, rocks or minerals from a national park without a specimen collection permit.[230] A distinction is made between

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[224] Environment Canada, *ABS Policies in Canada: Scoping the Questions and Issues* (Ottawa: Government of Canada, 2004), online: <http://www.ec.gc.ca/apa-abs/documents/ABS_policies_e.pdf>.

[225] Canadian Intergovernmental Conference Secretariat, "Backgrounder on Canadian Councils of Resource Ministers/Canadian Council of Ministers of the Environment (CCRM/CCME)," online: <http://www.scics.gc.ca/cinfo06/830895004a_e.pdf>.

[226] Government of Canada, *Access to Genetic Resources and Sharing the Benefits of Their Use in Canada: Opportunities for a New Policy Direction* at 9, online: < http://www.biodivcanada.ca/default.asp?lang=En&n=936B63F8-1>.

[227] Federal, Provincial and Territorial Working Group on Biodiversity, "Access and Benefit-Sharing (ABS)," online: <http://www.biodivcanada.ca/default.asp?lang=En&n=A9326342-1>, states that "Any decision on ABS policy in Canada will take into account the views of interested individuals, organizations and Aboriginal groups. If it is decided to proceed with ABS policy in Canada, further discussions could be held at that point."

[228] Preston T. Scott, "The United States of America: The National Park Service Experience" in Santiago Carrizosa *et al.*, eds., *Accessing Biodiversity and Sharing the Benefits* (Gland, Switzerland: IUCN, 2004) at 177-178.

[229] 36 C.F.R. §2.1(c)(3)(v).

[230] 36 C.F.R. §2.5(a).

research in a park that may or may not lead to commercial applications (which is allowed with a permit), and the direct sale or commercial use of products found in a park (which is prohibited).[231] Applications for a permit are submitted via a centralized internet system, but decisions on the applications are made by the staff of the individual park or parks where the proposed research will take place. Applications are evaluated according to their favourable and unfavourable characteristics. The former can include research that will contribute to the understanding of park resources or provides for the sharing of information with park staff or the public. The latter can include activities that will negatively affect the experiences of park visitors or that may have an adverse impact on the park's resources.[232] Permits can also only be issued to "an official representative of a reputable scientific or educational institution or a State or Federal agency for the purpose of research, baseline inventories, monitoring, impact analysis, group study, or museum display…"[233] This provision includes corporate institutions and commercial research in its scope.[234]

The Code of Federal Regulations does not mention prior informed consent in the context of collection permits but the "permit application process helps ensure that the permit applicant discloses the information required to enable the park to determine that the proposed research activities are consistent with [National Park Service (NPS)] regulations and policy."[235] Similarly, the regulations do not refer to the negotiation of mutually agreed terms in the granting of access permits. The permits themselves, however, include general conditions applicable to all research. These conditions include a requirement that any specimens or components of specimens (which includes "genetic materials") be used for scientific or educational purposes only.[236] Commercial use is only allowed where the permittee has entered into a Cooperative Research and Development Agreement (CRADA) "or other approved benefit-sharing agreement with the NPS".[237] The use of benefit-sharing agreements in the NPS was spurred by increased interest in the biological materials in Yellowstone National Park, the successful commercial use of an enzyme found in Yellowstone,[238] and the passage of the *National Parks Omnibus Management Act of 1998*, which allows the Secretary of the Interior to "enter into negotiations with the research community and private industry for equitable, efficient benefit-sharing arrangements."[239] Last, the general permit conditions also include two standard benefit-sharing requirements: researchers must report annually on their activities, and they must submit any reports and publications resulting from their study. Under the federal regulations, a permit can be suspended or revoked if its terms are violated. In addition, the general permit conditions provide that if a commercial product results from a permittee's collection activities and the permittee does not have a CRADA, the NPS is entitled to a royalty of 20% and may also seek other damages.[240]

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[231] Scott, *supra* note 232 at 185.

[232] United States Department of the Interior, National Park Service, "Application Procedures and Requirements for Scientific Research and Collecting Permits", online: NPS Research Permit and Reporting System <http://science.nature.nps.gov/research/ac/ResearchIndex>.

[233] 36 C.F.R. § 2.5(b).

[234] Scott, *supra* note 232 at 184.

[235] *Ibid.*

[236] United States Department of the Interior, National Park Service, "General Conditions for Scientific Research and Collecting Permit", online: NPS Research Permit and Reporting System http://science.nature.nps.gov/research/ac/ResearchIndex [General Conditions].

[237] *Ibid.*

[238] Scott, *supra* note 232 at 181.

[239] *National Parks Omnibus Management Act of 1998*, Pub. L. 105-391, § 205(d), 112 Stat. 3497 at 3500.

[240] General Conditions, *supra* note 234 at para. 6.

The permitting system of the NPS is used frequently – approximately 275 research projects per year in Yellowstone National Park alone.[241] One means by which these permits are monitored is by staff accompanying researchers during their specimen collection activities. The permit system has also resulted in the benefit-sharing contract between Yellowstone National Park and Diversity Corporation. This contract was challenged in the courts and upheld, but the Federal court did order the NPS to prepare an environmental impact statement on the effects that the implementation of benefit-sharing arrangements might have on the units of the NPS (i.e., the individual parks, monuments, etc.).[242]

C. ASIA

Like Latin America, several Asian countries have been at the forefront of creating and implementing ABS measures. Regionally, the Association of South East Asian Nations (ASEAN) has drafted a Framework Agreement on ABS and there are efforts to develop a harmonized system for the Himalayan Region.[243] Other countries that have legislation in place are India, Bhutan, the Philippines, Malaysia (at a sub-national level), and Afghanistan, while still other countries, such as China, have developed sectoral legislation. Relevant initiatives are reported in Indonesia, Thailand, Bangladesh, and Nepal among others.

The Association of South East Asian Nations (ASEAN)[β]

ASEAN is a regional grouping of ten South East Asian countries that was formed in 1967.[244] In September 1997, at the eighth meeting of the ASEAN Senior Officials on Environment, the Philippine delegation proposed the formulation of a common protocol among ASEAN member countries on access to genetic resources and IPR.[245] Two Technical Expert's Meetings were held resulting in the draft *ASEAN Framework Agreement on Access to Biological and Genetic Resources* in February 2000.[246] According to the Hanoi Plan of Action adopted during the 6th ASEAN Summit in 1998, the draft Framework Agreement was to have been adopted in 2004, although this does not appear to have occurred.[247]

The scope of the Framework Agreement is very broad. It covers biological and genetic resources, which are defined to include "genetic materials, organisms and parts thereof, population, or any other biotic component of ecosystems with actual or potential use or value for humanity."[248] Access may also include access to the TK associated with the resources, although this is not automatic.[249] The Framework Agreement does not apply to traditional uses of biological and genetic resources by Indigenous and local communities.

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[241] Scott, *supra* note 232 at 184.

[242] National Park Service, "Benefits-Sharing for Conservation? Benefits-Sharing Update" (12 April 2002), online: National Park Service <http://www1.nature.nps.gov/benefitsharing/eis_scoping_letter.pdf>.

[243] See Krishna Prasad and Ghanashyam Sharma, "Issues and Challenges of Access and Benefit Sharing Mechanisms in the Hindu-Kush Himalayan Countries" in *Triggering the Synergies between Intellectual Property Rights and Biodiversity*, GTZ, Germany, 2010.

[244] The member countries are Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam.

[245] Paz J. Benavidez II, "Philippines: Evolving Access and Benefit-Sharing Regulations" in Santiago Carrizosa *et al.*, eds., *Accessing Biodiversity and Sharing the Benefits* (Gland, Switzerland: IUCN, 2004).

[246] *ASEAN Framework Agreement on Access to Biological and Genetic Resources*, 24 February 2000 (draft) [ASEAN Framework Agreement].

[247] Hanoi Plan of Action, 6th ASEAN Summit 15-16th December 1998 at para. 6.11.

[248] ASEAN Framework Agreement, *supra* note 244 at Art. 3.

[249] *Ibid.* at Arts. 3 & 4, para. 1.

The Framework Agreement does not establish an access procedure *per se*; rather, it leaves each Member State to determine the nature of the country's access instrument. Each Member State is required to designate a CNA who is responsible for creating and implementing national access legislation, among other things. The Framework Agreement also calls for using an existing ASEAN body as a clearinghouse to implement the Agreement.[250]

The Framework Agreement requires a Member State to grant its prior informed consent before access can take place. It is up to the CNA to establish procedures for how this is to be done and also to establish legally-binding procedures for obtaining PIC at the local level. The latter must "provide for the active involvement of indigenous peoples and local communities embodying traditional lifestyles."[251] In addition, the PIC process must "respect and comply with the customary laws, practices and protocols of indigenous peoples and local communities and the disclosure of any information pertaining to the access shall be in a language understandable to the local communities."[252]

Under the draft Framework Agreement, all resource providers, and Indigenous peoples and local communities in particular, are to be actively involved in the negotiation of benefits. Any benefit-sharing agreements must not negatively interfere with TK systems and practices. The negotiation of benefit-sharing agreements is left to the discretion of Member States, although it must include a minimum set of requirements such as the participation of nationals in research activities and royalty-free access for resource providers of all technologies developed from research on accessed materials.

The draft Framework Agreement leaves it to the individual Member States to establish compliance mechanisms for users within their national access systems. Disputes between Member States, between communities and a Member State, or between communities regarding access, are to be settled through dialogue.[253] Disputes among Member States may also be settled through international arbitration.[254] The Agreement makes no specific mention of monitoring the accessed resources, but the regional clearinghouse is required to adopt a warning system for Member States on access applications that have been denied and disseminate information on access applications that have been granted by Member States.

Afghanistan[β]

In 2005, Afghanistan adopted the Environment Act, which contains provisions governing access to genetic resources. The law applies to all genetic resources of all living organisms, except for human beings, whether *in-situ* or *ex-situ*, and to TK associated with those resources.[255] The exchange of GR among local communities and groups for traditional, non-commercial purposes are exempt from the application of the law.[256] Access is subject to prior authorization in the form of an access permit from the National Environmental Protection Agency (NEPA).[257] Upon written application and payment of the fee, the NEPA may issue an access permit so long as access is not detrimental to the

[250] *Ibid.* at Art. 6.
[251] *Ibid.* at Art. 10, para. 2.
[252] *Ibid.* at Art. 10, para. 1.
[253] *Ibid.* at Art. 9.
[254] *Ibid.*
[255] Afghanistan, *Environment Act*, Official Gazette No. 873 of 29 Jadi 1384, Article 61(1).
[256] *Ibid.* at Art. 61(2).
[257] *Ibid.* at Art. 62(1).

survival of the species or the ecosystem.[258] Access to genetic resources in *in-situ* conditions is also subject to the environmental impact assessment processes of the Act.[259]

An application for access must contain background information on the applicant, a description of the species or organism, and a description of the intended use of genetic resources.[260] For *in-situ* access, a description of the site must be provided, along with a description of proposed activities including collection methods and the volume required, and the result of the environmental impact assessment, including the conservation status of the species or organism.[261] For *ex-situ* access, the institution must be identified and a material transfer agreement attached.[262] The NEPA may request any other information required to make an informed decision.[263]

Different forms of consent are required depending upon where access is sought. If access to GR is sought on privately-owned land, the consent of the owner is required, and the access permit must include provisions for equitable benefit-sharing with the owner.[264] If access is sought on land used by nomadic pastoralists or other communities or groups with traditional interests in the land, the consent of that group or community is required, and the access permit must include provisions for benefit-sharing with the group or community.[265] If access is sought to a protected area, the prohibitions and restrictions established in the management plan apply.[266] NEPA cannot issue an access permit unless it is satisfied that the applicant has made full disclosure of all material information to the person or persons involved, that consent was obtained on the basis of that information, and that a fair and equitable benefit-sharing agreement has been signed between the applicant and the relevant person(s).[267]

The access permit must reflect the MAT between the applicant and NEPA and contain, at a minimum: a description of the species or organism, including sex and developmental stage; a description of the sites where collection is permitted; the number and volume of samples which may be collected; the time period for which access is granted; the consent of any group or community involved; restrictions on future use of the genetic resources; restrictions on third party use of the genetic resources; requirements for sharing of benefits resulting from the use of genetic resources; provisions guaranteeing the participation of Afghan nationals and national institutes in any research carried out with the genetic resources; requirements for technology transfer; reporting requirements; and any other conditions NEPA deems appropriate.[268] The permit constitutes the authorization to collect the biological resources containing the genetic resources mentioned therein, in the locations and quantities specified.[269]

NEPA, in cooperation with the relevant ministry, national institutions, Provincial Councils, Village Councils and District Councils, will monitor compliance with the terms of the access permit.[270]

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[258] *Ibid.* at Art. 62(2).
[259] *Ibid.* at Art. 62(3).
[260] *Ibid.* at Art. 63(1).
[261] *Ibid.* at Art. 63(2).
[262] *Ibid.* at Art. 63(3).
[263] *Ibid.* at Art. 63(4).
[264] *Ibid.* at Art. 64(1).
[265] *Ibid.* at Art. 64(2).
[266] *Ibid.* at Art. 64(3).
[267] *Ibid.* at Art. 64(4).
[268] *Ibid.* at Art. 65(1).
[269] *Ibid.* at Art. 65(2).
[270] *Ibid.* at Art. 66(1).

When NEPA is satisfied that the permit terms have been satisfied, it shall issue a certificate of origin for the genetic resources accessed.[271] A certificate of origin is required for the export of any genetic resource from Afghanistan.[272] A certificate of origin, or its equivalent, is also required for the import of any genetic resource into Afghanistan.[273]

Bhutan[β]

Article 5 of Bhutan's Constitution[274] states that "[e]very Bhutanese is a trustee of the Kingdom's natural resources and environment for the benefit of the present and future generations and it is the fundamental duty of every citizen to contribute to the protection of the natural environment, conservation of the rich biodiversity of Bhutan and prevention of all forms of ecological degradation." The objectives of this article are to protect, conserve and improve the pristine environment, and to safeguard the biodiversity of the country; to prevent pollution and ecological degradation; to secure ecologically balanced sustainable development while promoting justifiable economic and social development; to ensure a safe and healthy environment; and to maintain a minimum of sixty percent of Bhutan's total land under forest cover for all time. Article 5 also allows Parliament to enact environmental legislation to ensure the sustainable use of natural resources and maintain equity between generations.

The National Assembly enacted the Biodiversity Act of Bhutan on the 4th of August 2003. The Biodiversity Act regulates three main issues: access to genetic resources and benefit-sharing, the protection of TK, and plant breeders (and farmers) rights. With regard to the issues addressed, the Biodiversity Act has taken an approach similar to that found in the African Model Law. The preamble recognizes, among other things, the value of biological and genetic resources in the development of products, compounds and substances that have medicinal, industrial and agricultural and related applications, and the need to protect and encourage cultural diversity by giving due value to the knowledge, innovations and practices of local communities in Bhutan, including the fundamental principles that prior informed consent (PIC) and mutually agreed terms (MAT) for benefit-sharing must be secured before access can take place.

The objectives of the Law are very comprehensive, including:

- To ensure national sovereignty over genetic resources in accordance with relevant National and International Law;
- To ensure the conservation and sustainable use of the biochemical and genetic resources;
- To promote the equitable sharing of benefits derived from the use of genetic resources;
- To promote technology transfer and capacity building at the national and local levels, including the building of scientific and technological capacity relevant to the conservation and sustainable use of biological diversity;
- To recognize and protect TK, innovation and practices of local communities associated with biodiversity;
- To regulate and facilitate the process by which collectors may legally obtain genetic resources;
- To prevent illegal access to genetic and biochemical resources and associated TK;

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[271] *Ibid.* at Art. 66(2).
[272] *Ibid.* at Art. 66(3).
[273] *Ibid.* at Art. 66(4).
[274] *The Constitution of the Kingdom of Bhutan*, 2008, online: <http://www.constitution.bt/>.

- To recognize and protect the farmers' and breeder's rights; and
- To provide legal recognition of varieties which are not protectable under the internationally existing patent and/or plant breeders rights laws, and thereby to recognize farmers' plant variety improvements and innovations and provide a means of sharing benefits derived from the use of traditional varieties as breeding material for commercial purposes.

The scope of the Law is also very broad, covering all genetic and biochemical resources including wild, domesticated and cultivated species of flora and fauna, both *in-situ* and *ex-situ*, found within the territory of the Kingdom of Bhutan. Also, the Act shall apply to the TK, innovation and practices associated with biodiversity.[275] The Act shall not apply, however, where the biological material is used as a commodity for the purpose of direct use or consumption as determined by the Competent Authority (the Biodiversity Centre a body of the Ministry of Agriculture), based on the processes and end use of genetic resources, in accordance with the provisions of the Act; to the access, use and exchange of biological and genetic resources among local communities resulting from their traditional and customary practices; or where the Competent Authority may determine plant and animal genetic resources access, which will be governed by Special Rules and Regulations or Conditions such as those established by multilateral systems for ABS, especially in the case of plant genetic resources for food and agriculture, in accordance with the international law.

Access covered by the Act is subject to the PIC of the Competent Authority of Bhutan, which represents national interests and the interests of the local communities harbouring, cultivating, developing and maintaining the biological diversity concerned. The applicant must submit an application for access to the Authorized Agency. In the event the Authorized Agency is satisfied that the application for access complies with the requirements under the Act, such an application may be submitted to the Competent Authority to arrive at a decision to grant or refuse a permit. Detailed information to be provided by the applicant is listed in the Act. All the information deemed confidential as per the Act, such as trade secrets or other forms of intellectual property rights, will be protected.

The competent Authority, through the Authorized Agency, may grant access if several minimum conditions are met, including that duplicates of each sample collected are deposited with the Authorized Agency; that the Competent Authority, through the Authorized Agency, is informed of all findings from subsequent research and development on the collected samples; that none of resources accessed or associated TK are transferred to any third party without the authorization of the Competent Authority; and that Competent Authority is notified prior to applying for intellectual property rights relating to the collected material or intellectual property rights relating to an invention, which is based on associated TK obtained in Bhutan.

Upon fulfilment of these conditions, the Competent Authority may grant access if one or more of the following minimum conditions for benefit sharing, which are to be included in the MTA or contract signed between the Competent Authority and the Applicant, are met. These conditions may also be considered in any MTA or contract signed between the applicant and any other relevant stakeholder: a flat fee and upfront payments; the sharing of research results and relevant information; royalties; milestone payments; recognition as a partner in intellectual property ownership of products derived from the supplied material; joint research activities; concessionary

[275] Traditional Knowledge includes any knowledge that generally fulfills one or more of the following conditions: (1) is or has been transmitted from generation to generation; (2) is regarded as pertaining to a particular traditional group, clan and community of people in Bhutan; (3) is collectively originated and held.

rates or free supply of commercial products derived from the resources provided; transfer of technologies; training and capacity building; the acknowledgment of the origin of the genetic resources in any publication resulting from the research activities; donation of equipment to national institutions; other benefits, monetary or non-monetary.

The Competent Authority must issue a Certificate of Origin for monitoring, which states that the procedures and conditions for granting access to the applicant have been met. The Act provides for offences, civil liability, criminal sanctions and the revocation of the permit in cases of non-compliance with the provisions of the Act or the terms of the permits.

The Act also provides a *sui generis* system for the protection of plant varieties including farmers' varieties. In addition, Chapter 4 provides for the protection of TK that was in existence before the entry into force of the Biodiversity Act or is created on or after the commencement of the Act. The owners of TK are the holders of the rights in the TK. There are two mechanisms to protect TK: the condition set in the Act to obtain the prior informed consent of the traditional owners of the TK for the use of TK for a non-customary purposes (including conditions for benefit-sharing); and the inventory of TK to be carried out by the Authorized Agency in collaboration with the owners of the TK. The Regulations set the terms and conditions for applicants for access to the information inventoried. The Competent Authorities are in the process of drafting the Regulations of the Law. So far no access request has been submitted.

China[β]

Recently, with an aim to protect genetic resources and to ensure the equitable sharing of benefits arising from the use of genetic resources, national laws and regulations governing the management of biological genetic resources have been updated by applying the framework provisions of the CBD to provide for IP ownership in the cooperative use of genetic resources by Chinese and foreign partners.

Notably, in 2008, the State Council promulgated the Measures for the Examination and Approval of Entry & Exit and the Foreign Cooperative Research on the Application of Genetic Resources of Livestock and Poultry (hereinafter referred to as "the Measures"), in accordance with Article 17 of the Animal Husbandry Law of the People's Republic of China. Article 8 of the Measures states that "any research cooperatively conducted in China with overseas entities or individuals that uses genetic resources of livestock and poultry, which are included in the List of Protected Genetic Resources of Livestock and Poultry, must: (i) have clearly defined objectives and scope, and definite time limits for cooperation; (ii) be carried out consistent with the protection and utilization plan of genetic resources of livestock and poultry; (iii) have clear clauses on IP ownership, and a reasonable program on benefit sharing of the research achievements; (iv) constitute no threat to domestic genetic resources of livestock and poultry or ecological environment security; and (v) have a reasonable benefit-sharing plan for countries concerned. …"

In 2008, a series of National Pilot Projects for IP Protection of TK were launched. To date, such pilot projects have been developed in 15 counties/municipalities/regions. For example, the Project on the Protection of Genetic Diversity of the Sichuan Snub-nosed Monkeys (Rhinopithecus roxellana) in the Shennongjia Forest Area has been developed in Hubei Province to protect and ensure the survival of this precious biological species, and a special Research Team has been set up under the Project. Another example concerns a project on the protection of Tibetan medicine – a project that has been developed in Kang Ding County of Sichuan Province to protect and develop technologies on related medicinal planting, animal breeding, and pharmaceutical production and

processing. Such pilot projects have contributed to further advancing and improving the protection of TK and genetic resources across the country.

The new Patent Law, after being amended for the third time, became effective on October 1, 2009, and includes two new paragraphs directly related to the protection of genetic resources, namely:

- Article 5 (2), which states that "no patent right shall be granted for any invention/creation that relies on genetic resources accessed or used in violation of the provisions of relevant laws or administrative regulations"; and
- Article 26 (5), which states that "for inventions/creations that rely on genetic resources, the patent applicant shall disclose, in the application, the direct source and the original source of the genetic resources, and shall, in the case where the applicant fails to disclose the original source, provide a reason for such a failure".

Accordingly, specific provisions on these two paragraphs have been further set out in the revised Implementing Regulations under the Patent Law and the Guide on Patent Examination, respectively, to make the amendments operational.

India[β]

The Biological Diversity Act of India 2002[276] and its 2004 Rules[277] primarily address issues concerning access to genetic resources and associated TK by both foreign and domestic individuals, institutions and companies, as well as the equitable benefit-sharing arising from such access. The Act provides for regulated access to biological and genetic resources by users for both non-commercial and commercial purposes, and provides special regard for the role of ILCs.

The Act governs ABS through a coordinated approach involving three institutions: the National Biodiversity Authority (NBA), the State Biodiversity Board (SBB) and the Biodiversity Management Committees (BMC). The NBA is the national competent authority to discharge all decisions pertaining to ABS including: handling foreign requests for access to or transfer of GR and associated TK,[278] imposing terms and conditions to secure equitable benefit sharing,[279] and approving or opposing the granting of IP recognition based on GR/TK obtained from India both domestically and internationally.[280] The SBB deals with access to GR/TK by Indians for commercial purposes.[281] The mandate of the BMC is conservation, sustainable use, and documentation of biodiversity,[282] with BMCs consulted by the national and state bodies on matters related to the use of biological resources and associated TK within their jurisdiction.[283] In establishing procedures and guidelines to govern ABS activities, the NBA also coordinates the ABS activities of the SBB and the BMC by providing them with technical assistance and guidance.

The Act stipulates norms for access to biological resources and TK in three forms: (i) foreign access to biological resources and TK based on the prior approval of the NBA,[284] (ii) domestic access on

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[276] *Biological Diversity Act* (2002), online: <http://www.wipo.int/wipolex/en/text.jsp?file_id=185798> [BD Act].
[277] *Biological Diversity Rules* (2004), online: <http://www.wipo.int/wipolex/en/text.jsp?file_id=200357> [BD Rules].
[278] BD Act, *supra* note 274 at s. 18.
[279] *Ibid.* at s 21.
[280] *Ibid.* at s. 19(2) and s 18(4).
[281] *Ibid.* at s. 23.
[282] *Ibid.* at s. 41(1).
[283] *Ibid.* at s. 41(2).
[284] *Ibid.* at s. 18(2).

the basis of prior approval from the SBB,[285] and (iii) access for traditional practices and conventional farming, breeding and agricultural uses, which are exempted.[286] Access to the biological resources or associated traditional knowledge is be restricted if such access is detrimental to these resources,[287] with those undertaking such exploitation required to give a declaration that the activities shall not affect the resources adversely.[288] Any person or organization aiming to obtain access regardless of intended use must provide prior information to and receive prior approval from the relevant State Biodiversity Board for domestic applicants,[289] with foreign applicants having to gain the approval of the NBA.[290]

The 2004 Rules establish procedures for (i) access to GR or TK,[291] (ii) the transfer of research results internationally,[292] (iii) receiving prior approval for patent applications,[293] and (v) third party transfer.[294] Access to genetic resources and associated traditional knowledge must be done using Form I.[295] Upon submission and payment of the fee, the authority will consult with local bodies to process applications and communicate notice within 6 months.[296] Approval comes in a grant of access, which is signed by the Authority, and establishes the terms of access, benefit-sharing, and compliance.[297] If rejected, relevant reasoning must be provided, as well as an opportunity to appeal the decision.[298] The relevant authority will monitor compliance with the conditions of access, and can revoke the access approval on reasonable belief that a violation has occurred.[299] It may also recover damages if there are any.[300] Applications for transfer of research results abroad for monetary consideration require Form II.[301] Decisions are provided within three months, with relevant reasoning for rejections along with an opportunity for appeal.[302] Applications for prior approval for a patent use Form III, and third party transfers require the use of Form IV, with both applications having similar review procedures, written notifications and option for appeal.[303]

Access to genetic resources and traditional knowledge must be based on mutually agreed terms established between persons applying for such approval, local bodies concerned and those claiming the benefits. The formula for such benefit-sharing will be determined on a case-by-case basis.[304] The conditions of benefit-sharing may entail either the granting of individual and/or community IP

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[285] *Ibid.* at s. 7.
[286] *Ibid.*at s. 1(f).
[287] BD Rules, *supra* note 275 at rule 16.
[288] *Ibid.* at rule 14 (see in conjunction with Form 1).
[289] BD Act, *supra* note 274 at s. 7.
[290] *Ibid.* at s. 18(2); BD Rules, *supra* note 275 at rule 14.
[291] BD Rules, *supra* note 275 at rule 14.
[292] *Ibid.* at rule 17.
[293] *Ibid.* at rule 18.
[294] *Ibid.* at rule 19.
[295] *Ibid.* at rule 14(1).
[296] *Ibid.* at rule 14(3).
[297] *Ibid.* at rule 14(4-6).
[298] *Ibid.* at rule 14 (8-9).
[299] *Ibid.* at rule 15(1).
[300] *Ibid.* at rule 15(2).
[301] *Ibid.* at rule 17(1).
[302] *Ibid.* at rule 17(3-6).
[303] *Ibid.* at rule 18-19.
[304] BD Act, *supra* note 274 at sub-section 21 (1), read with BD Rules sub-rule 20(3).

rights to benefit claimers,[305] or to the NBA where benefit claimers cannot be identified, and/or other options such as technology transfer, product development, education and awareness raising activities, institutional capacity building, and payment of monetary and non-monetary benefits.[306]

Biodiversity funds are established at the national,[307] state,[308] and local levels,[309] aimed at channelling benefits to claimants, facilitating the conservation of GR/TK, and contributing to the socio-economic development of the areas where the resources where accessed.[310] People's Biodiversity Registers (PBRs) are also established under the management of local BMCs to record traditional health practitioners, and users of biological resources and traditional knowledge, for use by domestic and international Authorities to ensure that prior informed consent (PIC) of the local communities is obtained.[311] Lastly, the Indian Patent Law (2002) requires the disclosure of the source origin of biological material, when used in an invention. [312]

Japan[α]

After the adoption of the Nagoya Protocol, in March 2012, the Japan Bioindustry Association (JBA) and Ministry of Economy, Trade and Industry (METI) released a second version of their *Guidelines on Access to Genetic Resources for Users in Japan* to reflect the key principles of the Nagoya Protocol. The Guidelines have three aims: to help providers and users enjoy benefits and build win-win relationships through streamlined access to GR according to relevant laws or regulations of the provider countries, and by fair and equitable benefit-sharing; to minimize the risk of problems for users when they seek to use GR for commercial purposes, promoting business flexibility; and, to facilitate users' understanding of ABS by providing explanations and examples about relevant provisions and terminology of the CBD, Nagoya Protocol and Bonn Guidelines. They are voluntary and, as such, do not create or modify any existing legal obligations.[313]

The scope of the guidelines is based on Article 3 of the Nagoya Protocol, subject to the differing scopes of laws and regulations adopted in provider countries. GR covered by the ITPGRFA are excluded. Nevertheless, all other access to foreign genetic resources, whether inside or outside of Japan, falls within the scope of the guidelines.[314]

The basic premise for access to genetic resources is that a user should conform to the laws and administrative measures stipulated in the providing country. Where there are no such laws or administrative measures, access must be governed by a contract, which should refer to the principles found in the CBD, Nagoya Protocol and Bonn Guidelines.[315] The Guidelines provide a useful overview of prior informed consent, mutually agreed terms, benefit sharing, compliance, dispute resolution, and in-house management systems for corporations and organizations. To complement the Guidelines, the JBA provides advice upon request to corporations, universities, research

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[305] BD Act, *supra* note 274 at s. 1(a): "benefit claimers" refer to the conservers of biological resources, their by-products, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application.
[306] *Ibid.* at sub-section 21 (2), read with BD Rules r 20.
[307] *Ibid.* at s. 27.
[308] *Ibid.* at s. 32.
[309] *Ibid.* at s. 43.
[310] *Ibid.* at s. 27(2), s. 32(2), and s. 44(2).
[311] BD Rules, *supra* note 275 at sub-rrule 22 (8).
[312] *Patents (Amendments) Act* (2002), Sec 10, 25, online: <http://www.wipo.int/wipolex/en/text.jsp?file_id=207496>.
[313] *Guidelines on Access to Genetic Resources for Users in Japan, Second Edition* (JBA and METI, 2012) at 3.
[314] *Ibid.* at 4.
[315] *Ibid.* at 5.

institutes, and individuals on ABS-related matters. The METI can also be consulted in situations that corporations may find difficult to deal with on their own.[316]

Malaysia[α]

Malaysia ratified the CBD on 24 June 2004. The state of Sarawak passed a State Law in 1997 to establish a Sarawak Biodiversity Centre to manage the state biodiversity (amended subsequently in 2003) and regulations were passed in 2004.[317] Similar steps were taking by the Sabah Biodiversity Ordinance in 2000, and the subsequently established the Sabah Biodiversity Centre

In Peninsular Malaysia, a permit is required for prospecting in the forest under the Forestry Act of 1984. In addition to permits for the removal of plants or resources from the forest, researchers must apply for a Use Permit under section 34 of the Forestry Act. To obtain a Use Permit, they must submit a research proposal, which the Forestry Department will study. Once approval is granted, certain conditions will be attached, and in certain cases there may be a joint expedition with department staff.

Specific requirements exist in the State of Sabah based on the Sabah Biodiversity Act 2000,[318] and the subsequent establishment of the Sabah Council. Any collector who intends to obtain biological resources from the State will need to apply in writing to the Council for an access license.[319] Collectors are required to lodge a good duplicate of any collections with the Forestry Department within 30 days. When the field work is finished, the collector must submit a report listing the plants collected.

In Malaysia the Federal Government has worked for several years to finalize a bill on ABS, building upon the policies already enacted at the state level in Sarawak and Sabah, with the current draft of the bill seeing potential approval by the end of 2014. The Draft ABS Bill introduces provisions similar to those found at the state level under a harmonized framework. ILCs are provided continued access to biological resources based on traditional and customary practices, including harvesting plants and animals for food, and storing plant materials for propagation and for carrying out forestry,[320] with small farmers receiving similar protection for plant breeding as stipulated in New Plant Varieties Act 2004 (Act 634).[321]

The Ministry of Natural Resources and Environment (MNRE) is designated as the Competent National Authority, and acts to coordinate governance over access to GR/TK. An Advisory Committee and Advisory Body provide advice on relevant technical matters to MNRE,[322] with the Advisory Body comprised of representatives of ILCs, and providing guidance on issues pertaining to ILCs and traditional knowledge.[323] Multiple ministries are designated powers,[324] including the

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316 *Ibid.* at 40.

317 Sarawak Biodiversity Centre, *Sarawak Biodiversity Centre (amendment) Ordinance* (2003), online: <http://www.sbc.org.my/media-centre/publications/sarawak-biodiversity-ordinance-and-regulations/5-laws-of-sarawak-chapter-a106-sarawak-biodiversity-centre-amendment-ordinance-2003/file>; Sarawak Biodiversity Centre, *Sarawak Biodiversity Regulations* (2004), online: <http://www.sbc.org.my/media-centre/publications/sarawak-biodiversity-ordinance-and-regulations/6-the-sarawak-biodiversity-regulations-2004/file>.

318 *Sabah Biodiversity Enactment* (2000), online: <http://www.wipo.int/edocs/lexdocs/laws/en/my/my055en.pdf>.

319 See http://www.sabah.gov.my/sabc/

320 *Draft Access to Biological Resources and Benefit Sharing Bill* (2012), Art 4(3)(a) {Draft Bill].

321 *Ibid.* at Art. 5.

322 *Ibid.* at Art. 11(2).

323 *Ibid.* at Art. 11(3).

324 *Ibid.* at Art. 30.

Department of Wildlife and National Parks, and the Department of Marine Parks under the Ministry of Natural Resources and Environment, the Department of Fisheries in the Ministry of Agriculture and Agro-based Industries, the Forestry Department Peninsular Malaysia, and the Sarawak Biodiversity Centre.[325] Each authority has the power to initiate investigations,[326] including powers of arrest,[327] search and seizure[328] (without a warrant if necessary),[329] access to computerized data,[330] and the examination of people acquainted with the investigation.[331]

All access for GR or TK requires a permit, regardless of whether the access is for commercial[332] or non-commercial use,[333] and the bill outlines grounds for refusal of a permit.[334] Non-commercial access must be done in conjunction with a domestic institution,[335] and requires the PIC of relevant ILCs,[336] with changing commercial applications initiating the need for a new commercial permit.[337] Commercial applicants must obtain PIC and establish a fair and equitable benefit-sharing agreement with relevant ILCs.[338] PIC must be obtained in accordance with the customary laws, community protocols, and the procedures of ILCs,[339] and from recognized representatives or organizations as established by the ILCs themselves.[340] Benefit-sharing agreements must also be based on mutually agreed terms.[341]

Consent of the Competent National Authority is required for all foreign and domestic applications for intellectual property rights relating to GR/TK,[342] and imports of genetic material and/or traditional knowledge from a jurisdiction requiring a permit for access (ie. PIC/MAT) must include a copy of the permit documentation showing legal access.[343] When a corporate body commits an offense under the Act, any person who at the time of offense was a director, manager, secretary or other officer of the board may be charged severally or jointly.[344] If the corporate body is found guilty, the corporate officers will be found guilty as well unless they can show the act was done without their knowledge or consent, or that they took all reasonable precautions in exercising due diligence to prevent the offense.[345]

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[325] *Ibid.* at Second Schedule.
[326] Draft Bill, *supra* note 317 at Art. 31.
[327] *Ibid.* at Art. 33.
[328] *Ibid.* at Art. 34.
[329] *Ibid.* at Art. 35-36.
[330] *Ibid.* at Art. 37.
[331] *Ibid.* at Art. 42-43.
[332] *Ibid.* at Art 12.
[333] *Ibid.* at Art. 14.
[334] *Ibid.* at Art. 13.
[335] *Ibid.* at Art. 14(3).
[336] *Ibid.* at Art. 14(6).
[337] *Ibid.* at Art. 14(8).
[338] *Ibid.* at Art. 18(1).
[339] *Ibid.* at Art. 18(2).
[340] *Ibid.* at Art. 18(3)(a).
[341] *Ibid.* at Art. 17.
[342] *Ibid.* at Art. 26(1).
[343] *Ibid.* at Art. 29(1).
[344] *Ibid.* at Art. 56(a).
[345] *Ibid.* at Art. 56(b).

Philippines[β]

The Philippines has a relatively long history of regulating bioprospecting and ABS. Prior to the CBD, a permit system was in place for the collection of biological samples.[346] In response to the Philippines' ratification of the CBD in 1993, the country began to draft Executive Order 247 (EO 247), establishing a framework for access to genetic resources that entered into force on May 18, 1995,[347] and is considered to be the first ABS law globally. In 1996, the Department of Environment and Natural Resources (DENR) issued Administrative Order No. 20,[348] (DAO No. 20), the implementing rules and regulations for EO 247.

Experience with EO 247 highlighted some difficulties with the Order, particularly its broad scope and some of the procedures for prior informed consent. On July 30, 2001, the Philippine Legislature enacted the *Wildlife Resources Conservation and Protection Act*[349](Wildlife Act) to rectify these problems. The Wildlife Act is a piece of general environmental legislation that codifies existing wildlife laws.[350] Only two parts of the Act address bioprospecting – sections 14 and 15 – but they change the bioprospecting procedures significantly. On May 18, 2004, DENR, the Department of Agriculture (DA), and the Philippine Council for Sustainable Development (PCSD) jointly issued Administrative Order No. 1 (AO No. 1) which contains Guidelines for Bioprospecting Activities in the Philippines,[351] as well as a set of rules for joint implementation.[352] EO 247 and DAO No. 20 are now repealed or amended to the extent that they conflict with the Wildlife Act and AO No. 1.[353]

Under the Wildlife Act, bioprospecting is defined as "the research, collection and utilization of biological and genetic resources for purposes of applying the knowledge derived there from solely for commercial purposes."[354] In order to engage in bioprospecting, a proponent must enter into a Bioprospecting Undertaking (BU) that binds it to comply with the terms and conditions imposed by the Secretary of DENR and/or the Secretary of DA.[355]

A BU applicant must receive the prior informed consent of Indigenous people, protected area management boards (PAMBs), local government units (LGUs), private individuals or other agencies having special jurisdiction over specific areas.[356] It is during the PIC process that concerned communities can negotiate benefit-sharing terms with the applicant.[357] Minimum benefit-sharing

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[346] Benavidez, P. 2004. "Philippines: evolving Access and Benefit Sharing Regulations." in S. Carrizosa, et al, eds, *Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity* at 154-155.

[347] Executive Order No. 247, *Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By-Products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes*, (1995), online: <http://www.wipo.int/wipolex/en/text.jsp?file_id=225249> [EO 247].

[348] Department of Environment and Natural Resources Administrative Order No. 20, *Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources*, 21 June 1996.

[349] Philippines, Republic Act 9147, Wildlife Resources Conservation and Protection Act, enacted July 30, 2001, online: <http://faolex.fao.org/docs/texts/phi41009.doc> [Wildlife Act].

[350] Benavidez, *supra* note 350, at 165.

[351] Philippines, The Joint DENR-DA-PCSD-NCIP *Administrative Order No. 1*, Series of 2005, online: <http://faolex.fao.org/docs/pdf/phi93259.pdf> [AO 1].

[352] Philippines, Joint Department of Environment and Natural Resources, Department of Agriculture, Philippine Council for Sustainable Development Administrative Order No. 1, *Joint Implementing Rules and Regulations Pursuant to Republic Act No. 9147* (May 2004), online: <http://www.chm.ph/index.php?option=com_docman&task=doc_details&gid=36&Itemid=56> [AO 1 Rules].

[353] Wildlife Act, *supra* note 347 at s. 40.

[354] *Ibid.* at s. 5(a).

[355] AO 1, *supra* note 349 at s. 6.1.

[356] *Ibid.* at s. 13.1.

[357] Benavidez, *supra* note 350, at 157.

requirements are not established, but detailed benefit-sharing provisions are provided outlining mandatory bioprospecting fees, royalty payments, and up-front payments, as well as other non-monetary benefits that may be agreed to by the users and providers.[358]

For non-commercial research access, a researcher must enter into an Affidavit of Undertaking or Memorandum of Agreement (MOA) with the Secretary of DENR and/or the DA or its authorized representative, and the Secretary must issue a gratuitous permit.[359] PIC must be similarly established with providers,[360] and non-domestic applicants are required to collaborate with a domestic institution.[361] There are also certain minimum terms for the Affidavit or MOA, including the requirement that spin-off technology must not be developed from the results of scientific work; IP rights over the results are not to be applied for without the prior approval of the concerned agency; and the proponent is to submit results and recommended action plans, where applicable, at the conclusion of the research.[362]

Chapter VII of the Guidelines sets out how bioprospecting will be monitored. The resource user must submit an annual progress report to the implementing agencies concerned, covering the status of procurement of PIC, the progress of the collection of samples, benefit-sharing negotiations, and progress on payment of benefits or other provisions of the BU.[363] Certifications as proof of compliance with the proper procurement of PIC, compliance with the sample quota, and acceptance by the providers of monetary and/or non-monetary benefits provided in the BU must also be appended to the annual progress report.[364] The Guidelines include a model checklist of indicators to monitor whether benefit-sharing is equitable.[365] The Department of Foreign Affairs and the Department of Science and Technology can assist in overseas monitoring, including the monitoring of inventions and commercialization in foreign countries.[366] Finally, civil society is encouraged to participate in the monitoring of Bioprospecting Undertakings.[367]

The Wildlife Act does not specifically mention liability for illegal bioprospecting, but the "unauthorized collection, hunting, and possession of wildlife is punishable with imprisonment of up to four (4) years and a fine of up to $300,000P depending on the species illegally collected, hunted, or possessed."[368]

In addition to this legislation, the Philippines has an Indigenous Peoples Rights Act No. 8731 of 1997 and its associated rules and regulations.

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[358] AO 1, *supra* note 349 at s. 14-16.
[359] AO 1 Rules, *supra* note 350 at rule 15.1.
[360] *Ibid.* at rule 15.2.
[361] *Ibid.* at rule 15.3.
[362] *Ibid.* at rule 15.4.
[363] AO 1, *supra* note 349 at s. 23.
[364] *Ibid.* at s. 23.2.
[365] *Ibid.* at Annex V.
[366] *Ibid.* at s. 25.1.
[367] *Ibid.* at s. 26.1.
[368] Wildlife Act, *supra* note 347 at s. 27(f) and 28.

Vietnam[β]

Vietnam adopted a comprehensive Biodiversity Law to implement the CBD in 2008.[369] It also acceded to the Nagoya Protocol on 23 April 2014, and is in the process of developing regulations for its implementation.[370]

Chapter V of the Biodiversity Law addresses the Conservation and Sustainable Use of GR. Section 1 of Chapter V addresses the management of, and access to, GR and the sharing of benefits from GR. The State is responsible for managing all GR in its territory, but assigns organizations and individuals to manage genetic resources in the following manner: (a) conservation area management units and organizations assigned to manage conservation areas shall manage GR in conservation areas; (b) heads of biodiversity conservation facilities, scientific research and technological development institutions, and GR storage and preservation establishments shall manage their own GR; (c) organizations, households and individuals assigned to manage or use land, forests or water surface shall manage GR assigned to them for management or use; and d) community-level People's Committees shall manage genetic resources in their localities, except in the above-mentioned cases.[371]

The Biodiversity Law also designates the rights and obligations of organizations, households and individuals assigned to manage genetic resources. The rights of organizations and individuals assigned to manage genetic resources include rights: (a) to investigate and collect GR assigned to them for management; (b) to exchange, transfer and supply GR assigned to them for management to other organizations or individuals in accordance with law; and (c) to enjoy benefits shared by organizations or individuals that are granted access to GR under Articles 58 and 61.[372] Organizations and individuals assigned to manage genetic resources must: (a) notify competent state management agencies of the exchange, transfer or supply of genetic resources to other organizations or individuals for purposes of research and development and production of commercial products; (b) enter into contracts on access to genetic resources and benefit sharing with organizations or individuals that are granted licenses for access to GR under Article 59; (c) control the investigation and collection of GR by organizations and individuals that are granted licenses for access to GR; and (d) take responsibility before legal and competent state management agencies for the management of GR.[373]

Furthermore, the Law lays out procedures for access to genetic resources. First, access to genetic resources must be registered; second, a written contract for access to genetic resources and benefit-sharing must be concluded with the organizations, households or individuals assigned to manage genetic resources under Articles 58 and 61; and third, an application for licenses for access to genetic resources under Article 59 must be made. The Government must still provide greater specificity on the order of, and procedures for, access to genetic resources.[374]

The Biodiversity Law also provides details on ABS contracts. First, after registration, organizations or individuals wishing to access genetic resources must enter into written ABS contracts with organizations, households or individuals assigned to manage genetic resources. ABS contracts must be certified by community-level People's Committees in the localities where the GR are accessed.

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[369] *Biodiversity Law*, Law No. 20/2008/QH12 [*Biodiversity Law Vietnam*].
[370] See: http://vietnamnews.vn/environment/247905/workshop-discusses-genetic-resources.html
[371] *Biodiversity Law Vietnam, supra* note 368 at Art. 55.
[372] *Ibid.* at Art. 56(1).
[373] *Ibid.* at Art. 56(2).
[374] *Ibid.* at Art. 57.

The contract must contain the following details: (a) the purpose of access to GR; (b) the GR to be accessed and the volume of GR to be collected; (c) the place of access to GR; (d) the plan on access to GR; (e) the transfer of the results of any survey and collection of GR to a third party; (f) R&D activities or the production of commercial products using GR; (g) participants in R&D or the production of commercial products using GR; (h) the place for conducting R&D or production of commercial products using GR; and (i) the sharing of benefits with the State and related parties, including the distribution of IPR over invention results. Furthermore, ABS contracts must be sent to commune-level People's Committees of localities where GR are accessed, and to state agencies competent to grant licenses for access to GR under Article 59 of this Law. Disputes or complaints relating to access to GR and benefit-sharing will be settled under Vietnamese law and other treaties to which Vietnam is a contracting party.[375]

To obtain a license for access to genetic resources, an organization or individual must meet the following conditions: (a) registry with a competent state management agency; (b) the signature of a contract on access to genetic resources and benefit-sharing with the organization, household or individual assigned to manage genetic resources; and (c) access to GR does not fall into either of the cases specified in Article 59(4)[376](i.e. GR of species on the list of endangered, rare and precious species prioritized for protection, except cases licensed by competent state agencies; or, the use of genetic resources that threatens to harm humans, the environment, security, defense or national interests).[377]

A dossier of application for a license for access to genetic resources consists of: (a) the application for a license for access to GR; and (b) a copy of the ABS contract with the organization, household or individual assigned to manage the GR.[378] A license for access to GR must contain the following details: (a) the purpose of using GR; (b) the GR to be accessed and the volume of GR to be collected; (c) the place of access of GR; (d) the activities to be carried out with GR; and (e) periodical reporting on the results of R&D or production of commercial products related to the GR to be accessed.[379] In the interest of the country and the community, state management agencies competent to grant licenses for access to GR may grant such licenses without having to seek the consent of organizations, households or individuals assigned to manage GR.[380] The Government must still specify the competence, order of, and procedures for granting licenses for access to genetic resources.[381]

Organizations and individuals licensed to access genetic resources have the right to: (a) investigate and collect GR and carry out other activities as indicated in their license for access to GR; (b) remove GR from Vietnam provided they are not on the list of those banned from export under law; (c) trade in products made from the GR they are licensed to access; and (d) enjoy other rights as specified in their licenses for access to GR and ABS contracts.[382] Organizations and individuals licensed to access to GR are obliged to: (a) adhere to the provisions of their licenses for access to genetic resources; (b) submit reports to agencies competent to grant licenses for access to GR on the results of R&D or the production of commercial products according to the timelines prescribed in

375 *Ibid.* at Art. 58.
376 *Ibid.* at Art. 59(1).
377 *Ibid.* at Art. 59(4)
378 *Ibid.* at Art. 59(2).
379 *Ibid.* at Art. 59(3).
380 *Ibid.* at Art. 59(5).
381 *Ibid.* at Art. 59(6).
382 *Ibid.* at Art. 60(1)

the licenses; (c) share benefits with related parties, including the distribution of IPR over invention results based on their access to GR and TK copyrights on GR; and (d) adhere to the other obligations specified in their licenses for access to GR and ABS contracts.[383] Benefits obtained from access to GR must be shared with: (a) the State; (b) organizations, households and individuals assigned to manage GR; and (c) organizations and individuals licensed for access to GR and other related parties as prescribed in the licenses.[384] Benefits obtained from access to GR must be shared on the basis of ABS contracts and in accordance with relevant laws.[385]

Section 2 of Chapter V addresses the storage and preservation of genetic specimens; assessment of GR; management of information on GR; and, TK copyrights on GR. For the storage and preservation of genetic specimens, Ministries and ministerial-level agencies will, within the ambit of their tasks and powers, organize the permanent storage and preservation of genetic specimens of species on the list of endangered, precious, and rare species prioritized for protection, and species imported for the research, propagation, hybridization, application and development of GR.[386] The State encourages organizations and individuals to invest in permanently storing and preserving genetic specimens to create gene banks, thus contributing to biodiversity conservation and socio-economic development.[387] Ministries and ministerial-level agencies are also to organize the implementation of programs on the investigation, collection, assessment and building of databases on GR under their management, and supply information on databases on genetic resources to the Ministry of Natural Resources and Environment, which manages a national database on GR.[388] The State encourages organizations and individuals to investigate, collect, assess and supply information on GR for building databases on GR and ensures the right to access databases on GR.[389]

Vietnam supports the copyright of traditional knowledge relating to GR, and encourages and supports organizations and individuals to register TK copyrights on GR.[390] The Ministry of Science and Technology has primary responsibility for guiding procedures for the registration of TK copyright on GR, and for coordination with concerned ministries and ministerial-level agencies.[391]

D. MIDDLE EAST

Since the COP10, Arab countries have launched a number of initiatives on regional level, beginning with the Arab Regional Workshop on Biodiversity and Finance, held in Cairo on 30 November 2010, which agreed on the immediate need for the region's countries to ratify the NP and develop national policies and legal frameworks on ABS. This workshop was followed by the Regional Capacity-Building Workshop on the Nagoya Protocol on Access and Benefit Sharing for the Middle East Region and Djibouti, Libya, Mauritania. Leading this call, Jordan and Egypt ratified the NP, and the Syrian Arab Republic acceded to the NP in April 2013. Additionally, a significant number of Arab countries are now in various stages of developing access and benefit-sharing policies and regulations, including the United Arab Emirates, Qatar, Saudi Arabia, Iraq, Egypt, Algeria and Morocco.

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[383] *Ibid.* at Art. 60.
[384] *Ibid.* at Art. 61(1)
[385] *Ibid.* at Art. 61(2).
[386] *Ibid.* at Art. 62(1).
[387] *Ibid.* at Art. 62(3).
[388] *Ibid.* at Art. 63(1)
[389] *Ibid.* at Art. 63(2).
[390] *Ibid.* at Art. 64(1).
[391] *Ibid.* at Art. 64(2).

Most of the proposed access and benefit-sharing laws seek to put into place a framework to regulate access to plant genetic resources and to ensure fair and equitable benefit-sharing. Most of the emphasis has been on access, while limited provisions on conservation were salvaged and placed in these drafts. Many of these draft laws do not recognise the principle of state sovereign rights over biological resources. They also use concepts such as collecting permits and possession permits as equivalent to prior informed consent, including no explicit references to prior informed consent or mutually agreed terms. Importantly, a number of these drafts ban the claiming of intellectual property rights over materials accessed and associated traditional knowledge.

It is important to mention that most of the existing and the proposed ABS legislation or administrative measures in the region focus on the implementation of ITPGRFA, though most Arab countries are parties to the CBD. In a related development, the Arab Organization for Agricultural Development of the Arab League established the Arab Network for Plant Genetic Resources, which aims to support the efforts of Arab countries in the implementation of the International Treaty on Plant Genetic Resources, and to protect their rights over plant genetic resources.[392] The Arab Network for Plant Genetic Resources is a scientific body helping to maintain the intellectual property rights of Member States to plant genetic resources, through the establishment of an information system and databases to document those genetic resources and associated traditional knowledge. It is also an effective tool to promote the exchange of genetic information between Member States through the collection and dissemination of information about the status of plant genetic resources.

Egypt[β]

The 2008 Egyptian National Biodiversity Strategy and Action Plan (NBSAP) placed institutional capacity building amongst its top priorities. Although Egypt does not have dedicated ABS or biodiversity legislation, it is the first of the Arab countries to regulate access to genetic resources and associated traditional knowledge. The *Egyptian Intellectual Property Law* (82/2002) establishes a benefit-sharing regime in the context of Plant Variety Protection. Article 200 of the law obliges plant breeders to share the profits gained from using Egyptian GRs or TK to breed new varieties with the interested party. It requires plant breeders to disclose the origin of GRs or TK relied on to develop the new variety and makes plant variety protection contingent upon the genetic resource having been acquired legitimately under Egyptian law.

Plant breeders that use Egyptian GRs to develop new varieties must obtain collection approval from the relevant competent authority – the National Programme for Plant Genetic Resources. It appears from the language of Article 200 that the regime is only applicable within the context of plant variety protection because it requires patent applicants to disclose the origin of the GRs or TK without reference to ABS. The patentability of microorganisms, and non-biological and microbiological processes for the production of plants and animals by the Egyptian Intellectual Property Law underlines the need to adopt a comprehensive ABS law.

Iraq[β]

The Ministry of Agriculture developed a draft act on the protection and exchange of plant genetic resources in 2012, but the act has not yet been adopted. The proposed act aims to protect and conserve Iraqi plant genetic resources, which constitute a strategic stock for biological diversity in Iraq, and to facilitate access to these resources. In line with Article 9 of the NP, which encourages users and providers to direct benefits arising from the utilization of genetic resources toward the

[392] See: http://www.aoad.org/gb/Newsdetails.aspx?Id=28.

conservation and the sustainable use of biological resources, the draft provides that part of the benefits arising from the utilization of plant genetic resources must be directed toward the conservation of these resources.[393] Nevertheless, the conservation aspects of the proposed Act need further elaboration and strengthening to ensure that they do not veer considerably from the original CBD intent.

Article 1 defines plant genetic resources (PGRs) as "living genetic resources from plant origin".[394] The definition seems very brief and unclear. Considering how the rapid development of technologies, scientific knowledge and bioeconomy changes the understanding of genetic resources in relation to ABS, the CBD definition seems to more effectively ensure the functionality of the ABS system. It defines genetic resources, including PGRs, as "genetic material of actual and potential value" and genetic material as "any material of plant, animal, microbial or other origin containing functional units of heredity".

Article 1 of the draft also defines derivatives as "genetic materials that have been developed through the use of plant genetic material that has been accessed according to this law"; however, what is meant 1 by the term "derivatives" is unclear. A derivative is defined in the Nagoya Protocol as "a naturally occurring compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity".[395]

Additionally, the draft recognizes that plant genetic resources and all related information are a property right of the state.[396] It uses the concept of "collecting permission" rather than CBD principles such as prior informed consent, or mutually agreed terms. Nor does it regulate access to traditional knowledge associated with genetic resources.

However, the scope of the proposed act is very broad. It regulates access to plant genetic resources that are held in both *in situ* and *ex situ* conditions.[397] It further establishes three different categories of access. The first category is access to plant genetic resources for food and agriculture according to Annex 1 of the ITPGRFA. Access under this category is for research, training and plant breeding for food and agriculture, and is subject to the Multilateral System. Transfer of these plant genetic resources is subject to the Standard Material Transfer Agreements.[398] The draft act, in contrast to the ITPGRFA, which prevents intellectual property rights from being claimed on material accessed under the MLS in the form received, does not prohibit claiming such rights over these resources. The second category is for non-commercial access for academic, educational and scientific uses, and the third category is for commercial access, which is for commercial investment. The draft excludes from the scope of access for non-commercial purposes and for commercial purposes plant genetic resources for food and agriculture of Annex 1 to the ITPGRFA.

However, the draft does not draw clear distinction between commercial and non-commercial uses. In particular, both private and public research institutions can engage in both commercial and non-commercial research, and to use of similar research methods and processes that may contribute to biodiversity conservation.[399] This distinction is one of the problematic issues of the NP, as access for

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[393] Nagoya Protocol, *supra* note 3 at Art. 9.
[394] Article 1 of the Iraqi proposed protection and exchange of plant genetic resources Act.
[395] Nagoya Protocol, *supra* note 3 at Art. 2(e).
[396] Article 3(c) of the proposed Act for the protection and exchange of plant genetic resources.
[397] Article 8.2 of the proposed Act for the protection and exchange of plant genetic resources.
[398] Article 9(a-c) of the proposed Act for the protection and exchange of plant genetic resources.
[399] IUCN Explanatory Guide to the Nagoya Protocol, *supra* note 82 at 119.

both commercial and non-commercial purposes is characterized by the intent of the research undertaking and not the form.[400]The result of the distinction is that the draft law bans claiming intellectual property rights over genetic resources and associated traditional knowledge accessed for commercial purpose.

The prohibition of claiming intellectual property rights, along with the recognition of state property rights over plant genetic resources and related information, as set out in the draft, conflicts with Order 81(2004) on Patent, Industrial Designs, Undisclosed Information, Integrated Circuits and Plant Variety Law, which was issued by the Coalition Provisional Authority (CPA) and amended the Patents and Industrial Designs law (65/1970).[401] The Order recognizes the patentability of life forms and private ownership over genetic resources, without requiring disclosure of origin or prior informed consent. The Order also provides dual protection for new plant varieties either via patent or plant breeders' rights. The Order recognizes that plant breeders have the right to register old plant varieties if they are the first to register them, and prevents farmers from breeding registered varieties.

Jordan[β]

Jordan has issued a number of laws and regulations related to the conservation and utilization of GR, either directly or indirectly, including the Agriculture Law (44/2002), the Environment Protection Law (1/2003), the Protection Law of New Varieties (67/2003), the Exploitation of Private Forest (Z/12/ 2003), the Patent Rights Law (32/1999), Control of Seed Production 1987, Seed Trade of Agricultural Crops 1990, Conditions for Seed Trade 1990, Condition for Variety Registration 1990, Licensing Agricultural Companies for Seed Import 1990, Licensing Seed Companies 1990, Variety Registration of Agricultural Crops 1993, Seed Production and Trade of Cereals, Forage, Vegetables and Fruit Trees 1996. Some of these laws' objectives are very similar to those of the ITPGRFA and the CBD. For example, the objectives of the Agriculture Law are to sustainably use natural agricultural resources without harming the environment, to increase the production of food and agricultural products, and to increase farmers' income and standard of living. Article 12 of the Law prohibits the transfer of GRs without prior permit issued by the minister. Violation of this provision is subject to a fine and the materials will be confiscated. Despite this array of laws and regulations, laws with ABS as a specific area of focus are still a new issue. An International Development Research Centre (IDRC)-supported project on ABS issues is currently working together with a team from the National Centre for Agricultural Research and Extension (NCARE) and the International Centre for Agricultural Research in Dry Areas (ICARDA) to explore a workable model for ABS on PGRFA in the country.[402]

Syria[β]

The Syrian Arab Republic (Syria) has unique biological diversity in the region. The estimated number of plant species is more than 3150.[403] Syria signed and ratified the CBD in 1995, and ratified the ITPGRFA in 2003. Syria is the only Arab country with ABS legislation in place. The *Act for the*

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[400] *Ibid.* at 17.

[401] The Act was originally amended by Law (28/1999) and Law (3/2000).

[402] Adnan Al-Yassin, "Jordan: In search of new Benefit Sharing Practices through Participatory Plant Breeding" in Manuel Ruiz and Ronne Vernooy, eds., *The Custodians of Biodiversity: Sharing Access to and Benefits of Genetic Resources* (New York: Earthscan, 2012) at 67.

[403] Ministry of Environment-Syrian Arab Republic, Biodiversity Strategy and Action Plan, and Report to the Conference to the Parties (NBSAP Project sy/97/g31)6.

Protection and Exchange of Plant Genetic Resources No.20 was adopted in 2009.[404] The Syrian Act is not only the first stand-alone access and benefit-sharing law in the region, but it has also been the most emulated regime in the Arab region.

This Act aims to protect, maintain and facilitate access to plant genetic resources;[405] to ensure fair and equitable benefit-sharing of the utilization of plant genetic resources;[406] to ensure the participation of public and private entities as well as farmers in the conservation and maintenance of plant genetic resources;[407] and to use the benefits of the utilization of plant genetic resources in the conservation and development of national scientific and technological capacity, and the transfer of technology and information to national institutes concerned with plant genetic resource conservation and agricultural development.[408]

The Act for the Protection and Exchange of Plant Genetic Resources applies only to plant genetic resources. The Act refers to access that is subject to the Multilateral System (MLS) of the ITPGRFA, as well as access to plant genetic resources that are beyond the scope of the MLS. However, the Act does not cover access to traditional knowledge. Derivatives are also not protected under the Act, despite Article 1 of the Act, which defines derivatives.

The Act specifies that the plant genetic resources for food and agriculture in Annex 1 to the ITPGRFA will be subject to the MLS, and their transfer subject to the Standard Material Transfer Agreements. In parallel, plant genetic resources, including plant genetic resources for food and agriculture that are not listed in Annex 1, can be accessed for commercial and non-commercial purposes. This implies that access to plant genetic resources for commercial and non-commercial purposes will be in accordance with the Convention on Biological Diversity and its Protocol. Article 8.2 allows access to plant genetic resources that are held both in *in situ* and *ex situ*, and requires applicants to specify in their application the access system endorsed and the source of the plant genetic resources. This broad scope of access in the act will likely be difficult to implement given the current technical, institutional and legal capacities of Syria.

The Act also established a national plant genetic resources authority, which is part of the General Commission for Scientific Agricultural Research. The Authority is designated to grant access and collection permissions, as well as to sign material transfer agreements with applicants.[409] However, no reference has been made in the Act to the concepts of prior informed consent and mutually agreed terms, and the only requirement for access is permission from the designated national authority. In addition, the Act includes no reference the CBD principle of national sovereignty over biological resources; instead, it recognizes that all plant genetic resources and related information are the property of the state.[410]

With regard to addressing farmers and Indigenous people, the Act acknowledges that the state shall ensure and protect farmers' rights.[411] It recognizes farmers' rights to participate in decision-making

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[404] An official copy of the Act for the Protection and Exchange of Plant Genetic Resources No.20 is available online at: <http://www.gcsar.gov.sy/gcsarAR/spip.php?article236>.
[405] *Ibid.* at Article 2(a).
[406] *Ibid.* at Article 2(c).
[407] *Ibid.* at Article 2(h).
[408] *Ibid.* at Article 2(d).
[409] The Authority is also responsible of setting national policy and studies for the conservation and sustainable use.
[410] *Act for the Protection and Exchange of Plant Genetic Resources No.20*, Article 3.
[411] *Ibid.* at Article 7(a).

related to the conservation of plant genetic resources, and to share part of the benefits arising from of the utilization of genetic resources.[412]

United Arab Emirates[α]

In May 2013, the UAE Parliament referred a draft law on plant genetic resources to the Committee of Foreign Affairs, Planning, Petroleum and Mineral Resources, Agriculture and Fisheries for further consideration. The aim of the proposed law, which is composed of 21 articles, is to protect and preserve plant genetic resources for food and agriculture, and the sustainable use of these vital resources for food and agriculture, in a way that achieves the state strategy to promote food security. It also aims to facilitate access to plant genetic resources for food and agriculture, and to ensure the fair sharing of benefits arising from the utilization of these resources.

Thus, the law is mainly intended to implement the ITPGRFA. While access to PGRFA of Annex 1 will be subject to the MLS, non-Annex 1 plant genetic resources will be transferred through the Material Transfer Agreement. The framework of the draft law includes the regulation of access to plant genetic resources held in *in situ* and *ex situ* conditions, as well as to associated agricultural traditional knowledge. As with other ABS laws in the region, the broad scope of the act raises concerns including those related to the technological, institutional and professional experience required to regulate access to both in *in situ* and *ex situ* plant genetic resources.

The main access conditions for plant genetic resources set out in the draft act require prior approval for access from the Ministry of Environment and Water, as the designated national authority. The Ministry of Environment and Water also has the authority to grant collecting permission. In relation to benefit-sharing, the draft states that the Ministry of Environment and Water and the competent national authority will share benefits that may arise from the utilization of genetic resources, according to the prior approval and collecting permission.

E. PACIFIC

Australia[β]

Australia is a megadiverse country[413] and the growing attention to the potential value of Australia's biodiversity as a source of food, pharmaceutical, medicinal and industrial products, as well as the awareness of ensuring that Australia benefits from such uses, was reflected in Objective 2.8 of the *National Strategy for the Conservation of Australia's Biological Diversity*, which is to "Ensure that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia".

Section 301 of the *Environment Protection and Biodiversity Conservation Act of 1999*[414] (EPBCA) establishes the general framework for future, more specific regulations on access to genetic resources.[415] The section states that "the regulations may provide the control of access to biological resources in Commonwealth areas" and, further, that these regulations may contain provisions on the equitable

[412] *Ibid.* at Article 7(b).
[413] But not a member of the LMMC group.
[414] *Environment Protection and Biodiversity Conservation Act of 1999* (Cth.)
[415] In addition to the federal actions, the State of Queensland and the Northern Territory both have in place ABS/biodiscovery legislation.

sharing of benefits arising from the use of biological resources; the facilitation of access; the right to deny access; the granting of access; and the terms and conditions of such access.[416]

With the purpose of designing the regulations under Section 301 and implementing a scheme on access to biological resources, an Inquiry into Access to Biological Resources in Commonwealth Areas was initiated in December 1999. The result of the Inquiry was a report containing recommendations on the creation of an ABS system.[417]

In order to establish a coherent legal framework in the Australian federal structure, the 14 Commonwealth, State and Territory Ministers of Australia constituting the Natural Resource Management Ministerial Council endorsed the *Nationally Consistent Approach for Access to and Utilisation of Australia's Native Genetic and Biochemical Resources* (NCA) on October 11, 2002. The NCA sets general principles that must be applied when developing or reviewing ABS systems established within Australian jurisdictions. These principles include certainty, transparency and accountability for facilitating biodiscovery; the sustainable use of biological resources; and the equitable sharing of benefits.

Under Australia's Federal system, existing ownership rights to native biological resources depend on whether they are found in Commonwealth, State or Territory government lands or waters, Indigenous lands (of which there are different types with different associated rights), freehold or leasehold lands. Access to biological resources in Commonwealth areas[418] is governed by the *Environment Protection and Biodiversity Conservation Regulations 2000* (EPBC Regulations).[419] Under the EPBC Regulations, those seeking access to genetic resources must apply to the Department of the Environment, Water, Heritage and the Arts (DEWHA) for a permit to access biological resources of native species for research and development of any genetic resources, or biochemical compounds, comprising or contained in the biological resource.

Permits for access to biological resources are available for either commercial, potentially commercial or non-commercial purposes. The applicant for a permit for commercial purposes must enter into a benefit-sharing agreement (BSA) with each relevant Access Provider for the resource in question.[420] The process for permit applications for non-commercial purposes is slightly less complicated; the applicant must obtain the written permission from each Access Provider to:[421]

(a) enter the Commonwealth Area;

(b) take samples from the biological resources of the land; and

(c) remove samples from the area.

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[416] *Environment Protection and Biodiversity Conservation Act of 1999* at section 301(2).

[417] For details about the process leading to the regulation see Rally Petherbrige, "Australia: Draft Regulations on Access and Benefit Sharing" in Santiago Carrizosa *et al.*, eds., *Accessing Biodiversity and Sharing the Benefits* (Gland, Switzerland: IUCN, 2004).

[418] Commonwealth areas are defined in section 525 of the EPBC Act to include land owned or leased by the Commonwealth, the Australian coastal sea, continental shelf and waters of the EEZ.

[419] The full text of the Commonwealth access regime is set out in Part 8A and Part 17 of the EPBC Regulations and is available online: <http://www.comlaw.gov.au/comlaw/legislation/legislativeinstrumentcompilation1.nsf/framelodgmentattachments/BD9AB11F19E7F55ECA25718F00156738>.

[420] *Environment Protection and Biodiversity Conservation Regulations 2000*, r 8A.07(1); (See permit application and BSA at: http://www.environment.gov.au/biodiversity/science/access/permits/index.html).

[421] *Ibid,* r 8A.12(1).

Both the BSA and written permission may potentially affect Native Title rights and interests in relation to land and water,[422] which means applicants must consider the application of the *Native Title Act 1993* (Cth) (NTA). In general, acts that affect Native Title in land or water are considered "future acts", which may permanently extinguish existing Native Title rights.[423] Should the potential arise, the Applicant may need to enter into and register an Indigenous Land Use Agreement with the Native Title holders – the registration of which will protect Native Title rights and interests.[424] The Native Title rights will remain unless the act is wholly inconsistent the continuation of those rights.[425] Considerations of the NTA will only apply to the extent an Access Provider is a Native Title holder.

For commercial purposes, the BSA must provide reasonable benefit-sharing arrangements between the parties. Regulation 8A.08 states this includes the protection, recognition, and valuing of any Indigenous people's knowledge to be used, along with, for example:[426] (a) the purpose of access; (b) the quantity of resources that may be removed from the areas; (c) a statement of any Indigenous people's knowledge and the benefits to be provided, or any agreed commitments given in return for the use of the knowledge; (d) if any Indigenous people's knowledge of the Access Provider (or another group of Indigenous persons) is to be used, a copy of the agreement regarding the use of the knowledge; and (e) details of the benefits that the Access Provider will receive for having granted access.

DEWHA has developed model contracts as a guide to assist parties developing benefit-sharing agreements, where the Commonwealth is the access provider and where the Commonwealth is not the access provider[427]. Benefits are as determined by the parties to the contract, and can include contributions to conservation and scientific knowledge or any other agreed benefit as well as any revenue generated by the commercialisation of IP related to the genetic resource where relevant.

Applicants for permits for non-commercial purposes must provide a statutory declaration stating that the applicant does not intend to allow the collection to be used for commercial purposes, will report on the results of the research, will offer a taxonomic duplicate of each sample to an Australian public institution that is a taxonomic repository, and will not carry out any research for commercial reasons.

The Australian system has been developed as a transparent system, where users can browse a record of permits that have been issued and samples collected under those permits.[428] As of 20 February 2014, one-hundred and eighty-one permits had been issued through the Protected Areas Policy Section under Part 8A of the EPBC Regulations since December 2005. Notably, there have been only three commercial permits issued to date, and the remaining permits are for non-commercial purposes.[429]

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[422] *Ibid,* r 8A.07(1).
[423] *Native Title Act 1993* (Cth), part 15, division 2, s. 233.
[424] *Ibid.* at s. 24EB.
[425] *Ibid.* at s. 238.
[426] *Environment Protection and Biodiversity Conservation Regulations 2000, supra* note 424, r 8A.08.
[427] The model contracts are available online: <http://www.environment.gov.au/biodiversity/science/access/model-agreements/index.html>.
[428] Browse the record of permits online: <http://www.environment.gov.au/grid/public/perrep.jsp>.
[429] Australia, Department of Environment, "List of permits issued", online: <http://www.environment.gov.au/biodiversity/science/access/permits/list.html>.

Australia has also empowered regional organizations and specialized government divisions with responsibilities relating to overseeing region-specific ABR. Examples of these include the Great Barrier Reef Marine Park Authority (GBRMPA) and the Australian Government Antarctic Division (AGAD).

The GBRMPA was established to manage certain aspects of the Great Barrier Reef Marine Park (GBR Marine Park).[430] ABR requirements for the GBR Marine Park are regulated under the *Great Barrier Reef Marine Park Act 1975* (Cth) and the *Great Barrier Reef Marine Park Regulations 1983* (Cth), as well as the Great Barrier Reef Marine Park Zoning Plan 2003. One of the functions of the GBRMPA is to carry out, independently or in co-operation with other institutions, or arrange for other persons to carry out, research and investigations in the Marine Park,[431] which includes assessing and issuing permission through the use of permits.[432]

The Australian Antarctic Territory (AAT) is also covered by the ADR regime since Commonwealth Areas include external territories (except Norfolk Island). Due to the special status of the ATT, it is managed by the Australian Government Antarctic Division, which is a unit specializing in the Antarctic. As with all other Commonwealth Areas, BSAs will apply to commercial research, with simpler arrangements for non-commercial research.[433]

DEWHA continues to work with state and territorial jurisdictions to ensure their approaches are nationally consistent. In addition to the legislation covering Commonwealth land, the Queensland and Northern Territory Governments have legislation in place, with Victoria and Tasmania recently implementing legally effective measures to implement Australia's nationally consistent approach to ABS.

French Polynesia[α]

French Polynesia modified its environmental code through the adoption of Law No 2012-5 of 23 January 2012 relating to access to biological resources and the sharing of benefits resulting from their valorization.[434] The Law modifies the Environmental Code by adding a number of new definitions, including biological resources, biotechnology, biopiracy, bioprospecting, biochemical derivative, genetic material, associated traditional knowledge, and Indigenous origin. It also inserts a new chapter in the Environmental Code – Chapter 5 – on Access to biological resources and the sharing of benefits arising from their valorization.

Section 1(1) of Chapter 5 defines the scope of application. Chapter 5 applies to all access to biological resources, under whatever form, of animal, plant, microbial or other species, whether terrestrial or marine, for scientific research purposes, higher education, conservation and/or collection on a purely professional basis, as well as for bioprospecting, industrial application or commercial use, whether the resources are exported or not.[435] For clarification, the law indicates that access to biological resources refers to the collection and/or use of such resources, their biochemical derivatives, their genetic material, or associated traditional techniques or practices, by any individual

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[430] Australia, *Great Barrier Reef Marine Park Act 1975* (Cth), s 6.
[431] *Ibid.* at s. 7(1)(b).
[432] *Great Barrier Reef Marine Park Regulations 1983 (Cth),* r 2.6.3(d).
[433] Australia, Department of Environment, 'External Territories', online: <http://www.environment.gov.au/biodiversity/science/access/contacts/territories/index.html#antarctic>.
[434] *Loi du Pays N° 2012-5 du 23 Janvier 2012 Relative à l'accès aux ressources biologiques et au partage des avantages résultant de leur valorisation.*
[435] *Ibid.* at Art. 125-1.

or corporation, whether established under private or public law.[436] There are several exemptions to the law. Plant genetic resources used for food and agriculture covered by the ITPGRFA are excluded, as are biological resources that are used strictly for domestic purposes, and biological resources that are used and exchanged by local communities in a traditional, cultural, religious, spiritual or customary manner. Biological resources used in the artisanal, agricultural, aquacultural, perlicultural, or fishing context are also excluded, so long as they are not the object of R&D, but rather are harvested or simply transformed without any analysis, selection or improvement.[437]

Section 1(2) addresses administrative authorization for access. All access to biological resources requires prior authorization accorded by ministerial decree, upon a proposal from the ministry of environment after receiving advice from the ministry in charge of research and all other ministries concerned. This authorization will be immediately registered with the ABS Clearing-House and will thus become an internationally recognized certificate of compliance.[438] The user must obtain the agreement of the owner(s) of the site where the biological resource sought is found, to allow them to enter on the site and undertake the collection of the resource. Similarly, the user must obtain the agreement of the holder(s) of the traditional knowledge associated with the biological resource under study. The holder(s) must indicate the aboriginal source of the traditional knowledge or the request will be deemed inadmissible. This agreement must occur prior to any request for access and must be attached to the request; access cannot be authorised in its absence. When the site where the biological resource is found is located in the public or private domain of Polynesia or its exclusive economic zone, authorization to enter the site is granted in the decree authorizing access. The same applies when French Polynesia is the holder of the associated traditional knowledge. The user may solicit, if necessary and at their expense, the support of the competent national authority in identifying the holders of property rights over sites or associated traditional knowledge, according to the regulations in force.[439]

The procedure and modalities for authorization of access are defined by a ministerial decree, which indicates the following elements: the authority or authorities or administrative services qualified to receive and investigate access requests; the organizations from which advice must be solicited, notably the commission for natural sites and monuments and one or multiple scientific organisations; the procedure for investigation and timelines; modalities for a simplified procedure as well as the cases in which this procedure may be used, notably the renewal and modification of an access permit, or the urgency of the expected use; the amount of the required fee if necessary, the recipients of a total or partial exemption, and the modalities for reimbursement in case of refusal; the criteria for evaluation of the project in light of the objectives of environmental protection and sustainable use of resources, as well as from the perspective of the economic and social development of French Polynesia; the procedure for registering the authorization with the ABS Clearing House; and the conditions for access to associated traditional knowledge, such as the identification of sources.[440]

The request for use of the resource will be examined in light of the objectives of protection of the environment and the sustainable use of resources, and from the perspective of the economic and social development of French Polynesia, notably on the following criteria: the scope of the project;

[436] *Ibid.* at Art. 125-2.
[437] *Ibid.* at Art. 125-3.
[438] *Ibid.* at Art. 125-4.
[439] *Ibid.* at Art. 125-5.
[440] *Ibid.* at Art. 125-6.

the size of the research budget involved; the level of scientific interest; the state of conservation of the resource; the contribution of the project to the conservation and sustainable use of biological resources; the impacts, risks and dangers of the project for biodiversity and its sustainable use; compliance with fair and equitable benefit-sharing resulting from the undertaking of the project; local economic and social development; interest for local research; the valorization of French Polynesia in terms of research; respect for the identity of the holders of traditional knowledge associated with the resource; and the purpose of the research. A ministerial decree will elaborate the modalities of these criteria as required.[441]

The decree authorizing access is constituted by the following elements, which may be completed by a ministerial decree: precise identification of the beneficiary of the authorization; precise designation of the biological resources, biochemical derivatives, genetic material or associated traditional knowledge for which access is granted; the date(s) and duration of collection; the location(s) for collection and the holders of related property rights; the modalities of access to the collection site, which may include the mandatory presence of a guide, borne by the user; the method of collection; the quantity collected; expected transport and storage; the predicted nature of use; and the duration of the authorization granted. The authorization contains all the necessary instructions required to guarantee the conservation of biological diversity in the case of the collection of biological resources, and respect for populations in the case of the collection of associated traditional knowledge. The authorization granted is particular, individual and non-transferrable. It may be renewed if the user justifies the need for new collection in the context of the initial project. It may also be modified as the project evolves.[442] The competent national authority will catalogue the activities linked to the valorization of biological resource, and may request information from the user on the resource used and its activities. All new access required for the user to re-obtain the resource in the process of valorization or any other resource must conform to the regulations.[443]

All export of biological resources is forbidden, except for those resources that are excluded from the scope of application of the law, as well as those for which an access permit has been granted, provided that an export permit has been obtained according to the applicable regulations. The access permit does not constitute a permit for export. This is without prejudice to applicable sanitary requirements, nor provisions applicable to the export of certain species.[444] Benefits resulting from the valorization of biological resources, their derivatives, and associated traditional knowledge may be monetary or non-monetary. They must be shared between the user of the resources and French Polynesia, according to the conditions established in the contract established prior to authorization for access.[445]

The contract established between the user and French Polynesia aims to establish the reciprocal obligations of the parties regarding the utilization of biological resources, their derivatives or associated traditional knowledge. French Polynesia commits itself to facilitate access to its resources. Users commit themselves to use the resources in conformity with the terms of the contract and to share the benefits resulting therefrom with French Polynesia. The contract must consist of the following terms: the identity of the parties; the object of the contract; a detailed description of the methods of use of the resources, the expected results, and the types and quantities of financing

[441] *Ibid.* at Art. 125-6 Bis.
[442] *Ibid.* at Art. 125-7.
[443] *Ibid.* at Art. 125-8.
[444] *Ibid.* at Art. 125-9.
[445] *Ibid.* at Art. 125-10.

obtained; an evaluation of the monetary or non-monetary benefits that will result from the use of the resources; a continual obligation to provide information at the expense of the user through the provision of activity reports and reports on results according to a timeline established by the parties; an allocation of the monetary benefits between the user and French Polynesia according to the percentages fixed by the parties; and, details on the non-monetary benefits granted to French Polynesia. When it is not possible to assess expected benefits at the time that the contract is established, an amendment is required at the time that the benefits are known. All substantial modifications of the conditions of use of the resources and the aims of the user must be subject to the consent of French Polynesia by way of an amendment.[446]

When the owner of the site on which the resource was obtained or the holder of the traditional knowledge associated to the biological resources transferred to the user is not French Polynesia and is identified, they must receive from the user the monetary or non-monetary benefits, negotiated between the parties in the framework of a contract, that are intended for the preservation or valorization of the biological resources or traditional knowledge collected. This contract is established when the owner gives their consent to access the site. It must take place prior to the granting of an access permit, and a copy will be annexed to the request for access submitted by the user to the CNA.[447] Monetary benefits allotted to French Polynesia shall be directed to the conservation and valorization of biodiversity and associated traditional knowledge under the conditions envisaged by the budgetary regulations and public treasurer.[448] Access shall only be granted in compliance with the regulations on bioethics, security, public health, and environmental protection applicable in French Polynesia.[449] To monitor access, a register will be established containing all access requests and permits to allow for comprehensive monitoring, from the collection of resources to their valorization. The terms regulating its creation and holdings, as well as the topics included, will be determined by ministerial decree.[450]

The law also establishes sanctions for biopiracy. The collection of biological resources, their biochemical derivatives, their genetic material, or associated traditional knowledge, in ignorance of the dispositions of Chapter 5, constitutes a fourth class infraction, subject to a fine of 89,000 Pacific francs. The sum of the fine is multiplied by five when the contravening party is a corporation. If the infraction is carried out in a protected area or area under the environmental code, the planning code or fisheries regulations, the applicable fines are found in those respective laws.[451] The use or attempted use, in ignorance of the rules found in Chapter 5, of biological resources, their biochemical derivatives, their genetic material or associated traditional knowledge for the purposes of scientific research, higher education, conservation and/or collection for professional use, bioprospecting, industrial application, or commercial use, whether the resources are exported or not, constitutes a punishable offense that may lead to imprisonment for three years and a fine of 35,799,000 Pacific Francs. The fine is multiplied by five when the author of the offense is a moral person. It may also include up to half of the monetary benefits generated by fraudulent use.[452] Individuals also incur additional penalties, including: the seizure and confiscation of all material or elements that were used to commit the infraction; the seizure and confiscation of any product

[446] *Ibid.* at Art. 125-11.
[447] *Ibid.* at Art. 125-12
[448] *Ibid.* at Art. 125-13
[449] *Ibid.* at Art. 125-14
[450] *Ibid.* at Art. 125-15
[451] *Ibid.* at Art. 125-16.
[452] *Ibid.* at Art. 125-17.1

resulting from the infraction; the reintroduction of living specimens into their original environment, if possible, or if not, their surrender to individuals or corporations working on research or conservation of nature, or their destruction; and a prohibition against undertaking the activity based on fraudulent use.[453] Corporations will incur the following additional penalties: prohibition, for a period of five or more years, of directly or indirectly carrying out the activity through which the infraction was committed; the seizure and confiscation of all products resulting from the infraction committed; and the reintroduction of living specimens into their original environment, if possible, or if not, their surrender to individuals or corporations working on research or conservation of nature, or their destruction.[454]

Independent of any criminal prosecutions carried out in the application of Chapter 5, and after formal notice by the CNA, the following administrative measures can be applied to individuals and companies: withdrawal of the access permit and suspension of the activity aimed at the biological resource or associated traditional knowledge obtained without authorization or used in ignorance of the legal requirements; instructions for emergency measures aiming at the protection of species illegally accessed; the requirement to carry out an act prescribed by the administration, such as restoration, at the expense of the offender; closing the establishment that illegally used a local biological resource; and placement of a species held illegally at the expense of the offender. These provisions are without prejudice to the application of relevant customs provisions that may apply.[455]

New Zealand[β]

New Zealand is a biodiversity 'hotspot', and both a strong user and provider of genetic resources. It administers three natural World Heritage Sites and has declared that halting the decline of its biodiversity is one of its ten strategic priorities.[456] Besides this natural richness, New Zealand is especially relevant in the context of recognising Indigenous communities and TK in ABS regimes.

Not being a signatory to the Nagoya Protocol, New Zealand has a Focal Point within the Ministry of Foreign Affairs and Trade[457] and has not established a Competent National Authority (CNA). The government has announced it will not sign the Nagoya Protocol until two domestic issues are solved – namely, claims of inadequate representation of Maori culture and interests in domestic policies over biological resources, and the ambiguity of the Protocol regarding its application to the health and agriculture sectors. At present, New Zealand has no comprehensive national ABS regime in place. However, the Ministry of Economic Development is working on establishing such a policy,[458] which will take into account the Nagoya Protocol "in order to minimise obstacles to possible accession in the future."[459]

Current laws on ABS in New Zealand are fragmented and uncoordinated. Access to specimens on private land is subject to permission from the land owner, with some species being protected under the Wildlife Act 1953, and the inclusion of biodiversity considerations in New Zealand's overarching

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[453] *Ibid.* at Art. 125-17.2
[454] *Ibid.* at Art. 125-17.3
[455] *Ibid.* at Art. 125-18.
[456] More information on what New Zealand is doing to halt the loss of biodiversity, online: <http://www.biodiversity.govt.nz/picture/doing/index.html>.
[457] Details on the New Zealand Focal Point, online: <https://www.cbd.int/doc/lists/nfp-cbd.pdf>.
[458] More information on the ongoing development of domestic ABS laws by the New Zealand Ministry for Economic Development, online: <http://www.med.govt.nz/sectors-industries/natural-resources/biodiscovery>.
[459] The Cabinet Briefing Paper on recommendations for New Zealand following the adoption of the Nagoya Protocol, online: <http://www.mfat.govt.nz/downloads/environment/Nagoya_Protocol_Cab_PaperL.pdf>.

resource management legislation, the Resource Management Act 1991. Because approximately 29 per cent of New Zealand's land and 1.27 million hectares of its coastal zone are protected areas, a significant amount of the country's biodiversity is under government management.

The applicable rules on ABS are inconsistent, due to the fact that various government departments administer different areas according to their own policies. In 2000, New Zealand's National Biodiversity Strategy[460] identified gaps in the current ABS approach. The Strategy aims for an integrated ABS regime, including fair and transparent rules on genetic resources traditionally held by Maori, in accordance with the CBD. Similarly, the 2003 New Zealand Biotechnology Strategy highlighted the need for an overarching ABS framework.

In constructing an ABS regime, a central feature is the incorporation of TK of the Maori people, an issue that has been the subject of the important Wai 262 "Flora, Fauna and Cultural Intellectual Property" claim. The claim asserts rights over Indigenous species of flora and fauna for the Maori people. Moreover, it alleges that New Zealand is in breach of its contractual obligations towards the Maori through neglecting such rights in national laws.[461] Presently, New Zealand has no guidelines or policies on the usage of traditional Maori knowledge in bioprospecting.

In its June 2011 final report, the Waitangi Tribunal found that the government must provide for greater inclusion of the Maori in decision making processes, and ensure that Maori knowledge can no longer be used for commercial or scientific purposes without consent or acknowledgement. The recommended changes include: (1) building an ABS regime centred around a Department of Conservation committee deciding on access to New Zealand's resources and assessing equitable sharing of benefits, taking into account Maori rights and concerns in the resources in question; (2) creating a Maori committee with a broad mandate to advise the Commissioner of Patents *inter alia* on whether inventions are derived from Maori knowledge; and (3) facilitating greater Maori involvement in formulating New Zealand's position for international treaty negotiation.[462] Additionally, the Tribunal Report and the National Biodiversity Strategy support an obligation to require applicants of intellectual property rights to disclose any TK or genetic resources used in research that led to the patent application. Any such usage may only occur with the consent of the traditional holders and any future benefits have to be shared with them.

The outcome of the Wai claim now provides the framework for finalising a domestic ABS regime, work on which began in 2007. The vision of the regime is "that access to New Zealand's biological resources for bioprospecting is facilitated in a way that ensures the benefits derived are captured and shared, that social, cultural and environmental values are respected, and Maori traditional knowledge of biological resources is recognised and, where appropriate, protected."[463] One suggestion to ensure the adequate inclusion of TK holders is to establish an advisory council to assist the CNA with facilitating the negotiations on sharing the benefits of using Maori knowledge. It might also be

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[460] For more information on the New Zealand Biodiversity Strategy, see: <http://www.biodiversity.govt.nz/picture/doing/nzbs/index.html>.

[461] For more information on the Wai 262 claim, see: <http://www.waitangitribunal.govt.nz/news/media/wai262.asp>.

[462] Waitangi Tribunal, "*Ko Aotearoatēnei : A Report into Claims Concerning New Zealand Law and Policy Affecting Maori Culture and Identity. Te Taumata Tuatahi"* (2011), online: <http://www.waitangitribunal.govt.nz/scripts/reports/reports/262/05AC7023-0EEA-4ECC-8B6E-AB136A2EA7F8.pdf>.

[463] New Zealand Ministry of Economic Development, "Bioprospecting: Harnessing Benefits for New Zealand - A policy framework discussion", online: <http://www.med.govt.nz/sectors-industries/natural-resources/pdf-docs-library/biodiscovery/bioprospecting-harnessing-benefits-for-new-zealand.pdf>.

appropriate for such an advisory body to develop guidelines for the use of Maori knowledge, and to assist with identifying the most appropriate knowledge holders with whom to negotiate the terms.[464]

Solomon Islands[β]

The Solomon Islands regulates bioprospecting in protected areas in the *Protected Areas Act 2010*.[465] Part 2 addresses the creation, functions and powers of a Protected Areas Advisory Committee. Section 6 of the Act endows the Committee with the power to negotiate and provide matters in relation to permits, and to require holders of permits to provide reports.[466] Part 5 of the Act addresses biodiversity research and bioprospecting in three articles. Article 16 prohibits biodiversity research or bioprospecting without a permit,[467]with offenders subject to a fine of 500,000 penalty units or imprisonment for up to five years.[468]

The Advisory Committee has the power to issue a permit authorizing the permit holder to undertake biodiversity research or bioprospecting research or both, subject to the terms and conditions established by the Committee.[469] The Committee's powers include the right to refuse the application for access, to vary, suspend or cancel a permit, and to impose, vary, suspend or cancel conditions of the permit.[470] All bioprospecting permits and ABS agreements require the prior endorsement of Cabinet.[471] Reasons must be given for refusing a permit application,[472] and the Committee must give the permit holder an opportunity to be heard if it decides to cancel, vary or impose new conditions on the permit.[473] A permit cannot be transferred or assigned to a third party,[474] or it will be rendered void.[475]

Persons may apply to the Director of the Environment and Conservation Division for a permit in the prescribed form accompanied by the prescribed fee.[476] The form must fully describe the applicant, including providing a list of persons who may be involved in the research; the nature, extent, type and method of research; the beneficiaries to the research; and any other relevant information.[477] The Director forwards the application to the Advisory Committee for processing and consideration,[478] which may require the applicant to provide further information when determining an application.[479] The Committee cannot approve an application for a permit involving customary land or fishing areas unless it is satisfied that the written consent of the owners is attached to the application; that an agreement has been entered into with the owners on the right of access, acquisition of biological resources, technology transfer, monetary benefit or compensation for

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[464] See *ibid.* for further options.
[465] Solomon Islands, *An Act for the Declaration and Management of Protected Areas or Areas Where Special Measures Need to be Taken to Conserve Biological Diversity and the Regulation of Biological Diversity and Prospecting, Research and for Related Matters* (No. 4 of 2010).
[466] *Ibid.* at s. 6(1)(f) and (g).
[467] *Ibid.* at s. 16(1).
[468] *Ibid.* at s. 16(3).
[469] *Ibid.* at s. 17(1).
[470] *Ibid.* at s. 17(3).
[471] *Ibid.* at s. 17(2).
[472] *Ibid.* at s. 17(5).
[473] *Ibid.* at s. 17(6).
[474] *Ibid.* at s. 17(7).
[475] *Ibid.* at s. 17(8).
[476] *Ibid.* at s. 18(1).
[477] *Ibid.* at s. 18(2).
[478] *Ibid.* at s. 18(3).
[479] *Ibid.* at s. 18(4).

bioprospecting, and acquisition of biological resources, or for any commercial benefit that may be obtained as a result of the permit; and that the applicant has submitted a plan outlining the nature and extent of the research, the investigation and sampling method, the specimens to be removed, and a monitoring and auditing system to verify all activities that will be undertaken.[480] When the Committee has made a decision, the Director must inform the applicant as soon as possible, including of the reasons for the decision if refused and the right of appeal.[481] An applicant can appeal to the Minister, within 28 days of the decision, who will hear and determine the appeal. If the appeal is allowed, the Minister refers the matter to the Committee for its reconsideration.[482] The Minister can appoint a panel made up of legal practitioners and up to two more members to hear the appeal and issue a report, including any recommendation on whether the appeal should be granted.[483]

F. AFRICA

African Regional Intellectual Property Organization (ARIPO)[α]

Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the Framework of the African Regional Intellectual Property Organization

The Swakopmund Protocol was adopted by ARIPO in 2010 and entered into force in January 2012. It aims to: (a) protect traditional knowledge holders from any infringement on their rights as recognized within the Protocol, and (b) protect cultural expressions against misappropriation, misuse and/or exploitation.[484] The protocol employs broad definitions of traditional knowledge and folklore,[485] along with a unique set of protections. Specifically, the holders of traditional knowledge under the Protocol are deemed the beneficiaries,[486] and receive exclusive rights over the authorization of use of their TK,[487] prevention of the exploitation of TK without prior informed consent,[488] the institution of legal proceedings to remedy infringements of rights protected under the Protocol,[489] and fair and equitable benefit-sharing arising from the commercial use of their TK.[490]

African Union[αβ]

OAU Model Law

The Organization of African Unity (OAU, now the African Union) crafted its Model Law[491] in 2000 in response to the potential for conflicts between the CBD, particularly Article 15, and the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), particularly Article 27.3(b). African countries have consistently expressed the position that they are against the patenting of life forms.

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480 *Ibid.* at s. 18(5).
481 *Ibid*, at s. 18(6).
482 *Ibid*, at s. 23(1).
483 *Ibid*, at s. 23(2).
484 ARIPO, *Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore* (2010), at Art. 1.1, online: <http://www.cbd.int/doc/measures/abs/msr-abs-aripo-en.pdf> [Swakopmund Protocol].
485 *Ibid.* at s. 2.1.
486 *Ibid.* at s. 6.
487 *Ibid.* at s. 7.1.
488 *Ibid.* at s. 7.2.
489 *Ibid.* at s. 7.4.
490 *Ibid.* at s. 9; See: Jorge Cabrera Medaglia, Frederic Perron-Welch and Freedom-Kai Phillips, "Legal Aspects of Aichi Biodiversity Target 16" (Rome: IDLO, 2014).
491 *Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*, 2000 [Model Law].

The Model Law was thus an effort to create a *sui generis* form of plant protection that complies with the requirements of Article 27.3(b), but which also integrates the goals of the CBD. The Model Law is not binding on member states; rather, it is intended as a guide and resource tool for African countries as they create their own national systems on ABS. The Model Law is very broad in scope. It covers a wide range of access activities including the acquisition of biological resources, their derivatives, and community knowledge, innovations, technologies or practices.[492] The definition of "biological resources" is similarly broad and includes genetic resources as a subset of biological resources, in conformity with the definition in the CBD.[493]

Under the Model Law, access requires the written prior informed consent of a country's NCA as well as the local communities concerned.[494] The NCA is to consult with the local communities to determine that their consent has been sought and granted. The Model Law does not provide details on how an applicant should solicit prior informed consent. Once consent has been obtained, access is to be granted on the basis of a written agreement between the NCA and the concerned local community/communities, on the one hand, and the applicant on the other.[495] This agreement must include commitments on the part of the applicant to share benefits and "to contribute economically to the efforts of the State and concerned local community or communities in the regeneration and conservation of the biological resource, and the maintenance of the innovation, practice, knowledge or technology to which access is sought".[496] Further benefit-sharing obligations are set out in section 12. These require the payment of a fee prior to the commencement of collection and entitle the state and the communities concerned to a share of the earnings derived from a biological resource or knowledge.[497] The sum of the initial fee can vary according to whether, *inter alia,* the collection is for commercial purposes.

The Model Law creates distinctions among access for commercial, academic and traditional purposes. The scope of the law states that it is not intended to affect traditional systems of access or "[a]ccess, use and exchange of knowledge and technologies by and between local communities".[498] Section 11 allows the NCA to set different terms and conditions in the access agreement depending on whether the user is a research institution, a public agency, or an inter-governmental institution. Finally, section 13 creates three types of access permits: the academic research permit, the commercial research permit, and the commercial exploitation permit. The section does not, however, elaborate as to what different rights and responsibilities might accompany each type of permit.

Part VIII of the Model Law includes provisions on sanctions and penalties, which complement earlier provisions on prior informed consent. Section 5 makes it an offence to carry out access without the prior informed consent of the state and the concerned local communities. This offence is subject to the penalties in section 67, which includes a list of possible sanctions such as warnings, fines, confiscation of collected material, and a permanent ban from future access in the country.

The Model Law is currently being reviewed in response to the Nagoya Protocol, under the aegis of the African Union.

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[492] *Ibid.* at Article 1, definition of "access".
[493] *Ibid.*
[494] *Ibid.* at s. 5.1.
[495] *Ibid.* at s. 7.2.
[496] *Ibid.* at s. 8.1(vi) & (vii).
[497] *Ibid.* at s. 12.1 & 12.2.
[498] *Ibid.* at s. 2.2.

Regional Guidelines to Implement the Nagoya Protocol

The African Union has initiated a process to develop guidelines for the coordinated implementation of the Nagoya Protocol in Africa (tentatively titled the *African Union Policy Framework for the Coordinated Implementation of the Nagoya Protocol on ABS*). The guidelines were commissioned by the AU Commission Department of Human Resources, Science and Technology (DHRST) as mandated by the participants in the 6th pan-African ABS workshop held at Limbé, Cameroon in January 2012. The AU is overseeing the process, and it is expected to result in the adoption of a policy instrument by the African Ministers Conference on the Environment (AMCEN) or other AU policy organs (e.g. the AU Assembly). The Policy Framework was discussed in detail at a technical expert consultation meeting held in Addis Ababa, Ethiopia in October 2013, but has not been adopted formally and is therefore subject to change.

The Policy Framework consists of a Preamble, Policy Guidance for Coordination, and Policy Guidelines. The key elements relate to the consistent use of terms; a coordinated approach to awareness raising and information sharing; a coordinated approach to access for utilization; a coordinated approach to benefit sharing; a coordinated approach to monitoring and compliance; and a coordinated approach to supporting community and farmers' rights, economic development, capacity building, technology transfer, sustainable use and conservation.

The strategic principles of the Framework aim to ensure that a coordinated implementation of the Nagoya Protocol produces positive socio-economic, development and biodiversity conservation outcomes in Africa:

- The NP and Framework must be implemented nationally and locally.
- Implementation must increase legal certainty for providers and users of GR and associated TK.
- A learning-by-doing approach must be adopted to incorporate lessons and best practices derived from implementation experience.
- Implementation must remain flexible and responsive to new international policy developments.
- The regulatory focus must be on the utilization of GR and associated TK and on the sharing of benefits derived from such utilization.
- Utilization must be encouraged by putting in place straightforward permitting procedures for an initial discovery phase, under standard MAT that include a provision to obtain further PIC, and to negotiate more detailed MAT when the commercialisation stage is reached.
- MAT for any subsequent applications and commercialisation must be negotiated on a case-by-case basis, accompanied by information sharing between providers aimed at developing benefit-sharing standards and improving model clauses.
- ILCs must be provided with the technical and commercial support needed to improve their bargaining position in the ABS value chain.
- Monitoring and compliance systems must ensure that users comply with domestic ABS measures of provider countries, and with MAT.

- Shared benefits must be directed towards supporting the sustainable use and conservation of biodiversity, and towards capacity building and technology transfer, scientific and technological development nationally and locally.[499]

Commission on the Forests of Central Africa (COMIFAC)[β]
Within the spectrum of the COMIFAC convergence plan, the 10 COMIFAC countries (Burundi, Cameroon, Congo, Democratic Republic of Congo, Gabon, Guinea Equatorial, Central African Republic, Rwanda, Sao Tome and Principe and Chad) have adopted a common approach for the development and implementation of an ABS policy applicable to all COMIFAC member countries.

The objective of the strategy is that between now and 2015, the Central Africa sub-region will have put in place the institutional, legal and administrative frameworks for the implementation of national ABS measures in member countries. The aim of the strategy is thus to facilitate policy coherence in the sub-region with respect to ABS implementation, and in the long run, to increase the contribution of biological and genetic resources in the GDPs of Central African countries with a view to ameliorating the well-being of local populations.

The Strategy is also anchored in specific objectives, which include:

- Strengthening Capacity building for stakeholders who are involved in the process of ABS implementation;
- Promoting access to, and valorisation of, genetic resources in the sub-region;
- Improving awareness to avoid the misappropriation of genetic resources within the COMIFAC Zone;
- Creating synergies and coordination mechanisms within the COMIFAC region with a view to fostering a common strategy for the management of genetic resources; and
- Devising strategies for the mobilization of resources and sustainable financing of ABS implementation strategies.

Cameroon[α]
Following the lead of the COMIFAC, Cameroon adopted a National Strategy on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising From Their Utilization in August 2012. In this Strategy, Cameroon committed to put in place a national ABS legal and institutional framework. Starting in 2013, Cameroon began preparing a regulation to lay down modalities on access to genetic resources, associated traditional knowledge, and the fair and equitable sharing of benefits arising from their utilization.[500]

Although Cameroon has not ratified the Nagoya Protocol, the Protocol inspired the regulation, which adopts terms from the Nagoya Protocol and the Convention on Biological Diversity and lays down provisions on access and benefit-sharing. The regulation gives definition to certain terms used by the NP and CBD. "Genetic resource" is defined in slightly broader terms than those used in the CBD, as any material from plant, animal, microorganism or other organism that contains functional units of heredity.[501] Indigenous and local communities are also defined separately in the regulation.

[499] Working document cited with the consent of the AU DHRST. Subject to further additions and revisions.
[500] The title of the available French version is « Arrêté fixant les modalités d'accès aux ressources génétiques, aux connaissances traditionnelles associées et de partage juste et équitable des avantages découlant de leur utilisation ».
[501] Genetic resource in the CBD is narrowly defined as "genetic material of actual or potential value".

Since the term "Indigenous peoples" does not yet[502] have a legal definition in Cameroon, the regulation adopts the characteristics of Indigenous peoples found in UNDRIP. According to national legislation, the term "local community" is defined as traditional communities.

The regulation applies to all genetic resources included under article 15 of the CBD. It covers access to plant, animal and micro-organism GR; access to TK over GR held by people or by Cameroonian ILCs; the transfer of GR to third persons, and the results of research associated to these GR for development and or commercialization; obtaining patents on GR and TK; fair and equitable sharing of benefits arising from the utilization of GR and TK; and the creation and functioning of ABS entities.

Cameroonian regulation excludes material governed by instruments other than the Nagoya Protocol, including human genetic material, the exchange of GR between national researchers and traditional doctors that are not used for development and commercialization, and GR used by farmers and breeders.

Access to GR and TK is regulated for non-Cameroonians, Cameroonians living abroad, and any association, corporation, organization, foreign entity not registered in Cameroon. The authority responsible for granting prior informed consent is the Ministry of Environment, after the advice of the National Competent Authority. When ILCs are concerned, their approval, involvement and the establishment of mutually agreed terms are required.

The application for GR or TK comes at a cost. For example, the application for access to GR or TK is Central African Franc (CFA) 100,000 for individuals and CFA 200,000 for corporations.

The authority in charge of sharing benefits is the Ministry of the Environment. Benefit-sharing must be governed by the principle of equity between generations, ILCs that contribute to the conservation of such resources, the owners of TK and the institutions that valorized the resource, and the State of Cameroon. Benefits can be monetary or non-monetary. Check-points for compliance are created by a decision of the Ministry. An internationally recognized certificate is granted by the administration in charge of environment to the appropriate applicant. While waiting for the creation of the NCA, the National Committee on ABS shall fulfill this role.

Ethiopia[β]

Ethiopia issued a Proclamation in 2006,[503] and Regulations in 2009,[504] providing a framework for regulating access to GR and TK. The country also ratified the Nagoya Protocol in 2012 by proclamation.[505] The Proclamation lays down guiding principles for the fair and equitable sharing of the benefits arising from the utilization of community resources and traditional knowledge,[506] and aims to empower ILCs in decision-making processes involving traditional knowledge by establishing clear rights on benefit-sharing arising.[507] The scope of the Proclamation covers genetic resources

[502] The definition is in process in Cameroon.

[503] Ethiopia, *Access to Genetic Resources and Community Knowledge, and Community Rights*, Proclamation No. 482/2006, preamble, online: <http://www.cbd.int/doc/measures/abs/msr-abs-et2-en.pdf> [Proclamation 482/2006].

[504] Ethiopia, Access to Genetic Resources and Community Knowledge, and Community Rights Council of Ministers Regulation No. 169/2009, online: <http://www.abyssinialaw.com/uploads/r169.pdf> [Regulation 169/2009].

[505] Ethiopia, Nagoya Protocol on ABS, Proclamation No. 753/2012, online: <http://chilot.files.wordpress.com/2013/04/proclamation-no-753-2012-nagoya-protocol-on-access-to-genetic-resources-and-the-fair-and-equitable-sharing-of-the-benefits-arising-from-their-utilization-ratification.pdf>.

[506] Proclamation 482/2006, *supra* note 505 at Articles 9 and 10.

[507] *Ibid.* at Art. 9(1).

found in both *in situ* or *ex situ* conditions, community knowledge,[508] and derivatives,[509] but does not apply to customary use or the exchange of genetic resources and community knowledge by and among ILCs, or to the sale or production of biological resources for direct consumption.[510] Ownership of genetic resources is vested in the state,[511] while local communities are vested with ownership over community knowledge.[512]

The Ethiopian Institute of Biodiversity Conservation (IBC), as the competent national authority, is empowered to monitor and ensure compliance with the domestic ABS permit system, which includes the granting of PIC by the Institute for both commercial and non-commercial applications.[513] The IBC has also issued a code of conduct establishing the basic principles for access and utilization of genetic resources and traditional knowledge, including: integrity and good faith, confidentiality, conservation and sustainable use, Prior Informed Consent, Mutually Agreed Terms, and benefit sharing.[514] The provisions of the Code assist in facilitating compliance in conjunction with the use of standard templates and formats that are provided along with the Regulation.[515]

Local communities are recognized as being the beneficiaries of the genetic resources in their locality and of their traditional knowledge.[516] As such they possess the right to regulate access through PIC, the right of refusal based on cultural or socio-economic grounds, an inalienable right to use such resources as is customarily recognized, and a right to share in benefits arising from utilization.[517] In addition to sharing in benefits arising from the use of community knowledge, ILCs also share in half of the benefits accrued by the State for access to GR.[518]

Access applications must be submitted to the register, with the requisite information provided in a standard form, for IBC review. If sufficient grounds are found to allow the application to pass under initial examination, the application is listed for public notice, at the expense of the applicant, in newspapers and public locations. Public notice must include the particulars of the applicant, description of the proposed use and type of genetic material and/or traditional knowledge, with anyone empowered to lodge an objection within 30 days of publication.[519] If the IBC is satisfied, they will provide consent to access and will facilitate the PIC of ILCs.[520] A special-access permit system is also established for domestic research institutions and organizations, to streamline access for the purposes of development and academic research activities by empowering the institution to monitor compliance internally.[521] In addition, access is provided under the Multilateral System of Access, solely for research and breeding purposes, requiring a similar submission under the

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[508] *Ibid.* at Art. 4(1).
[509] *Ibid.* at Art. 2(3): "derivative" means product extracted or developed from biological resource this may include products such as plant varieties, oils, resigns, gums, chemicals and proteins.
[510] *Ibid.* at Art. 4(2).
[511] *Ibid.* at Art. 5(1).
[512] *Ibid.* at Art. 5(2).
[513] *Ibid.* at Art. 12(1-2).
[514] Genetic Resources Transfer and Regulation Directorate, Institute of Biodiversity Conservation**,** *Code of Conduct to Access Genetic Resources and Community Knowledge and Benefit Sharing in Ethiopia* (2012), Art. 6, online: <http://www.ibc.gov.et/wp-content/plugins/download-monitor/download.php?id=95>.
[515] Regulations No 169/2009, *supra* note 506 at Annex.
[516] Proclamation No. 482/2006, *supra* note 505 at Article 6.
[517] *Ibid.* at Articles 7-10; Regulations No 169/2009, *supra* note 506 at Articles 21-24.
[518] Proclamation No. 482/2006, *supra* note 505 at Article 9.
[519] Regulation 169/2009, *supra* note 506 at Art. 3-10.
[520] *Ibid.* at Art. 10(2).
[521] Proclamation 482/2006, *supra* note 505 at Art. 15; Regulation 169/2009, *supra* note 506 at Art. 11-13.

prescribed form, but with the addition of monitoring to ensure that use of the genetic resource is in compliance with the standard material transfer agreement.[522] Lastly, access by foreign applicants requires certification from the Competent National Authority that MAT will be upheld in the transfer jurisdiction.[523]

Kenya[β]

The Environment Management and Co-ordination Act (1999) is Kenya's framework legislation coordinating all environmental management activities in the country.[524] Section 53 of the Act mandates the National Environment Management Authority (NEMA) to "issue guidelines and prescribe measures for the sustainable management and utilisation of genetic resources of Kenya for the benefit of the people of Kenya."[525] Pursuant to these provisions, NEMA issued relevant regulations – the Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations – in 2006.[526]

The scope of Kenya's ABS regulations does not address access to genetic resources within the context of approved research for educational purposes by recognized Kenyan academic and research institutions, transfer between local Kenyan communities for personal use, human genetic resources, or genetic resources regulated by the Kenyan plant breeders' legislation.[527] An access permit is required for access to a genetic resource,[528] which must be based on the prior informed consent of relevant agencies and parties, and must be accompanied by a research certificate issued by the National Council for Science and Technology.[529] Any transfer of genetic resources outside of Kenya must be based on a Material Transfer Agreement.[530] A benefit-sharing agreement must also be established, which is intended to promote the active involvement of domestic institutions, and provides for both monetary and non-monetary benefits.[531] The provision contains an exhaustive list of the types and examples of monetary and non-monetary benefits similar to the one in the adopted in the annex of the Bonn Guidelines, except for some omissions.[532] NEMA is designated as the competent national authority, however multiple other agencies including the wildlife conservation agency and the forestry service are also involved. NEMA has established an inter-agency ABS technical committee to assist in the evaluation of access permit requests.

While established through a participatory and consultative process, certain gaps remain in the regulatory framework governing access to genetic resources and equitable benefit-sharing. Although the law contains specific provisions on benefit-sharing, none of the provisions indicate mandatory terms, or clearly articulate how benefits are to be distributed to local communities (which themselves are not clearly defined). There is also a lack of clarity regarding the procedures to be followed in

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[522] Regulation 169/2009, *supra* note 506 at Art. 14-20.
[523] *Supra,* IBC Code of Conduct, Art 11.
[524] Kenya, Environmental Management and Coordination Act No. 8 (1999), online: <http://faolex.fao.org/docs/pdf/ken41653.pdf> [EMCA].
[525] *Ibid.* at s. 53.
[526] Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations (2006), online: <http://www.wipo.int/wipolex/en/text.jsp?file_id=194558> [EMCR].
[527] *Ibid.* at s. 3.
[528] *Ibid.* at s. 9(1).
[529] *Ibid.* at s. 9(2).
[530] *Ibid.* at s. 18.
[531] *Ibid.* at s. 20(1-2).
[532] CBD, *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization* (2002), Appendix II, online: <http://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf>.

identifying these communities as potential beneficiaries. While the law embodies the concepts of MAT and PIC, there is very little detail as to what the contents of PIC and MAT ought to be. Lastly, the law does not clearly enunciate a demarcation between commercial versus non-commercial research causing potential difficultly in establishing distinctive enforcement mechanisms.

Malawi[β]

The *Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi*[533] were promulgated by the National Research Council of Malawi (NRCM), which is empowered under a 1974 Presidential Decree to coordinate all research activities conducted in Malawi and to ensure that any research project proposed for execution is geared to national development needs and goals. The guidelines aim to ensure that research of Malawi's genetic materials does not lead to loss of biodiversity; to ensure that the exchange of genetic resources and germplasm, and the commercialisation of research results are done in such a way that Malawi benefits economically from whatever is exported; to encourage the establishment of gene banks and genetic gene banks (*in-situ* and *ex-situ*) and the formation of strong linkages with these banks, including the SADC gene-bank; to ensure that research projects involving the exchange of genetic resources and germplasm are effected in a manner that encourages collaboration with foreign researchers; to ensure that expatriate researchers/collectors work closely with competent local researchers to safeguard Malawi's interests; and to ensure that research projects on genetic resources are geared towards Malawi's socio-economic development and that their execution does not lead to fragmentation and duplication of research efforts.

The guidelines apply to foreign scientists and research institutions that plan to conduct research involving the collection of genetic resources; to local scientists and research institutions that plan to collect and export genetic resources for analysis or as part of an exchange programme with a foreign institution; to local scientists and research institutions that are funded by external sources on research projects involving the collection of Malawi's genetic resources; and to Malawi government officials and ports of entry. Applicants may be students, academic or research institutions, non-profit institutions, and commercial public and private institutions. The application must be submitted to the NRCM by the affiliated institution, which means that a natural person cannot apply directly. For local researchers, the guidelines only apply where the local research institution plans to collect and export genetic resources for analysis, or as part of an exchange with a foreign institution. Each application by foreign researchers must include evidence of affiliation to a local and foreign academic or research institution. A non-refundable fee must accompany each application and the fee varies depending on the origin of the institution (foreign or local), and its nature (academic or research, non-profit, or commercial).

The procedure for the approval of research involves several institutions. The certifying institutions, which are designated by the government to control certain sectors of genetic resources, review research proposals prior to their submission to the NRCM. After approval by the NRCM, these certifying institutions will be required to issue a certificate of collection to the applicant. Moreover, all foreign or local researchers wishing to export genetic resources need to obtain an export license from the Minister of Natural Resources and Environmental Affairs. The guidelines also provide for the conclusion of Research and Material Transfer Agreements to define rights and obligations respectively between parties in the collection and use of the genetic resources. These agreements must be provided by the NRCM or any of the certifying institutions, and endorsed by the NRCM.

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[533] *Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi*, online: <http://www.sdnp.org.mw/nrcm/policies/guideline4.htm>.

Therefore, to access and export genetic resources, the applicant must enter into a research and material transfer agreement, and obtain an export licence and a certificate.

Finally, the guidelines contain few provisions on compliance. Affiliating and certifying institutions must verify that duplicate specimens of all collections are deposited with an appropriate designated Malawian research organisation or institution. These institutions are also required to ensure that all research on genetic resources has the necessary approval and certificates, and that PIC has been obtained from the research communities/authorities under whose jurisdiction the desired genetic resources fall, prior to commencement of any research work. Moreover, those who violate these regulations may be punished by fine or imprisonment or both, and may be subject to further prosecution.

The guidelines do not provide detail on ILCs and traditional knowledge, nor on benefit-sharing, which is only mentioned as one of several objectives.

Morocco[β]

Morocco is a centre of biological and cultural diversity, with varied ecosystems and a rich mix of cultural histories and identities.[534] Morocco is a signatory to the NP and has been a party to the CBD since 1995. One of its NBSAP objectives is to develop legislation and institutional capacity building, in addition to the conservation, rational management and sustainable use of biological resources. To this end, Morocco has benefited from the support of the GEF's Project "ID/2328-2716-4B54" for capacity building on the biodiversity clearinghouse mechanism (CHM) and ABS.[535] Morocco subsequently prepared a study on the status of biological diversity, including the legal and regulatory framework, and national capacity assessment. The primary result of this study indicates that there are no legal or administrative measures to adequately govern access to Moroccan GRs.

Despite not having ABS regulations, the country has experience with bioprospecting. Patents have been pursued for inventions based on the Argan tree since 1980. For example, Pierre Fabre holds three valid worldwide patents on their product Argane™, while Cogins S.A. has six patent applications and three active patents, and Ekomaat OOD has a valid Belgium patent.[536] Because the Argan patent applications indicate Morocco as the source country, questions have arisen as to whether an ABS law should require benefit-sharing from new or continuing uses.[537] Furthermore, a recent study indicates that although Argan oil has become the most expensive oil in the world, and the standard of living of local people has improved as a result, the unplanned exploitation of Argan trees poses a serious threat to the country's forest cover.[538]

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[534] Within the country efforts to conserve biological diversity, the country established national gene bank and 10 national parks.

[535] The GEF funded the Project.

[536] Travis J. Lybbert, "Patent Disclosure requirements and Benefit Sharing: A Counterfactual Case of Moroccan Argan" (2007) 64 Ecological Economics 12.

[537] D. Robinson *et al.* refer to these voluntary cases of benefit-sharing as the "corporate social responsibility model." See also: Daniel Robinson and Eric Defrenne, *Argan: A case Study on Access and Benefit Sharing* (Union for Ethical Bio Trade 4th August 2010).

[538] Travis J. Lybbert *et al.* "Booming Market for Moroccan Argan Oil appear to benefit some rural households while threatening the endemic Argan Forest" (2011) 108 (34) Proceedings of the National Academy of Science of the United States of America, online: <www.pnas.org/cgi/doi/10.1073/pnas.1106382108>.

Mozambique[β]

Mozambique adopted its ABS regulation in 2007, the *Regulamento sobre Acesso e Partilha de Benefícios Provenientes de Recursos Genéticos e Conhecimento Tradicional Associado*.[539] The Mozambican Parliament approved the ratification of the Nagoya Protocol on 13 March 2014.[540] The regulation has eight chapters covering general dispositions, institutional attributes, access and transfer, the protection of associated TK, access to technology and technology transfer, benefit-sharing, administrative sanctions, and final dispositions. The objective of the regulation is to establish rules governing access to, and protection of, genetic resources, as well as the associated TK relevant to the conservation and sustainable use of biodiversity, and fair and equitable benefit sharing resulting from their use and exploitation.[541] The rules apply to: (a) access to components of GR in the national territory, the continental shelf and exclusive economic zones for the purposes of scientific research, technological development or bioprospecting; (b) access to TK associated with GR relevant for the conservation of biodiversity, the integrity of natural resources and the use of its components; (c) the fair and equitable sharing of benefits derived from the development of components of GR and associated TK; and (d) access to technology and the transfer of technology for the conservation and use of biodiversity.[542] The dispositions apply to all individuals and enterprises involved in bioprospecting, whether domestic or foreign.[543]

The Ministry for Coordination of Environmental Affairs is the CNA for access and benefit-sharing of GR. In this role, it presides over an Inter-institutional Group on the Management of GR (GIGRG). This group is composed of representatives from the Ministry for the Coordination of Environmental Affairs, the Ministry of Science and Technology, the Ministry of Agriculture, the Ministry of Fisheries, the Ministry of Health, the Ministry of Education and Culture, the Ministry of Tourism, the Ministry of Mineral Resources, and the Ministry of Industry and Commerce. Guest participants may be invited from public and private entities, along with specialists in ABS.[544]

The CNA, in consultation with the GIGRG, is responsible for: (a) granting authorization for access to samples of components of GR existing *in situ*, in the national territory, on the continental shelf, the territorial sea or exclusive economic zone, and associated TK; (b) granting authorization for the shipment of samples of components of GR and associated TK by national institutions, public or private, or foreign institutions; (c) supervising any shipment of samples of components of GR and associated TK; (d) publicizing lists of species for facilitated exchange (information exchange), consistent with international agreements to which the country is signatory; (e) granting special authorization for access to public or private national institutions that carry out research and development activities in biological or similar areas; (f) authorizing the shipment of samples of components of GR for foreign institutions; (g) accrediting a national public or private institution as faithful depositary of representative samples of components of GR to be sent by public or private national or foreign institutions; (h) authorizing access to components of GR and associated TK that contribute to the advancement of knowledge and that are not associated with bioprospecting when a foreign legal entity is involved; (i) concluding or granting contracts for use of GR and benefit-

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[539] Mozambique, *Decreto Nº 19/2007 Aprova o Regulamento sobre Acesso e Partilha de Benefícios Provenientes de Recursos Genéticos e Conhecimento Tradicional Associado.*

[540] See: "Mozambique: Assembly Votes to Ratify Nagoya Protocol", online: <http://allafrica.com/stories/201403140038.html>.

[541] *Decreto Nº 19/2007*, *supra*, Art 2(1).

[542] *Ibid.* at Art. 2(2).

[543] *Ibid.* at Art. 3.

[544] *Ibid.* at Art. 4(1)-(4).

sharing, as well as the terms for transfer of material; (j) periodically producing and disseminating a list of authorizations for access and shipping, terms of material transfers and contracts for use of GR and benefit sharing; and, (k) approving complimentary norms necessary for the implementation of the Regulation.[545] The CNA is also responsible for the creation and maintenance of a database that contains information obtained from the field during the collection of samples of GR, information on associated TK, information on all permits for access to GR and associated TK, information on *ex situ* collections, and terms of material transfer agreements and ABS contracts.[546]

The GIGRG is responsible for: (a) assisting the CNA in taking decisions under the regulations; (b) monitoring the implementation of the terms of material transfer agreements and utilization of GR, and for the sharing of benefits concluded or granted by the National Authority; (c) coordinating the actualization of standards on ABS for GR and associated TK at the national level; (d) ensuring, in cooperation with other competent organizations, the implementation of norms on ABS for GR and associated TK; (e) developing annual technical reports on the status of ABS for GR and associated TK in Mozambique; (f) serving as a vehicle for the exchange of information on ABS on GR, and on associated TK at the national, regional and international level; (g) promoting programs for communication and public awareness on questions related to ABS on GR and associated TK at the national level; (h) proposing technical standards, criteria for authorization of access and shipping, as well as the elaboration of guidelines for ABS contracts and terms of material transfer agreements; and, (i) promoting training programs on ABS on GR and associated TK.[547]

Access to components of GR located *in situ* on the national territory, continental shelf and exclusive economic zone, and to associated traditional knowledge by means of a sample and/or request for information, is only authorized for national institutions, public or private, which carry out research and development activities in biological and similar areas, with prior authorization of its owners.[548]

The person responsible for an expedition to collect GR under the Regulation must furnish the CNA with a declaration listing the material accessed at the end of their activities in the area accessed.[549] The participation of foreign legal persons in the expedition undertaken to collect components of GR *in situ* and/or for access to associated TK is only permitted when undertaken in conjunction with a public national institution, which is responsible for coordinating the activities.[550] When there is a significant public interest, as determined by the CNA or GIGRG, entry to a public area, community area or area on which there is a right of use and enjoyment of land for access to samples of GR does not require prior approval of the owners, but the owners must still benefit from the benefit-sharing obligations of the Regulation.[551] The *ex situ* conservation of samples of components of GR should be undertaken in the national territory and may, in addition, at the discretion of the CNA on the advice of the GIGRG, be held abroad.[552] *Ex situ* collections must be registered with the CNA, but the authority to register collections may be delegated to one or more institutions under the Regulation.[553]

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[545] *Ibid.* at Art. 5(1).
[546] *Ibid.* at Art. 5(2).
[547] *Ibid.* at Art. 6.
[548] *Ibid.* at Art. 7.
[549] *Ibid.* at Art. 8(1).
[550] *Ibid.* at Art. 8(2).
[551] *Ibid.* at Art. 9.
[552] *Ibid.* at Art. 10(1).
[553] *Ibid.* at Art. 10(2)-(3).

The shipment of samples of the components of GR can only be made from materials in *ex situ* conditions, held pursuant to the Regulation, and based on information on the intended use prior to signing a MTA.[554] Whenever there is the prospect of commercial use of the product or process resulting from the use of components of GR, an ABS contract must be signed in advance.[555] The shipment of samples of GR for facilitated interchange under international agreements must be done in accordance with the conditions defined in those agreements.[556]

Authorization for access and shipping requires the prior consent of the local community involved, with the advice of the legal authority; the competent organ, when access takes place in a protected area; the holder of the right to use and enjoyment of the land, when access occurs in an area where these rights exist; or the competent fishing or maritime authority when access takes place in national waters, the continental shelf or the EEZ.[557] The holder of the access permit is responsible for reimbursing the rights-holders in the case of damage or prejudice when these are duly proven.[558] The access permit for species with restricted endemism or those species that are threatened with extinction requires prior authorization from the competent organ.[559] The institution possessing special authorization for access and shipping must forward the prior authorizations to the GIGRG during the period of validity, or they will be treated as cancelled.[560] The terms of material transfer agreements will be based on the model approved by the CNA, in consultation with the GIGRG.[561]

Articles 14-15 of the Regulation address the protection of associated traditional knowledge. Articles 16-18 address access to technology and technology transfer. Articles 19-24 address benefit-sharing. Article 25 lays out administrative sanctions. Articles 26-29 cover IP rights, supervision, destination of royalties, and the adequacy of activities.

South Africa[β]

South Africa uses an ad-hoc approach to govern ABS. The ABS framework is made up of sections of South Africa's Biodiversity Act of 2004,[562] amendments to the Patents Act made in 2005,[563] and the Bioprospecting and Access and Benefit-Sharing Regulations of 2008.[564] Bioprospecting Guidelines were also issued in 2012 for users, providers, and regulators.[565] South Africa ratified the Nagoya Protocol on 10 January 2013 and is undergoing a process of legal reform to bring its laws into compliance.

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[554] *Ibid.* at Art. 11(1).
[555] *Ibid.* at Art. 11(2).
[556] *Ibid.* at Art. 11(3).
[557] *Ibid.* at Art. 12(1).
[558] *Ibid.* at Art. 12(2).
[559] *Ibid.* at Art. 12(3).
[560] *Ibid.* at Art. 12(4).
[561] *Ibid.* at Art. 13.
[562] *National Environmental Management: Biodiversity Act 2004*, Act No.10 2004, online: <http://faolex.fao.org/docs/pdf/saf45083.pdf> [SA Biodiversity Act].
[563] Act No.20 of 2005: Patents Amendment Act, 2005, *Government Gazette* Vol. 486, No. 28319 (9 December 2005), online: <http://www.wipo.int/tk/en/laws/pdf/sa_patent_amend.pdf> [Patents Amendment Act 2005].
[564] *National Environmental Management: Biodiversity Act 2004* (Act No.10 2004) Regulations on Bioprospecting and Access and Benefit Sharing 2008, online: <http://www.wipo.int/wipolex/en/text.jsp?file_id=179663> [ABS Regulations].
[565] *South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework: Guidelines for Providers, Users and Regulators*, (2012), online: <https://www.environment.gov.za/sites/default/files/legislations/bioprospecting_regulatory_framework_guideline.pdf>.

A key objective of the Biodiversity Act is to ensure the fair and equitable sharing of benefits arising from bioprospecting,[566] which is defined as research, development or the application of indigenous biological resources for commercial or industrial use, which leverages traditional knowledge or applications of TK in the use of such resources.[567] In regulating bioprospecting, the Act institutes an ABS regime over bioprospecting, including indigenous biological resources,[568] administered by a Bioprospecting Trust Fund,[569] to provide protection to traditional knowledge as key a contributor to the commercial or industrial application of biodiversity resources, and to ensure that royalties received are equitably dispersed.

To be eligible for a permit for bioprospecting derived from traditional knowledge,[570] or from the traditional use of a biological resource,[571] the applicant must disclose to stakeholders the full nature of the bioprospecting project.[572] The applicant must also gain the prior informed consent of the Indigenous community providing access,[573] and have both a mutual transfer agreement and a benefit-sharing agreement in place.[574] The mutual transfer agreement must identify the particulars of the provider and the recipients of the biological resources,[575] along with the type, area of source, quantity, purpose and present potential uses of the biological resource.[576] Similarly, the benefit-sharing agreement must specify the characteristics of the indigenous biological resources subject to the agreement,[577] the parties to the agreement, the scope of the use of the biological resources, regular review intervals, and the manner and extent to which communities will share in the royalties derived from bioprospecting.[578]

Both respective agreements must be in a standard form,[579] and are of no effect without Ministerial approval.[580] Approval is granted when the Minister is satisfied there has been adequate disclosure to affected stakeholders, and that the benefit-sharing agreement is equitable.[581] The Minister may also seek technical advice on the agreement,[582] or interfere with the contractual terms to ensure that the equitable sharing of benefits occurs.[583] Lastly, the holder of the permit is liable for all mitigation costs to remedy any adverse impact on the environment deriving from the bioprospecting project.[584]

The Patents Amendment Act of 2005 integrates protection for indigenous biological resources and traditional knowledge into existing patent legislation. In addition to incorporating definitions for

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566 SA Biodiversity Act, *supra* note 565 at *Preamble*; Art.2(a)(iii).
567 *Ibid.* at Art. 1.
568 *Ibid.* at Art. 80(1).
569 *Ibid.* at Art. 85(1); ABS Regulations, Sec. 19.
570 SA Biodiversity Act, *supra* note 565 at Art. 82(1)(b)(ii).
571 *Ibid.* at Art. 82(1)(b)(i).
572 ABS Regulations, *supra* note 567 at Sec. 8(2).
573 SA Biodiversity Act, *supra* note 565 at Art. 82(2)(a) and 82(3)(a); ABS Regulations, *supra* note 567 at Sec. 8(1)(d).
574 SA Biodiversity Act, *supra* note 565 at Art. 82(2)(b)(i-ii) and 82(3)(b); ABS Regulations, *supra* note 567 at Sec. 8(1)(c).
575 SA Biodiversity Act, *supra* note 565 at Art. 84(1)(b)(i) and 84(1)(b)(vii).
576 SA Biodiversity Act, *supra* note 565 at Art. 84(1)(b)(ii-vi).
577 *Ibid.* at Art. 83(1)(b)(i-v).
578 *Ibid.* at Art. 83(1) (c-g).
579 ABS Regulations, *supra* note 567 at Annexure 7-8.
580 Biodiversity Act, *supra* note 565 at Art. 83(2) and 84(2).
581 ABS Regulations, *supra* note 567 at Sec. 17(3).
582 *Ibid.* at Sec. 17(3)(b).
583 *Ibid.* at Sec. 17(4); A.F. Myburgh, "Legal Development in the Protection of Plant-Related Traditional Knowledge: An Intellectual Property Lawyer's Perspective of the International and South African Framework," South African Journal of Botany, 77 (2011) 844-849 at 846 [Myburgh].
584 ABS Regulations, *supra* note 567 at Sec. 12(f).

indigenous biological resources and traditional use, the Amendment Act also requires applicants for patents to disclose if the patent is based on traditional knowledge or the use of the biological resources, and to show proper title for access. To demonstrate proper title, as required by the Biodiversity Act, an applicant must have material transfer and benefit-sharing agreements in place. Lastly, the submission of false information in relation to the role of traditional knowledge in the patent, and/or the holding of proper title via the required mutual transfer and benefit-sharing agreements are both grounds for revocation of the patent.

Uganda[β]

The National Environment (Access to Genetic Resources and Benefit-Sharing) Regulations, 2005, were adopted pursuant to sections 44 and 107 of the National Environment Act. The object of the regulations is to: (a) prescribe the procedure for access to genetic resources for scientific research, commercial purposes, bioprospecting, conservation or industrial application; (b) provide for the sharing of benefits derived from genetic resources, and (c) to promote the sustainable management and utilisation of genetic resources, thereby contributing to the conservation of the biological resources of Uganda.

The scope of the regulations is defined in article 4 to include access to genetic resources or parts of genetic resources, whether naturally occurring or naturalised, including genetic resources bred or intended for commercial purposes or for export. The regulations do not apply to certain situations, such as the exchange of genetic resources where the exchange is done by a local community among themselves and for their own consumption, or where the exchange is certified to be only for food, in cases of access to human genetic resources, and in cases of approved research activities intended for educational purposes.

The Uganda National Council for Science (UNCS) is designated as the CNA. Its functions include facilitating the negotiation and conclusion of all accessory and material transfer agreements, including the terms and conditions upon which access is to be granted. It is also responsible for ensuring that these agreements contain sufficient provisions on benefit-sharing, and ensuring that representative samples and specimens of genetic resources collected are deposited in Uganda, and that technology transfer and information exchange in relation to genetic resources is undertaken by the persons accessing the genetic resources.

To access genetic resources, the applicant must obtain a written PIC form, and enter into an accessory agreement with the lead agency, local community or owner. The applicant must also carry out an environmental impact assessment where required, enter into a materials transfer agreement, and pay a fee. The nature of the person who can apply is undefined, but it appears that any individual or corporation can apply, and that foreign applicants do not require a local collaborator.

The regulations provide schedules for PIC, the accessory agreement, and the material transfer agreement. The MTA must clearly state the rights and obligations of parties, guarantee the deposit of duplicates of all specimens of the genetic resources accessed, and require the collector to provide for the sharing of benefits arising from the intellectual property rights accruing from genetic resources. It may also provide for the future application and use of genetic resources, including the sharing of benefits arising from the future application and use of genetic resources.

Moreover, the regulations require that benefits be shared in accordance with the principle of fairness and equity, and on mutually agreed terms. The regulations give examples of benefits, including monetary and non-monetary benefits. They also highlight that the PIC, accessory agreement and

MTA do not entitle any person to access genetic resources; rather, they enable an applicant to proceed with the application for an access permit. Applications must be submitted to the competent authority, which transfers them to the lead agencies that are responsible for the management and regulation of access to genetic resources under the Regulations. A lead agency reviews the application and advises the competent authority, in writing, as to whether consent for access should be granted or not. In so doing, the lead agency must ensure that the rights of local communities are protected, including verifying compliance with consent requirements and ensuring that accessory agreements have been concluded between the applicant and all affected parties.

Several provisions of the regulations are also dedicated to compliance. Indeed, where a collector has violated the regulations, the competent authority may revoke the access permit. Moreover, any person who breaches certain rules of the regulations (such as the obligation to obtain PIC, accessory agreement and MTA), commits an offence and may be liable to a fine or imprisonment, as well as other sentences. Lastly, the permit holder must submit regular status reports to the competent authority and the lead agency on research and development relating to the genetic resources concerned.

G. EUROPE

European Union[α]

The European Union approved the Nagoya Protocol on May 16, 2014 and was an active participant in the negotiations. On 14 April 2014, the European Union Council of Ministers adopted a decision approving the ratification, as well as a regulation that modifies EU legislation to meet the requirements of the Protocol, following adoption by the European Parliament on 11 March 2014.[585] The EU ratification will count as another new ratification for the purposes of the entry into force of the Protocol. However, because the Nagoya Protocol concerns areas of shared competence between the EU and its member states, the EU does not have exclusive jurisdiction to negotiate and ratify all aspects. Thus, the EU ratification does not lead to an automatic ratification by all member states; each of the 28 member states must also individually ratify the Protocol, and not all EU member states will ratify the before July 2014 (in time the Protocol to have its first COP-MOP at CBD COP 12).

The Regulation establishes an implementing framework for the Nagoya Protocol that enhances available opportunities for nature-based research and channels benefits from utilization to poverty eradication, while preventing the illegal acquisition and use of GR or traditional knowledge.[586] It is intended to contribute to the development, maintenance and increasing of trust between parties and stakeholders, particularly ILCs,[587] while securing reliable and equitable access for EU researchers or companies to quality samples.[588]

The Regulation comes into force on the same day as the Nagoya Protocol.[589] Users are granted a one-year transition period, as all due diligence requirements pertaining to access of GR and traditional knowledge come into effect one year following the date that the Nagoya Protocol enters

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585 Maeli Astruc, "EU's Nagoya Protocol Ratification: How It Works" IP-Watch, May 7, 2014.

586 *Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*, *Preamble* sub 8. [EU Regulation]

587 *Ibid.* at Preamble subparagraph 8a.

588 EU Regulation; and *Explanatory Memorandum,* sec 1 at p 4.

589 *Ibid.* at Art. 17(1a).

into force.[590] The Regulation applies to all sovereignly held GR and associated traditional knowledge accessed following the entry into force of the Nagoya Protocol, and the benefits arising from the utilization of their resources.[591] Due diligence must be exercised to determine if the GR and traditional knowledge being utilized were accessed in accordance with provider-country/country of origin access and benefit-sharing legislation or regulations, and whether benefits are being equitably dispersed based on mutually agreed terms.[592] The transfer and utilization of GR and traditional knowledge must be done in accordance with terms established by the parties, if required by applicable legislation or regulatory requirements.[593] Competent authorities need to accept internationally recognized certificates of compliance as evidence that the GR covered were legally accessed and that mutually agreed terms were established regarding use, in satisfaction of the due diligence requirement.[594]

Recognized certificates of compliance are to be requested by users, maintained and transferred to subsequent users along with information pertaining to mutually agreed terms.[595] Where no such certificate is available, users must retain record of: (i) the date and place of access, (ii) a description of the resources utilized (GR/TK), (iii) the source where it was obtained, (iv) any rights and/or obligations associated with access, including benefit-sharing, subsequent applications and commercialization, (v) all permits where applicable, and (vi) all mutually agreed terms, including benefit-sharing.[596] If the information held by the user is insufficient or uncertainty about the legality of access and utilization persist, the user must obtain a new permit for access, and establish mutually agreed terms, or discontinue utilization.[597] Users are also required to keep records of access and benefit-sharing for twenty years following cession of utilization.[598] Where genetic material is obtained from a recognized collection as listed in the Register of Collections within the Union, users are to be considered to have fulfilled the due diligence requirement.[599]

A voluntary register of Trusted Collections is established for the EU,[600] and Member States are tasked with considering the inclusion of collections based on the demonstration of: (i) the application of standardized procedures for exchange of genetic material in line with the Protocol, (ii) all transferred material being accompanied with documentation providing evidence of legal access, in compliance with domestic ABS requirements, (iii) requisite administrative records of all samples, both GR and TK, supplied, (iv) use of unique identifiers, where possible, for samples provided, and (v) use of appropriate monitoring and tracking procedures for exchange of samples.[601] Collections must be regularly verified by national authorities, with remedial actions developed where parts of

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590 *Ibid.* at Art. 17(2).

591 EU Regulation, *supra* note 589 at Art. 2. The temporal scope of the provisions was one of the most critical points in the negotiations. Developing countries wanted the Protocol to apply to existing collections of genetic resources and thus to genetic material acquired prior the adoption of the Protocol and prior to the adoption of the CBD. But the EU and others argued that this would go against legal clarity and certainty. See Gurdial Singh Nijar, *The Nagoya Protocol on Access and Benefit-Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries* (Geneva: South Centre, 2011).

592 EU Regulation, *supra* note 589 at Art. 4(1).

593 *Ibid.* at Art. 4(1a).

594 *Ibid.* at Preamble subparagraph 14.

595 *Ibid.* at Art. 4(2)(a).

596 *Ibid.* at Art. 4(2)(b).

597 *Ibid.* at Art. 4(2b).

598 *Ibid.* at Art. 4(3).

599 *Ibid.* at Art. 4(4).

600 *Ibid.* at Art. 5(1).

601 *Ibid.* at Art. 5(2)-(3).

collections are found to be incompliant. Non-compliant collections must also be reported to the Commission and removed from the register.[602] Member States are required to determine and designate one or more relevant bodies as competent national authority,[603] along with a focal point to liaise with the Secretariat of the CBD regarding matters covered by the Regulation.[604]

When requested, users must declare and provide evidence that they have exercised due diligence I two cases: (1) all recipients of research funding from Member States and the EU that involves the utilization of GR and traditional knowledge;[605] and (2) at the final stage of development of a product developed via the utilization of GR or traditional knowledge (to competent national authorities).[606] National authorities must communicate user compliance to the Clearing House to ensure the exchange of information for monitoring and compliance, with due respect for the sensitivity or confidential nature of the information provided.[607]

The tools and measures leveraged by users to exercise due diligence – particularly in the absence of internationally certified certificates of compliance – are supported through the recognition of best practices and complementary measures in support of sectoral codes of conduct, model contractual clauses and guidelines, with a view to increasing legal certainty and reducing costs.[608] Users may submit procedures, tools or mechanisms specifically developed to facilitate compliance with the obligations for recognition as a best practice.[609] The Commission decides whether to grant recognition as a best practice.[610] Changes made to recognized best practices must be communicated,[611] and best practice status is revocable if evidence shows that usage of the practice resulted in continued cases of non-compliance.[612]An up-to-date register of best practices is to be established by the Commission to provide user guidance.[613]

Competent national authorities in Member States are required to verify compliance with user obligations in provider countries, recognizing that the use of a best practice on the part of the user reduces the risk of non-compliance. Verification is intended to be effective and proportionate, and to dissuade to non-compliance.[614] These checks are to be conducted periodically based on a risk-based plan and with special consideration paid to cases of user non-compliance raised by Member States.[615] Periodic checks must also include the examination of measures taken to comply with due diligence requirements, documentation demonstrating compliance with due diligence, and instances where a user was required to make declarations of compliance, with spot checks as appropriate.[616] Users are obliged to cooperate with the performance of checks, and if shortcomings are detected,

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602 *Ibid.* at Art. 5(4).
603 *Ibid.* at Art. 6(1).
604 *Ibid.* Art. 6(3).
605 *Ibid.* at Art. 7(1).
606 *Ibid.* at Art. 7(2).
607 *Ibid.* at Art. 7(3)-(3a).
608 *Ibid.* at Art. 8 and 14 (2).
609 *Ibid.* at Art. 8(1-2).
610 *Ibid.* at Art. 8 (2)
611 *Ibid.* at Art. 8(3).
612 *Ibid.* at Art. 8(4-5).
613 *Ibid.* at Art. 8(6).
614 *Ibid.* at Art. 9(1-1a).
615 *Ibid.* at Art. 9(3).
616 *Ibid.* at Art. 9(4).

the competent national authority must issue remedial measures. Failure to comply will result in potential additional interim measures.[617]

Domestic penalties for non-compliance with user obligations should be effective, proportionate, and dissuade non-compliance.[618] Additionally, Member States must: (i) promote and encourage capacity building, (ii) encourage the establishment of sectional guidelines, best practices, codes of conduct and model contractual clauses to benefit university institutions and non-commercial researchers, (iii) promote the application of cost effective tools and mechanisms for communication, compliance and monitoring of GR and traditional knowledge, (iv) provide technical support to users, particularly university institutions and non-commercial researchers, to facilitate compliance, (v) encourage both users and providers to directly benefit from use of acquired resources, and (vi) promote measures which support collections contributing to the conservation of biodiversity.[619]

Belgium[β]

Belgium has adopted national legislation to include disclosure of origin in (Belgian) applications for patents where the subject matter of the application makes use of GR in its development. Belgium has amended its patent law of 28 March 1984 (BPL) in function of the implementation of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. The requirement (Article 15, § 1, 6 BPL) "that patent applications must contain the geographic source of the plant or animal material, if known, that formed the basis for the development of the invention" is a formal requirement that aims to contribute to transparency. The standard form for national patent applications requires applicants to declare whether use has been made of GR in the sense of Article 15, § 1, 6 BPL. The applicant is further invited to provide information on the geographical source, or permitted to declare that he is not aware of it. The patent office will not investigate the geographic source of the material. The information is available in the public part of the patent file.

Bulgaria[β]

Access to GR is regulated in Bulgaria's 2002 *Biodiversity Law*,[620] which establishes that "GR may be provided for use to other States on the basis of advance agreement in writing on the terms and manner of sharing the benefits arising from such transfer under mutually advantageous terms" and, further, that the terms and a procedure for provision of access to GR will be established by a regulation adopted by the Council of Ministers. According to this law, GR may be provided for free where the resources are intended for non-commercial purposes such as scientific research, education, conservation of biological diversity, or public health.

Denmark[αβ]

The Danish requirement for proof of origin is provided in Chapter 2, 2(4), of the *Danish Order on Patents and Supplementary Protection Certificates*, Order No. 93 of 29 January 2009, which implements Directive 98/44, Recital 27. Denmark has developed draft legislation to implement the Nagoya Protocol,[621] but this will likely need to be reconsidered in light of the forthcoming EU Regulation on ABS.

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[617] *Ibid.* at Art. 9(6-7).
[618] *Ibid.* at Art. 11(1-2).
[619] *Ibid.* at Art. 14.
[620] Law on Biological Diversity, State Gazette No. 77/9.08.2002.
[621] Danish Ministry of the Environment, "Implementing the Nagoya Protocol in Denmark" (PowerPoint Presentation), online: <http://www.cbd.int/abs/side-events/cop-11/denmark-en.pdf>.

Germany[β]
According to sec. 34a of the German Patent Code, a patent application for an invention based on plant or animal biological material should contain information on the geographical origin of such material, if the origin is known to the applicant. This provision is without prejudice to the examination of patent applications and the validity of rights arising from the patents. It was introduced into German patent law in the course of the implementation of the EC Directive 98/44. Turning Recital 27 into German law was intended to enhance transparency and not to predetermine any possible outcome of the international negotiations on the issue of disclosure of origin in patent applications.

Croatia[β]
Croatia regulates access to genetic material in a general way in the Nature Protection Act of 2003, without any specific reference to benefit-sharing.[622]

Malta[β]
Malta has developed legislation dealing with ABS. The Flora, Fauna and Natural Habitats Protection Regulations No. 311 of 2006 contain a section on access to GR, which requires PIC, MAT and benefit-sharing, and provides some exclusions.[623]

Portugal[β]
Portugal has adopted a registration regime for the protection of indigenous plant material of current or potential interest to agrarian, agroforestry and landscape activities,[624] although this regime excludes varieties protected by intellectual property rights. An application for registration may be filed by any entity representing the interests of the geographical area in which the local variety is most widely found, or where the spontaneously occurring indigenous material displays the greatest genetic variability. The entity is responsible for the *in situ* maintenance of the plant material. Once the specific plant material has been registered, it will be included in the National Directory of Registration of Plant Genetic Resources. Traditional knowledge may also be registered in order to prevent reproduction, commercial or industrial use. Accessing the germplasm of plant material and using plants or parts thereof for industrial or biotechnological purposes requires prior authorization from the Technical Council of the Ministry of Agriculture, Rural Development and Fisheries on Agrarian Genetic Resources, Fisheries and Aquaculture. The entity owning the registration of the plant material has the right to be consulted prior to access, and to share in any benefits resulting from the use of the registered variety.

Spain[β]
Spain signed the Nagoya Protocol on the 21 July 2011. The Natural Heritage and Biodiversity Law[625] provides a general article enabling Spain to further develop detailed ABS regulations to implement the CBD and the FAO International Treaty.[626] A Royal Decree (Decreto Real) will lay down the terms and conditions for access including PIC and MAT. The power to give consent and negotiate

[622] See Nature Protection Act of 2003, arts. 89-91.
[623] See Part VIII of the Regulations.
[624] Decreto Lei Nº 118/2002, DR 93, I-A Série de 2002.04.20, Conselho de Ministros .*Estabelece o regime jurídico do registo, conservação, salvaguarda legal e transferência do material vegetal autóctone com interesse para a actividade de agrária, agro-florestal e paisagística.*
[625] Ley No. 42 de 2007, *Patrimonio Natural y la Biodiversidad*
[626] See Article 68.

terms corresponds to the State government where GR or *ex situ* conservation institutions are located.[627]

Sweden[β]

Patent applications in Sweden include a disclosure requirement. If an invention relates to biological material from animals or plants, a patent application should include information on the geographical origin of the material, and if the origin is not known, this should be indicated. The absence of information regarding the origin of biological material is without prejudice to the processing of patent applications or to the validity of rights arising from granted patents.[628] This demand is unsanctioned and does not affect the examination of patent applications or the validity of the rights conferred with a granted patent.[629] There is no particular procedure at the Swedish Patent and Registration Office, nor is a notification sent to a provider of resources, since disclosure and compliance are not actively sought during the examination of patent applications. As a consequence, no figures regarding the exact number of applications can be presented. All patent applications are published 18 months after the filing, thus enabling third parties to search for biological material subject to benefit-sharing agreements. Government bill 2003/04:55 *Limits on Gene*[630] states that the object of this regulation is to facilitate the monitoring of countries providing GR regulations and contracts regarding access to and sharing of benefits from GR.

United Kingdom[β]

The UK signed the Nagoya Protocol on 23 June 2011, and has established a Biodiversity Action Plan,[631] as well as the 2011-2020 Biodiversity Strategy.[632] In June 2011, the UK government published its White Paper, "The Natural Choice – Securing the Value of Nature", responding to the commitments made at Nagoya.[633] At present there is no CNA because PIC from the Government is not required in the UK, but a Focal Point has been established within the Department for Environment, Food and Rural Affairs (DEFRA).[634] Specific legislation on ABS does not yet exist, but research is underway to determine implementation options, which may lead to a more coordinated approach, as existing rules are found in various areas of domestic law.[635]

Permission to access genetic resources in the UK must be obtained from the owner of the resources (including those in *ex situ* collections) and any holder of IPR on the resources. For *in situ* access, this

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[627] Recursos genéticos en el CDB, online: <http://www.magrama.gob.es/es/biodiversidad/temas/recursos-geneticos/recursos-geneticos-en-el-CBD/>.

[628] Swedish Patents Decree (1967:838), Section 5a.

[629] Certifying untruthful information can be a crime, penalized under the Swedish Penal Act Chapter 15, Section 11. However, withholding information in a patent application is not a criminal act in Sweden. This means that if the applicant leaves out information on geographical origin of a biological material he/she cannot be penalized.

[630] Government bill 2003/04:55 *Limits on Gene Patents etc. - Implementation of Directive 98/44/EC on the Legal Protection of Biotechnological Invention* at 134.

[631] Information on the Biodiversity Action Plan, online: <http://jncc.defra.gov.uk/page-5155>.

[632] DEFRA Report, "*Biodiversity 2020: A Strategy for England's Wildlife and Ecosystem Services*" (2011), online: <https://www.cbd.int/doc/world/gb/gb-nbsap-v3-en.pdf>.

[633] DEFRA, "*The Natural Choice – Securing the Value of Nature*" (2011) at 60, online: <http://www.defra.gov.uk/environment/natural/whitepaper/>.

[634] Information on the Focal Point, online: <http://www.defra.gov.uk/environment/natural/biodiversity/internationally/access-genetic-resources/>. Personal communication with Julian Jackson of DEFRA.

[635] DEFRA, "*Access and Benefit Sharing: a Summary of Aspects of UK Law Touching on Access and Benefit Sharing*" (2010), online: <http://archive.defra.gov.uk/environment/biodiversity/geneticresources/documents/access-legal.pdf>. Personal communication with Julian Jackson of DEFRA.

includes the owner of the land upon which the resources are found. The collection of specimens is subject to the law of trespass, and specific plants and animals are legally protected from picking, uprooting, destruction, or sale under the Wildlife and Countryside Act of 1981. Licenses to obtain such resources for scientific or educational purpose can be requested from Natural England or the Countryside Council for Wales.

In 2005, a review of the implementation of ABS arrangements in the UK was concluded. Its recommendations included considering the development of a specific ABS policy to ensure a consistent approach for the overseas territories, and creating a wider stakeholder network.[636] The UK strongly encourages the use of the voluntary Bonn Guidelines by its stakeholders, and a number of institutions have developed best practice documents on ABS based on the Bonn Guidelines. Furthermore, the UK endorses the European Community initiative to the World Intellectual Property Organization, which proposes to make disclosure of origin a formal condition of patentability.

Implementation of the CBD and the Nagoya Protocol is led by DEFRA and supported by the Royal Botanic Gardens, Kew (RBG), which hosts one of the largest plant collections worldwide. In March 2001, RBG endorsed the "Principles on Access to Genetic Resources and Benefit-Sharing", developed by 28 botanic gardens and herbaria from 21 countries worldwide, in a project managed by Kew and funded by the Department for International Development.[637] The voluntary principles, in line with the CBD and the Bonn Guidelines, provide the basis for the ABS policies of individual institutions. Additionally, the RBG has developed a "Policy on Access to Genetic Resources and Benefit-Sharing"[638] and an "Access and Benefit-Sharing Bibliography."[639] The RBG has also produced a pilot study on preparing national ABS strategies[640] and it runs training modules on the practical implementation of ABS in UK and internationally.

Norway[ß]

Norway ratified the Nagoya Protocol on October 1, 2013. The 2009 Nature Diversity Act is the key legislation for conservation of biological diversity and GR in Norway, and contains a number of provisions pertinent to ABS.[641] Chapter II contains the general substantive provisions of the Act, including provisions on sustainable use, management objectives for maintaining the diversity of habitat types and ecosystems,[642] management objectives for species,[643] general duty of care,[644]

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636 F. Latorre García, "*Review of the Experience of Implementation by UK Stakeholders of Access and Benefit Sharing Arrangements under the Convention on Biological Diversity*" (DEFRA, 2005).

637 More information on the "*Principles on Access to Genetic Resources and Benefit-Sharing*" is available online: <http://www.kew.org/conservation/principles.html>.

638 Royal Botanic Gardens, Kew, "Policy on Access to Genetic Resources and Benefit-Sharing", online: <http://www.kew.org/conservation/docs/ABSPolicy.pdf>.

639 C. Williams, "*Access and Benefit-Sharing Bibliography*" (Royal Botanic Gardens, Kew, 2008), online: <http://www.kew.org/conservation/access-benefit.pdf>.

640 K. ten Kate and A. Wells, "*Preparing a national strategy on access to genetic resources and benefit-sharing"*, Pilot Study for the UNDP/UNEP/GEF Biodiversity Planning Support Programme, (Royal Botanic Gardens, Kew, 2000), online: <http://teebforbusiness.earthmind.net/files/Preparing_a_National_Strategy_on_Access_to_Genetic_Resources_and_Benefit-Sharing.pdf>.

641 Norway, *Act relating to the management of biological, geological and landscape diversity,* (2009), online: <http://www.wipo.int/wipolex/en/text.jsp?file_id=179529> [Nature Diversity Act].

642 *Ibid.* at s. 4.

643 *Ibid.* at s. 5.

644 *Ibid.* at s. 6.

principles for official decision making,[645] the knowledge base for decision making,[646] the precautionary principle,[647] the ecosystem approach,[648] the users pay principle,[649] environmentally sound techniques and methods of operation,[650] and other important public interests including Saami (indigenous) interests.[651]

Chapter VII of the Act regulates access to genetic material, which is defined as "genes or other hereditary material in any biological material that can be transferred to other organisms with or without the help of technology, except human genetic material."[652] Genetic material obtained from the natural environment is a common resource belonging to Norwegian society as whole, and is managed by the State. The resource must be utilization for the greatest possible benefit to the environment and the human population, both domestically and internationally, ensuring that appropriate measures for benefit-sharing are established to safeguard the interests of Indigenous peoples and local communities.[653]

The State may determine that the collection of biological material requires a permit from the Ministry. If a collection permit has been granted, no new permit is required for subsequent utilization, but the conditions for the permit apply to any person that subsequently acquires material or results arising from the collection. Regardless, the owner always retains the right to deny access on other grounds: (a) to the biological material, or (b) to the land from which the material is obtained. Regulations can be put in place outlining the information that the application must contain, including for the use of the traditional knowledge of Indigenous peoples or local communities. Further regulatory provisions may include requiring that any benefits arising from the utilization of genetic material collected domestically accrue to the State, and stating how the interest of landowners and ILCs can be reasonably safeguarded. Conditions may also be set for the further utilization of material to ensure the promotion of sustainable use and the conservation of genetic resources.[654] Collections from the natural environment fall within the gambit of the Act, but collection for use strictly in public collections and for the use of breeding and cultivation in agriculture or forestry do not require a permit.[655]

The provisions on access to genetic material apply both on land and in the sea. In the sea, the Nature Diversity Act works in conjunction with the Marine Resources Act, 2009. Both Acts contain substantively similar provisions requiring a permit for the harvesting of biological material, and the equitable sharing of benefits arising from utilization.[656] Reforms are ongoing to provide for a singular application process through the harmonized application of these instruments.[657]

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[645] *Ibid.* at s. 7.
[646] *Ibid.* at s. 8.
[647] *Ibid.* at s. 9.
[648] *Ibid.* at s. 10.
[649] *Ibid.* at s. 11.
[650] *Ibid.* at s. 12.
[651] *Ibid.* at s. 14.
[652] *Ibid.* at s. 3(f).
[653] *Ibid.* at s. 57.
[654] Nature Diversity Act, *supra* note 644 at Sec. 58.
[655] *Ibid.*
[656] Norway, Marine Resources Act (2009), Sec 7, 9-10, 24, online: <http://www.regjeringen.no/upload/FKD/Vedlegg/Diverse/2010/MarineResourcesAct.pdf>.
[657] Norwegian Ministry of Environment, "Summary of Proposition No. 52 (2008-2009) to the Storting concerning an Act relating to the management of biological, geological and landscape diversity (Nature Diversity Act)", at 14, online:

Specific provisions are also established relating to public collections of genetic material, including the obligation of any person that receives genetic material derived from a public collection to refrain, domestically or internationally, from claiming intellectual property or other rights to the material that would hinder its use for food and agricultural purposes.[658] Any person is able to invoke conditions under this section empowering the competent national authority to pursue legal action against any party aiming to enforce IP rights in contravention of the Act. The system further aims to support the implementation the Multilateral System under the ITPGRFA by ensuring that the standard conditions laid down under the agreement apply.[659]

Genetic material obtained from another country but utilized in Norway for both commercial and non-commercial purposes requires accompanying information regarding the provider country, and the country of origin, if these differ. Under these user measures, if domestic law in either the provider country or the country of origin requires consent for the collection of biological material, it must be accompanied by information showing that such consent has been obtained and that access was obtained legally. If information under this paragraph is not known, this must be stated. Information pertaining to the use of the TK of ILCs must also be included within the disclosure, if so prescribed by regulation.[660] If the material is covered under the ITPGRFA, it must require a Standard Material Transfer Agreement (SMTA),[661] with further regulations providing clarification on the implementation of the ITPGRFA possible.[662]

The Patents Act has a number of provisions relevant to ABS. Patent applications must provide a disclosure of the provider and country of origin of any biological material and traditional knowledge, and must show that prior informed consent was obtained for access and for the equitable sharing of benefits.[663] The Norwegian Plant Variety Act also contains a similar provision.[664] It defines "biological material" as material that contains genetic information, and can reproduce itself or be reproduced in a biological system.[665] However, the duty to disclose does not apply to biological material derived from the human body. The provisions on human genetic material also do not apply to international applications.[666]

For biological material, the duty to disclose information applies even where the inventor has altered the structure of the received material. If access to biological material has been provided pursuant to Article 12.2 and Article 12.3 of the ITPGRFA, a copy of the standard material transfer agreement (SMTA) stipulated in Article 12.4 must be enclosed with the patent application, rather than the aforementioned information. Breach of the duty to disclose is subject to penalty in accordance with s. 166 of the General Civil Penal Code.[667] Nevertheless, the duty to disclose information is without

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<http://www.regjeringen.no/pages/2265991/PDFS/OTP200820090052000EN_PDFS.pdf> [Summary of Proposition No. 52].

[658] Nature Diversity Act, *supra* note 644 at Sec. 59 (third paragraph).

[659] *Ibid.* at Sec. 59.

[660] *Ibid.* at Sec. 60.

[661] *Ibid.*

[662] *Ibid.* at Sec. 61.

[663] *Patents Act* (as amended 2013), Art. 8b, online: <http://www.patentstyret.no/en/For-Experts/Patents-Expert/Legal-texts/The-Norwegian-Patents-Act/> [Norway Patents Act].

[664] Plant Variety Act, Act No. 32 (1993), Sec 4, online: <http://www.wipo.int/wipolex/en/text.jsp?file_id=129013>.

[665] Norway Patents Act, *supra* note 666 at Art. 1(3).

[666] *Ibid.* at Art. 33(2).

[667] *Ibid.* at Art. 8b.

prejudice to the processing of patent applications or the validity of rights arising from granted patents.[668]

Switzerland[α][β]

To promote the legal use of GR under the CBD, Switzerland amended its Patent Law in 2008, responding to the increased usage of GR and TK in various commercial and non-commercial sectors. The amendment requires disclosure of the source of genetic material and/or TK used as the source for a patent.[669] The generic term "source" should be understood in its broadest sense, covering any type of provenance or origin, including: national governments and their authorities; the geographical origin; the Multilateral System on ABS of the FAO International Treaty; individuals and corporations; Indigenous and local communities; *ex situ* collections; scientific publications and books; and databases.[670] Patent applicants must declare the source of GR and TK, in particular the provider country, country of origin and/or ILCs, if they have the information at hand.[671] The Act requires only the declaration of information readily available to the applicant, and if the source is not known to either the applicant or the inventor, the applicant must confirm this in writing.[672] International patent applications must submit a declaration of the source to the Swiss Federal Institute of Intellectual Property within 30 months from the filing date.[673] Failure to fulfill this requirement can prevent the granting of the patent, if the defects are not corrected within a certain timeframe,[674] and an intentionally false declaration of the source may result in fines (up to 100,000 Swiss Francs - CHF). The judge may also order publication of the ruling.[675] Wrongful declaration of source is an offense to be prosecuted *ex officio*.

As Switzerland is in the process of ratifying the Nagoya Protocol, amendments have been made to the *Federal Act on the Protection of Nature and Cultural Heritage* (NCHA) to implement certain provisions of the Protocol.[676] The NCHA contains provisions protecting domestic flora and fauna, biodiversity and natural habitats, and regulates some aspects of use, such as the sustainable management of regional natural parks,[677] and the commercial use of plants and animals.[678] Users or beneficiaries of GR and/or associated TK that originated from a Party to the Protocol must apply due diligence appropriate to the circumstances to ensure that the resources have been accessed lawfully, and that MAT for the fair and equitable sharing of benefits have been established.[679] Compliance with the

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[668] *Civil Penal Code*, Sec 166: lays out fines or imprisonment for up to two years for providing false testimony in court, before a notary public, in any statement presented to a court as a party to or legal representative in a case, orally or in writing to any public authority as a witness in a case, or where the testimony is intended to serve as proof. The same penalty applies for any person who assists in or is accessory to false testimony.

[669] Swiss Confederation, *Federal Act on Patents for Inventions* (2008) at Art. 49(a); see also Art 59(2), 59(a)(3)(b), 81(a), and 138 letter b., online: <http://www.admin.ch/opc/en/classified-compilation/19540108/index.html> [Patents Act 2008].

[670] See "Policies, Measures and Experiences regarding intellectual property and genetic resources: Submission by Switzerland", UN Doc. WIPO/GRTK/IC/16/INF/14, February, 2010.

[671] Patents Act 2008, *supra* note 673 at Art. 49(a)(1).

[672] *Ibid.* at Art. 49(a)(2).

[673] *Ibid.* at Art. 138.

[674] *Ibid.* at Art. 59A(2).

[675] *Ibid.* at Art 81(a).

[676] Swiss Confederation, *Federal Act on the Protection of Nature and Cultural Heritage* (*Draft Amendments*) October 2013, online: <http://www.env.go.jp/nature/biodic/abs/conf/conf01-03/ref03_1.pdf> [Draft NCHA].

[677] Swiss Confederation, Federal Act on the Protection of Nature and Cultural Heritage October 2013, Art. 23(g), online: <http://www.admin.ch/ch/e/rs/4/451.en.pdf> [NCHA].

[678] *Ibid.* at Art. 19.

[679] Draft NCHA, *supra* note 680 at Art. 23(n), 23(p).

due diligence requirement must demonstrated to the FOEN before market authorisation has been obtained or, if such authorisation is not required, before the commercialisation of products developed on the basis of utilised GR.[680] If GR are sourced domestically, the Federal Council is empowered to make access authorization subject to an ABS agreement.[681] In cases of either intentional or negligent violation of the due diligence notification requirements, criminal measures may be applied with a fine of up to 100,000 CHF. The judge may also order publication of the judgment.[682] If the due diligence requirement is not complied with, the user must ensure that it is fulfilled subsequently, or must renounce use and benefit of the GR concerned. The government may take appropriate administrative measures in this regard.

3. TRENDS, CHALLENGES AND OPPORTUNITIES IN IMPLEMENTATION

A. COMPARISON OF PRE-EXISTING LEGISLATION WITH CORE OBLIGATIONS

Access to Genetic Resources

The Protocol obliges provider countries, if they decide to establish ABS measures at the national level, to meet basic criteria, including: (1) legal certainty, clarity and transparency; (2) fair and non-arbitrary rules and procedures; and (3) clear rules and procedures for PIC and MAT.

Legal Certainty, Clarity and Transparency of Domestic Requirements

Most ABS regulations provide for legal certainty, clarity and transparency of domestic requirements. Those regulations are written in a clear and simple manner. However, in some cases, difficulties arise in a country's institutional arrangements due to a lack of internal coordination. The procedure for obtaining a permit is generally precisely described, as well as the criteria that applicants must fulfil, including the potential restrictions and limitations on obtaining genetic resources. The requirements for PIC and benefit-sharing agreements are also clearly expressed.

Fair and Non-Arbitrary Rules and Procedures on Access

Most countries provide for non-arbitrary rules and procedures for accessing genetic resources. Generally, the applicant can either be local or foreign person, but natural persons are often required to be affiliated to an institution or corporation. In some cases, foreign applicants must be affiliated with, or represented by, a local person (for example, in Costa Rica), or affiliated with a national research institution, at least for some types of ABS applications (for example, in Brazil, the Andean Community, and Venezuela) or certain national bodies are excluded from the scope of the ABS measures, such as educational and training organizations (Sarawak).

For example, South Africa's ABS regulations require that the applicant for a permit be either a corporation registered under South African law, or a natural person who is a citizen or a permanent resident of South Africa. If the applicant is a foreign natural or corporation, they must apply jointly with a South African corporation or citizen/permanent resident. Therefore, foreign individuals, corporations or institutions cannot apply for a permit alone. Similar provisions are found in multiple jurisdictions. The Philippines put in place a reduced fee structure for access by domestic students in fulfillment of academic requirements at a local institution (pegged at 3% of the prescribed fee).[683]

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[680] *Ibid.* at Art. 23(o)(1).
[681] *Ibid.* at Art. 23(q).
[682] *Ibid.* at Art. 24(a), para. 2.
[683] Philippines, Administrative Order No. 1, Series of 2005, Sec 15.4.

In Costa Rica, if the applicant lives in a foreign country, he or she must assign a legal representative who is a resident of Costa Rica. India also has a differential procedure to handle foreign applications, as does the Andean Community, Brazil and others. Some countries like India have created a separate procedure depending on nationality, or if the materials accessed or research results will be sent abroad.

Moreover, most ABS regulations require that access should be approved or refused by a decision in writing by the CNA. In some cases, two CNA can exist – one granting access to genetic resources for commercial purposes (or when TK is involved), and the other dealing with access for non-commercial purpose or with export permits (for example, in Brazil), or for different types of genetic resources (such as Peru). In most countries, the CNA must process applications and notify applicants of its decision within a reasonable period of time (between 15 and 60 days depending on the legislation; in practice timelines are not always strictly followed). If the CNA rejects the application, the decision must give reasons for the refusal and the applicant should have the opportunity to appeal this decision. Furthermore, several jurisdictions require the applicant to pay a fee to obtain a permit for accessing to genetic resources (e.g. Kenya, South Africa, Sarawak, and the OAU Model Legislation), and this fee may vary depending on the origin (foreign or local), and the nature (research institution, non-profit organization, company) of the applicant. Some ABS regulations, including Norway's Nature Diversity Act, do not provide information on reasonable time periods or fees for the permit.

Finally, a few countries have addressed the issue of transboundary GR or associated TK, especially Peru, the Andean Community and the Central American Protocol.

Clear Rules and Procedures for PIC and MAT

Most ABS regulations provide for PIC and benefit-sharing agreements between the applicant and the provider. South African regulations also provide for the establishment of a benefit-sharing agreement between the applicant and affected Indigenous communities. Other countries have similar provisions requiring the applicant to sign a contract (sometimes called an accessory contract) with the provider of the genetic resources or associated TK (for example, in the case of Panama, Venezuela, Colombia, Peru, Brazil, and Costa Rica).

While the procedure to obtain a permit is generally clearly described, the procedures to obtain PIC and MAT are generally not, especially when PIC and MAT are also required from other stakeholders (such as ILC). For example, in Kenya, very little detail is provided regarding what the content of PIC and MAT should be. Some regulations are more precise, however. For example, Costa Rica's legislation describes the content of PIC and points out that applicants must meet with representatives of the place of access and with the ILC in order to discuss the meaning and implications of access to genetic resources, and the terms of the protection of TK. The Costa Rican regulation also describes what the MAT should contain, and provides for the elaboration of a model contract by the TO of the CONAGEBIO. Uganda's regulations also provide schedules for PIC, materials transfer agreements, and access permits. Australia has also developed more detailed requirements on the process to obtain PIC and establishing MAT in its legislation.

Fair and Equitable Benefit-Sharing Resulting from Utilization

Most ABS regulations provide for the establishment of a benefit-sharing agreement between the applicant and one or several providers, as well as requiring proof that benefit-sharing has been established with relevant providers (for example, in India). The applicant can enter into this agreement with a state agency, ILCs or other owners. Sometimes more than one contract is

necessary (one with the State Agency and one with the provider of genetic resources or associated TK). Benefit-sharing mechanisms also exist when TK is accessed, as well as in the case of genetic resources located on the land or territories of ILCs.

Before the CNA approves an access permit, it must be satisfied that a benefit-sharing agreement has been established and that the agreement is fair and equitable to all parties. A large number of ABS regulations refer to monetary and non-monetary benefits and some list examples (e.g. Kenya, Bhutan, and India). South Africa established a mechanism to manage the monetary benefits, so that all money due to stakeholders in terms of any benefit-sharing agreement must be paid into the Bioprospecting Trust Fund. India has taken a similar approach. Some countries also provide that some benefits should be directed to conservation (e.g. Australia, Costa Rica)

Traditional Knowledge Associated with Genetic Resources

Safeguarding or protecting the interests of ILCs over their knowledge and practices is often one of the objectives of ABS legislation. The Andean Community's common regime, as well as Peru and Brazil's regulations also recognize and protect the rights of Indigenous peoples with respect to their innovations, practices and knowledge associated with genetic resources. In some countries, specific legislation exists to guarantee the rights of Indigenous peoples over their TK or genetic resources, in addition to broader ABS measures (e.g. Venezuela, Panama, Peru, and the Philippines).

Most ABS legislation requires the applicant to obtain the PIC of local communities for access to genetic resources on land that is owned or managed by local communities having an established right to grant access to those resources. According to the ASEAN Framework Agreement, even if PIC is only given by the State/ State agency, the PIC process must provide for the active involvement of local communities, and must respect the customary laws, practices and protocols of local communities. However, very few laws set out procedures for obtaining the PIC of ILC. Costa Rica's legislation nevertheless describes the content of PIC and stipulates that an applicant must meet with representatives of the place of access and with ILCs in order to discuss the meaning and implications of access to genetic resources, and the terms of the protection of traditional knowledge.

According to most ABS legislations, affected ILC must also be involved in the negotiation of benefit-sharing, including by entering into a benefit-sharing agreement with the applicant. Australia has developed model contracts as a guide to assist parties in establishing such agreements. The model contract must include a copy of the agreement regarding the use of knowledge if any indigenous people's knowledge is to be used. Costa Rica, the Andean Community and Peru also have developed some model contracts. However, very few other countries have developed model contractual clauses for MAT. In some legislation, such as in Kenya, none or very few provisions clearly determine how benefits are to be distributed to ILCs. Specific recognition of customary law or community protocols is provided indirectly in some ABS systems, but there is a lack of detailed guidance on these issues.

Compliance with Provider Legislation and with PIC/MAT

Most regulations require the CNA to ensure that PIC has been obtained and that MAT has been regularly established before granting access to genetic resources. The CNA must also be satisfied that the benefit-sharing agreement is fair and equitable to all parties. For example, in Australia, the minister must consider whether the access provider had adequate knowledge of the ABS regulations and was given adequate time to negotiate the benefit-sharing agreement. In Peru, ABS regulations create a monitoring mechanism in order to ensure the fair and equitable distribution of benefits.

Almost all of the regulations reviewed in this study provide for enforcement mechanisms and sanctions in case of non-compliance with their provisions. Bioprospecting or exporting biological resources without a permit is generally considered an offence, which can be subject to a fine or even imprisonment. Administrative sanctions, cancellation or revocation of the permit, and the seizure of samples are also often foreseen. Furthermore, some regulations establish monitoring mechanisms (inspections *in situ*, registers, co-operation mechanisms between authorities and the applicant), and an obligation for the user to submit periodical progress reports.

Not all the ABS measures include a provision recognizing the right to access to justice in cases of breach of the contractual obligations (between the applicant and the provider), but this legal recourse is usually found in other kinds of legislation in force in the country (such as civil codes). However, there are very few examples of legislation that provides for co-operation in cases of alleged violations of another contracting party's requirements, or that encourage the adoption of contractual provisions on dispute settlement in MAT (except in some model contracts, such as in the case of Australia and the Andean Community). Some countries require a certificate of legal provenance (which, in practice, requires PIC and MAT), while others require more general information on the source and origin of the GR (or the associated TK in some cases like Norway), which could be seen as a collection of information regarding the utilization of GR (through an innovation for which a patent is sought).

In some countries, there are check points for compliance; especially located in patent or IP offices. In most developing countries, the patent office (or the plant variety protection office in the case of Costa Rica and Ecuador) must receive information and sometimes also a copy of the contract, the ABS permit, or a certificate of compliance, but just for GR accessed in the country, not in foreign jurisdictions. This is the situation of all Latin American measures, as well as in India, Bhutan, and most of the African countries. Several developed countries (especially in their IP legislation) also provide for the "disclosure of origin," which also applies when the GR were collected in foreign jurisdictions. Most of the European countries have a similar provision. Nevertheless, the scope, language and legal consequences vary between countries. Few countries have developed specific measures to insure that the GR or associated TK used in their jurisdictions comply with the national ABS legislation (with the notable exception of Norway).

B. OBLIGATIONS TO SUPPORT THE IMPLEMENTATION OF THE NAGOYA PROTOCOL

Designation of ABS National Focal Point and Competent National Authority

Almost all CBD Parties have an ABS NFP and are thus in compliance with the institutional obligation of the Protocol (even if very few regulations provide for the creation or designation of a NFP, such as Costa Rica). In most legislation, a CNA is also designated. In some legislation, there is a reference to a CNA, but it is not specifically designated (Bhutan). Regulations sometimes provide for the designation of several CNAs. One CNA can be responsible for granting access for commercial purposes, and another for non-commercial purposes (e.g. South Africa). Several CNAs can also intervene depending on the nature of the genetic resources that the applicant seeks to access (e.g. Peru). The functions of the CNA and the ABS NFP can also be performed by the same authority, as is the case in Costa Rica, where the TO of the CONAGEBIO serves as both the CNA and the ABS NFP.

ABS Clearing-House Mechanism

Several regulations provide for the establishment of a register of information about permits issued and related documents (e.g. Australia, Kenya, Costa Rica and the Andean Community). While ABS

regulations frequently encourage exchanges of information, they do not create strong mechanisms resembling a CHM. For example, the 2000 ASEAN Framework Agreement on Access to Biological and Genetic Resources calls for the creation of a Regional Clearing House to implement the Agreement. However, until now, no proper ABS Clearing House mechanism has been created and the ASEAN Center for Biodiversity remains the main place of exchanges of information, through the ASEAN Biodiversity Information Sharing Services.

C. ANALYSIS OF POST-NAGOYA LEGISLATION

Several countries have developed and passed legislation following the adoption of the Nagoya Protocol. Nicaragua adopted legislation in 2012, but the drafting and review process had largely taken place before the Protocol's adoption. Nevertheless, this legislation addressed a number of relevant issues. Regardless of intent, all access to genetic resources and their derivatives requires the issuance of a permit by the National System of Licences and Permits based on prior informed consent, and the publication and registration of the mutually agreed terms. Once a permit for access has been granted for genetic resources and/or traditional knowledge, the State and the applicant will enter into negotiations for a Permit of Access Agreement (the Agreement), which should include a clause on the fair and equitable sharing of benefits. Nicaragua also offers strong protection for TK through a *sui generis* approach, which recognizes community IP rights and requires comparable permitting procedures for access and utilization. For IP rights based on GR/TK to be registered domestically under a patent, a certificate of disclosure of origin issued by the competent national authority must be submitted. Transfer of technology and domestic capacity building are also key aspects of the regime, including the requirement that a Nicaraguan scientist be involved in the research, to support the development of national scientific capacity.

Malaysia, similarly, addresses GR and TK under a common framework, which requires access to be based on prior informed consent, as well as the establishment of mutually agreed terms, including a benefit-sharing agreement with relevant ILCs. PIC is to be obtained in accordance with the customary laws, community protocols, and procedures of ILCs, and from recognized representatives or organizations as established by ILCs (or the competent national authority in the absence of a clear representative or organization). In cases where the same TK is shared by more than one ILC, PIC and MAT are required from all holders of the TK, and if this impractical, as many as can be reasonably ascertained. Monitoring and compliance will be based on disclosure checkpoints administered across ministries, including authorities in intellectual property, product registration, product approval and public research grants. Registration of intellectual property rights, domestically or internationally, over genetic resources or related traditional knowledge is restricted without the written consent of the Competent National Authority.

Switzerland and the EU have developed synergistic systems that focus on establishing user measures emphasizing due diligence in sourcing, and the use of multiple checkpoints to incentivise compliance. Switzerland amended pre-existing legislation to introduce a due diligence requirement, which requires users or beneficiaries of genetic resources or the associated traditional knowledge originating from a party to the NP to comply with the domestic regulatory requirements on ABS, and establishes a centralized checkpoint at the Federal Office for the Environment (FOEN) for disclosure and the fulfillment of due diligence requirements prior to market authorization/commercialization. The EU similarly requires that due diligence be exercised to determine that GR and TK were accessed in accordance with provider-country ABS legislation or regulations, where access occurs following the entry into force of the Nagoya Protocol. The use of an internationally-recognized certificate of compliance with information on the content and

establishment of mutually agreed terms must also be included, and where a certificate is not available, sufficient information must be provided to effectively ascertain compliance. Trusted collections established within the EU are also set up based on a standardized and approved access procedure, with access from such a collection deemed sufficient to meet the requisite due diligence requirements. Users may submit effective tools or mechanisms specifically developed to facilitate compliance with due diligence to be recognized as a 'best practice,' with an up-to-date register of best practices is to be established across the Euro-zone. Checkpoints will be set in place by Member States to validate compliance with the due diligence requirements set out.

4. CONCLUSIONS

A. CHALLENGES

The Nagoya Protocol is a highly complex treaty that will be challenging to implement in both industrialised and developing countries. Some of the challenges in implementation and operationalization are discussed below.

Defining Ownership

Ownership of genetic resources will have to be fleshed out in order to meet the Protocol's obligations related to genetic resources owned by Indigenous and local communities. Users of genetic resources need to be sure that a provider has the authority to provide such resources. Such authority does not, in many cases, rest only with the government, but also with those who have private, or other rights or tenure over the land or resources. Therefore, questions of ownership and tenure invariably have an important bearing on the practicalities of ABS and are important elements of national legislation on the basis of which competent national authorities "determine access" to resources. The definition of property rights over genetic resources will thus have implications for the right to participate in the decision-making processes on ABS and be the recipient of potential benefits.

Understanding the term "utilisation"

The Nagoya Protocol contains a somewhat broad definition of utilisation of genetic resources, capturing major types of utilisation of genetic resources.[684] On the basis of its wording alone, the Protocol does not clarify which uses fall under its scope, nor does it provide an operational definition of the term "derivative."[685] In addition, the operative provisions of the Protocol do not create clear obligations upon user countries to implement national laws obliging their private company users of foreign GR to share a fair and equitable part of the benefits arising out of utilisation of GR. Despite the adoption of the Nagoya Protocol, therefore, the problem of establishing a functional system on the basis of clear obligations on private parties still remains, and national regulation may provide useful information in the implementation phase to that end. In that regard, the experience of those countries regulating derivatives or biochemicals may be relevant.

Operationalising PIC requirements

With regard to PIC,[686] there appear to be difficulties in making relevant requirements operative and in ensuring legal certainty. This is one of the most complex and difficult aspects of obtaining access to genetic resources, particularly because of practical the difficulties in obtaining PIC in specific

[684] Nagoya Protocol, *supra* note 3 at Article 2(c).
[685] *Ibid.* at Article 2(e).
[686] *Ibid.* at Article 6(2).

instances.[687] More clarity on PIC and MAT requirements, especially where Indigenous and local communities are concerned, will thus be necessary to create functional domestic ABS systems. In particular, implementation challenges may be foreseen with regard to the interaction between community protocols and customary law, on the one hand,[688] and national legal instruments, on the other hand, even when the role of communities' customary laws is recognised in the constitutions of some countries in the region.

Dealing with special considerations

Implementing the provisions of the Nagoya Protocol on special considerations[689] will require legal and institutional development. In relation to access and utilisation of genetic resources for food and agriculture, very few countries provide specific procedures or have created different conditions. Things are different, however, in countries that are a party to the Food and Agriculture Organisation's International Treaty and have provided specific consideration in their domestic ABS frameworks. Nonetheless, in some countries the synergistic implementation of CBD provisions on ABS and those of the International Treaty have been complicated. Some doubts have also arisen regarding the legal space provided by ABS measures to implement the Multilateral System under the International Treaty.

In light of the Nagoya Protocol provisions on basic research,[690] not all countries in differentiate between commercial and non-commercial research and when they do, determining whether an application is for basic research or for commercial purposes has proven difficult. Accordingly, one of the criticisms of ABS legal frameworks from sectors involved in basic research (universities and other research centers) concerns the lack of, or insufficient recognition of, the intrinsic advantages of basic research and its contribution to the conservation and the sustainable use of biodiversity.[691] Countries will thus face several challenges from a legal certainty perspective; they may want to consider providing for flexibility for basic research, while establishing a clear differentiation for access for commercial purposes.[692] They should also consider guaranteeing protection of the rights of the provider when a commercially valuable result is obtained from an activity initially considered as basic research. Similarly, they will consider how to provide certainty to users so that it will eventually be possible to seek commercial results in cases of change of intent.[693]

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[687] See L. Lange, "CBD: Status, Pitfalls, Actions Needed and Perspectives," in JBA-UNU/IAS Symposium on Access to and Benefit-Sharing of Genetic Resources: How Industry and Government are Coping with the Current Situation (Tokyo: Proceedings Update, 2005) and J. Rosenthal, "Politics, Culture and Governance in the Development of Prior Informed Consent and Negotiated Agreements with Indigenous Communities" (unpublished paper in file of the author).

[688] Nagoya Protocol, *supra* note 3 at Article 12(1).

[689] *Ibid.* at Article 8(c).

[690] *Ibid.* at Article 8(a).

[691] See A. Grajal, "Biodiversity and the Nation State: Regulating Access to Genetic Resources Limits Biodiversity Research in Developing Countries," Conservation Biology 13(1) (1999).

[692] S. Carrizosa *et al.*, eds., *Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity* (Gland, Switzerland: IUCN, 2004) [*Accesssing Biodiversity*].

[693] Rosenthal indicates: "It may also be useful to consider a two phase approach to preserve elements of both the freedom to academic research and the flexibility to pursue industrial development of potential discoveries, while offering security to providers" (J. Rosenthal, "Politics, Culture, and Governance in the Development of Prior Informed Consent in Indigenous Communities" Curr Anthropol. Feb 1, 2006; 47(1): 119–142.

Finally, expedited access to pathogens[694] is a completely new issue for most countries. The EU Regulation and the Swiss Regulation both contain specific measures in the context of the due diligence requirement for emergency situations.

Drafting and implementing "compliance measures"

Few of the national ABS measures in this study contain clear compliance-related provisions. As stated above, the Protocol leaves a great degree of latitude to parties as to the types of measures they may adopt to meet their compliance obligations, so it will be incumbent on countries to put in place adequate compliance mechanisms within their national ABS frameworks. As a result, the compliance provisions of the Protocol will be largely informed by the type of measures that countries adopt at the national level. So far, most of the draft proposals dealing with compliance measures under articles 15-17 of the Protocol come from developed countries.

B. OPPORTUNITIES

The Nagoya Protocol also presents some interesting opportunities. It could, for instance, provide the basis for strengthening national competent authorities and for using information technologies relevant for the notification of the permit/internationally recognised certificate. It may also create new opportunities for strengthening research and development on genetic and biochemical resources in developing countries, most likely through partnerships with users.

The need to clarify the subject-matter scope of national ABS frameworks,[695] including the definitions of "utilisation" and "derivatives", may have a positive impact on legal certainty leading to a more coherent and homogenous interpretation and implementation of ABS measures by national authorities. In addition, the need to appropriately address non-commercial research in national ABS frameworks should take into account the fact that most of ABS permits/contracts in some countries are for basic research and mostly concern nationals. Thus, the design of a proper system to facilitate basic research and effectively differentiate between commercial and non-commercial access, while factoring in the potential change of use and intent, may lead to increased acceptance of domestic ABS frameworks by the research community, particularly at the national level.

Furthermore, the adoption of the Nagoya Protocol provides new impetus for the adoption of national ABS laws in countries where these are still missing, and for the updating of dated draft laws that do not reflect the innovative provisions of the Protocol. Finally, capacity building and cooperation between national competent authorities and other relevant stakeholders may take place as a result of the process of developing new measures required to implement the Protocol.

Countries can also benefit from the growing jurisprudence regarding Indigenous peoples' rights, especially in relation to rights over their lands and territories, and the right to participate in any decision-making affecting them. Accordingly, the relevant cases of the Inter-American Court of Human Rights can shed light on implementation options concerning key provisions of the Nagoya Protocol related to the rights of Indigenous and local communities,[696] including the right to grant PIC for using genetic resources located within their lands. In this regard, attention should be paid to the Court's recognition of the "special meaning of communal property of ancestral lands for the

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[694] Nagoya Protocol, *supra* note 3 at Article 8(c).

[695] *Accessing Biodiversity, supra* note 704; Jorge Cabrera Medaglia & Christian Lopez Silva, Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty (Gland and Bonn: IUCN, 2007).

[696] Nagoya Protocol Articles 5, 7 and 9

indigenous peoples, including the preservation of their cultural identity and its transmission to future generations, as well as the steps that the state has taken to make this right fully effective."[697]

Accordingly, conservation obligations on the state flow from Indigenous peoples' relationship with their ancestral lands, considering "the fundamental basis of their cultures, their spiritual life, their integrity, and their economic survival."[698] In addition, the Court has ruled that Indigenous lands must be delimited and titled with the full participation of the community concerned, taking into account the community's customary laws, values and customs.[699] Finally, the Court also held that states must put in place three safeguards vis-à-vis Indigenous peoples: mechanisms for their effective participation in decision-making; benefit-sharing; and environmental and social impact assessments.[700] In this context, the has Court pointed out that the duty to actively consult Indigenous peoples requires the state to both develop and disseminate information, ensure constant communication between the parties, and ensure that consultations are held in good faith, through culturally appropriate procedures, with the objective of reaching agreement.[701]

C. THE WAY FORWARD

As this study demonstrates, much work has been done - and remains to be done - in implementing the ABS provisions of the CBD and the Nagoya Protocol. Based on recent progress in the ratification of the Nagoya Protocol, and the adoption Regulations by the European Union,[702] the Protocol may still enter into force in time for COP-MOP 1 of the Protocol to take place alongside CBD COP 12.

Many countries view the Protocol as a compromise because it lacks binding user measures, meaning that it will be important to ensure effective implementation of such measures if the hopes of developing countries to obtain a greater share of benefits are to be met.[703] However, there is a clear obligation for all Parties to develop user compliance measures. An effective ABS regime will need to have the capability to set incentives for the conservation and sustainable use of biodiversity; facilitate access to genetic material; and enhance fair and equitable benefit-sharing by preventing the misappropriation and unapproved use of genetic resources.[704] Lessons learned from implementation of the ABS provisions of the CBD will be important to consider and will provide useful guidance to Parties. The work done at ICNP 1, 2 and 3 will also contribute to the effective and timely implementation of the provisions of the Protocol. Work has been done in preparation for COP-MOP 1 on the ABS learing-House,[705] global benefit-sharing mechanism,[706] capacity-building and

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[697] Inter-American Court of Human Rights, *Case of the Yakye Axa Indigenous Community v Paraguay*, Judgment of 17 June 2005, Series C No. 125.

[698] Inter-American Court of Human Rights, *Case of the Mayagna (Sumo) Awas Tingni Community v Nicaragua*, Judgment of 31 August 2001, Series C No. 79.

[699] *Ibid.*

[700] Inter-American Court of Human Rights, *Case of the Saramaka People v Suriname*, Judgment of 28 November 2007, Series C No. 172.

[701] *Ibid.*

[702] *Regulation of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, Brussels*, 16 April 2014, PE-CONS 131/2/13 REV 2.

[703] Carmen Richerzhaugen, "Effective Governance of Access and Benefit Sharing under the Convention on Biological Diversity" (2011) 20 Biodiversity Conservation 2243 at 2244.

[704] *Ibid.* at 2235

[705] *Report on Progress in the Implementation of the Pilot Phase of the Access and Benefit-Sharing Clearing-House*, online: <http://www.cbd.int/doc/meetings/abs/icnp-03/official/icnp-03-06-en.pdf>.

development,[707] compliance,[708] monitoring and reporting,[709] model contractual clauses, voluntary codes of conduct, guidelines, best practices and standards.[710]

COP-MOP 1 will need to decide what to do in regard to these issues, and take the necessary steps to operationalize the Nagoya Protocol. It will be critical to continue providing the necessary financial and institutional resources to build capacity to implement the Nagoya Protocol. More actors are undoubtedly needed, further research must be conducted, and new approaches to capacity development will need to be developed. The operationalization of the Nagoya Protocol subsequent to its entry into force will be a great challenge and all Parties will need to work together to ensure that it meets the hopes and expectations of all involved.

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[706] *Report of the Expert Meeting on Article 10 of the Nagoya Protocol on Access And Benefit-Sharing*, online: <http://www.cbd.int/doc/meetings/abs/icnp-03/official/icnp-03-05-en.pdf>.

[707] *Draft Strategic Framework for Capacity-Building and Development under the Nagoya Protocol*, online: <http://www.cbd.int/doc/meetings/abs/icnp-03/official/icnp-03-07-en.pdf>.

[708] *Cooperative Procedures and Institutional Mechanisms to Promote Compliance with the Nagoya Protocol and to Address Cases of Non-Compliance*, online: <http://www.cbd.int/doc/meetings/abs/icnp-03/official/icnp-03-08-en.pdf>

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