

WORKING PAPER

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



Version 1.0



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LIST OF ACRONYMS

ABS	Access and Benefit-Sharing
ANAM	National Environmental Authority
ARIPO	African Regional Intellectual Property Organization
ATS	Antarctic Treaty System
AU	African Union
CBD	Convention on Biological Diversity
CGEN	Genetic Heritage Management Council
CGRFA	Commission on Genetic Resources for Food and Agriculture
CNPQ	National Council for Scientific and Technological Resources
CONAGEBIO	National Commission for the Management of Biodiversity
COP	Conference of the Parties
EO	Executive Order
EPO	European Patent Office
EU	European Union
FAO	Food and Agriculture Organization
GR	Genetic Resources
HPFI	Health Performance and Food International
IBAMA	Brazilian Institute of Environment and Renewable Natural Resources
IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IHR	International Health Regulations
ILC	Indigenous and Local Communities
IP	Intellectual Property
IPR	Intellectual Property Rights
IP/GR	Intellectual Property Issues Related to Genetic Resources
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	Mutually Agreed Terms
MEE	Ministry of Environment and Energy
MLS	Multilateral System
MTA	Material Transfer Agreement
NBSAPs	National Biodiversity Strategies and Action Plans

Legal Preparedness for Achieving the Aichi Biodiversity Targets

PA	Protected Areas
PIC	Prior Informed Consent
PIPF	Pandemic Influenza Preparedness Framework
R&D	Research and Development
S&T	Science and Technology
TCE	Traditional Cultural Expressions
TK	Traditional Knowledge
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNARGEN Unit for Access to Genetic Resources	
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
UNDRIPS United Nations Declaration on the Rights of Indigenous Peoples	
UPOV	International Union for the Protection of New Varieties of Plants
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WSSD	World Summit on Sustainable Development
WTO	World Trade Organization

FEATURES OF THIS SCOPING PAPER

What function does it have?

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 research. This survey of legal knowledge is intended to provide a foundation for future research work on the most promising instruments that will support the implementation of Target 16. The survey will also examine the effectiveness of specific regional, national and subnational legal approaches. Finally, the foundational research will serve to develop practical legal guidance to assist policy-makers and other stakeholders in their attempts to achieve Target 16 through concrete action at the national level. This scoping paper forms part of a series of publications prepared under the Legal Preparedness for Achieving the Aichi Biodiversity Targets program.

What questions does it set out to answer?

This scoping paper sets out to answer four important research questions on the role of law and regulatory instruments necessary for countries to achieve their goals related to Aichi Biodiversity Target 16.

The research questions are:

- > What is the legal context of Target 16 and what are the rationale and meaning of its elements?
- > What are the international and regional regimes that inform and/or impact the implementation of Target 16 at the national level?

- > What are some promising legal approaches for further research that are helping countries achieve Target 16 or parts of it?
- > What are the relevant legal and non-legal publications related to Target 16?

Who are the contributors?

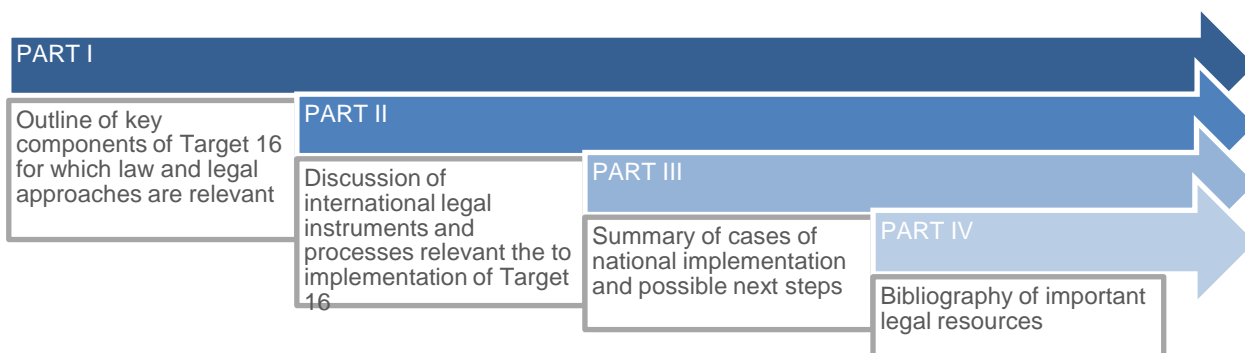
This paper has been authored by legal experts from the Centre for International Sustainable Development Law who have researched leading legal publications, measures, national experiences, and programs to survey and assess legal considerations relevant to the achievement of Target 16. These legal experts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

What is the intended audience?

Audience members are:

- > the community of lawyers, policy-makers, legislators and jurists who will be directly involved in the development and implementation of national and regional measures related to the Nagoya Protocol; and
- > academics, communities, private sector actors, and other stakeholders involved in implementing provisions related to the CBD and ratification or implementation of the Nagoya Protocol for whom this scoping paper will serve as an important resource.

How is it organized?



PART I: CONTEXT AND BACKGROUND

Target 16: By 2015, the Nagoya Protocol on Access to Genetic Resources (GR) 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 GR 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 GR and the fair and equitable sharing of benefits arising out of the utilization of GR, on the basis of prior informed consent (PIC) and mutually agreed terms (MAT).

Following the adoption of the 2002 Bonn Guidelines at the 6th meeting of the Conference of the Parties (COP 6) to the CBD,² the call for the negotiation of an international regime on access and benefit-sharing (ABS) issued at the 2002 World Summit on Sustainable Development,³ and six years of negotiations, the COP 10 adopted the Nagoya Protocol on ABS in 2010. Target 16 was approved as a part of the Strategic Plan for Biodiversity 2011-2020, a decade-long action plan to promote the Nagoya 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 update 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.



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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 Nagoya 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 Depository establishes binding consent.⁶ Upon its entry into force, the Protocol will only be binding upon the States that have ratified it. 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.

As a matter of domestic law, the treaty ratification process gives countries sufficient time to seek approval and input from their citizens, and, when applicable, to enact the required legislation and other instruments for protocol operationalization. This process varies by country. Some countries do not need to adopt national measures prior to ratification. In these cases, a standalone measure such as an executive decree suffices for ratification of the Protocol. Others must undertake a more comprehensive process that may include the implementation of legislation which accepts the Protocol as binding and details implementation standards, for example, or other legal measures. 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. Strong political commitment from interested levels of

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 The Bonn Guidelines were adopted to assist Parties in establishing administrative, legislative or policy measures on access and benefit-sharing (ABS) and/or when negotiating contractual arrangements for access to GR and benefit-sharing.

³ *Report of the World Summit on Sustainable Development*, Johannesburg, South Africa, 26 August-4 September 2002, chap. IV, sect. 44 (A/CONF.199/20).

⁴ Greiber et al, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing*, IUCN Environmental Policy and Law Paper No. 83 (2012) 274.

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

⁶ *Convention on Biological Diversity*, opened for signature 5 June 1992, Rio de Janeiro, Brazil, 1760 UNTS 79 / 31 ILM 818 (1992), art 34 (entered into force 29 December 1993).

government in favor of a vigorous pursuit to ratify the Protocol with a clear timeframe for execution is key to its successful entrance into force by 2015.

OPERATIONALIZATION OF THE NAGOYA PROTOCOL

The Nagoya Protocol contains five 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 be recognized.

The five operative components are:

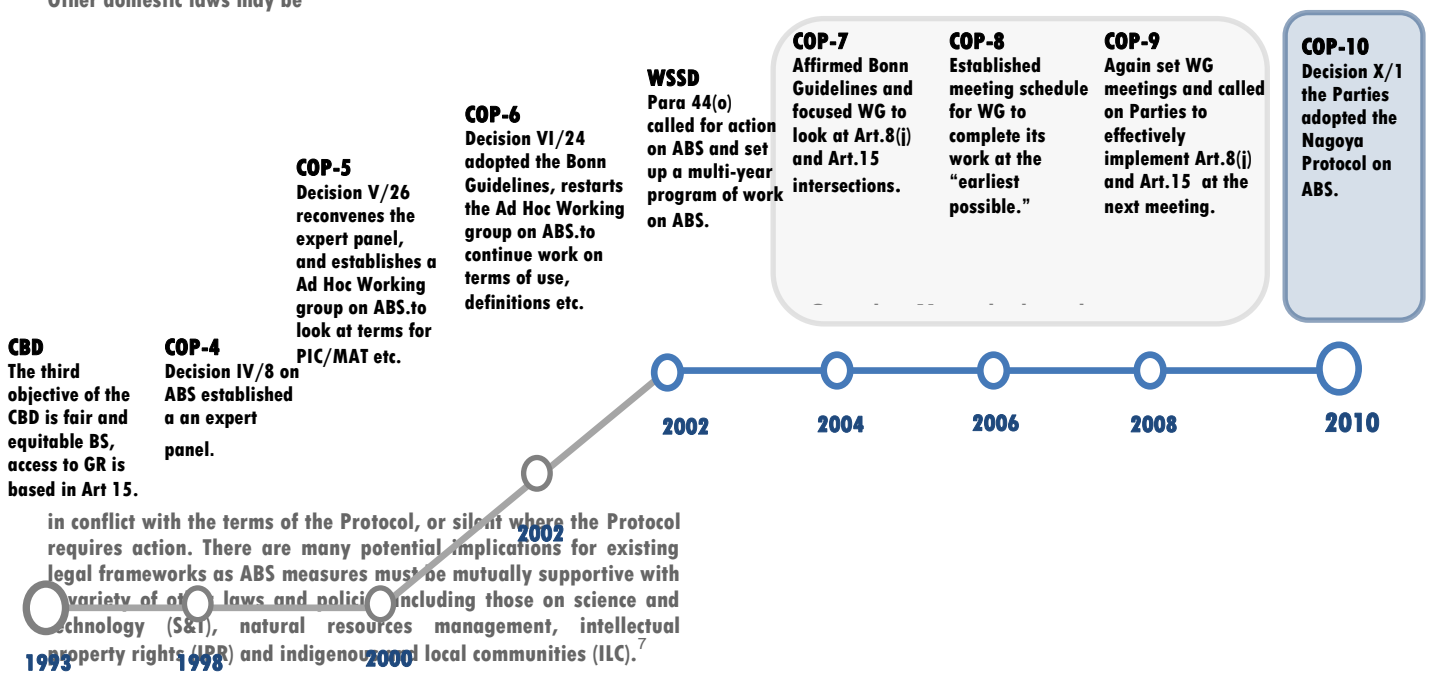
- > ABS requirements related to commercial and non-commercial use;
- > transparency, monitoring and compliance;
- > protection of traditional knowledge (TK) associated with GR;
- > scope of measure, including delineating the use of GR; and
- > creation of supportive institutional and administrative structures.

These main components highlight important themes to be addressed including access to GR, access to TK, 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

FAVOR OF A VIGOROUS PURSUIT TO RATIFY THE PROTOCOL WITH A CLEAR TIMEFRAME FOR EXECUTION IS KEY TO ITS SUCCESSFUL ENTRANCE INTO FORCE BY 2015

Few countries have experience with the implementation of the Nagoya Protocol; this is, in part, because the Protocol has not yet come into force. As a consequence, there is a great need to seek guidance by looking back at past ABS implementation experiences in places such as Australia, Brazil, Costa Rica, and South Africa to draw on lessons learned and areas for improvement. Another important source of instruction comes from recent attempts to operationalize the Nagoya Protocol in CBD Party countries such as Denmark, the European Union, Malaysia, Mexico, Switzerland that have begun adopting or reforming laws and regulations to meet the obligations set out in the Protocol. This paper focuses on drawing 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 revised on an ongoing basis to assess the implementation of updated measures.



STRONG POLITICAL COMMITMENT FROM INTERESTED LEVELS OF GOVERNMENT IN

⁷T Greiber et al, above n 4, 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 allusion to international agreements referenced in the Preamble to the Nagoya Protocol, and provide 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.⁸ Not all of the laws, instruments and processes listed are relevant or of equal importance for every country.

International Treaty on Plant GR for Food and Agriculture 2001 and Food and Agriculture Organization Commission on GR for Food and Agriculture 1983

GR for food and agriculture are vital for food security globally. The Commission on GR for Food and Agriculture (CGRFA) of the Food and Agriculture Organization (FAO) was established in 1983 to address issues pertaining to plant GR, 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 International Treaty on Plant GR for Food and Agriculture (ITPGRFA) are conservation, the sustainable use of plant GR for food and agriculture, and the equitable sharing of benefits from use.⁹ The ITPGRFA creates a Multilateral System (MLS) for ABS under article 10(2), to facilitate access to specific GR (35 major food crops and 29 forage genera). Access is facilitated under specific terms as outlined in article 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 article 12(4); and, recipients may not claim IPR over material in the form received from the MLS pursuant to article 12(3)(d). Article 13 of the ITPGRFA outlines the benefit-sharing requirements under the MLS, with the Parties acknowledging the obligation to share equitably the benefits arising from use of plant GR. Article 13(2)(d) discusses the sharing of monetary and other benefits of commercialization in particular. In practice, crops held by CGIAR, formerly known as the Consultative Group on International Agricultural Research, and other research centers which are not a part of the MLS are traded using the same standard MTA, in effect applying an equivalent standard of protection as crops under the MLS.¹⁰



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International Union for the Protection of New Varieties of Plants 1961

The International Union for the Protection of New Varieties of Plants (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* intellectual property (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.¹¹

United Nations Convention on Combatting Desertification 1994

The United Nations Convention on Combatting Desertification (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. This ensures that that such technology, knowledge, know-how and practices are adequately protected and that local populations benefit directly, on an equitable basis and as mutually agreed, from

⁸Secretariat of the Convention on Biological Diversity, *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: text and annex*, opened for signature 29 October 2010, Nagoya, Japan, K3488 .A48 2011.

⁹*International Treaty on Plant Genetic Resources on Food and Agriculture*, opened for signature 3 November 2001, art 1 (entered into force 29 June 2004).

¹⁰For more information see: J Cabrera Medaglia et al, *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 No. 1 (2013).

¹¹*International Convention for the Protection of New Varieties of Plants of 2 December 1961, as revised at Geneva on November 1972 and on 23 October 1978*, opened for signature on 23 October 1978, Geneva, Switzerland, art 15(1) (entered into force 8 November 1981).

their commercial utilization or from any technologically developed derivative.¹²

United Nations Convention on the Law of the Sea 1982

The United Nations Convention on the Law of the Sea (UNCLOS)¹³ was adopted in 1982 and came into force in 1994; it 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 possess 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.¹⁴ 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 GR found in outer zones.

United Nations Declaration on the Rights of Indigenous Peoples 2007

The United Nations Declaration on the Rights of Indigenous Peoples (UNDRIPS) was adopted by the UN General Assembly in 2007 and addresses the rights of indigenous peoples on subjects including knowledge, lands, territories and resources.¹⁵ The UNDRIPS is relevant because it addresses issues related to the implementation of measures regarding indigenous and local communities, genetic resources, and TK. For example, article 31 states that indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, their TK and traditional cultural expressions (TCE), as well as the manifestations of their sciences, technologies and cultures, including human and GR, seeds, medicines, and knowledge of the properties of fauna and flora in addition to their IP over such cultural heritage, TK, and TCE. Article 18 holds that indigenous peoples have the right to participate in decision-making in matters that affect their rights, through autonomous selection of representatives in accordance with their own procedures, as well as the right 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 and PIC 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 and Influenza Framework 1983

Rapid access to pathogenic material is vital to safeguarding human health in times of crisis. The International Health Regulations (IHR), global standards developed by the World Health Organization (WHO) to enhance public health security on national and regional bases, remind Parties of the importance of access to pathogens for pandemic preparedness and response.¹⁶ 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.¹⁷ The PIPF could be considered a specialized instrument under the article 4(4) of the Nagoya Protocol.

World Intellectual Property Organization Intergovernmental Committee on IP and GR, TK and Folklore 2000

Negotiations in the World Intellectual Property Organization's (WIPO) Intergovernmental Committee on IP and GR, TK and Folklore (IGC) have resulted in draft articles providing for three international instruments for the protection of TK, TCE, and IP issues related to GR (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. Agreement on Trade-Related Aspects of Intellectual Property Rights 1995)¹⁸

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)¹⁹ 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 meet novelty, inventiveness, and industrial applicability requirements.²⁰ On the contrary, treatment methods for animals and humans,²¹ plants and animals themselves,²² and biological processes for plant and animal production are not patentable. Finally, the TRIPS Agreement commands the protection of plant varieties either by a patent-based system, a *sui generis* system (e.g. UPOV), or a combination thereof.²³

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 1993

With the passing of Decision 391 in 1993, the Andean Community comprised of Bolivia, Colombia, Ecuador, Peru, and Venezuela (that has since withdrawn) created the first regional approach to ABS.²⁴ This Decision, which came into force in 1996, outlines both general principles and specific rules for access. Rights under Decision 391 include national sovereignty over GR²⁵ and the participation of indigenous peoples in decision-making regarding TK,²⁶ with access regulations applying to GR and their derivatives, as well as intangibles such as TK, innovations and cultural practices.²⁷ Decision 391 further prescribed respect of the rights and interests of the provider, including interests over the biological resources or associated TK as part of access contracts.²⁸ Finally, access contracts

¹²United Nations Convention on Combating Desertification in Those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa, opened for signature 14 October 1994, Paris, France, UNTS 1954, art 18(2)(b) (entered into force 26 December 1996).

¹³United Nations Convention on the Law of the Sea, opened for signature on 10 December 1982, Montenegro, Jamaica, UNTS 1833, art 14, 15 (entered into force 16 November 1994).

¹⁴Ibid art 77(4).

¹⁵United Nations General Assembly, Declaration on the Rights of Indigenous Peoples: resolution/adopted by the General Assembly, 13 September 2007 (A/RES/61/295)

¹⁶World Health Organization, The International Health Regulations, Preamble (3rd ed 1983).

¹⁷World Health Organization, Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (2011) art 3.

¹⁸Several Bilateral and Regional Free Trade Agreements also incorporate specific provisions on the relationship between ABS and IP often in the environmental or IP chapters.

¹⁹Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Marrakesh, Morocco (entered into force 1 January 1995).

²⁰Ibid art 27(1).

²¹Ibid art 27(3)(a).

²²Ibid art 27(3)(b).

²³Ibid.

²⁴Andean Community Decision No. 391 of July 2, 1996 - Common Regime on Access to Genetic Resources (Caracas, Venezuela) art 2.

²⁵Ibid art 5, 6.

²⁶Ibid art 7.

²⁷Ibid art 17.

²⁸Ibid art 34.

must also include an annex outlining monetary and/or non-monetary benefits to be equitably shared with the supplying party.²⁹

African Model Law on the Rights of Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources 2000

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 TK; (ii) the recognition of plant breeders' rights; (iii) the provision of a mechanism for access to community resources based on PIC; and (iv) the promotion of a mechanism for the fair and equitable sharing of benefits arising from the use of biological resources or TK.³⁰ Any access to the biological resources or TK of local communities must be done with PIC,³¹ and benefit-sharing, including an up-front payment, must be incorporated into the access permit.³² Furthermore, the Model Law recognizes the rights of communities: (i) their right over their biological resources, (ii) the right to collectively benefit from the use of their biological resources, (iii) their right to 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.³³ 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 with direct impact.



Swakopmund Protocol on the Protection of TK and Expressions of Folklore within the Framework of the African Regional IPOrganization 2010

The Swakopmund Protocol was adopted by the African Regional IP Organization (ARIPO) in 2010 and entered into force January 2012. The Protocol aims to: (a) protect TK holders from any infringement on their rights as recognized within the Protocol, and (b) protect cultural expressions against misappropriation, misuse and/or exploitation.³⁴ Broad definitions of TK and folklore are employed,³⁵ along with a unique set of protections for holders of TK. Specifically, holders under the Protocol are deemed beneficiaries,³⁶ and receive exclusive rights over: the authorization of use of their TK,³⁷ prevention of the exploitation of TK without PIC,³⁸ the institution of legal proceedings to remedy infringements of rights protected under the Protocol,³⁹ and fair and equitable benefit-sharing arising from the commercial use of their TK.⁴⁰

²⁹Ibid art 35.

³⁰Organization of African Unity, *Model Law on the Rights of Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*, Algeria (2000), part I.

³¹Ibid art 5.

³²Ibid art 12.

³³Ibid art 16.

³⁴African Regional Intellectual Property Organization, *Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore*, opened for signatures on 9 August 2010, Swakopmund, Namibia, art 1.1.

³⁵Ibid s 2.1.

³⁶Ibid s 6.

³⁷Ibid s 7.1.

³⁸Ibid s 7.2.

³⁹Ibid s 7.4.

⁴⁰Ibid s 9.

PART III: NATIONAL AND SUBNATIONAL IMPLEMENTATION

Various experiences of national implementation of Target 16 goals will be discussed in the following section. First, a look at the implications for domestic implementation with a focus on the two interlinked components of the Nagoya Protocol will be explored. Next, a survey of legal approaches from seventeen countries will provide an overview of the range of legal instruments used at the domestic level. Lastly, the rationale for choosing and focusing upon the aforementioned legal approaches in further research will be discussed. This section is primarily focused on possible next steps toward achieving Target 16 through concrete action at the national level.

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 have their needs addressed?

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 commitments 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 GR and TK (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 TK associated with GR of indigenous peoples, smallholder farmers and local communities (e.g. *sui generis* protection); and
- > 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. These include lessons regarding: the scope of application and legal status of GR and associated TK, the necessity of providing PIC 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, negotiate and enforce benefit-sharing, as well as monitor and check compliance.⁴¹

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 country specific legislative, administrative or policy measures need to be developed 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

As 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 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 implemented components of the Protocol (eg. Nicaragua), or are well in 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.⁴² Australia's ABS measures clearly define the object of exchange, and imposing obligations on subsequent users through PIC

⁴¹ T Greiber et al, above n 4, 279–280.

⁴² *Environment Protection and Biodiversity Conservation Act 1999* (Australia) art 3.

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 Provisional Act No. 2,186-16, Dated August 23 2001

Brazil has regulated access to GR/TK through a provisional measure since 2001, and their experience illustrates the key challenge of ongoing monitoring and compliance. The measure designates 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 TK for scientific purposes, bio-prospecting and technological development. Research institutions IBAMA (Brazilian Institute of 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 GR as a way to decentralize the system.⁴³ A comprehensive draft law is pending approval following 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 the Management of Biodiversity (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 research and development (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.⁴⁴

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

Danish draft legislation prohibits the use of GRs or TK acquired in contravention of access regulations in the access country. The draft bill also provides for sanctions including fines and imprisonment.⁴⁵

Ethiopia - Access to GR and Community Knowledge, and Community Rights Proclamation

Ethiopia has detailed ABS legislation applicable in cases of access to GR found in both *in situ* or *ex situ* collections, and to the TK of local communities.⁴⁶ Despite the inclusion of legislative components reinforcing co-ownership of IP, experience has shown the difficulty of ensuring compliance. An example of this difficulty is the benefit-sharing agreement with the Dutch company Health and Performance Food International (HPFI) around *teff*, a cereal crop species.⁴⁷ This particular agreement 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.⁴⁸ While the legality of the patent remains clouded, the Ethiopian experience highlights the importance of having explicit regulation on transference and instruction on how to ensure ABS is to be applied and monitored effectively.

European Union - Draft Regulation on Access to GR and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

The current European Union (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 Nagoya Protocol in both the jurisdictions.

Kenya - Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to GR and Benefit-Sharing) Regulations 2006

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 explanation 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.⁴⁹

India - Biological Diversity Act 2002 and Biological Diversity Rules 2004

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 misappropriation of GR and TK continue. Domestic and foreign challenges (e.g. Neem Tree)⁵⁰ illustrate the continued difficulty of regulating access, monitoring and enforcement. The 2002 Act covers the conservation, use of biological resources and associated TK 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 biological resources in India. The 2004 Rules lay out detailed requirements for access to GR, TK, IPR, material transfer to third parties, criteria for equitable benefit-sharing, dispute settlement, and revocation of access or approval.⁵¹

Malaysia –Draft Law Access to Biological Resources and Benefit-Sharing Act 2013

Presently, Malaysia only has sub-national regulations on ABS.⁵² 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

⁴³F Álvares Silva and L Salmen Espindola, 'Access Legislation on Genetic Resources

Patrimony and Traditional Knowledge' (2001) 21(1) Brazilian Journal of Pharmacology

⁴⁴For further information see: Secretariat of Convention on Biological Diversity, *Regional or National Measures: Costa Rica*, Convention on Biodiversity <<http://www.cbd.int/abs/measures/group/default.shtml?code=cr>> at 23 January 2014.

⁴⁵Unofficial Translation of Draft Bill on Sharing Benefits Arising from the Utilisation of Genetic Resources <<http://www.cbd.int/doc/measures/abs/post-protocol/msr-abs-dnk-en.pdf>> at 23 January 2014.

⁴⁶World Intellectual Property Organization, *Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482* (2006) art 4.

⁴⁷R Andersen and T Winge, *The Access and Benefit-Sharing Agreement on Teff Genetic Resources: Facts and Lessons*, FNI Report No. 6 (2012).

⁴⁸Ibid.

⁴⁹*The Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations*, Legal Notice No. 160 (2006).

⁵⁰Boards of Appeal of the European Patent Office, *Decision of 8 March 2005* (Case No. T0416/01 - 3.3.2).

⁵¹*Biological Diversity Act and Biological Diversity Rules 2002* (India).

⁵²Examples include: Sabah Biodiversity Enactment 2000, Sarawak Biodiversity Centre Ordinance of 1997, and amendment of 2003, and Sarawak Biodiversity Regulations 2004.

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 TK.



Mexico –Access to GR and Associated TK Protection Draft General Law and Related Legislations

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

Nicaragua -Biodiversity Law 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 GR 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.⁵³ *Sui generis* IP rights exist in the cultural practices and knowledge of indigenous communities without any formal recognition to acquire such status.⁵⁴

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 GR. Another interesting provision involves governed access on 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 a way that safeguards the interests of indigenous peoples and local communities.⁵⁵

Panama –Executive Decree No. 25, April 29 2009, regulating article 71 of the General Law on Environment (Law No. 41 of July 1, 1998)

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. The National Environment Authority (ANAM) regulates and controls access, while the Unit for Access to GR (UNARGEN) oversees applications and contracts for access. Scope includes access to genetic and biological resources (*in-situ* and *ex-situ*), 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 TK, PIC and benefit-sharing, Certificate of origin or provenance. Additional laws and regulations govern the protection of TK through a *sui generis* system.

Peru –Regulations on Access to Genetic Resources, Supreme Decree 003-2009-MINAM and Law No. 27, 811 (2002), Andean Decree No. 391

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 TK 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 GR for which Peru is the country of origin, or that come from Peruvian territory. Access contracts are required for access to GR,⁵⁶ with the minimum terms being, *inter alia*: the prohibition on claiming ownership over GR 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.⁵⁷ Lastly, transfer of material to domestically situated *ex-situ* collections must occur under a material transfer agreement (MTA),⁵⁸ with the MTA having minimum standards, including restrictions on claiming ownership over the material, and authorization for its transfer.⁵⁹ Peru's experience highlights role of regional agreements in establishing common standards.

⁵³ Ley de Conservación y Utilización Sostenible de la Diversidad Biológica 2006 (Nicaragua) art 72.

⁵⁴Ibid art 86.

⁵⁵ Nature Diversity Act (Act No. 100 of June 19, 2009 relating to the Management of Biological, Geological and Landscape Diversity) 2009 (Norway), s 57.

⁵⁶ Regulation on Access to Genetic Resources (Ministerial Resolution No. 087-2008-MINAM of December 31, 2009) (Peru) art 20.

⁵⁷Ibid art 23.

⁵⁸Ibid art 29.

⁵⁹Ibid art 33.

Philippines - Administrative Order No.1 2005 prescribing Guidelines for Bioprospecting Activities and Related Legislation

The Philippines was an early adopter of ABS rules, starting with Executive Order (EO) 247 of 1995.⁶⁰ Experience with EO 247 highlighted operational and procedural issues which the Wildlife Resources Conservation and Protection Act of 2001 was intended to address.⁶¹ Lessons learned from implementation informed the development of Administrative Order No. 1 of 2005, which provides Guidelines for Bioprospecting Activities in the Philippines.⁶² 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,⁶³ with the equity of the benefit-sharing agreement also monitored.⁶⁴

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 PAA restricts bioprospecting without a permit.⁶⁵ 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 research to be conducted.⁶⁶ 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 South Africa's Biodiversity Act of 2004,⁶⁷ amendments to the Patents Act made in 2005,⁶⁸ and the Bioprospecting and ABS Regulations of 2008. Seventy bioprospecting guidelines have been issued for providers, users and regulators, and a lively debate on the protection of TK 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,⁶⁹ providing for due diligence and reporting requirements and the potential for the national regulation of GR. With the focus of the measure being to

minimize violations of ABS obligations, the Swiss approach may inform the development of monitoring and compliance mechanisms.

NEXT STEPS AND RATIONALES FOR FURTHER RESEARCH INTO NATIONAL MEASURES

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 GR.

In the table that follows, a summary of the cases of national implementation is provided along with the rationale for further research into each of these legal instruments. Much can be gained from a further look into the aforementioned instruments with particular attention to their novel aspects and associated remaining challenges. The legal instruments are divided according to their chronological reference to Nagoya Protocol: pre-Nagoya Protocol, post-Nagoya Protocol, and legislative processes underway to ratify the Nagoya Protocol.

⁶⁰ 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, Executive Order No. 247 (Philippines).



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Country	Law or regulation	Rationale for Further Study
<p>a) Pre-Nagoya Protocol legislation</p> <p>Since the entry in force of the CBD in 1993, countries have enacted legislation to implement article 15 of the CBD. Review of these laws can produce lessons learned as they implement components – MAT, PIC, ABS, etc. - contained within the Nagoya Protocol.</p>		
Costa Rica	Biodiversity Law(1998), and Executive Decrees on ABS (2003, 2007, 2008)	An example of effective and comprehensive ABS legislation , with indications of implementation success (150 approved access permits as of 2010). Despite its efficiency, lessons can also be learned from its remaining challenges – gap in binding requirements of use of benefits, lack of proper protocols and guidelines for PIC, and need for capacity building for MAT negotiations to balance bargaining power.
Australia	Environment Protection and Biodiversity Conservation Act (1999) and Environment Protection and Biodiversity Conservation Regulations (2000)	An ABS framework in a user jurisdiction that sets up a strong institutional framework. Shows promise in terms of monitoring through the legal empowerment of regional administrative or protective organizations with specialized knowledge.
Brazil	Provisional Act No. 2,186-16, 23 August 2001	An early ABS framework that illustrates continuing challenges of monitoring and compliance . Notably, a new comprehensive draft law has been under consultation for years to address these challenges.
India	Biological Diversity Act (2002) and Biological Diversity Rules (2004)	An ABS framework that has evolved through years, but demonstrates continuing challenges in misappropriation of GR and TK, and extraterritorial monitoring and enforcement .
Philippines	Administrative Order No. 1 (2005) prescribing Guidelines for Bioprospecting Activities and Related Legislation	An ABS framework evolving since 1995 with novel legal approaches of phased payment and review/reporting aimed at ensuring equity of benefit-sharing agreements. However, the complexity of the system imposes a functional moratorium on bioprospecting.
Ethiopia	Access to GR and Community Knowledge, and Community Rights Proclamation No. 482 (2006)	Detailed ABS legislation with challenges in ensuring compliance . Highlights the importance of having explicit regulation on transference and explanation on how to ensure ABS is applied and monitored effectively.
Kenya	Environmental Management and Coordination Regulations (2006)	Broad regulations with an expansive list that sets out the range of monetary and non-monetary benefits to provide clarity in benefit-sharing negotiations.
South Africa	Bioprospecting, ABS Regulations (2008)	Shows how ABS issues can be monitored through a multi-layered ABS regulatory framework - comprised of a laws, regulations and guidelines.
Panama	Executive Decree No. 25 (2009) regulating article 71 of the General Law on Environment No. 41 (1998)	One of the most detailed Pre-Nagoya Protocol laws , enacted just one year prior to Protocol's adoption.
Peru	Regulations on Access to GR, Supreme Decree 003-2009-MINAM and Law No. 27, 811 (2002), Andean Decree No. 391	Peru's experience highlights the role of regional agreements (Andean Community Decision No. 391) in establishing common standards across regions.
Norway	Act of Relating to the Management of Biological, Geological and Landscape Diversity (2009)	One of most advanced ABS frameworks from an industrialized, user jurisdiction with a novel requirements for disclosure and consent from country of origin and a legal principle on the use of GR for the benefit of global environment and humanity, especially ILCs.
Solomon Islands	Protected Areas Act (2010)	One of the few examples from the Pacific Island region , implementing an approach where bio-prospecting rules are contained within PA legislation.
<p>b) Post-Nagoya Protocol legislation</p> <p>Since the adoption of the Nagoya Protocol in 2010, several countries have led efforts to enact comprehensive legislation that addresses all components contained within the Protocol. Although implementation experience is minimal or lacking for these newly enacted and/or draft laws, an examination of these latest efforts can provide lessons learned on designing comprehensive regulatory frameworks that satisfy all requirements under the Protocol.</p>		
Nicaragua	Biodiversity Law (2012)	First country to pass a framework biodiversity law post-adoption of

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		the Nagoya Protocol. Incorporates many of the Protocol's provisions and shows strong potential.
Denmark (draft)	Draft Bill on Sharing Benefits Arising from the Utilization of GR	A draft law from a user jurisdiction with rigorous compliance and enforcement measures. Prohibits the use of GR or TK acquired in contravention of access regulations from the country of origin.
European Union (draft)	Draft Regulation on Access to GR and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union	A draft law with potentially broad implications across the EU. It raises potential legal conflicts by being applicable only following ratification of the Nagoya Protocol in both jurisdictions.
Switzerland (draft)	Amendments to Federal Act on the Protection of Natural and Cultural Heritage	A draft law focused on minimizing violations of ABS obligations, which may inform the development of monitoring and compliance mechanisms.
<p>c) Legislative processes underway to ratify the Nagoya Protocol</p> <p>One of the two required components of the Nagoya Protocol is ratification at the national level. The process of ratification varies within each country, however, instructive lessons learned can be gained on the range of processes and stakeholders to engage in the ratifications process.</p>		
Mexico	Access to GR and Associated TK Protection Draft General Law and Related Legislations	Mexico underwent a comprehensive process towards the ratification of the Nagoya Protocol, involving widespread consultations and engagement of key stakeholders.
Malaysia	Draft Law Access to Biological Resources and Benefit-Sharing Act 2013	Ratification of the Nagoya Protocol in Malaysia requires national legislation, and the legislative process is in its final stages. Existing sub-national legislation may be useful in informing the process.

PART IV: LEADING LEGAL PUBLICATIONS FOR FURTHER READING

T Bubela and E Richard Gold (eds), *Genetic Resources and Traditional Knowledge: Case Studies and Conflicting Interests* (2012).

G Burton et al, *ABS Management Tool: Best Practice Standard and Handbook for Implementing Genetic Resource Access and Benefit-Sharing Activities* (2012).

J Cabrera Medaglia, F Perron-Welch and O Rukundo, *Overview of National and Regional Measures on Access to Genetic Resources and Benefit-Sharing: Challenges and Opportunities in Implementing the Nagoya Protocol*, (5th ed 2011) <http://www.sib.admin.ch/uploads/media/Overview_of_ABS_Measures_2011_01.pdf> at January 23 2014.

J Cabrera Medaglia, M Walløe Tvedt, F Perron-Welch, A Jørem and F-K 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 No. 1 (2013).

I Glowka, *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources*, IUCN Environmental Policy and Law Paper No. 34 (1998).

I Glowka et al, *A guide to the Convention on Biological Diversity*, IUCN Environmental Policy and Law Paper No. 030(1994).

T Greiber et al, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing*, IUCN Environmental Policy and Law Paper No. 83 (2012).

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*(2013).

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

M Ruiz and R Vernooy(eds),*The Custodians of Biodiversity: Sharing Access and Benefits to Genetic Resources*. (2012).

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

G Singh Nijar, *The Nagoya Protocol on Access and Benefit-Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries*(2011).

M S Suneetha and B Pisupati, *Benefit Sharing in ABS: Options and Elaborations* (2009).

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.

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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.

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