Legal Preparedness for Achieving the Aichi Biodiversity Targets: Scoping paper on Aichi Target 16: ratification and...

Data · March 2014

CITATIONS
0

READS
111

1 author:

Jorge Cabrera Medaglia
University of Costa Rica
96 PUBLICATIONS **20** CITATIONS

SEE PROFILE

WORKING PAPER

LEGAL ASPECTS OF THE AICHI BIODIVERSITY TARGET 16: A SCOPING STUDY

Version 1.0

CONTENTS

IDLO

LIST OF ABBREVIATIONS

ABS	Access and Benefit Sharing
ATS	Antarctic Treaty System
CBD	Convention on Biological Diversity
CGRFA	Commission on Genetic Resources for Food and Agriculture
COP	Conference of the Parties
IP/GR	Intellectual property issues related to genetic resources
ITPGRFA	International Treaty on Plant Genetic Resources on Food and Agriculture
MAT	Mutually Agreed Terms
NBSAPs	National Biodiversity Strategies and Action Plans
PIC	Prior Informed Consent
R&D	Research and Development
S&T	Science and Technology
TCE	Traditional Cultural Expressions
TK	Traditional Knowledge
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCCD	United Nations Convention to Combat Desertification in Those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa
UNCLOS	United Nations Convention on the Law of the Sea
UPOV	International Union for the Protection of New Varieties of Plants
WSSD	World Summit on Sustainable Development

OVERVIEW OF SCOPING PAPER

PURPOSE

The purpose of this scoping paper is to set out the state-of-the-art legal knowledge on Aichi Biodiversity Target 16 and identify priority areas for future legal research. This survey of legal knowledge is intended to provide a foundation for future research work that will examine the effectiveness of specific regional, national and subnational legal approaches, and develop practical legal guidance to assist policy-makers and other stakeholders to utilize legal approaches to achieve Target 16. It forms part of a series of scoping papers prepared under the Legal Preparedness for Achieving the Aichi Biodiversity Targets program.

SCOPE

This scoping paper documents the legal foundations of Target 16 in international and domestic law regimes, with a focus on facilitating ratification and implementation at the national level. At the international level, the paper will explore the requirements for the entry into force of the Nagoya Protocol. At the domestic level, it will investigate the legal obligations created by the Protocol, how countries have implemented their obligations on access to genetic resources under Article 15 of the CBD, and how countries are now putting in place legal, administrative or policy measures to operationalize the Protocol in a manner consistent with national legislation.

ANALYTICAL FRAMEWORK AND METHODOLOGY

In reviewing and assessing the domestic approaches taken to achieve Target 16, this scoping paper will outline the substantive rationale for further research, and identify core aspects of the law which provide opportunities for lessons to be drawn. In-depth research will be conducted on each of the countries identified and the findings used to supplement the conclusions made by this scoping paper. Countries which have ratified the Protocol, or are in the process of reform to enable them to do so, will also be used to provide additional insight into the various methods available at the domestic level to operationalize the Protocol.

Lessons, good practices and procedures will be identified through a comparative analysis of country studies that is focused on five core aspects in the national implementation of the Nagoya Protocol: (1) Access and benefit sharing requirements (PIC and MAT), including differences between commercial and non-commercial use; (2) Transparency, monitoring and compliance; (3) Protection of traditional knowledge associated with genetic resources; (4) Scope of measure, including definition of utilization of genetic resources; and, (5) Creation of supportive institutional and administrative structures.

APPROACH AND ORGANIZATION

This paper has been authored by legal experts from the Centre for International Sustainable Development Law, advised by an Expert Review Panel, who have researched leading legal publications, measures, national experiences, and programs to survey and assess legal considerations relevant to the achievement of Target 16.

The paper begins by providing a brief overview of the key aspects of Target 16 for which law and legal approaches are relevant. The second section describes international legal instruments and processes that are relevant to the implementation of Target 16. The third section summarizes cases of national implementation, looking briefly at the scope of the measure, access and benefit sharing requirements, transparency, monitoring and compliance, and institutional and administrative measures. The final section will provide a bibliography of key relevant resources.

AUDIENCE

The primary audience for this paper is the community of lawyers, policy-makers, legislators and jurists who will be directly involved in the development of national/regional ABS measures and their implementation. It will also provide a resource for academics, communities, the private sector, and other stakeholders involved in implementing ABS provisions of the CBD and the ratification and implementation of the Protocol.

PART I: CONTEXT AND BACKGROUND

Target 16: By 2015, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization is in force and operational, consistent with national legislation.

The fair and equitable sharing of benefits arising from the use of genetic resources is the third objective of the Convention on Biological Diversity (CBD).[1] Article 15 of the CBD sets out the related principles and obligations of Parties on access to genetic resources and the fair and equitable sharing of benefits arising out of the utilization of genetic resources, on the basis of prior informed consent (PIC) and mutually-agreed terms (MAT).

Following the adoption of the 2002 Bonn Guidelines at the 6th Conference of the Parties (COP) to the CBD,[2] the call for the negotiation of an international regime on ABS issued at the World Summit on Sustainable Development,[3] and six years of negotiations, the COP 10 adopted the Nagoya Protocol on Access and Benefit Sharing (ABS) in 2010. Target 16 was adopted as a part of the Strategic Plan 2011-2020, as a driver to promote the Protocol's entry into force and operationalization. It is expected that the adoption of relevant legislative and regulatory measures at the national level will play a central role in achieving Target 16, while the revision and updating of National Biodiversity Strategies and Action Plans (NBSAPs) in line with Target 17 provides an additional opportunity to implement the Protocol as a part of a country's broader biodiversity policy.[4]

Aichi Biodiversity Target 16 calls on CBD Parties to ratify or accede to the Protocol in sufficient numbers for it to enter into force by 2015 and be operational nationally. The Target is comprised of two interlinked components:

- Entry into force of the Protocol by 2015; and
- Operationalization of the Protocol consistent with national legislation.

Target 16 is inherently legal in both its components, first requiring countries to undertake the necessary domestic legal and political process to adhere to an international treaty, and second to assess and modify existing national legislation or develop new legislation to ensure effective implementation of the treaty commitments.

ENTRY INTO FORCE OF THE PROTOCOL BY 2015

This section will discuss the processes and main challenges to ratifying the Nagoya Protocol, including the political process, as well as country-specific opportunities and obstacles.[5] It will examine how legal approaches, institutions, frameworks, processes and mechanisms can assist in creating a supportive climate and reducing obstacles to ratification. It will also discuss how relevant lessons can be learned from the ratification experiences of various countries.

The Protocol will enter into force 90 days after the deposit of the 50th instrument of ratification, acceptance or approval, meaning that the requisite number of countries must undertake the domestic and international acts necessary to ratify by October 2015 at the very latest to achieve the first part of Target 16. Under the CBD, ratification, acceptance or approval is required for all States and Regional Economic Integration Organizations to be bound by the Nagoya Protocol and the deposit of an instrument of ratification, acceptance, or approval with the United Nations Treaty Depositary establishes consent to be bound.[6] Upon its entry into force, the Protocol will be binding upon only those States which have ratified it.

As a matter of domestic law, the treaty ratification process gives countries the time necessary to seek approval and input from their citizens, and to enact the legislation and other instruments necessary to operationalize the Protocol if necessary. This

[1] Genetic resources, defined by the CBD as "genetic material of actual or potential value", are used for a variety of purposes in research and development by research institutes, universities and private companies operating in the pharmaceutical, agriculture, horticulture, cosmetics and biotechnology sectors.

[2] Adopted to assist Parties in establishing administrative, legislative or policy measures on access and benefit-sharing and/or when negotiating contractual arrangements for access to genetic resources and benefit-sharing.

[3] World Summit on Sustainable Development, *Johannesburg Plan of Implementation*, paragraph 42.

[4] Thomas Greiber et al, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing* at 274. [Nagoya Protocol Explanatory Guide]

[5] The mix of actors, priorities, and discourses often determines success at the time of ratification.

[6] Convention on Biological Diversity, Article 34(1): *This Convention and any protocol shall be subject to ratification, acceptance or approval by States and by regional economic integration organizations...* Instruments of acceptance or approval have the same legal effect as instruments of ratification; they express the consent of a State to be bound by a treaty. In some States, acceptance and/or approval are used instead of ratification when the Constitution does not require the treaty to be ratified by the head of State.

process varies by country. Some countries do not need to adopt national measures in order to ratify, meaning that ratification can be done through a stand-alone measure like an executive decree. Other countries must undertake a more comprehensive process that may include legislation or other legal measures (e.g. legislation accepting the Protocol as binding and detailing how it will be implemented). Since the domestic ratification process for a treaty can be cumbersome and time-consuming, it is important to ensure that the Nagoya Protocol remains a priority among domestic political considerations. It is important to have strong political commitment at an appropriate level in the government to vigorously pursue the ratification of the Protocol, possibly with a clear timeframe for execution.

OPERATIONALIZATION OF THE NAGOYA PROTOCOL

The Nagoya Protocol contains various components that must be operationalized in a manner consistent with national legislation. To achieve this, the specific obligations contained under the Nagoya Protocol, the means of implementation for each obligation, and their implications for existing national and subnational legislative frameworks must all be recognized.

The main components under the Protocol relate to access to genetic resources, access to traditional knowledge, fair and equitable benefit-sharing, compliance, and capacity building. Although over fifty countries have adopted ABS measures since the entry into force of the CBD, because the Protocol creates new obligations and requirements, these pre-existing laws may no longer suffice or may conflict with new requirements under the Protocol. Other domestic laws may be in conflict with the terms of the Protocol, or silent where the Protocol requires action. There are many potential implications for existing legal frameworks as ABS measures must be mutually supportive with a variety of other laws and policies including those on science and technology (S&T), natural resources management, intellectual property rights and indigenous and local communities (ILC).[7]

› IT IS IMPORTANT TO HAVE STRONG POLITICAL COMMITMENT AT AN APPROPRIATE LEVEL IN THE GOVERNMENT TO VIGOROUSLY PURSUE THE RATIFICATION OF THE PROTOCOL‹

We argue that due to limited experience (and also because the Protocol is not into force yet) in implementing the Nagoya protocol, there is a need to seek guidance by looking back at past ABS implementation experiences (e.g. Australia, Brazil, Costa Rica, South Africa) to draw on lessons learned and areas for improvement, and also to learn from recent attempts to operationalize the Nagoya Protocol in CBD Parties that have begun adopting or reforming laws and regulations to meet the obligations created by the Protocol (e.g. Denmark, European Union, Malaysia, Mexico, Switzerland). This paper will try to draw out lessons from legal approaches to ABS that are broadly applicable and transferable. Because one of the key aspects of operationalization is the establishment of the administrative and institutional measures needed to implement ABS at both the national and international level, the paper will be updated on an ongoing basis to review the implementation of updated measures.

[7] *Supra,* Nagoya Protocol Explanatory Guide at 275.

PART II: INTERNATIONAL LAW REGIME

RELATED INTERNATIONAL LAWS, INTERNATIONAL INSTRUMENTS AND INTERNATIONAL PROCESSES

This section will illuminate the potential interactions between different areas of international law and the Nagoya Protocol, with reference to international agreements referenced in the Preamble to the Nagoya Protocol, and a brief description of their relevance to implementing the Protocol at the national level. Although the Nagoya Protocol is the framework treaty for ABS, Article 4(4) recognizes the interdependence and mutual supportiveness of specialized instruments. Not all of the laws, instruments and processes listed are relevant or of equal importance for every country.

International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and FAO Commission on Genetic Resources for Food and Agriculture (CGRFA)

Genetic resources for food and agriculture are vital for food security globally. The Commission on Genetic Resources for Food and Agriculture (CGRFA) of the FAO was established in 1983 to address issues pertaining to plant genetic resources, with the mandate later broadened to address all biodiversity issues impacting food and agriculture, including a specific mandate to address ABS issues. Negotiated under the CGRFA, the objectives of the ITPGRFA are conservation, the sustainable use of plant genetic resources for food and agriculture, and the equitable sharing of benefits from use.[8] The ITPGRFA creates a Multilateral System (MLS) for ABS under Art. 10(2), to facilitate access to specific genetic resources (35 major food crops and 29 forage genera) found in Annex I. Access is facilitated under specific terms as outlined in Art. 12: access is only provided for purposes of conservation, research, and breeding for food, and not for chemical, pharmaceutical and/or other non-food/feed industrial uses; access is governed by a standard material transfer agreement (MTA) found in Art. 12(4); and, recipients may not claim IP rights over material in the form received from the MLS pursuant to Art. 12(3) (d). Art.13 of the ITPGRFA outlines the benefit-sharing requirements under the Multilateral System, with the Parties acknowledging the obligation to share equitability the benefits arising from use of plant genetic resources. Art. 13.2(d) discusses the sharing of monetary and other benefits of commercialization in particular. In practice, crops held by the Consultative Group on International Agricultural Research (CGIAR) and other research centers which are not a part of the Multilateral System (MLS) are traded using the same standard MTA, in effect applying an equivalent standard of protection as crops under the MLS. [9]

International Union for the Protection of New Varieties of Plants (UPOV)

The UPOV was created by the International Convention for the Protection of New Varieties of Plants (entered into force in 1968, and most recently amended in 1991) and aims to provide an effective system for the protection of global plant varieties to provide for the development of novel varieties which can benefit society. The UPOV provides rights and *sui generis* IP protection for new varieties developed by breeders. UPOV outlines plant breeder exceptions for: private and non-commercial purposes, for experimental purposes, and for the purpose of breeding other varieties.[10]

United Nations Convention on Combatting Desertification (UNCCD)

The UNCCD was negotiated after the 1992 Rio Conference, adopted in 1994 and entered into force in 1996. It requires Parties, subject to national capacity, laws and policies, to protect, promote and use relevant traditional and local technology, knowledge, know/how and practices, and ensure that such technology, knowledge, know-how and practices are adequately protected and that local populations benefit

[8] International Treaty on Plant Genetic Resources on Food and Agriculture, at Art. 1.

[9] For more information see: Jorge Cabrera Medaglia, Morten Walløe Tvedt, Frederic Perron-Welch, Ane Jørem and Freedom-Kai Phillips, "The Interface between the Nagoya Protocol on ABS and the ITPGRFA at the International Level: Potential Issues for Consideration in Supporting Mutually Supportive Implementation at the National Level" FNI Report 01/2013, available at: http://www.fni.no/doc&pdf/FNI-R0113.pdf.

10 UPOV, Art 15(1).

directly, on an equitable basis and as mutually agreed, from any commercial utilization of them or from any technological development derived therefrom.[11]

United Nations Convention on the Law of the Sea (UNCLOS)[12]

The UN Convention on the Law of the Sea (UNCLOS) was adopted in 1982 and came into force in 1994, and is the basis of international legal governance over the oceans and seas. UNCLOS identifies three relevant maritime zones with differing levels of control. The first includes internal and territorial waters under the sovereign control of the State, including the living and non-living resources contained therein. The second is the contiguous zone and the exclusive economic zone (200 nautical miles from coastal baselines) where States also possesses a sovereign right over living resources. The third is the extended continental shelf (not exceeding 350 nautical miles from the baseline) where States can exercise rights over living organisms belonging to sedentary species.[13] Discussions have begun on a Protocol to UNCLOS relating to biodiversity in areas outside national jurisdiction, which may help determine how ABS measures will apply to marine genetic resources found in outer zones.

United Nations Declaration on the Rights of Indigenous Peoples (UNDRIPS)

The UNDRIPS was adopted by the UN General Assembly in in 2007 and that addresses the rights of indigenous peoples on subjects including knowledge, lands, territories and resources.[14] Therefore, it may guide the implementation of measures relating to indigenous and local communities, genetic resources and traditional knowledge. For example, Article 31 states that Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, and knowledge of the properties of fauna and flora, and they also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions. Article 18 holds that indigenous peoples have the right to participate in decision-making in matters which would affect their rights, through representatives chosen by themselves in accordance with their own procedures, as well as to maintain and develop their own indigenous decision-making institutions. Article 19 indicates that States shall consult and cooperate in good faith with the indigenous peoples concerned through their own representative institutions in order to obtain their free, prior and informed consent before adopting and implementing legislative or administrative measures that may affect them. Article 24 asserts that Indigenous peoples have the right to their traditional medicines and to maintain their health practices, including the conservation of vital medicinal plants, animals and minerals.

World Health Organization International Health Regulations (IHR) and Influenza Framework (PIP Framework)

Rapid access to pathogenic material is vital to safeguard human health in times of crisis. The International Health Regulations, global standards developed by the WHO to enhance public health security on a national and regional basis, remind Parties of the importance of access to pathogens for pandemic preparedness and response. [15] The Pandemic Influenza Preparedness Framework (PIPF) was adopted by the WHO following the adoption of the Protocol. The PIPF stresses the norm of sharing viruses for preparedness purposes, but fails to create any binding obligation on the Parties.[16] The PIPF could be considered a specialized instrument under the Art. 4(4) of the Nagoya Protocol.

World Intellectual Property Organization Intergovernmental Committee on IP and GR, TK and Folklore (IGC)

Negotiations in WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) have resulted in draft articles providing for three international instruments for the protection of traditional knowledge (TK), traditional cultural expressions (TCE), and intellectual property issues related to genetic resources (IP/GR), respectively. Potential linkages exist between the implementation of the Nagoya Protocol and the work of the IGC on these subjects, especially TK, and IP/GR.

World Trade Organization Agreements (e.g. TRIPS)[17]

The World Trade Organization *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS Agreement)[18] is relevant to IP aspects of ABS. The TRIPS Agreement states that both products and processes in all fields of technology (including biotechnology) may be patented if they fulfil the test of: novelty, inventiveness, and industrial applicability. [19] Members may exclude treatment methods for animals or humans [20] and plants and animals [21] from patentability. However, Members are obliged to protect plant varieties either by a patent-based system, a *sui generis* system (ex. UPOV), or a combination thereof.[22]

11 United Nations Convention on Combatting Desertification at Article 18(2)(b)
12 United Nations Convention on the Law of the Sea (1982).
13 Ibid at 77(4)
14 United Nations Declaration on the Rights of Indigenous Peoples, UN General Assembly Resolution A/RES/61/295.
15 See International Health Regulations, Preamble.
16 WHO, Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (2011), at Art. 3, available at: http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf.
17 Several Bilateral and Regional Free Trade Agreements also incorporates specific provision on the relationship between ABS and IP sometimes in the environmental or IP chapters.
18 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), available at: http://www.wto.org/english/docs_e/legal_e/27-trips.pdf. [Hereinafter TRIPS Agreement].
19 Ibid, at Art. 27(1)
20 Ibid, at Art. 27(3)(a)
21 Ibid, at Art. 27(3)(b)
22 Ibid.

RELATED REGIONAL AGREEMENTS

The first two agreements below were developed to support implementation of the CBD ABS provisions while the Swakopmund Protocol was adopted after the Nagoya Protocol.

Andean Pact Decision 391

In passing Decision 391 in 1993, the Andean Community (Bolivia, Colombia, Ecuador, Peru, and Venezuela–who has subsequently withdrawn) created the first regional approach to ABS.[23] Decision 391, which came into force in 1996, outlines both general principles and specific rules for access. Rights under the Decision include national sovereignty over genetic resources [24] and the participation of indigenous peoples in decision-making regarding TK, [25] with access regulations applying to genetic resources and their derivatives, as well as intangibles such as TK, innovations and cultural practices. [26] Furthermore, access contracts must be respectful of the rights and interests of the provider, including interests over the biological resources or associated TK.[27] Finally, access contracts must also include an annex outlining monetary and/or non-monetary benefits to be equitably shared with the supplying party.[28]

African Model Law on the Rights of Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources

The African Model Law on Biological Resources is a draft legal framework to assist nations in implementing governance over farmers' and breeders' rights, as well as equitable benefit-sharing. The aims of the Model Law include: (i) the recognition and protection of the inalienable rights of local communities to their biological resources and traditional knowledge; (ii) the recognition of plant breeders' rights; (iii) the provision of a mechanism for access to community resources based on prior informed consent; and (iv) the promotion of a mechanism for the fair and equitable sharing of benefits arising from the use of biological resources or traditional knowledge.[29] Any access to the biological resources or traditional knowledge of local communities must be done with prior informed consent,[30] and benefit-sharing–including an up-front payment–must be incorporated into the access permit.[31] Furthermore, the Model Law recognizes the rights of communities over: (i) their biological resources, (ii) the right to collectively benefit from the use of their biological resources, (iii) their cultural innovations, practices and knowledge, (iv) the right to collectively benefit from the use of cultural innovations, practices and knowledge, (v) their rights to use their cultural practices in conservation of biodiversity, and (vi) the exercise of collective rights as stewards and users of biological resources.[32] Guidelines are presently being drafted under the oversight of the AU Commission to provide guidance to African countries on the implementation of the Nagoya Protocol in light of the Model Law. This will provide focused guidance on the development of ABS measures, which may have a more direct impact.

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 January 2012. The Protocol 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.[33] Broad definitions of traditional knowledge and folklore are employed,[34] along with a unique set of protections. Specifically, the holders of traditional knowledge under the Protocol are deemed the beneficiaries,[35] and receive exclusive rights over: the authorization of use of their TK,[36] prevention of the exploitation of TK without prior informed consent,[37] the institution of legal proceedings to remedy infringements of rights protected under the Protocol,[38] and fair and equitable benefit sharing arising from the commercial use of their TK.[39]

23 Andean Community, Common Regime on Access to Genetic Resources, Decision 391, 2 July 1996, Official Gazette 17 July 1996, at Art. 2, available at: http://www.wipo.int/wipolex/en/details.jsp?id=9446.
24 *Ibid,* at Art. 5-6.
25 *Ibid,* at Art. 7.
26 *Ibid,* at Art. 17.
27 *Ibid,* at Art. 34.
28 *Ibid,* at Art. 35.
29 OAU, Model Law on the Rights of Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (2000), at Part I: Objectives, available at: http://www.farmersrights.org/pdf/africa/AU/AU-model%20law00.pdf
30 Ibid, at Art. 5.
31 Ibid, at Art. 12.
32 Ibid, at Art. 16.
33 ARIPO, Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore (2010), at Art. 1.1, available at: http://www.cbd.int/doc/measures/abs/msr-abs-aripo-en.pdf. [Swakopmund Protocol]
34 *Ibid,* at Sec. 2.1.
35 *Ibid,* at Sec. 6.
36 *Ibid,* at Sec. 7.1.
37 *Ibid,* at Sec. 7.2.
38 *Ibid,* at Sec. 7.4.
39 *Ibid,* at Sec. 9.

PART III: NATIONAL AND SUBNATIONAL IMPLEMENTATION

IMPLICATIONS FOR DOMESTIC IMPLEMENTATION

Entry into Force of the Nagoya Protocol

Once country studies are complete, this section will provide a brief overview of a range of national processes for ratification of an international treaty, providing a description of the process undertaken by countries that have ratified the Nagoya Protocol.

Guiding Questions for Legal Preparedness

1. What are the economic, environmental and social costs and benefits of ratifying the Protocol? What are the trade-offs to consider?
2. What is the process for ratifying international treaties in your country? Is there a need for implementing legislation prior to ratification?
3. Who is involved in the ratification process in your country? Which stakeholders might be affected? How can stakeholders be involved and their needs addressed?
4.

Operationalization of the Protocol Consistent with National Legislation

Parties to the Protocol will need to undertake various actions to implement their commitments under the Nagoya Protocol. Some are obligations and others are mechanisms for implementing these obligations. Rules must be developed and put in place through legislation, regulation and/or administrative measures. Capacity development will be needed in many cases to develop the mechanisms necessary to operationalize the Protocol.

Actions that countries should take to operationalize the Protocol include:

- establishing multi-level legal frameworks for access to and benefit-sharing from genetic resources and traditional knowledge (e.g. laws, regulations and administrative instruments)
- mainstreaming and identifying linkages of Protocol commitments with related national law across sectors to ensure coherence in implementation;
- addressing legal issues related to access and benefit-sharing in the context of nature conservation (e.g. bioprospecting in protected areas);
- ensuring legal recognition and reward for sustainable customary use and community-based environmental management practices (e.g. sustainable forest management);
- guaranteeing the protection and promotion of traditional knowledge associated with genetic resources of indigenous peoples, smallholder farmers and local communities (e.g. *sui generis* protection);
- identifying commercial opportunities at different levels (industry, ILC, etc.);

Comprehensive ABS regimes in developed and developing countries share some similarities, allowing lessons learned to be drawn, including with respect to: the scope of application and legal status of genetic resources and associated traditional knowledge; the determination of whether PIC is required for access; procedures for determining access if PIC is required; rules on mutually agreed terms, and fair and equitable benefit-sharing; monitoring and compliance mechanisms; and the establishment or designation of appropriate institutions to share ABS-relevant information, grant access, and negotiate and enforce benefit-sharing, as well as monitor and check compliance.[40]

Guiding Questions for Legal Preparedness

- Are there legislative, administrative or policy measures already in place that need to be revised/updated in order to meet the obligations set out in the Nagoya Protocol?
- What type of new/additional legislative, administrative or policy measures need to be developed in your country in order to meet the obligations set out under the Protocol?
- What administrative and institutional structures need to be established for the implementation of the Protocol?
- What additional resources (financial, human and technical) will be required to make the Protocol operational?
- What are potential sources of funds and how can additional funds be raised for the implementation of the Nagoya Protocol?

A SURVEY OF LEGAL APPROACHES

Since the Protocol has not yet entered into force, national practices for implementation are difficult to identify. However, aspects of the Protocol have been addressed in laws

[40] Greiber et al, *supra* note at 279–280.

implementing Article 15 of the CBD. This means that legislation on ABS established since the entry into force of the CBD may be instructive, and many valuable lessons can be learned from the various challenges that countries have faced in regulating ABS after the entry into force of the CBD in 1993. Some countries have already adopted laws that reflect the broader provisions of the Protocol, have partially implementing component of the Protocol as in the case of Nicaragua, or are well into the process of doing so. An analysis of the experiences of these new and emerging legal approaches can yield lessons and inform ongoing processes of national implementation in other countries. The following survey of national legal approaches intends to identify relevant measures for further study.

Australia - Environment Protection and Biodiversity Conservation Act 1999 and Environment Protection and Biodiversity Conservation Regulations 2000

ABS in Australia is federally regulated with the aim of providing incentives for the conservation and sustainable use of biological resources.[41] Australia's ABS measures clearly define the object of exchange, and imposing obligations on subsequent users through PIC and MAT which is administered nationally, as well as regionally through a network of designated authorities. The legal empowerment of regional administrative or protective organizations with specialized knowledge to establish ABS agreements relating to their jurisdiction has proven an effective way to delegate monitoring the spectrum of conditions addressed by each ABS agreement.

Brazil - Medida Provisória no 2.186-16, de 23 de Agosto de 2001

Brazil has regulated access to genetic resources and traditional knowledge through a provisional measure since 2001, and their experience illustrates the key challenge of ongoing monitoring and compliance. The measure makes the Genetic Heritage Management Council (CGEN), a legislative and deliberative body under the Ministry of Environment, responsible for the evaluation of research projects related to genetic patrimony and traditional knowledge for scientific purposes, bio-prospecting and technological development. Research institutions IBAMA (Brazilian Institute for the Environment and Renewable Natural Resources) and CNPQ (National Council for Scientific and Technological Development) have been accredited by CGEN to issue permits for research involving access to genetic resources as a way to decentralize the system.[42] A comprehensive draft law is pending on approval after year of consultations.

Costa Rica - Biodiversity Law, 1998 and Decrees on ABS

Costa Rica has a longstanding and effective ABS system administered by the National Commission for Biodiversity Management (CONAGEBIO). The law applies to all components of biodiversity found within the country and regulates the utilization of genetic resources and associated knowledge to ensure equitable distribution of benefits from use. Accessing parties are obliged to gain prior informed consent from the owners or indigenous authorities, and this consent must be registered, along with a benefit-sharing agreement, with the Technical Office of the Commission, barring no cultural, spiritual, social or economic objections. The system is effective, with a total of 150 approved access permits for bio-prospecting as of 2010, and requirements for collateral of a portion of the R&D budget, and equal royalty sharing with the Ministry of Environment and Energy (MEE) both providing unique routes to try to ensure compliance and equity.[43]

Denmark - Draft Bill on Sharing Benefits Arising from the Utilisation of Genetic Resources

Danish draft legislation prohibits the use of GRs or TK acquired in contravention of access regulations from the country of access. The draft bill also provides for sanctions including fines and imprisonment.[44]

Ethiopia - Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation

Ethiopia has detailed ABS legislation applicable in cases of access to genetic resources found in both *in situ* or *ex situ* collections, and to the TK of local communities.[45] Despite the inclusion of legislative components reinforcing co-ownership of IP, experience has shown the difficulty of ensuring compliance as exhibited by the benefit-sharing agreement for *teff* with HPFI resulting in minimal monetary benefits prior to the issuance of a broad patent for *teff* processing, a questionable bankruptcy and the eventual transfer of exclusive IP rights to *teff* without ABS obligations. While the legality of the patent remains clouded, the Ethiopian experience highlights the importance of having explicit regulation on transference and explanation on how to ensure ABS is to be applied and monitored effectively.

European Union (EU) - Draft Regulation on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

The current EU draft law implementing the Nagoya Protocol within the EU uses *access* to prompt compliance with ABS obligations, and is applicable only to GRs accessed in provider countries following the ratification of the NP in both the jurisdictions. This approach, which is in contravention to the conventional trigger of a *new use of GRs*, raises questions of downstream use, and potential legal conflicts.

41 Australia, Environment Protection and Biodiversity Conservation Act (1999), at Art. 3, available at: http://www.comlaw.gov.au/Details/C2013C00301.
42 Fernanda Álvares Silva and Laila Salmen Espindola "Access legislation on genetic resources patrimony and traditional knowledge" Brazilian Journal of Pharmacology 21(1): Jan./Feb. 2011
43 For full info, see http://www.cbd.int/abs/measures/group/default.shtml?code=cr
44 Draft Bill online: http://www.cbd.int/doc/measures/abs/post-protocol/msr-abs-dnk-en.pdf
45 Ethiopia, Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation (No. 482/2006), at Art. 4, available at: http://www.wipo.int/wipolex/en/text.jsp?file_id=179080. [Ethiopia ABS Proclamation]

Kenya - Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations

Kenya includes ABS as part of its national environmental management framework, with broad regulations noting an expansive list of monetary and non-monetary benefits to provide clarity in the benefit-sharing negotiations. While access is based on MAT and PIC, there is little content of what constitutes either, and gaps remain in clarifying what Competent Authorities or the kind of local communities that can grant PIC in practice. Kenya's experience can be helpful in identifying and informing options to overcome challenges.[46]

India - Biological Diversity Act and Biological Diversity Rules

India has been regulating ABS in a general manner since 2002, issued regulations on the subject in 2004, and ratified the Nagoya Protocol in 2012. Yet, it continues to see misappropriation of genetic resources and traditional knowledge continue. Domestic and foreign challenges to patents (e.g. *Bt* Brijnal, Neem Tree) illustrate the continued difficultly of regulating access, monitoring and enforcement. The 2002 Act covers the conservation, use of biological resources and associated traditional knowledge for commercial or research purposes, or for the purposes of bio-survey and bio-utilization. It provides a framework for ABS, including the transfer of research results and application for intellectual property rights (IPRs) relating to Indian biological resources. The 2004 Rules lay out detailed the requirements for access to genetic resources, traditional knowledge, intellectual property rights, material transfer to third parties, criteria for equitable benefit sharing, dispute settlement, and revocation of access or approval.[47]

México, Ley General de Acceso a Recursos Genéticos y Protección del Conocimiento Tradicional Asociado (draft) and related legislations

As a Party to the Nagoya Protocol, Mexico has initiated the legislative process to pass a law that governs access to genetic resources and the protection of associated traditional knowledge. The bill aims to create a legal framework to protect genetic resources, associated traditional knowledge, and the fair and equitable sharing of benefits deriving from their use. It also aims to recognize and protect the rights of indigenous and local communities over biological and genetic resources that are found in their lands and territories, as well as the traditional knowledge and practices associated with these resources. The law will apply to genetic resources from all components of biodiversity, whether in situ or ex situ. It establishes competencies on the subject of access to genetic resources, protection of associated traditional knowledge, and the fair and equitable sharing of benefits. The law will not cover human genetic resources and their derivatives; the exchange of genetic resources, derivatives, or associated traditional knowledge carried out by indigenous communities for their own use and which are products of their customary practices; the exchange of genetic resources for food and agriculture with non-commercial purposes which take place between farmers, ejidos, and indigenous and local communities; and the use and exploitation of elements of biodiversity used as natural resources.

Panamá, Decreto Ejecutivo No 25 de 29 de Abril de 2009 que Reglamenta el Articulo 71 de la Ley 41 de 1 Julio de 1998, General de Ambiente

Panama adopted regulations that govern ABS only one year before the adoption of the Nagoya Protocol. As a result, they are some of the most detailed. National Environment Authority (ANAM) regulates and controls access, Unit for Access to Genetic Resources (UNARGEN) oversees applications and contracts for access. Scope includes access to genetic and biological resources (in-situ and ex-situ), Prior Informed Consent (PIC) Procedures Applications for access, Transfer of materials, Benefit-sharing agreements, including disclosure of certificate of origin or provenance and sharing of results; compliance mechanisms include cancellation of access contract and sanctions, Classification and registration of traditional knowledge, PIC and benefit-sharing, Certificate of origin or provenance. Additional laws and regulations govern the protection of TK through a sui generis system.

Peru, Decreto supremo 003-2009-MINAM, reglamento de acceso a los recursos genéticos & Ley N° 27811, Régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológicos

Peru was an early adopter of ABS legislation, beginning in 1996 with the implementation of the Andean Community Decision 391. In 2002, Peru became one of the first globally to comprehensively address the protection of traditional knowledge through Law 27811, which establishes a unique system on collective knowledge, explicitly recognizing the country of origin in both TK and ABS legislation. In 2008, Peru issued ABS regulations under Decision Nº 391 of 1996, which addresses all genetic resources for which Peru is the country of

[46] Kenya - Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006 (L.N. No. 160 of 2006).

[47] India, Biological Diversity Act and Biological Diversity Rules

origin, or which in any way come from Peruvian territory. Access contracts are required for access to genetic resources,[48] with the minimum terms being, *inter alia*: the prohibition on claiming ownership over genetic resources or derivative products; a restriction on transferring the genetic material to third parties without authorization; recognition of Peru as the country of origin; and, a commitment to exchange information, transfer technology, and provide economic benefits from the application of the genetic material.[49] Lastly, transfer of material to domestically situated *ex-situ* collections must occur under a material transfer agreement (MTA),[50] with the MTA having minimum standards, including restrictions on claiming ownership over the material, and authorization for the transfer of material.[51] Peru's experience highlights role of regional agreements in establishing common standards.

Philippines - Administrative Order No. 1 of 2005 prescribing Guidelines for Bioprospecting Activities in the Philippines and related legislation

The Philippines was an early adopter of ABS rules, starting with Executive Order 247 of 1995.[52] Experience with EO 247 highlighted operational and procedural issues which the Wildlife Resources Conservation and Protection Act of 2001 was intended to address.[53] Lessons learned from implementation informed the development of Administrative Order No. 1 of 2005, which provides Guidelines for Bioprospecting Activities in the Philippines.[54] They outline some of the more innovative legal approaches to benefit-sharing including: annual and cumulative royalty payments, an upfront payment and an annual progress report and equity review. However, challenges posed by the complexity of the system beginning with EO 247, while clarified by the Bioprospecting Guidelines in 2005, continue in effect to impose a functional moratorium on bioprospecting. One of the innovative approaches taken is the use of an annual progress report outlining compliance with PIC, benefit-sharing discernments, and collection quotas,[55] with the equity of the benefit-sharing agreement also monitored.[56]

Malaysia - Access to Biological Resources and Benefit Sharing Act 2013 (draft)

Presently, Malaysia only has sub-national regulations on ABS.[57] However, a bill has been prepared to implement the ABS provisions of the Convention on Biological Diversity, and it is in the final stages of consideration by the legislature. Once adopted, Malaysia can become a Party to the Nagoya Protocol, as domestic legislation is required for ratification. The purpose of the Bill is to regulate bio-prospecting activities in Malaysia, particularly R&D activities with commercial or potential commercial purposes. It implements CBD requirements to promote the fair and equitable sharing of benefits arising from the utilization of biological resources, and has provisions recognizing the role of indigenous and local communities with regard to biological resources and associated traditional knowledge.

Nicaragua, Ley de Biodiversidad, 2012

Nicaragua was the first country to pass a framework biodiversity law post-adoption of the Nagoya Protocol. While the text was drafted prior to the conclusion of the negotiations of the Protocol, the Act nonetheless incorporates many of its provisions. It establishes procedures for access and use of genetic resources and incorporates ABS explicitly into the compliance framework. Also including *sui generis* recognition of indigenous IP rights over cultural practices and knowledge, it shows strong potential. Applications for access permits must outline research participation from within Nicaragua, technology transfer, payments of benefits to be paid arising out of commercialization, and an appointed central repository for samples.[58] S*ui generis* IP rights exist in the cultural practices and knowledge of indigenous communities without any formal recognition to acquire such status.[59]

Norway, Act of Relating to the Management of Biological, Geological and Landscape Diversity (Nature Diversity Act), 2009

Norway has gone the furthest as an industrialized country in developing user measures, and may be fairly close to being in compliance with the requirements of the Nagoya Protocol. A key strength is the emphasis in Norwegian legislation requiring disclosure and consent of the country of origin, with the State empowered to enforce such conditions, providing a safeguard against the misappropriation of genetic resources. Another interesting provision is that access is governed by the principle that genetic material obtained from the environment is to be used, both domestically and internationally, for the greatest possible benefit to global humanity, and in such a way that safeguards the interests of indigenous peoples and local communities.[60]

Solomon Islands, Protected Areas Act, 2010

The Solomon Islands is one of the few Pacific countries to have bioprospecting rules, and they are contained within protected areas (PA) legislation. The Protected Areas Act restricts bioprospecting without a permit.[61] Obtaining a permit requires the written consent of the owners of the land, an agreement for access, acquisition of the biological resources, relevant technology transfer, monetary and non-monetary benefit or compensation, and a plan outlining the nature and extent of the

[48] *Ibid,* at Art. 20.
[49] *Ibid,* at Art. 23.
[50] *Ibid,* at Art. 29.
[51] *Ibid,* at Art. 33.
[52] Philippines, 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, 18 May 1995, available at: http://www.wipo.int/wipolex/en/details.jsp?id=9627. [EO 247]
53 Philippines, Wildlife Resources Conservation and Protection Act (2001), available at: http://www.wipo.int/wipolex/en/details.jsp?id=9575.
54 Philippines, Joint DENR-DA-PCSD-NCIP Administrative Order No. 1 of 2005 prescribing Guidelines for Bioprospecting Activities in the Philippines, available at: http://faolex.fao.org/docs/pdf/phi93259.pdf. [Bioprospecting Guidelines]
55 Ibid, at Art. 23.
56 Ibid, at Art. 24.
57 E.g. Sabah Biodiversity Enactment 2000, Sarawak Biodiversity Centre Ordinance of 1997, and amendment of 2003, and Sarawak Biodiversity Regulations 2004.
58 Nicaragua, Ley de Biodiversidad at Art. 72. Online: http://www.cbd.int/doc/measures/abs/post-protocol/msr-abs-nic-es.pdf
59 Ibid, at Art. 86.
60 Norway, Act relating to the management of biological, geological and landscape diversity (2009), at s 57, available at: http://www.wipo.int/wipolex/en/details.jsp?id=5707 [Nature Diversity Act].
61 Solomon Islands, Protected Areas Act (2010), at Art. 16, available at: http://faolex.fao.org/docs/pdf/sol94186.pdf.

research to be conducted.[62] While still relatively new, the approach taken by the Solomon Islands may prove instructive to peers in the Pacific.

South Africa, Bioprospecting, Access and Benefit Sharing Regulations of 2008

South Africa's regulatory approach is wide ranging and has proven operational at a basic level. While wide-scale compliance with the rules remains an issue, the approach taken by South Africa highlights how multiple avenues are available to domestic decision-makers when implementing the provisions of the Nagoya Protocol. The ABS framework is made up of sections of the South Africa's Biodiversity Act of 2004,[63] amendments to the Patents Act made in 2005,[64] and the Bioprospecting and Access and Benefit Sharing Regulations of 2008.[65] Bioprospecting guidelines have been issued for providers, users and regulators, and a lively debate on the protection of traditional knowledge continues.

Switzerland – Amendments to Federal Act on the Protection of Nature and Cultural Heritage

Draft measures in Switzerland propose to amend the Federal Act on the Protection of Nature and Cultural Heritage,[66] providing for due diligence and reporting requirements and the potential for the national regulation of genetic resources. With the focus of the measure being to minimize violations of ABS obligations, the Swiss approach may be able to inform the development of monitoring and compliance mechanisms.

EMERGING TRENDS OF GOOD LEGAL PRACTICE AND REMAINING CHALLENGES

This preliminary assessment has identified innovative practices and differing degrees of commonality and divergence regarding the approach taken by countries in the development of a domestic ABS framework, the type of institutions utilized, and the effectiveness of the regime in preserving biodiversity while facilitating equitable access to genetic resources. Australia and Norway are notable examples based on both the prevalence of high-use industries domestically, and the relative success of their regimes.[67]

Access and benefit sharing

South Africa's approach is based on reforming its existing body of biodiversity laws. It is operational at a basic level.

Compliance and Monitoring

Norway emphases in its legislation the requirement for disclosure and the consent of the country of origin, with the state empowered to enforce such conditions, provides a safeguard against the misappropriation of genetic resources.

Costa Rica has a longstanding and effective system administered by the National Commission for Biodiversity Management, with a total of 150 approved access permits for bioprospecting as of 2010.[68] Costa Rica's requirements for collateral of a portion of the R&D budget, and equal royalty sharing with the Ministry of Environment and Energy (MEE) both provide unique routes to ensuring compliance and equity.

Brazil has had a provisional measure in place since 2001. Their experience illustrates the key challenge of ongoing monitoring and compliance, with one report noting that of the 110 patents issued that had a high probability of using Brazilian genetic resources or associated traditional knowledge, only 18 disclosed the origin of the genetic material and only 27 mentioned traditional knowledge.[69]

Traditional Knowledge associated with Genetic Resources

Peru is one of the first countries in the world to comprehensively address the protection of traditional knowledge through its unique system for collective knowledge, and explicitly recognizes country of origin in both TK and ABS legislation. One example of local empowerment in Peru is the training of local women to document traditional practices, and the distribution of video cameras to local communities to assist in facilitating TK filings with the local registries

Scope of the Measure

Nicaragua, having passed its law in 2012, post-adoption of the Nagoya Protocol, incorporates ABS explicitly into the compliance framework with *sui generis* recognition of indigenous IP rights over cultural practices and knowledge, and shows strong potential as a broadly scoped piece of legislation.

Institutional Measures

Australia has a clearly defined system which allows controlled access to its immense wealth of biological resources through PIC and MTA, administered nationally, as well as regionally through a network of designated authorities. The legal empowerment of regional administrative or protective organizations with specialized knowledge to establish ABS agreements relating to their jurisdiction has proven an effective

62 Ibid, at Art. 18(5).
63 Republic of South Africa, National Environmental Management: Biodiversity Act 2004, Act No.10 2004, available at: http://faolex.fao.org/docs/pdf/saf45083.pdf. [Biodiversity Act]
64 Republic of South Africa, Act No.20 of 2005: Patents Amendment Act, 2005, *Government* Gazette Vol. 486, No. 28319 (9 December 2005) available at: http://www.wipo.int/tk/en/laws/pdf/sa_patent_amend.pdf. [Patents Amendment Act 2005]
65 Republic of South Africa, National Environmental Management: Biodiversity Act 2004 (Act No.10 2004) Regulations on Bioprospecting and Access and Benefit Sharing 2008, available at: http://www.wipo.int/wipolex/en/text.jsp?file_id=179663. [ABS Regulations]
66 http://www.cbd.int/abs/side-events/cop-11/switzerland-en.pdf
67 David Vivas-Eugui, Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee, ICTSD's Programme on Innovation, Technology and Intellectual Property: Issue Paper No. 34 (Jan. 2012), at 9, 31, available at: http://ictsd.org/downloads/2012/02/bridging-the-gap-on-intellectual-property-and-genetic-resources-in-wipos-intergovernmental-committee-igc.pdf. [ICTSD 2012]
68 Ibid, at 10.
69 Supra, ICTSD 2012 at 31.

way to monitor the plethora of conditions addressed by each ABS agreement.

Remaining Challenges

While South Africa, Kenya, and Ethiopia all have ABS frameworks in place, their collective experiences highlight the gaps between legislation and actualization. South Africa's non-*sui generis* approach is unique and has proven operational at a basic level, but wide-scale compliance with the rules remains an issue. Kenya's legislation includes an expansive list of monetary and non-monetary benefits to provide clarity in benefit-sharing negotiations. But although the concepts of MAT and PIC are present, there is little content of what constitutes either, and gaps remain in clarifying what Competent Authorities or the kind of local communities that can grant PIC in practice. Ethiopia, similarly, has detailed bioprospecting legislation in place, including co-ownership of IP, but faces difficulties in ensuring compliance, often extra-territorially. An example of this difficulty is the benefit-sharing agreement for *teff* with HPFI, which resulted in minimal monetary benefits prior to the issuance of a broad patent for *teff* processing, a questionable bankruptcy, and the eventual transfer of exclusive IP rights to *teff* without ABS obligations.[70] While the legality of the patent remains clouded,[71] the Ethiopian experience highlights the importance of having explicit regulation on transfer, as well as clear explanations on the effective application and monitoring of ABS.[72]

Similarly India, which has been regulating ABS in a general manner since 2002, and promulgated specific rules on the subject in 2004, continues to face the unabated misappropriation of genetic resources and traditional knowledge. Domestic and foreign challenges – such as the case of *Bt Brijnal* involving a Monsanto subsidiary,[73] and the *Neem Tree* case, where in 2005 the Technical Board of Appeals of the European Patent Office (EPO) revoked a patent based on grounds of prior public use[74] -- illustrate the continued difficulty of extraterritorial monitoring and enforcement.[75] The Philippines outlines some of the more innovative legal approaches to benefit-sharing including: annual and cumulative royalty payments, an upfront payment, and an annual progress report and equity review. However, challenges have arisen due to the complexity of the system, beginning with EO 247. While clarified somewhat by the Bioprospecting Guidelines in 2005, this complexity continues in effect to impose a functional moratorium on bioprospecting. The Solomon Islands is one of the few Pacific countries to have bioprospecting rules, contained within protected areas legislation. While still relatively new, the approach taken by the Solomon Islands may prove instructive.

The challenges of developing an effective framework are great, with Australia, Norway and Costa Rica all illustrating promising institutional approaches. However, the continuing challenges relating to building capacity for ongoing monitoring, addressing the misappropriation of genetic resources, clarifying what constitutes valid PIC and MTA, and balancing the institutional need for information for enforcement, all while facilitating access for development purposes, remain difficult to cogently address.

[70] Regine Andersen & Tone Winge, The Access and Benefit-Sharing Agreement on Teff Genetic Resources:
Facts and Lessons (FNI Report 6/2012), available at:
http://www.fni.no/doc&pdf/FNI-R0612.pdf.
71 Ibid, at 143-144.
72 Ibid, at 27.
73 Leo F. Saldanha & Bhargavi S. Rao, Monsanto's Brinjal Biopiracy: A Shocking Expose of Callous Disregard for Biodiversity Law in India, in India Law News (Fall 2011), at 26-28, available at:
http://meetings.abanet.org/webupload/commupload/IC906787/newsletterpubs/India_Law_News_Fall_2011_Issue.pdf.
74 European Patent Office, Technical Board of Appeals, Decision 3.3.2 of 8 March 2005 (Case Number T 0416/01), at 3, available at:
http://www.epo.org/law-practice/case-law-appeals/pdf/t010416eu1.pdf.
75 Morten Walløe Tvedt, Elements for Legislation in User Countries to Meet the Fair and Equitable Benefit-Sharing Commitment, The Journal of World Intellectual Property (2006) Vol. 9, no. 2, pp. 189–212, at 191.

PART IV: LEADING LEGAL PUBLICATIONS FOR FURTHER READING

E Morgera, M Buck, and E Tsioumani, eds, The 2010 Nagoya Protocol on access and benefit-sharing in perspective: Implications for international law and implementation challenges (Leiden, The Netherlands: Martinus Nijhoff Publishers, 2013).

Geoff Burton, Jorge Cabrera, George Greene, and Michael Gullo, ABS Management Tool: Best Practice Standard and Handbook for Implementing Genetic Resource Access and Benefit Sharing Activities (Swiss State Secretariat for Economic Affairs, 2012)

Thomas Greiber, Sonia Peña Moreno, Mattias Åhrén, Jimena Nieto Carrasco, Evanson Chege Kamau, Jorge Cabrera Medaglia, Maria Julia Oliva and Frederic Perron-Welch in cooperation with Natasha Ali and China Williams, An Explanatory Guide to the Nagoya Protocol, IUCN Environmental Policy and Law Paper No. 83 (Gland, Switzerland: IUCN, 2012).

M Ruiz and R Vernooy, eds, The custodians of biodiversity: Sharing access and benefits to genetic resources. (New York, N.Y: Earthscan and IDRC, 2012).

Tania Bubela & E Richard Gold (2012). Genetic Resources and Traditional Knowledge: Case Studies and Conflicting Interests. Cheltenham: Edward Elgar Pub.

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)

MS Suneetha and Balakrishna Pisupati, Benefit Sharing in ABS: Options and Elaborations(UNU-IAS, 2009)

Secretariat of the Convention on Biological Diversity, Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors, Technical Series No 38 (Montreal: SCBD, 2008).

Balakrishna Pisupati, UNU-IAS Pocket Guide: Access to Genetic Resources, Benefit Sharing and Bioprospecting (2007)

Lyle Glowka, A guide to designing legal frameworks to determine access to genetic resources (Gland: IUCN, 1998).

Lyle Glowka, Françoise Burhenne-Guilmin and Hugh Synge, Guide to the Convention on Biological Diversity (Gland: IUCN, 1994)

Jorge Cabrera Medaglia, Frederic Perron-Welch and Olivier Rukundo, Overview of National and Regional Measures on Access to Genetic Resources and Benefit-Sharing: Challenges and Opportunities in Implementing the Nagoya Protocol, 5th Edition (Dec. 2011) available at: http://www.sib.admin.ch/uploads/media/Overview_of_ABS_Measures_2011_01.pdf.

Jorge Cabrera Medaglia, Morten Walløe Tvedt, Frederic Perron-Welch, Ane Jørem and Freedom-Kai Phillips, "The Interface between the Nagoya Protocol on ABS and the ITPGRFA at the International Level: Potential Issues for Consideration in Supporting Mutually Supportive Implementation at the National Level" FNI Report 01/2013, available at: http://www.fni.no/doc&pdf/FNI-R0113.pdf.

Legal Preparedness for Achieving the Aichi Biodiversity Targets

The global initiative on Legal Preparedness for Achieving the Aichi Biodiversity Targets is connecting people globally to collaborate on empowering laws for biodiversity. The Initiative focuses on sharing evidence, experiences and good practices on biodiversity-minded legal approaches being implemented in countries around the world. Through this knowledge exchange, it aims to rapidly foster new thinking, build new capacity, and provide practical guidance to engage governments, citizens and the private sector to develop new legal approaches, tailored to country and local contexts, to achieve the Aichi Biodiversity Targets.

Author:

This Working Paper on Legal Aspects of Aichi Biodiversity Target 16: A Scoping Study was authored by Jorge Cabrera Medaglia, CISDL; Frederic Perron-Welch, CISDL; and Freedom-Kai Phillips, CISDL. Special thanks and acknowledgement for their valuable expert reviews go to Dr. Alejandro Lago Candeira, Rey Juan Carlos University; Dr. Elisa Morgera, The University of Edinburgh; Dr. Evanson Chege Kemau, University of Bremen, Germany; Dr. Kaspar Sollberger, Swiss Federal Office of the Environment; Dr. Rachel Wynberg, University of Cape Town; Mr. Manuel Ruiz, SPDA; Mr. Thomas Greiber, IUCN; Ms. Maria Julia Oliva, Union for Ethical Biotrade; and Ms. Valerie Normand, ABS Capacity Development Initiative.

About the Scoping Study

This scoping study is a "living document" aimed at setting out the existing state of legal knowledge intended to provide a foundation for discussion and research, to be updated as new knowledge is gathered through consultations and further study. We appreciate your comments to add to and improve this study, please send to **AichiLaw@idlo.int**.

Download the PDF at www.idlo.int/AichiLaws