THE NAGOYA ABS PROTOCOL: A LEGALLY SOUND FRAMEWORK FOR AN EFFECTIVE REGIME?

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Abstract

On 30 October 2010, the 'Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits to the Convention on Biological Diversity' was successfully adopted by the tenth session of the Conference of the Parties to the Convention on Biological Diversity. By examining some of the core elements of the new treaty (scope, access, benefit-sharing and compliance), this analysis aims to assess the potential for effectiveness of the ABS international regime as complemented by the Nagoya Protocol. Foremost, this research identifies the strengths, weaknesses and issues still to be resolved of the new legal framework.

At the core, the Nagoya Protocol is built on the assumption that an effective ABS regime can only be achieved if Parties encourage users willing to participate in the conservation effort by favouring access to genetic resources but also by creating incentives to enter into ABS contracts. The new treaty develops a better common understanding on the manner ABS should operate and lays down a set of basic principles and processes Parties will need to implement in their domestic legal order. More specifically, three main evolutions may be found in the new legal framework. First of all, the scope of the ABS international regime is better defined, significantly expanded and limited in several manner. 'Utilization of genetic resource' constitutes the major theoretical breakthrough and becomes the cornerstone of the ABS concept. Secondly, the Protocol stresses that the exercise of States sovereign rights in designing access regulation may not run against the needs for certainty of users and user countries. Thirdly, the emphasis on user side measures is another major change. It explicitly recognizes that contractual provisions and provider legislation are alone markedly inadequate tools for an effective ABS regime.

Even if many practicalities remain to be defined, this research concludes that the new framework has potential to achieve the ABS objective of the CBD and thereby contribute to equity, sustainability and biodiversity conservation. If successfully implemented in a consistent and mutually supportive manner by its future States Parties, it is argued that ABS may develop to be a key instrument in the global governance of biodiversity conservation.

Abbreviations

ABS Working Group: the Ad Hoc Open-ended Working Group on Access and Benefit-sharing
ABS: Access and Benefit-Sharing
CBD: Convention on Biological Diversity
CHM: Clearing House Mechanism
COP: Conference of the Parties
FAO: Food and Agriculture Organization
GLTE: Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches
ILC: Indigenous and Local Communities
ING: Interregional Negotiating Group
IPR: Intellectual Property Rights
ITPGRFA: International Treaty on Plant and Genetic Resources for Food and Agriculture
MAT: Mutually Agreed Terms
NFP: National Focal Points
PIC: Prior Informed Consent
R&D: Research and Development
TK: Traditional Knowledge
UNESCO: United Nations Educational, Scientific and Cultural Organization
UPOV: Union for International Protection of New Varieties of Plants
WIPO: the World Intellectual Property Organization
WTO: World Trade organization

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Introduction

On 30 October 2010 at 2 am, in a state of generalized euphoria, the 'Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits to the Convention on Biological Diversity' ("the Protocol") was successfully adopted by the tenth session of the Conference of the Parties to the Convention on Biological Diversity (CBD COP10). The adoption of the Protocol was a precondition for the support of developing countries to the 2011-2020 Strategic Plan and the Strategy for Resource Mobilization, the two other main CBD policy instruments for biodiversity conservation and the sustainable use of its components.[1] "Standing ovations, tears of joy and a great feeling of relief"[2], the adoption of the "Nagoya Package" was seen by some delegates to mark "the rebirth of environmental multilateralism." [3]

CBD COP10 was of crucial importance to the global governance of biodiversity conservation. It started with the official acknowledgement of a dramatic failure: the international community had been unable to reach the "2010 Biodiversity target", which aimed to achieve "by 2010 a significant reduction of the current rate of biodiversity loss at the global, regional and national level as a contribution to poverty alleviation and to the benefit of all life on earth."[4] While "actions in favour of biodiversity mobilise ever growing resources, reinforce scientific capacities, and galvanize undeniable creativity"[5] and though some remarkable results were achieved during the last decade, some biologists predict a "sixth major extinction."[6] Against this backdrop, with the adoption of a new set of policy and legal instruments, COP10 concluded the 2010 International

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[1] See the interventions in this sense of Brazil and Yemen, on behalf of the G77, at the opening session of the United Nations High level Meeting on Biodiversity held in New York in September 2010 in General Assembly of the United Nations President session of the United Nations President if the 65th Session, High level Meeting on Biodiversity, Statements; found at <http://www.un.org/en/ga/president/65/issues/biostatements.shtml> last accessed 6 September 2011. For more information on CBD COP10, see CBD Secretariat, 'COP 10', found at <http://www.cbd.int/cop10/> last accessed 6 September 2011. The Nagoya ABS Protocol is reproduced in Annex II of the present research.

[2] S. Jungcurt et al., 'Summary of the tenth conference of the Parties to the Convention on Biological Diversity: 18-29 October 2010', Vol. 9, No 544, *Earth Negotiation Bulletin* (1 November 2010), found at: <http://www.iisd.ca/biodiv/cop10/> last accessed 6 September 2011.

[3] Ibidem.

[4] CBD COP6, 'Strategic Plan for the Convention on Biological Diversity', Decision VI/26, 7-19 April 2002.

[5] R. Billé et al., 'Should we be disappointed by the year of Biodiversity?', in R. Billé et al. (eds.), *Global Governance of Biodiversity: New perspectives on a shared challenge*, Health and Environment Reports, no 6, December 2010, p.90.

[6] S. H. M. Butchart, et al, Indicators of recent biodiversity decline, Science, vol. 29, April 2010; See also S. Pimm, T. Brooks, 'The sixth extinction: how large, where, and when?' In: P. H Raven (ed.), *Nature and human society*, 2005; Washington (D.C.), National Academy Press, 2005, pp. 46–62.

Year of Biodiversity on a positive note and succeeded in creating "new confidence in the multilateral process."[7]

The adoption of the Nagoya ABS Protocol played an important role in this renewed optimism. The third objective of the CBD, access to genetic resources and the fair and equitable sharing of benefits, has so far remained weakly implemented worldwide and constituted a contentious issue dividing the international community over the last two decades. Potentially phenomenal economic repercussions, polar political interests, and webs of complex and often totally new technical and legal issues, Access and Benefit-Sharing (ABS) contains all the ingredients of a Gordian knot. According to Young, a lead author on the issue, ABS is "one of the most novel and innovative legal concepts to be introduced in international law in the last century."[8] In this context, 18 years after the adoption of the CBD[9], 8 years after the beginning of the negotiation process that concluded *in-extremis* at the end of 10 straight days of electric discussions, the Protocol incontestably constitutes a significant achievement.

ABS is a concept created by the CBD to pursue an environmental developmental objective: it is aimed to involve non-state actors in the biodiversity conservation effort, and ensure technological and financial transfers towards developing countries while facilitating access to genetic resources for environmentally sound uses. Through Research and Development (R&D) activities as well as subsequent commercial applications, biological resources valuable for their genetic characters ("genetic resources")[10] are utilized in a wide range of sector of activities for commercial and non-commercial purposes, including cosmetics and personal care, plant and animal breeding, natural medicine, horticulture, biotechnologies and the pharmaceutical industry. ABS

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[7] E. Broughton, 'Introduction', in R. Billé et al. (eds.), *Global Governance of Biodiversity: New perspectives on a shared challenge*, Health and Environment Reports, No 6, December 2010, p.5.
[8] M. Tvedt., T. Young, *Beyond access: exploring the implementation of the fair and equitable sharing commitment in the CBD*, IUCN Environmental Policy and Law Paper No. 67/2, IUCN Environmental Law Center, Bonn Germany, 2007, p.5.
[9] See Convention on Biological Diversity (CBD), Rio de Janeiro, 14 June 1992.
[10] Pursuant to Art. 2CBD, "Genetic material" means "any material of plant, animal, microbial or other origin containing functional units of heredity." "Genetic resources" refers to genetic material with "actual or potential value." The unclear meaning if those definitions will be studied in paragraph 2.1.3.1.

targets the collection of new genetic resources in their natural environment ("in situ")[11] and foresees that the benefits arising from their utilization will be shared in a fair and equitable manner.

Pursuant to Article 15 CBD, the ABS mechanism should function as following: Countries have sovereign rights over the genetic resources within their jurisdictions and determine the conditions according to which genetic resources can be accessed. The country where a genetic resource is collected ("Provider country") decides whether authorisation to utilize this genetic resource ("Prior Informed Consent" (PIC)) is granted to the bioprospector. [12] In case a PIC is granted, a contractual agreement defining the modalities of utilization and the sharing of the benefits ("Mutually Agreed Terms" (MAT)) is concluded between the provider country and the collector ("the user"). The user utilizes the resources in a way that creates benefits and shares them with the provider in accordance with the MAT. Pursuant to Article 15.7 CBD, countries also need to adopt the necessary measures to ensure that users operating under their jurisdiction are complying with their ABS obligations ("User-side measures").

Beyond this apparent simplicity, the elusive provisions of the CBD raised many legal and practical challenges. For experts, insufficiently developed understanding of the concept, lack of user side measures, high transactions cost and legal uncertainty were the main causes of the poor implementation of the ABS objective.[13] Launched in 2002, the negotiation process for the development of an international regime evolved particularly slowly and, until the very end, the adoption of the Protocol remained highly uncertain. Thanks to a last ditch effort of the Japanese Presidency, a compromise was found in the ultimate hours of the conference. However, "instead of resolving outstanding issues by crafting balanced compromise proposals—an endeavour that would have been doomed to fail—the contentious references were either deleted from the text or replaced

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[11] In accordance to Art. 2CBD, "in-situ conditions" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties."

[12] Bioprospection is defined as "the exploration of biodiversity for commercially valuable genetic resources and biochemicals" (W.V. Reid et al., *Biodiversity prospecting: using genetic resources for sustainable development*, Washington, DC, World Resources Institute, 1993)

[13]The ABS contractual approach is far from doing the unanimity among scholars. For years, many scholars have advocate for other systems such as the creation of "biodiversity cartel" (see e.g. J. Vogel, *El Cartel de la Biodiversidad*, Care, Ecuador., 1998 found at: <http://www.biotech.bioetica.org/docta42.pdf> last accessed 6 September 2011) or the creation of common pools system (G. Winter, 'Towards Common Pools of Genetic Resources – Improving the Effectiveness and Justice of ABS', in E. Chege Kamau and G. Winter (eds.), *Genetic Resources, Traditional Knowledge and the Law. Solutions for Access & Benefit-sharing,* London, Earthscan, 2009, p.36).

by short and general provisions allowing flexible interpretation, but possibly also too wide a berth for implementation."[14]

Overall, the Protocol was seen as "the best possible solution at this point in time"[15] and is considered as a "good framework to regulate access and benefit-sharing at the national level."[16] Foremost, the adoption of the Protocol was lauded for integrating the progresses of 8 years of negotiations and providing a new momentum towards the operationalization of the ABS concept. Nevertheless, the Protocol is also considered as a "masterpiece of creative ambiguity"[17] leaving "significant room for interpretation – sometimes generating divergent perspectives – of key obligations." [18] Almost a year after its adoption, Parties are now fully active with preparing its implementation and about 40 countries have nowadays signed the Protocol.[19] So far, hardly any legal analysis has been published on the new framework, its coverage and main provisions. In this context, by looking at the functionality of the international regime, the present research intends to analyse whether the Nagoya Protocol constitutes a legally sound framework which has the potential to lead to an effective implementation of the ABS objective.

[14] S. Jungcurt et al, supra note 2.
[15] Ibidem.
[16] IUCN, 'Nagoya Protocol on Access and Benefit-sharing opened for signature', 11 February 2011; <http://www.iucn.org/cbd/?6950/Nagoya-Protocol-on-Access-and-Benefit-Sharing-opened-for-signature> last accessed 6 September 2011.
[17] S. Jungcurt et al, supra note 2.
[18] R. Billé et al, supra note 5.
[19] To this writing, 41 States have signed the Protocol and indicated their intention to become a Party to the Nagoya Protocol.

1 Setting the scene

Given the complexity and interconnectedness of the issues involved in the ABS debate, it is crucial to delimitate with accuracy the ambit and objectives of this research. The first section will emphasise the content and relevance of the "functionality quest" in the ABS context. The main elements of the Protocol determining the functionality of the international regime will be presented. The third subsection explains why several issues potentially affecting the functionality of the Protocol will not be studied in the present paper. Lastly, in the fourth subsection, I briefly comment my choice to opt for "functionality" as analytical concept. The second section shed some lights on the methodology and the sources of information used by the author to undertake this research

1.1 The Research subject

1.1.1 The "functionality challenge" of the ABS international regime

Functionality is not a common legal term. Nevertheless, many different scholars writing on ABS have recently used the notion as analytical concept, without providing much detail on its significance.[20] Inspired by the "law and economics" movement, legal functionality (from Latin function meaning "to perform") is a reflection on the most efficient way a legal system can be implemented. According to Tvedt, legal functionality refers to the "potential for a legal system to contribute to defined objectives."[21] In the context of this research, assessing the functionality of the international regime consists in determining whether the ABS international regime as complemented by the Nagoya Protocol has the potential to effectively achieve the goals it pursues, namely facilitating access to genetic resources, proceeding to a fairer sharing of the benefits arising out of their utilization and thereby contributes to the conservation of biodiversity and sustainable use of its components.[22]

To the author, an ABS international regime effectively contributing to its goals can only be achieved by (1) providing the necessary legal certainty, while (2) allowing for shifting towards

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[20] See e.g M. Tvedt. , T. Young, *Balancing building blocks of a functional ABS system*, Report 7/2009, Lysaker, FNI, 2009; M. Tvedt, O. Rukundo, *Functionality of an ABS Protocol*, Report 9/2010, Lysaker, FNI, 2010.
[21] M. Tvedt, 'Functionality of the Nagoya ABS Protocol with a view to AnGR and a side-look to Anti-Conterfeiting Trade Agreement (ACTA)', International Technical Expert Workshop AnGR –ABS, 8–10 December 2010, <http://documents.plant.wur.nl/cgn/seminars/Worshop20100812/Tvedt.pdf>, last accessed 6 September 2011.
[22] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, Nagoya, 29 October 2010, Art. 1.

incentive based user compliance, and (3) ensuring that the scheme serves the environmental developmental goals it pursues.

1. Legal certainty is the *sine qua non* basis for a functional ABS regime. In commercial law, legal certainty means "the ability of each user, provider, national legislator, official, judge, arbitrator or other person to know with a relatively high degree of confidence whether the regime applies to a particular person or action, and if so what the regime will require (or probably require) in each case." [23] The importance of providing legal certainty with respect to access to genetic resources and the fair and equitable sharing of the benefits arising from the utilization of such resources is explicitly recognized by the Parties in the 9th paragraph of Protocol's Preamble. In the ABS context, legal certainty is a two-sided reality.

    a. On the one hand, ABS relies on the ability of users to identify clearly and precisely the relevant economic costs and legal requirements for entering into a particular ABS Agreements ("User certainty").[24] In order to assess the commercial value of a particular ABS transaction, users needs to have a reasonable degree of confidence in regards to "process certainty" and "contract certainty." "Process certainty" refers to the ability for users to determine with certainty (i) the resources requiring authorisation or payment and the one which can be utilized freely, and (ii) the rules and procedures to be followed to acquire the rights and resources they desire. "Contract certainty" refers to the need of users to have a clear view of the exact scope and nature of the rights they acquire in ABS Agreements, the obligations associated with those rights and the moment the ABS relationship ends.[25] For economic operators, "Contract certainty" is crucial to secure and promote their investments in R&D programs and in product commercialization, and protect them against unwarranted accusations of biopiracy and negative publicity.[26]

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[23] M. Tvedt. , T. Young, *Balancing building blocks of a functional ABS system*, Report 7/2009, Lysaker, FNI, 2009, p.2.
[24] In the negotiation, the claim for "user certainty" is mainly an argument of developed country.
[25] For an in-depth analysis of the needs of certainty T. Young, 'Summary Analysis: legal certainty for users of genetic resources under existing Access and Benefit-sharing (ABS) legislation and policy', in T. Young. (ed.), *Covering ABS: Addressing the Need for Sectoral, Geographical, Legal and International Integration in the ABS Regime. Papers and Studies of The ABS Project,* IUCN, Gland, Switzerland, 2009, pp76-94.
[26] There is thus currently a clear lack of incentives encouraging users of genetic resources to comply with ABS. On the contrary, according to Cabrera Medaglia and Lopez Silva "it is generally noted that any formal negotiation of ABS agreements increases the user's risk of being sued". (J. Cabrera Medaglia, C. Lopez Silva, *Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty,* IUCN Environmental Policy and Law Paper No. 67/1, 2007, p.58).

b. On the other hand, legal certainty also consists of protecting the ABS rights of providers and ensuring effective "user compliance."[27] From this perspective, the ABS scheme aims to make sure that users fulfil with their ABS obligations. Namely, that (i) genetic resources utilized are legally accessed through PIC authorization, (ii) a MAT is concluded to organize the utilisation of the said resource and the sharing of the benefits in a fair and equitable manner and (iii) users are complying with the terms and conditions set out in the MAT. In order to ensure "user compliance", Parties will need to adopt "user side measures" *i.e.* laws (i) requiring users of foreign genetic resources to respect benefit-sharing obligations imposed by other countries and (ii) authorizing the provider of a foreign genetic resource to seek remedies against non-compliant users operating within their jurisdiction.[28]

User certainty and user compliance are clearly interconnected. For instance, "process certainty" and "contract certainty" favour user compliance by reducing transaction costs and the legal risk of entering into an ABS transaction; it also ensure to the provider a greater confidence in his own rights and increase its probability to get them enforced in case users do not comply with their obligations.[29] This strong link between the two dimensions of legal certainty emphasises another aspect of a functional regime, namely the need for access legislation and user country measures to be built in a mutually supportive manner. The legal certainty quest is further challenged by the wide range of situations covered by ABS international regime. Consequently, there is a need to introduce an important degree of flexibility which is sometimes difficulty concealable with the "legal certainty" requirement.[30]

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[27]In the negotiation, "User compliance" is principally a claim of developing countries and is often referred to as the need to ensure a "binding regime."

[28] In law, "the term 'remedy' refers to the use of laws, courts and administrative agencies to cure a legal problem". (T. Young, 'Administrative and Judicial remedies Available in Countries with Users under their jurisdiction and in International Agreements', in T. Young. (ed.), *Covering ABS: Addressing the Need for Sectoral, Geographical, Legal and International Integration in the ABS Regime. Papers and Studies of The ABS Project,* IUCN, Gland, Switzerland*.;* 2009, p.142)

[29] The fact that process certainty and contract certainty favour user compliance is confirmed by Laird: "companies often avoid countries which cannot grant legal certainty over material and work increasingly in countries where the rules are clear and where there is knowledge about the value of the genetic material." (S. Laird, R. Wynberg, *Access and benefit-sharing in practice: Trends in partnerships across sectors*, Vols. I, II and III. CBD Technical Series 38, Published by the Secretariat of the Convention on Biological Diversity, 2008, p.36).

[30] Two major sources of diversity require the introduction of flexibility in the ABS regime. First of all, as highlighted in section 2.3, ABS needs to take into account the specificities of the economic activities covered by the scheme. Secondly, the international framework has to be implemented by countries with significantly different national realities and juridical culture.

2. Contrary to what has been long assumed, an effective and legally certain ABS scheme cannot solely rely on contractual provisions and provider side legislation.[31] Due to the principle of territorial application of law, provider legislation only applies within the jurisdiction of the provider state, *i.e.* if the user is operating in its territory. In the ABS context, this is particularly problematic since the CBD framework only covers international situations *i.e.* when users are utilizing foreign-origin genetic resources.[32] Provider countries are thus unable to enforce their ABS rights if a user operating outside their jurisdiction is not complying with his obligations, unless the country of the user imposes such compliance.[33] Taken together, the internationality of the ABS concept and the principle of territorial application of the law explain why an international regime cannot function as an effective and legally certain scheme without active support of user countries.

User-side measures have a crucial role to play in a functional ABS regime. As stated by Young, "no matter what the laws of the provider country say, the measures in countries with jurisdictions over the user's activities will have the most direct impact on most users. Thus user-side measures will ultimately determine the functionality of the ABS regime."[34] The challenge of designing user measures effectively protecting provider's rights should however not be overlooked. No country has so far implemented its obligations of Article 15.7 CBD and there is thus little data to build upon. Legal experts have recently started to reflect on what elements user-side measures should incorporate for a functional regime. In my opinion, the main conclusion which should be drawn from a literature review is that more and more scholars are convinced that user countries cannot solely rely on mandatory measures to ensure effective "user compliance."

Indeed, there are many virtually irresolvable technical, political and legal challenges impeding effective compliance to be ensured solely through a traditional "command and control" approach. As stated by Young, "imposing direct mandatory requirements on users who do not

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[31] As it will be shown in section 2.2., this assumption has long prevailed after the CBD adoption.
[32] Strictly speaking, ABS only covers international situation. It seems however dubious that an ABS scheme could effectively function by regulating only international users; indeed, national users could then serve as a way to avoid the ABS international obligations.
[33] The CBD is not a self-executing treaty. Its provisions are binding for the States Parties who need to implement the obligations in their national legal order. The Convention is thus not directly applicable to the private and public parties involved in ABS.
[34] M. Tvedt, T. Young, supra note 8, p. 115.

have a string desire to comply can be effective only where there is possibility (i) to closely oversee the regulated users, (ii) to identify violations and potential violations to comply with their responsibilities, or (iii) to obtain clear documentation of purported violations (evidence must be of a type that is appropriate and sufficient to enable a fair decision by a court, agency or alternative dispute resolution process)."[35] In the ABS context, all of those three aspects are highly problematic.[36]

Strict monitoring is materially impossible since most of the activities regulated by ABS are taking place in private research laboratories. Even if it is scientifically and technically feasible, it is politically and materially impossible for a country to inspect all the concerned facilities and undertake the necessary analysis in order to determine whether (i) genetic resources are "utilized", (ii) whether PIC and MAT were concluded for the said resources and (iii) whether the utilization are in conformity with the terms described in the MAT. In addition, if genetic resources utilized in a product are identified, to ascertain the provenance of these genetic resources may constitute another layer of complexity.[37] Lastly, as observed by Cabrera Medaglia and Lopez Silva, "compounding this problem is the fact that the collection of material for one purpose might be quiet legitimate while collection of the same material for a different purpose might be an offence."[38] Taken together, all those reasons make it difficult to identify and prove violations, and thus to enforce the provider' rights *vis-à-vis* non-compliant user.

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[35] T. Young, 'Final Thoughts: Critical areas for further work', in T. Young. (ed.), *Covering ABS: Addressing the Need for Sectoral, Geographical, Legal and International Integration in the ABS Regime. Papers and Studies of The ABS Project,* IUCN, Gland, Switzerland, 2009, p.188.

[36] As stated by Cabrera Medaglia and Lopez Silva, "monitoring and enforcement for example, are problematic because the material in question can often be difficult to identify, consisting of things such as seeds, water samples or micro organisms. Authorities have no means of assessing what the samples might contain and what uses they might be put to. Even when identified their provenance cannot often be proven. Compounding this problem is the fact that the collection of material for one purpose might be quiet legitimate while collection of the same material for a different purpose might be an offence." (J. Cabrera Medaglia, C. Lopez Silva, supra note 23, p.53).

[37] As stated by Winter, "there are many technical difficulties in tracking the utilization of genetic resources back to a provider country. Often genetic material change hands before it is utilized in profitable ways. The chain of utilization can be very long reaching from the plant and the extracted gene to organisms modified by the original or synthesized genes. In the mean time, a strain of genes may have been replaced by newer ones that were obtained from another state or from another parent organism. These and other can easily blur the country of origin." (G. Winter, supra note13, p.25).

[38] J. Cabrera Medaglia, C. Lopez Silva, supra note 26, p.55.

Consequently, a large majority of experts nowadays estimate that an ABS regime favouring "voluntary" user compliance has the best potential for effectiveness.[39] According to Young, it appears that "the only way to create an effective benefit-sharing system will be to adopt strictly overseeable "incentives" and motivational measures, which encourage users to comply with benefit-sharing requirements. In essence, the user must obtain something of value to himself, which will make it worthwhile for him to comply, and to demonstrate his appropriate evidence."[40] This view is far from being shared by all the CBD Parties and the mandatory approach is still supported by an important number of countries. To the Author, a functional international regime must foresee the adoption of user side measure. It should, however, not impose excessive regulatory burdens on user country and allow for shifts towards an incentive based paradigm.

3. Lastly, a well-performing ABS scheme with a relatively high degree of user certainty and widespread user compliance however does not *per se* ensure that ABS is effective in reaching its environmental and developmental goals. A third challenge in making ABS functional is thus to create the necessary linkages between the sharing of the benefits and conservation of Biodiversity, of equity and of sustainability.

In sum, as the prior material highlights, the challenge of designing an effective ABS international regime relies on achieving three main critical requirements, namely ensuring a maximum level of user certainty, and guaranteeing effective and incentive based user compliance, and make sure that the benefits shared serves equity, biodiversity conservation and sustainability.

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[39] The creation of market incentive is seen by many experts as critical for the future effectiveness of the ABS regime. See for instance, T. Hodges, F. Casas, 'The International ABS Regime Negotiations: A Business Opportunity?', *Asian Biotechnology and Development Review,* Vol. 10, No.3, 2008, pp.81-84; G. Burton, personal communication, 2011; M. Buck, personal communication 2011). J. Cabrera Medaglia, C. Lopez Silva, supra note 23, p.58.

[40] T. Young, 'The Challenge of a New Regime: The Quest for Certainty in Access to Genetic Resources and Benefit-Sharing', *Asian Biotechnology and Development Review,* Vol. 10, No.3, 2008, pp. 128.

1.1.2 Research question

The present study aims to answer the following research question:

"Does the Nagoya Protocol enhance the potential of the ABS international regime to contribute to the goals it pursues, namely facilitating access to genetic resources, proceeding to a fairer sharing of the benefits arising out of their utilization and thereby contributes to the conservation of biodiversity and sustainable use of its components?"

Or put it differently:

"Does the Nagoya Protocol enhance the potential of the ABS international regime to ensure a maximum level of user certainty, allow for effective and incentive based user compliance, while making sure that the benefits shared serves the regime's environmental developmental objectives?"

1.1.3 Elements affecting the functionality of the international regime within the scope of this research

In order to assess whether the Nagoya Protocol increase the potential for effectiveness of the ABS system, four main elements of the new framework will be examined. As a functional scheme requires mutually supportive measures, the present research also analyses the interrelationship between the provisions contained in the Protocol.

First of all, the scope of the Protocol needs to be clearly and cautiously established. It serves to determine the situations covered by the ABS international regime; thus it has great influence on the rights and obligations of the Parties and is pivotal for the legal certainty of the whole scheme. Three main challenges had to be faced in the Nagoya Protocol. In regards to the application *ratione materiae*, the terms "utilization" and "derivatives" are defining the resources and activities regulated by the Protocol. In regards to the temporal scope, there was controversy over whether the international regime should apply the material accessed after the entry into force of the Nagoya Protocol, after the entry into force of the CBD or without distinction of the date of access. The application of the Protocol *ratione loci* focuses on the question whether the ABS apply for resources accessed in areas located beyond State sovereignty.

Furthermore, this study also analyses the backbone of the ABS scheme, the so-called "ABC" of the regime (Access, Benefit-sharing and Compliance).

Concerning access to genetic resources, the functionality challenge consists of ensuring that states' sovereign rights do not run against the needs for certainty of user and user country. As stated by Stoll, "access may be understood to refer to the entirety of entitlements rights and legal authorization necessary for all the different activities involved in the search for, collection of, exportation and use of genetic resources as ruled upon by the state on the basis of its sovereign rights. As this indicates, access requires a complex legal structure within the resources states, which provide for rights and entitlements, procedures and remedies and take into account all relevant rights and legal interest involved. Even more, that structure has to lay ground for negotiation, conclusion and execution of Agreements and Benefit-sharing taking into account any possible interest in this regard."[41] Since each domestic regime has its own juridical culture and specificities, it is therefore not possible or even desirable to fully harmonize the national regimes regulating access to genetic resources. A functional legal regime fortunately does not require a full harmonization of all aspects of access measures. Instead, it needs to identify the minimum requirements that all access regulations shall incorporate to allow for an effective and legally certain international scheme. In addition, access legislation must also constitute the necessary basis to ground the user side measures.

In regards to the benefit-sharing aspect of the ABS concept, the functionality challenge is twofold. First of all, it raises the question on how to ensure or promote that the benefits shared in the ABS context are actually used to promote biodiversity conservation and sustainable use of its components. The second impact of the benefit-sharing provision on the scheme functionality relates to the difficulty to determine what is a "fair" and "equitable" sharing of benefits.

Lastly, compliance was seen by many as the "core of the core" of the Protocol. As a preliminary remark, it is important to underscore that compliance can be understood in two very different ways in the ABS context. First of all, as a matter of international law, States must comply with their duties under the CBD and the Nagoya Protocol (Article 30). In addition, users of genetic resources have to comply with domestic legislation on ABS (Article 15 and 16) and with the terms

[41] R. Stoll, 'Access to Genetic resources and benefit-sharing – underlying concepts and the tale of justice' in E. Chege Kamau & G. Winter (eds.), *Genetic Resources, Traditional Knowledge and the Law. Solutions for Access & Benefit-sharing,* London, Earthscan, 2009, p.35.

they agreed in a MAT with the provider (Article 18). Importantly, only the second meaning of the term will be examined in the present study.[42]

As stated in the previous subsection, in my opinion, a functional international regime must foresee the adoption of user side measures. It should however not impose excessive regulatory burdens on user country and allow for shifting towards an incentive based paradigm. Two basic situations of non-compliance need to be distinguished in the ABS context. First of all, the user can utilize a foreign-origin genetic resource for which no PIC was granted and no MAT established at the time of access. Secondly, a user may also have legally access a genetic resource through PIC and MAT but may not be compliant in the implementation of the said contract. Under the Protocol, three provisions specifically address the "user-side measures" and aim to ensure the protection of the ABS provider' rights. Article 15 of the Protocol (Compliance with ABS domestic legislation) addresses the first hypothesis of non-compliance while Article 18 of the Protocol (Compliance with Mutually Agreed terms) deals with the second situation. Lastly, Article 17 of the Protocol is relevant to monitoring the utilization of genetic resources and defines the supervision responsibilities user countries have to achieve.

1.1.4 Elements potentially affecting the functionality of the international regime but beyond the ambit of this research

Many other aspects of the Protocol can significantly impact the potential for effectiveness of the ABS international regime. Some of those elements are here presented with a brief comment explaining their exclusion.

On the one hand, the relationship of the Protocol with other international agreements and instruments is not comprehensively addressed in this research.[43] The elaboration of the ABS

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[42] Art. 16 of the Protocol on "compliance with domestic legislation on ABS from traditional knowledge associated with genetic resources" will not be studied. As shown in subsection 1.1.3, traditional knowledge is beyond the scope of the present study. The two meanings of compliance in the ABS context are confusing. As explained by Casas, "Parties to the Protocol are bound by international law to comply with all their obligations under the Protocol, noting that these obligations include compliance with domestic legislation, as contained in Protocol Arts. 15-16, as well as compliance with MAT, as contained in Protocol Art. 18; and if a party does not take these compliance-related measures, this is considered non-compliance under the Protocol and will be reviewed under the compliance mechanism to be established by the COP/MOP." (F. Casas quoted by T. Kantai et al., Summary of the first meeting of the Intergovernmental Committee for the Nagoya Protocol to the Convention on Biological Diversity: 5-10 June 2011', Vol. 9 No. 551, *Negotiation Bulletin* (13 June 2011), found at: < http://www.iisd.ca/vol09/enb09551e.html> last accessed 6 September 2011.

international regime has to be seen in a larger landscape of interlocking frameworks of international law. The CBD ABS regime interacts with other instruments and organizations such as Food and Agriculture Organization (FAO), United Nations Educational, Scientific and Cultural Organization (UNESCO), the World Trade organization (WTO), the World Intellectual Property Organization (WIPO), the Union for International Protection of New Varieties of Plants (UPOV), etc. [44] For its functionality, the international regime needs to be cautiously designed in order to avoid overlaps, gaps and contradictions with the other frameworks. It is common for commercial operation to have more than one regime applicable. If clear dividing lines are not drawn, users could proceed to "forum-shopping" and opt for the set of international law offering the most favourable conditions.

Secondly, the relationship with the International Treaty on Plant and Genetic Resources for Food and Agriculture (ITPGRFA) is not examined in this research either. Though the ITPGRFA is part of the ABS international regime and complementary to the Nagoya Protocol, the special nature of agricultural biodiversity, its distinctive features and problems call for distinctive solutions.[45]

Thirdly, the provisions of the Protocol dealing with Traditional Knowledge (TK) are also beyond the ambit of this analysis. Building on Article 8 (j) of the CBD, the Protocol calls the Parties, in numerous provisions, to ensure the respect of the rights of Indigenous and Local Communities (ILC).[46] The Traditional Knowledge (TK) of ILC often constitutes an interesting basis

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[43] Though the potential overlaps, regulatory gaps and contradictions between the Nagoya Protocol and the Intellectual Property Rights arena (WIPO and WTO, and the TRIPS in particular) are not comprehensively examined, some reference to the relationship between ABS and the IPR regime are made in the study where appropriate.

[44] For information see e.g. G. Dutfield, *Intellectual Property Rights, Trade and Biodiversity*, London, Earthscan Publications ltd, 2000; K-J Ni, 'The Incorporation of the CBD Mandate on Access and Benefit-Sharing into TRIPS Regime: An Appraisal of the Appeal of Developing Countries with Rich Genetic Resources', *Asian Journal of WTO & International Health Law and Policy*, Vol. 1, No. 2, 2006, pp. 433-464; S. Safrin, 'Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life', *American Journal of international Law*, Vol. 98, 2004, found at <http://ssrn.com/abstract=658421>, last accessed 6 September 2011; CBD ABS Working Group, 'Study on the relationship between an International Regime on Access and Benefit-Sharing and other international instruments and forums that governs the use of genetic resources. The World Trade Organization (WTO), The World Intellectual Property organization (WIPO) and the International Union for the Protection of New Varieties of Plant (UPOV)', UNEP/CBD/WG-ABS/7/INF/3/Part.2, 3 March 2009, <http://www.cbd.int/doc/programmes/abs/studies/study-regime-04-en.pdf> last accessed 6 September 2011.

[45] This inclusion of the ITPGRFA in the ABS international regime is formally acknowledged by the Protocol in its para. 13th. The relationship of the Protocol with other international agreements and instruments and with the ITPGRFA will be briefly approached for their direct influence on the functionality of the Protocol in subsection 4.1.1.

[46] In the Protocol, traditional knowledge associated with genetic resources is referred to in many provisions, including in Arts. 3 (Scope), 5 (Benefit-Sharing), 6 (Access to genetic resources), 7 (Access to Traditional knowledge associated with genetic resources), 10 (Global multilateral benefit-sharing mechanism), 11 (transboundary cooperation), 12 (National Focal Points), 16 (Compliance with Access legislation), 18 (Compliance with MAT).

for developing commercial products.[47] It provides "leads for the use of genetic resources at several stages, ranging from the initial stage of identification of the uses of the resource to sometimes information on the precise dosages and preparation of a particular product using the resource."[48] Even if they are "interrelated"[49], Traditional Knowledge however encompasses very different dimensions than genetic resources *stricto sensu.* Sociological and cultural considerations are required for a well-grounded understanding of the sacred and holistic approach of nature Indigenous Local Communities usually adopt. From a legal point of view, TK also offers a twofold challenge. Firstly, a large set of human rights international instruments are involved. Secondly, at national level, ILC are generally regulated through customary law regimes. For all these reasons, due to the limited character of this study, it would be practically impossible to provide a meaningful analysis of TK related provisions.

1.1.5 The choice of functionality as analytical concept

The choice of functionality as analytical concept is motivated by the will to be objective, critical and constructive.

First of all, like many equity-related issues, the ABS debate is polarized through a North/South division and embedded in a web of highly sensitive development issues.[50] Therefore, many studies often reflect the implications, sensibilities and/ or interests of their authors. In this context, looking at the potential for effectiveness of the new regime appears to me as providing a

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[47] Although there is numerous definition of TK, "at their core, the y all involve knowledge, innovation and practices of indigenous and local communities that are transmitted orally between generations and are typically unique to a given geographic region." (C. Ho, 'Biopiracy and Beyond: Consideration of socio-cultural conflicts with Global Patent policies', *University of Michigan Law School*, Vol. 39, 2006, found at: <http://ssrn.com/abstract=912744> last accessed 6 September 2011).

[48] As stated by G. Nijar, "TK's role in increasing the efficiency of screening plants for medical properties is often highlighted, with various calculations". (G. Nijar, "Incorporating Traditional knowledge in an International Regime on Access to Genetic Resources and Benefit-sharing: Problems and Prospects", The European Journal of International Law, Vol. 21, No. .2, 2010, p. 458).

[49] This interrelation is expressly recognized in the 22nd para. of the Protocol's Preamble.

[50] To put it very simply, it can be said that most of the biodiversity and associated traditional knowledge is concentrated in the developing world while developed countries (multinational) companies dispose of the technologies and financial means to develop high-added value commercial products from those resources and knowledge. Then, through Intellectual Property Rights and especially patents, the companies may eventually secure their inventions and obtain exclusive rights on them. The North/ South prism is clearly an oversimplification of the situation and there are numerous of exceptions. For instance, Australia and the United States are Northern states but genetically-rich nations. In addition, some developing countries have an increasing number of users. However, the North/South division expresses the two major trends of the ABS debate, namely that most of the users are situated in the industrialized world while most of the genetic resources are originally coming from the developing world.

neutral and objective basis for this research as it allows me not to focus on the legitimacy of the decisions adopted but rather on their legal soundness.

Secondly, by analysing the potential of the international regime to achieve its goals, the author wants to emphasis that the Protocol is only a first step in the development of an effective ABS regime. The implementation of the Protocol "in law and in practice in a consistent and integrated way, across all CBD countries and sectors"[51] will require the involvement of a large number of stakeholders, the development of new legal and technical tools, and the adoption of mutually interactive regulatory measures at international, regional, national and local level. Therefore, even if legally well-framed and concretely understood, the real contribution of the new Protocol to the effectiveness of the ABS international regime will only appear in the future and is thus currently difficult to assess.

Lastly, functionality is also relevant as analytical concept due to the novel and uncertain character of the Protocol. In almost two decades, a large majority of the ABS aspects have been comprehensively analysed. Assessing the functionality of the international regime allows me to build on this important epistemic work to examine what the new legal framework adds to the existing international regime, what its strengths and weaknesses are and which issues still need to be resolved. In addition, the flexible language of the Protocol seems to leave significant room for interpretation. Early reactions to the new treaty show that there is no consensus as regard to the precise meaning and content of numerous provisions. The aim of this research is thusly also to modestly participate in developing an objective, critical and fruitful interpretation of the Protocol, and by doing so helping to move towards a functional ABS scheme.

[51] M. Tvedt, T. Young, supra note 20, p.8.

1.2 Methodology, sources and structure

The undertaking of this research was particularly challenging, especially due to the recent character of the Protocol, the lack of literature on the topic and the high level of complexity of the issues approached. To cope with those difficulties, a four steps methodology was followed by the author.

First of all, secondary materials (literature, reports, etc.) provided me a sound view of the major technical, political and legal challenges of the ABS concept. On this basis, I elaborated on the main elements a functional international regime would need to incorporate.

Secondly, the overarching CBD framework, relevant COP Decisions, report of CBD Meetings, submissions from Parties and Stakeholders, reports of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (ABS Working Group) and of expert group meetings served me to understand the negotiation dynamic and the evolution of the negotiated text.

Thirdly, the Protocol obviously served as the primary source for this analysis. To understand the meaning to be given to its provisions, Article 31 and 32 of the Vienna Convention on the law of Treaties was used as guiding principle. According to 31.1, "a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."[52] Article 31.2 also establishes that "the context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes: (a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty; (b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty." Article 31.3 provides that "there shall be taken into account, together with the context: (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation; (c) any relevant rules of international law applicable in the relations between the parties."

[52] See Vienna Convention on the Law of Treaties, Vienna, 3 May 1969.

Article 32 of the Vienna Convention deals with the supplementary means of interpretation According to the latter provision, "recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of Article 31, or to determine the meaning when the interpretation according to article 31: (a) leaves the meaning ambiguous or obscure; or (b) leads to a result which is manifestly absurd or unreasonable."

Fourthly, interviews of experts and negotiators were used to complement my understanding of the Protocol, the context surrounding its adoption and the underlying intention of the Parties.[53]

Concretely, this research is organised as following. While this chapter has set the scene of this research, Chapter 2 presents the "state of play" of the ABS concept before the adoption Protocol. Chapter 3 explains the context of the *in-extremis* adoption of the Protocol and offers an overview of its main provisions. In Chapter 4, the material, geographical and temporal scope of the Protocol is examined. Chapter 5 shed some lights on the main obligations relevant to Access to genetic resource. Chapter 6 clarifies the main elements of benefit-sharing under the new Protocol. Chapter 7 analyses the provisions as regard the compliance aspect of ABS. Finally, the conclusion will summarize the findings of this study and evaluate whether the Nagoya Protocol increases the potential for effectiveness of the ABS regime.

[53] A list of the persons interviewed and a brief note explaining their relationship with the ABS debate can be found in Annex 1. The author tried to take the care to interview people with various interests and position in the debate (civil society, scientific community, political actors). It is worth mentioning that the author did not manage to organise a meeting with a representative of the economic sphere. **Importantly**, the opinions expressed by the people interviewed do not necessarily reflect the views of the institutions or employers they represent.

2 Background of the Nagoya Protocol

This chapter aims to provide the reader with the background information necessary to understand the most striking aspects of the ABS issue. After having presented the circumstances under which the debate over control and ownership of genetic resources gained momentum in the international community, the first section sheds lights on the incomplete CBD ABS framework and its major weaknesses. Section 2 provides an overview on how Parties to the CBD attempted to implement this framework in the last two decades. In addition, the negotiation process which led to the adoption of the Nagoya Protocol is also briefly presented. The third section provides some information on the economic dimension of the ABS debate and shows how the basic economic features need to be taken into account in a functional regime.

2.1 Legal context

2.1.1 The premises

The debate over control and ownership of genetic resources is a longstanding-issue in international environmental law. Traditionally, genetic resources were considered as part of the common heritage of mankind and thus openly/ freely accessible.[54] Since the 1970's, the development of biotechnologies has however significantly modified the significance and value of biological resources. It has shown that "genetic and species diversity have commercial potential not only as a source of material, or as commodities, but also as a source of information for product development."[55] The common heritage approach implied that research and development on genetic resources could be conducted without limitations or compensations. As a result, "a commercial developer or researcher might obtain immense value by utilizing the properties of a particular species, subspecies or variety, having only taken a very small number of samples or extracts of the species. Developing countries, which hold must of the world's biodiversity, became increasingly concerned that this exploitation of genetic resources did not result in benefits." [56]

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[54] See e.g. the International Convention for the Protection of New Varieties of Plants (UPOV), (Paris, 2 December 1961) establishing genetic resources are part of the "common heritage of mankind."

[55] S. Laird, 'The Convention on Biological Diversity: changing ethical and legal frameworks for biodiversity research and prospecting', found at <http://www.fao.org/docrep/003/y1237e/y1237e05.htm >, last accessed 6 September 2011.

[56] S. Bhatti, T. Young, 'ABS contract and contract law', in S. Bhatti et al., (eds.), *Contracting for ABS: The Legal and Scientific Implications of Bioprospecting Contracts*, IUCN Environmental Policy and Law Paper No. 67, IUCN Environmental Law Center, Bonn, Germany, p.3.

In parallel to the biotechnology revolution, the expansion of the Intellectual Property Rights (IPR) system has also contributed to a radical shift in the paradigm of control, ownership and utilization of biological resources. As stated by Ten Kate and Laird, "the patent system - paralleling scientific and technological advances - has undergone a process of regulatory globalization and harmonization, and the scope of what is regarded as patentable has quietly expanded."[57] By providing protection and reward to genetic-based inventions, the development of the IPR's regime has led to an ever-increasing privatization of genetic resources. Over time however, biotechnology patenting activities have become heavily contested, "on both technical patent law and ethical grounds."[58] Several emblematic cases of biopiracy[59] brought the issue of the legal status of genetic resources on the political agenda of the International Community. Under the pressure of developing countries, the CBD expressly repudiates the common heritage approach and enshrines state sovereignty over its genetic resources.

2.1.2 The ABS principles in the CBD

2.1.2.1 The CBD great Compromise

The Convention on Biological Diversity (CBD) is the main instrument of international environmental law devoted to biodiversity conservation and the sustainable use of its components.[60]

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[57] S Laird, *Biodiversity and Traditional Knowledge. Equitable partnerships in practice*. Earthscan. 2002, p.xxvi. For an overview of the expansion of expansion of the biodiversity patenting, see e.g. P. Drahos, 'Biotechnology patents, markets and morality', *European Intellectual Property Review*, Vol. 21, No. 9, 1999, pp. 441-449.

[58] S. Picciotto, 'Property rights and regulation, Private and Public', Conference on Regulation in the Age of Crisis Standing Group on Regulatory Governance of the ECPR and the Regulation Network University College, Dublin, 17th-19th June 2010, found at < http://regulation.upf.edu/dublin-10-papers/4H1.pdf >last accessed 6 of September 2011; See generally, C.Ho, supra note 47.

[59] Biopiracy is an important notion in the ABS debate. It is a loose and political concept clustering a large panel of allegations. Fundamentally, "biopirates are those individuals and companies accused of one or of the following acts: (i) the theft, misappropriation of, or unfair free-riding on, genetic resources and/or traditional knowledge through the patent system; and (ii) the unauthorized and uncompensated collection for commercial ends of genetic resources and/or traditional knowledge." (G. Dutfield, 'What is Biopiracy?' Document presented at the Expert Workshop on Access and Benefit-sharing, Cuernavaca, Mexico, October 2004, found at <http://moderncms.ecosystemmarketplace.com/repository/moderncms_documents/I.3.pdf> last accessed 6 September 2011. Biopiracy claims resonated "with an existing mistrust of big business and globalization" (C. Ho, supra note 47). This morality/ fairness backdrop makes it particularly complex to distinguish acts of biopiracy and legitimate practices. Furthermore, as some analysis have shown, biopiracy claims also often contains their share of misunderstanding/ misconceptions as regard the IPR regime. (Ibidem). For a comprehensive analysis of biopiracy claims, T. Young, 'Analysis of Claims of 'Unauthorised Access and Missappropriation of Genetic Resources and Associated Traditional Knowledge', in T. Young. (ed.), *Covering ABS: Addressing the Need for Sectoral, Geographical, Legal and International Integration in the ABS Regime. Papers and Studies of The ABS Project,* IUCN Environmental Policy and Law Paper No. 67/5, IUCN, Gland, Switzerland, 2009, pp 97-135.

[60] Conservation of biological diversity and the sustainable use of its components are the two first objectives of the CBD. See CBD, supra note 9, Art.1.

Opened for signature in Rio in 1992 and entered into force in December 1993, it has been ratified by 191 countries and is often praised for its quasi-universal character.[61] As stated by Jardin, "because of its holistic approach and its innovative way of addressing biodiversity challenges, far from the conservation of selected species or habitats approach, the CBD can be perceived as a revolutionary instrument.[62] The CBD "was created as a platform from which national laws and practices for conservation and sustainable use could be integrated to ensure the protection of the global web of life."[63] It is a framework convention laying down "various guiding principles at the international level which states parties are required to take into account in developing national law and policy to implement its objective, but to which can also be added subsequent ad hoc protocols on related issues laying down more specific and detailed requirements and standards." [64]

The CBD is often described as a "grand bargain", as a deal crystallising a "great compromise."[65] It was adopted at the end of highly contentious negotiations and thus the treaty cannot be properly understood without acknowledging at the compromise it entails. As a starting point, the Convention relies on the assumption that States have the duty to conserve biodiversity within their national territory. With their greater level of biodiversity per hectare and per capita, a larger regulatory burden is thus often placed on developing states. To compensate this, the Convention, in numerous binding provisions, requires Parties to support biodiversity conservation through monetary and non-monetary funding. In particular, developing and developed States agreed on the creation of ABS, a mechanism aimed to associate non-state actors involved in activities taking advantage of genetic resources in the conservation effort. This environmental developmental

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[61] It is however worth mentioning that the United-States, particularly active in biotechnologies and biopatenting, is not a Party to the Convention and solely participates to discussions in the CBD forum as observer.

[62] M. Jardin, 'Global biodiversity Governance: The contributions of the main Biodiversity related Conventions', in R. Billé et al. (eds.), *Global Governance of Biodiversity: New perspectives on a shared challenge*, Health and Environment Reports, No. 6, 2010, p.31.

[63] M. Tvedt. T. Young, supra note 8, p.19.

[64] P. Birnie et al., *International Law and environment* (3rd ed.) Elliott, Lorraine, 2008, Oxford University press, p. 614. Before the adoption of the Nagoya ABS Protocol, the "Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Montreal, 29 January 2000)", was the unique Protocol laying down more specific requirements to the general principles of the CBD.

[65] Some "developing states envisaged the Convention as part of their agenda for restructuring world economic relations." (P. Birnie et al., supra note 64, p.632). As observed by Dutfield, "realising the potential economic value of their biodiversity wealth and needing to improve their scientific, technological and financial capacities to exploit it, their position was that they had the right to set conditions on those seeking their resources including the fair and equitable sharing of benefits such as the transfer of technology and financial resources. Needless to say, perhaps, developed countries and transnational corporations wanted as few restrictions and conditions as possible on access to biological resources." (G. Dutfield, supra note 44, p.28).

backdrop is the "*raison d'être*" of ABS and cannot be overlooked when trying to interpret or implement the regime.

2.1.2.2 The ABS fundamental *quid pro quo*

The CBD is the legal foundation of the ABS concept. Pursuant to Article 1, the CBD has for third objective "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies and by appropriate funding." At the core, ABS reflects a fundamental *quid pro quo* between the Southern and Northern states. As stated by Tvedt and Young, "nationally, countries committed to enabling access to genetic resources (a commitment sought by developed countries on behalf of their research and industrial sectors), and in exchange for developing countries' agreement to this commitment, developed countries agreed to a second commitment – to develop a mechanism for sharing the benefits of the utilization of genetic resources with the country of origin. In essence, both groups received a desired objective, in exchange for committing to one for which they have less desire."[66]

As already explained in the introduction, ABS targets the collection *in-situ* of genetic resources and its functioning is seemingly simple. Through Research and Development (R&D) activities as well as subsequent commercial applications, genetic resources are utilized in a wide range of sector of activities for commercial and non-commercial purposes, including cosmetics and personal care, plant and animal breeding, natural medicine, horticulture, biotechnologies and the pharmaceutical industry.[67] Users desiring to utilize genetic resources have to request authorization

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[66] M. Tvedt, T. Young, supra note 8, preface p. XV.

[67] The economic stakes and implications of the ABS international regime have been comprehensively examined by several authors in the recent years. For more information, see e.g. S. Laird, R. Wynberg, supra note 26; S. Laird, K. ten Kate, 'Biodiversity prospecting: the commercial use of genetic resources and best practice in benefit-sharing' In S. Laird (ed), *Biodiversity and traditional knowledge: equitable partnerships in practice*, London, Earthscan, 2002. The important lesson to be drawn from these analyses is that there are significant differences between the sectors and sub sectors of industry using genetic resources. According to Laird, the variation is mainly due to the "size of industries and markets for products, (…) the share of natural products in these markets, (…) relationship between commercial products and the genetic resources from which they are developed (…) and the use of traditional knowledge in research and development" (S. Laird, supra note 53). This diversity implies that "each sector is part of a unique market, undertakes research and development in distinct ways, and uses genetic resources and demands access to these resources very differently. They also enter into partnerships with providers of genetic resources in distinct ways, have specific sets of stakeholders, negotiate prior informed consent in diverse ways, and have different approaches through which they reach mutually agreed terms with regard to benefit-sharing and intellectual property. Agreements within and across sectors also vary considerably with regard to the legal remedies they use for compliance and enforcement"(CBD ABS Working Group, 'Access and Benefit-Sharing Arrangements existing in specific sectors', UNEP/CBD/WG-

(PIC) from the country where the resource is collected. Then, in a private law contractual agreement (MAT), the provider and the user defines the terms and conditions governing the utilization of the said resources and the fair and equitable sharing of the benefits arising from their utilization. Once the utilization has produced benefits, users share them with the provider in accordance with the MAT previously agreed, supporting equity, sustainability and biodiversity conservation.

Article 15 of the CBD is the provision laying down the set of basic principles meant to operationalize ABS. Article 15.1 provides for state sovereignty over their genetic resources. Countries have the authority to determine under which conditions genetic resources can be accessed within their national jurisdiction. Article 15.2 calls for the Parties to endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other contracting parties and not to impose restrictions that run counter to the objectives of the CBD. Pursuant to article 15.3 of the CBD, "the genetic resources being provided by a Contracting Party are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention." As stated by Glowka, "the latter category requires some explanation as it excludes two distinct cases: (i)resources acquired prior to the Convention's entry into force from the provider of genetic resources, and (ii) resources acquired illegally from the country of origin after the Convention's entry into force." Article 15.3 of the CBD also "incorporates the "non-retroactivity" principle. As a result, genetic resources acquired before the Convention enters into force are excluded from the ambit of articles 15, 16 and 19. Ex-situ genetic resource collections created prior to the Convention's entry into force belong to this category."[68] Pursuant to Article 15.4 and 15.5, access, where granted, shall be upon Mutually Agreed Terms and subject to Prior Informed Consent of the Contracting Parties.

In accordance with Article 15.7, Parties to the CBD also commit to undertake laws and policies ensuring that, within their jurisdiction, users utilizing foreign-origin GR comply with their ABS obligations.[69] In the CBD, if provider-side measures are expressed in terms of processes (PIC

ABS/6/INF/4/Rev.1, 2008, p.2). For the ABS system to be functional, it is critical to introduce sufficient modularity in the international regime to cope with these dramatic differences.

[68] L., Glowka, *A guide to designing legal frameworks to determine Access to Genetic Resources*, Environmental Policy and Law Paper No. 34, IUCN-ELC, 1998, p.78. Pursuant to Art. 2CBD, "Ex-situ conservation means the conservation of components of biological diversity outside their natural habitats."

[69] In ABS, every country may be providing Genetic resources and, in the same way, can be the jurisdiction under which users are operating. Depending of the particular ABS transaction involved, States have both user-side and provider-side obligations and therefore need to take the necessary steps to ensure both access and benefit-sharing.

and MAT), the requirements imposed to user-countries are worded in terms of result. The CBD provides a long list of general goals countries shall "endeavour" to reach but do not specify concrete measures to achieve them. According to Buck, "it is one of the most challenging features of this framework that benefit-sharing according to Article 15.7 CBD rests on a government to government approach, while in practice it is mostly private actors that manage transjurisdictional transactions of genetic resources: the authority to grant PIC is regularly attributed to non-state entities such as research institutes; and those acquiring and using genetic resources are in almost all cases non-states entities, mostly researchers, sometimes privates companies."[70] In article 16, 19, 20 and 21, the CBD specifies that the benefits to be shared are monetary or non monetary in character (including research, transfer of technology, biotechnologies, capacity, jobs, financial benefits, etc.). As aforementioned, it is necessary for Article of the 15 CBD to be read in combination with Article 8 (j) which calls the Parties to ensure the respect of the rights of Indigenous and Local Communities (ILC).

2.1.3 The CBD lacunae:

Beyond these general principles, the CBD provides scarce guidance to implement ABS in practice. Provisions are elusive, vague and many controversial questions are unanswered and left to the discretion of the Parties. As stated by Cabrera Medaglia and Lopez Silva, "even the most basic terms such as the meaning of genetic resources and utilization of genetic resources are not concretely understood and legally settled."[71] Though unique characters of the ABS called for the elaboration of "new legal concepts and tools, as well as new uses of existing tools"[72], the CBD draftsmen instead "assumed that existing national property and contract law would be able to regulate and implement ABS. As a result of this assumption, the legal parameters of an entirely novel right to utilize genetic resources were never specifically agreed."[73] The following subsections highlight two major gaps and inconsistencies of the ABS concept as instituted by the CBD. Firstly,

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[70] M. Buck, C. Hamilton, 'The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity', *Review of European Community & International Environmental Law* , Vol. 20, No. 1, 2011, p. 48.

[71] J. Cabrera Medaglia, C. Lopez Silva, supra note 26, p.21.Only the unclear meaning of the term "genetic resource" will be analysed hereafter. A definition of "utilization of genetic resources" is introduced in the Protocol and will be studied in subsection 4.1.1. However, it is worth noting that the ABS conceptual deficit is not limited to this unique notion. For example, concepts such as "benefit-arising from the utilization", "source country", "country of origin" and "provider" are not all defined in the CBD and the exact content of many of these notions is still controversial. For an overview of these definitional problems, see e.g. M. Tvedt, T. Young, supra note 8, p.13.

[72] J. Cabrera Medaglia, C. Lopez Silva, supra note 26, p.5.

[73] Ibidem, p.21.

the blurred outlines of the "genetic resources" notion are emphasised. Secondly, a closer look will be devoted to the ownership paradox of genetic resources.

2.1.3.1 The unclear meaning of "genetic Resource"

Prior to the CBD, "genetic resources" did not exist as a legal term. The CBD opted for a definition based on the notion of "genetic material". According to Article 2CBD, "genetic material" signifies "any material of plant, animal, microbial or other origin containing functional units of heredity." "Genetic resources" refer to genetic material with "actual or potential value." While, as a scoping concept, it is supposed to determine the actions and situations covered by the whole scheme, the term does not contain the necessary elements to be legally and practically implementable. Over time, except the large consensus on the exclusion of human genetic resource, the "genetic resource" notion has become a catch-all formula. It is generally agreed that genetic resources constitutes a "subset of biological resources"[74] and that it does not concern biological material traded in bulk-as commodities- where the genetic material is not utilized *per se*. However, beyond those general assumptions, no common understanding could be agreed on.

Two major controversies contributed to blur the contours of the "genetic resources" notion. On the one hand, the definition is relying on the presence of "functional units of heredity." As stated by Ten Kate and Laird, "units of heredity could be organism, cells, chromosomes, genes and deoxyribonucleic acid (DNA) fragments."[75] At the time of the CBD adoption, there was a general belief that the value to be captured through utilisation was lying in the genetic information of biological material. Over time, knowledge in the field of genetics has made significant progress and the choice of functional units of heredity as scoping criterion appeared largely unfortunate. In fact, scientific progress has shown that functional units of heredity often do not constitute the immediate basis of beneficial utilization: the value of genetic resources mostly lies in "the organism's components, the interaction of genes and the biochemical compounds they express."[76] These valuable components of genetic materials devoid of functional units of heredity, loosely referred as to "derivatives", quickly became a major bone of contention and were at the basis of many

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[74] CBD ABS Working Group, 'Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches', UNEP/CBD/WG-ABS/7/2, 2008, p.6

[75] K. ten Kate, and S. Laird, *The commercial use of biodiversity: access to genetic resources and benefit-sharing*. London, Earthscan, p.18.

[76] Cabrera Medaglia, J. and C. Lopez Silva, supra.note 26, p.39.

emblematic biopiracy cases. Dissensions were further amplified by a lack of agreed definition and potential conflicts with commodities trade.[77]

On the other hand, "genetic resources" refer to genetic material with "actual or potential value." For three main reasons, the attribution of value linked to genetic resources constitutes another highly contentious aspect. First of all, value is a protean notion and cannot be reduced to economic profitability.[78] Secondly, the terms "actual" and "potential" value refer to the current as well as future "state of the art values", which introduces a highly dynamic and uncertain dimension in the definition. Thirdly, the definition is foremost problematic as the actual or potential value of genetic resource is not manifest at the time of access and thus largely unpredictable.[79] The value creation occurs in a later step in the ABS process, namely through successful utilization. Therefore, at the time of access, the distinction between biological and genetic resources, and thus the scope of the ABS scheme, relies on the (declared) intention of the person accessing biological material. As stated by Tvedt and Rudunko, "if the user intends to take an action that will constitute the utilisation of a genetic resource, then the material used will be a "genetic resources." Taking the biological material for any other purpose will fall outside the definition and thus outside of the regime."[80] As concluded by Tvedt and Young, "to make this determination one must either accept the word of that person, or possess the supernatural ability to predict and prove the intended future use of the material."[81]

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[77] For an overview of the various meanings given to the term of "Derivatives" see e.g. CBD ABS Working Group, supra note 72.

[78] Instead, the actual "values" of genetic resources are "social, economic, cultural and spiritual in nature." (CBD ABS Working Group, 'The role of Commons/Open Source Licences in the International Regime on Access to Genetic Resources and Benefit-Sharing', UNEP/CBD/WG-ABS/8/INF/3, 2009, p. 28).

[79] The dynamic feature can be explained because these terms "could be read as a reference to the technological state of the art: the actual value would then concern the value of genetic material in combination with the techniques known and developed as of the time point of access; where as potential value could then be understood as the possible new techniques in the future which might realize the potential value of the functional units of heredity." (CBD ABS Working Group, 'The Concept of 'Genetic Resources' in the Convention on Biological Diversity and how it relates to a Functional International Regime on Access and Benefit-Sharing', UNEP/CBD/WG-ABS/9/INF/1, 2010, p.8) In addition, "at that point, the user will usually not know what can expect from an innovative research process based on the accessed material." (Ibidem, p.9). As a result of this "lack of manifest actual value of the genetic material at the access time point, the potential value becomes an important element of the definition. […] The value of the material at access timepoint is potential in the sense that one cannot know the specific value before it has been realised. Also the value might prove to be for something else than originally thought. Thus, also where there are no evident current values, the genetic material could qualify as being genetic resources. It is also impossible to conclude with certainty that the material will not have any value." (Ibidem, p.9).

[80] M. Tvedt, O. Rukundo, *Functionality of an ABS Protocol*, Report 9/2010, Lysaker, FNI, 2010.

[81] M. Tvedt, T. Young, supra note 20, p.12.

2.1.3.2 The inconsistencies in the legal treatment of "genetic resource"

The revolutionary character of ABS lies in the fact "it envisions/mandates the creation of a new specific legal right in the genetic properties of naturally occurring species. (…) In so stating, Article 15 essentially says that there is some type of valued tangible or intangible commodity (known in law as a *res*) that can be owned, transferred, restricted or granted and which can be tied to other responsibilities -*i.e*, to benefit-sharing."[82] The legal status of this entirely new legal right is however not specified in the CBD and is still today highly problematic. According to Young, the problems in the legal treatment of genetic resource ownership create "serious obstacles to consistent ABS legislation and implementation at the national level. These inconsistencies are the largest, most insurmountable obstacle to ABS implementation at present."[83] In this context, a closer look to what Young calls the "four-step paradox of ABS"[84] seems relevant.

Firstly, most genetic resources have a large number of potential sources. Since "the gene sequences and biochemical formulas of an entire species (subspecies or variety) are duplicated in all of its members"[85], it is therefore impossible to exercise a physical control on "all specimens of any natural species, and their use as samples for research, genetic analysis or biochemical analysis, even if the species is a narrow range endemic."[86]

Secondly, "the 'Ownership' and/or the right to control or dispose of genetic resources, is disseminated among many separate, unrelated holders."[87] Pursuant to Article 15 of the CBD, "every country in which a particular species is found *in situ* has sovereign rights in the genetic resources of that species. However, nearly all species have a natural distribution that extends to more than one country."[88] In addition, "some countries have laws which disseminate the ownership of, genetic resource widely, giving separate ownership of a species' genetic resources to every individual who owns any specimen of that species."[89] Nevertheless, "despite this diffusion of ownership, a country (community, person) that owns even a single specimen of a species may grant access to its genetic

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[82] Ibidem, pp.6-7.
[83] T. Young, supra note 40, p.124.
[84] Ibidem, p.124.
[85] S. Bhatti et al., supra note 56, p.18.
[86] T. Young, supra note 40, p.125.
[87] Ibidem, p.125.
[88] Ibidem, p.125.
[89] Ibidem, p.125; In other words, each individual/groups owing a specimen of a genetic resource may then be the "provider" in an ABS relationship.

resources without consulting any other country or person who has a parallel ownership of the genetic resources of that same species."[90]

Thirdly, "the user of genetic resources may need only a relatively small sample, obtained from one provider, in order to be able to utilize its genetic resources. Modern industrial and commercial development processes can often find ways to duplicate or synthesize a species' genetic and biochemical elements based upon only a few samples or in some cases, no samples at all (if they receive detailed research data). Once the initial research and development is complete, the user will often need no further physical specimens from any source. This will be true regardless of whether the user first obtained an ABS contract or permit."[91]

Fourthly, "following access, some users try to convert the non-exclusive genetic resource (legally held and potentially usable by a great many providers) into an exclusive resource, by patenting the naturally occurring gene, rather than only patenting their innovation or invention. If they receive the gene patent, the users could prevent (or require a royalty on) every other person, country or entity from any further commercial or pre-commercial use of the gene. This would theoretically prevent use or other transactions by (i) the country of origin, (ii) other countries-of-origin of the same genetic resource, (iii) other holders in those countries, or (iv) other users who may seek access to that genetic resource in the future Arguably, this kind of IPR defeats the purpose of ABS (which was intended to provide an incentive for conservation and sustainability), since the financial or potential value of species will be devalued following the issuance of the patent, thereby diminishing the conservation incentive. This type of IPR would also defeat the purpose of patents, which has been described as encouraging and protecting innovation. By contrast, an IPR which restricts the ability of other innovators to use the species' naturally occurring building blocks in other new products would appear to be an impediment to innovation."[92]

As the prior analysis highlights, the "four steps ABS paradox" expresses some major functional gaps in the legal treatment of genetic resources the international regime will need to address in order to be effectively implemented. At the core, it relates to the difficulty to reconcile the collective character of genetic resource with exclusive IPR's. More specifically, "the paradox

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[90] Ibidem, p.125.
[91] Ibidem, p.125.
[92] Ibidem, p.126.

boils down to a simple question: If the user obtain his right to genetic resources from one of a large group of holders, how can he rationally convert it into an exclusive right (patent of the natural gene or traditional variety) without permission from all other holders? Or stated another way, Why should the right of one person or community or country "win" over the identical right of others?"[93]

2.2 Development of the international ABS regime

2.2.1 From Rio to the Bonn Guidelines, the over-emphasis on Provider legislation

It was initially considered that Provider-side legislation would be alone sufficient to achieve the ABS objective. The CBD draftsmen seemed to assume that States and communities would be in state to ensure a physical control on all their national genetic resources. No utilization would occur prior to the granting of a PIC and the conclusion of a benefit-sharing agreement. Once countries would have regulated the access to their genetic resources in accordance with the CBD principles, ABS would have functioned at national level through contractual transactions without requiring further international collaboration or user-side measures. With the adoption of local, national and regional ABS instruments, some provider countries tried to regulate, sometimes very strictly, the movement and research activities devoted to the physical mediums of their genetic resources. In particular due to the lack of externally identifiable character of genetic resources at the time of access, they however remained very relatively successful in controlling the exportation of their genetic material.

Rapidly, provider states denounced the absence of user-side legislation and accused developed states not to collaborate in case of illegal access of genetic resources and associated TK. On the other hand, according to the latter, unreasonable monetary expectations, high transaction costs, legally uncertain and excessively strict processes were primarily the cause of infrequent compliance of genetic resources users.[94] Beside the CBD, discussion to improve the implementation of ABS took place in various international fora, including *i.a*. the Food and Agriculture Organization (FAO), UNESCO, the World Trade organization (WTO), the World Intellectual Property Organization (WIPO) and the Union for International Protection of New Varieties of

[93] Ibidem, p.126.
[94] Due to the infrequent compliance and the lack of user-side measures, access legislations were often enacted in an even more restrictive manner. This illustrates the interdependence between user certainty and user compliance already highlighted in chapter 1.

Plants (UPOV). Each organisation analysed the controversy with its own rationality and through the lens of its own mandate. Negotiations were often transferred from one arena to another, exacerbating the tensions between the countries. Over time, distrust was ruling and the lack of an effective ABS system "was becoming an impediment to commercial and research access to genetic and biological resources."[95]

At its fifth meeting, in 2000, the CBD COP established a Panel of Experts, the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (ABS Working Group), "with the mandate to develop guidelines and other approaches to assist Parties with the implementation of the access and benefit-sharing provisions of the Convention."[96] After two years of intense work, the Bonn Guidelines, a non-binding document, were adopted at COP6 (April 2002, The Hague, the Netherlands). The Guidelines provide guidance and assistance to the parties for "developing and drafting legislative, administrative or policy measures on access to genetic resources such as recommending the elements that should make up a prior informed consent (PIC) procedure."[97] Moreover, the Guidelines also aims "to assist providers and users in the negotiation of mutually agreed terms (MAT), by providing examples of what elements should be included in these agreements."[98] The Bonn Guidelines offer an interesting attempt towards ABS effectiveness. In particular, it identifies the various steps involved in the ABS process and enounces a useful set of basic principles[99] and recommendations[100] guiding provider country in the design, establishment

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[95] T. Young, supra note 40, p.115. As stated by Ruiz Muller and Lapeña, "since the mid-1990s, scientists from around the world have expressed their concerns that excessively zealous ABS legislation may have a negative impact on research activities, especially when these are clearly oriented towards non-commercial objectives". (M. Ruiz Muller, I. Lapeña, 'A Proposal on International Audits to Track and Monitor Flows of Genetic Resources and Verify Compliance with ABS Agreements', in M. Ruiz Muller & I. Lapeña (eds.), *A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows* , IUCN Environmental Policy and Law Paper No. 67/3, IUCN, Gland, Switzerland, 2007, p.116).

[96] CBD COP 7, 'Access and benefit-sharing as related to genetic resources (Art. 15)', Decision VII/199, 9-20 February 2004.

[97] CBD Secretariat, 'Factsheet: The Bonn Guidelines', found at <http://www.cbd.int/abs/infokit/print-ready/factsheet-bonn2-en.pdf> last accessed 6 September 2011.

[98] Ibidem.

[99] Those basic principles are (1) legal certainty and clarity, (2) facilitation of access to genetic resources at minimum cost, (3) restrictions on access to genetic resources that are transparent, based on legal grounds, and that do not run counter to the objectives of the Convention, and (4) consent of relevant competent national authorities in the provider country, and also consent of relevant stakeholders, such as indigenous and local communities, as appropriate to the circumstances and subject to domestic law. (CBD COP 7, supra note 96).

[100] In addition, the Guidelines also recommends several elements to be established in a PIC scheme: (1) competent authority(ies) granting or providing for evidence of prior informed consent; (2) Timing and deadlines; (3) Specification of use; (4) Procedures for obtaining prior informed consent; (5) Mechanism for consultation of relevant stakeholders; [and] (6) Process. Lastly, the Guidelines provide a suggested list of information which should be transmitted by GR applicants to the national authority granting the access. (CBD COP 7, supra note 96)

and management of their national access regime. Most importantly, the Guidelines "tend to make a proper balance of rights and obligations on PIC between genetic resources users and providers."[101]

Despite its non-legally binding character, significant progresses in designing access legislation were achieved thanks to the guidance document. However, the Bonn Guidelines lets salient problems unsolved. Most importantly, it still relied on the idea that only provider-oriented regulation is needed for an effective ABS scheme and contains little guidance concerning the implementation of User-side measures. As a result, the document did not provide the necessary impetus to improve the effectiveness of the existing ABS regime. Though between 50 and 100 states have so far tried to adopt ABS legislation, only about 40 countries of the 191 Contracting Parties have nowadays enacted specific ABS regulation.[102] At present, user measures constitute the "unfulfilled requirement" of the ABS concept.[103] No country has so far effectively implemented his user-side obligations in their national legal order. As stated by Bhatti and Young, the reasons behind this failure in developed country seem to be "legal, political and technical."[104] Norway and Japan constitute the only two countries which attempted to adopt specific user-side legislation

2.2.2 From Johannesburg to Nagoya, an 8 years long negotiation saga

In 2002, the international community agreed in the Plan of Implementation of the World Summit on Sustainable Development (WSSD) to "negotiate an international regime on ABS within the framework of the CBD."[105] As a result, at the CBD COP7 (February 2004, Kuala Lumpur, Malaysia), the ABS Working Group was mandated "to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions of Article 15 and Article 8(j) of the Convention and the three objectives of the Convention." [106] At its eight meeting (March 2006,

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[101] K.-J. Ni, 'Legal Aspects of Prior Informed Consent on Access to Genetic Resources: An Analysis of Global Lawmaking and Local Implementation Towards an Optimal Normative Construction', *Vanderbilt Journal of Transnational Law*, Vol. 42, No. 1, 2009, p. 256.
[102] CBD ABS Working Group, 'Overview of Recent Developments at National and Regional levels Relating to Access and Benefit-sharing', UNEP/CBD/WG-ABS/5/4, 2007.
[103] S. Batthy, T. Young, supra note 56, p. 23.
[104] Ibidem, p. 23.
[105] See 'Plan of Implementation of the World Summit on Sustainable Development, Johannesburg, South Africa, 26 August-4september 2002' (A/CONF.199/20, 4 september 2002), Resolution 2, Annex, para. 44 (o) found at <http://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/WSSD_PlanImpl.pdf> last accessed 6 September
[106] CBD COP 7, supra note 95.

Curitiba, Brazil), Parties instructed the ABS Working Group to complete the elaboration of the international regime on ABS at the earliest possible time before COP10, to be held in 2010.

In the ABS Working Group, the first years of negotiation were particularly chaotic, countries being divided on the meaning of the "nternational regime" to be elaborated (February 2005, Bangkok, Thailand; January 2006, Granada, Spain and October 2007, Montreal, Canada).[107] For a long time, general distrust, endless debate on the methodological approach to follow and repeated disputes between the main negotiating groups prevented the Working Group from moving into really substantive discussion.[108] At it eight meeting in March 2008, the COP succeeded in giving a new impulse to the negotiation process. At the 6th meeting of the ABS Working Group (January 2008, Geneva, Switzerland), the position of the major negotiating groups finally commenced to converge. In the so-called "Geneva Annex", Parties listed potential features and building blocks of the future international regime. At the ninth meeting of the CBD COP (May 2008, Bonn, Germany), Parties agreed to start text-based negotiations upon the "Geneva Annex." Parties also adopted a detailed timeline to complete the elaboration of the international ABS regime before the 2010 deadline and established three distinct expert groups on (i) compliance; (ii) concepts, terms, working definitions and sectoral approaches; and (iii) traditional knowledge associated with genetic resources.[109]

The negotiation atmosphere remained electric and little substantive progresses were achieved during the next three Working Group meetings. Most of the time of the seventh and eighth meetings of the Working Group (April 2009, Paris, France and November 2009, Montreal, Canada) was dedicated to elaborate the draft of a Protocol text. In the so-called "Montreal Annex", Parties found an "agreement on non-controversial provisions, and made progress on certain difficult issues, including the relationship with other instruments and compliance with domestic ABS requirements. Delegates also identified key issues that required further compromise, including scope and

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[107] To call the CBD Parties to negotiate an "international regime" was particularly unfortunate. Legally speaking, the CBD, the Bonn Guidelines, regional instruments, the FAO treaty, etc. already constitute an ABS International regime. As underlined by Ruiz, "whether these different instruments in their interaction are effective or not, that is another matter." (M. Ruiz, *Thinking Outside: Viable Options for an Operational Regime on Access and Benefit-sharing,* ICTSD Programme on Natural Resources, Issue Paper No.1, Geneva, Switzerland. 2010, p.16).

[108] C. Chiarolla et al.., 'Summary of the Seventh Meeting of the Working Group on Access and Benefit-sharing of the Convention on Biological Diversity : 2-8 April 2009', Vol. 9, No. 465, *Earth Negotiation Bulletin*, Friday 10 April 2009, found at: <http://www.iisd.ca/vol09/enb09465e.html> last accessed 6 September 2011.

[109] CBD COP9, 'Access and Benefit-Sharing', decision IX/12, Bonn, Germany, 19 - 30 May 2008.

pathogens, derivatives and the concept of utilization of genetic resources, and mechanisms to support compliance."[110]

The ninth meeting of the ABS Working Group (March 2010, Cali, Colombia) consolidated this draft but "barely entered into the text-based negotiations necessary to tackle the many outstanding and politically sensitive issues that have to be resolved before October [2010]."[111] At that meeting, the Working Group also proceeded to the creation of the Interregional Negotiating Group (ING) charged with the mission to pursue the elaboration of the draft Protocol. The resumed ninth meeting in Montreal (July 2010) was more constructive. Most importantly, a group of key negotiators listed the issues which remained to be resolved. This list showed the important differences in the position of the various negotiating groups. It however also helped to identify crosscutting issues needing to be dealt in priority due to their "knock-on" effect for the entire text. However, "while the meeting achieved some progress towards an improved common understanding on derivatives and the concept of utilization, key issues remained outstanding."[112]

2.2.3 The COP 10 negotiation

The ING was reconvened in Nagoya on 13th of October 2010 and worked until the formal reconvening and closure of the second resumed meeting of the ABS WG9 on 15th of October. The 16th of October 2010, at the opening meeting of the Conference, the Informal Consultative Group was mandated by the COP to continue negotiations on a draft Protocol. Several small groups were established to address key issues including utilization and derivatives, compliance-related issues, the Protocol's relationship with other instruments, emergency situations, TK-related issues, and the COP decision. Though steady progresses were booked during the negotiations, until the very end, it seemed unlikely that a compromise could be found on the most problematic issues, *i.a.* on

[110] J. Jungcurt et al, 'Summary of the Resumed Ninth Meeting of the Working Group on Access and Benefit-sharing of the Convention on Biological Diversity: 12-19 July 2010', Vol. 09, No. 527, *Earth Negotiation Bulletin*, Monday 19 July 2010, found at: < http://www.iisd.ca/vol09/enb09527e.html > last accessed 6 September 2011.
[111] J. Gnann et al., 'Summary of the Ninth Meeting of the Working Group on Access and Benefit-sharing of the Convention on Biological Diversity: 22-28 March 2010', Vol. 09, No. 503, *Earth Negotiation Bulletin*, Wednesday 31 March 2010, found at: <http://www.iisd.ca/vol09/enb09503e.html > last accessed 6 September 2011.
[112] T. Kantai et al., 'Summary of the First meeting of the Intergovernmental Committee for the Nagoya Protocol to the Convention on Biological Diversity 5-10 June 2010', Vol. 09, No. 551, *Earth Negotiation Bulletin,* Monday, 13 June 2011, found at: <http://www.iisd.ca/vol09/enb09551e.html> last accessed 6 September 2011.

derivatives, pathogens, scope and compliance.[113] In a last ditch effort, the Japanese COP presidency convened a meeting with a more limited number of participants (EU, Norway, Brazil and the African Group) in order to prepare a balanced negotiation basis for the informal ministerial consultations on Thursday 28 October. The deal accepted by the Ministers participating in the consultation was however not unanimously supported by other Parties as a compromise proposal. In an ultimate attempt, on Friday 29 October at 3 am, the Japanese COP Presidency presented a comprehensive compromise package for an ABS Protocol, providing creative solutions to the remaining outstanding issues.[114] As stated by Buck and Hamilton, "all Parties eventually accepted this text in the early afternoon of October 29 in a dramatic meeting with ministers behind closed doors."[115]

During the closing plenary, several countries expressed their dissatisfaction with the adopted text but did not obstruct its eventual adoption. On Friday 29 of October, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity was adopted by the COP during the closing plenary as part of the "Nagoya Package." While many praised the support and commitment of the Japanese Presidency, the manoeuvre to finalize the agreement was also criticized by some Parties.[116] At the end, the strategy allowed striking a deal that would have not been reached otherwise in Nagoya as negotiations were in a deadlock.

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[113] As observed by Jungcurt et al., "three days before the end of COP 10, assessments of the likelihood for adopting an ABS protocol at COP 10 ranged from "still possible" to "unrealistic""(Jungcurt et al., supra note 2). Those four issues were the main stumbling blocks of the negotiations.

[114] CBD Secretariat, 'Draft decision submitted by the President of the Conference of the Parties', UNEP/CBD/COP/10/L.43/Rev.1, 29 October 2010.

[115] M. Buck, C. Hamilton, supra note 70, p. 51.

[116] See G. Nijar, 'The Nagoya Protocol on Access and Benefit-sharing of Genetic Resources: An Analysis. CEBLAW Brief', 2011.

3 Overview of the Nagoya Protocol

The present chapter intends to give some information on the negotiation process during the COP10 in Nagoya. Section 2 provides an overview of the main provisions of the Protocol. Section 3 presents the provision

3.1 The Nagoya Protocol main provisions

The Nagoya Protocol is the "instrument for the implementation of the access and benefit-sharing provisions of the Convention" (Article 4.4). It specifies and details the ABS objective of the CBD. The Nagoya Protocol is a new and standalone legally binding international instrument for which no reservation is allowed (Article 34). The CBD framework will continue to play a highly important role as it "provides the substantive, institutional and procedural basis for the Nagoya Protocol."[117] For instance, "institutional arrangements such as dispute settlement mechanisms and secretariat services for the Nagoya Protocol will also be those already established under the CBD."[118]

The Protocol contains 27 preambular clauses, 36 operative provisions, and one Annex including an indicative list of monetary and non-monetary benefits. According to article 1, the objective of the Protocol is the "fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby (emphasis added) contributing to the conservation of biological diversity and the sustainable use of its components." Implicit in the CBD, the ABS environmental developmental objective is thus explicitly enshrined as the end goal of the ABS international regime. The facilitated access to genetic resources and the fair and equitable sharing of the benefits arising out of their utilisation are ultimately aiming to redistribute the costs of the conservation of Biodiversity and the sustainable use of its components. As

[117] Union for Ethical BioTrade, 'Nagoya Protocol on Access and Benefit-sharing -Technical Brief', 2010, found at <http://ethicalbiotrade.org/news/wp-content/uploads/UEBT_ABS_Nagoya_Protocol_TB.pdf> last accessed 6 September 2011.
[118] Ibidem.

previously highlighted, this equity backdrop should never be overlooked when CBD Treaty and Protocol provisions are interpreted and implemented.

Article 2 contains *i.a.* the definition of the terms "utilization of genetic resources" and derivatives. As stated in article 3, the scope of the Protocol covers genetic resources and Traditional Knowledge associated with genetic resources and the benefits arising from their utilization. Pursuant to Article 4, the Protocol shall be implemented in a mutually supportive manner with other international agreements and instruments. Article 5 develops the fair and benefit-sharing obligation. Articles 6 and 7 lay down the obligations of Parties as regard access to genetic resources and access to traditional knowledge associated with genetic resources. Article 8 calls for special consideration for crucial issues, namely non-commercial research, pathogens and genetic resource for food and agriculture. Article 9 reaffirms that benefit-sharing should strive towards conservation and sustainable use. Article 10 envisages the creation of a global multilateral benefit-sharing mechanism. Article 11 calls for transboundary cooperation where the same genetic resource and associated traditional knowledge are found *in situ* within the territory of more than one Party. Article 12 provides with special considerations to be devoted to traditional knowledge holders. Article 13 deals with national focal point and/or competent national authorities Parties are required to establish.

Article 14 establishes the "Access and Benefit-sharing Clearing House" which will serve as a means to share information related to access and benefit-sharing. Article 15 and 16 are devoted to the compliance with domestic legislation or regulatory requirements on ABS, respectively for genetic resources and TK. The monitoring of the utilization of genetic resources is addressed in Article 17 while article 18 focuses on compliance with Mutually Agreed Terms. Model contractual clauses (Article 19), codes of conducts, guidelines and best practices and/or standards (Articles 20), awareness raising (Article 21), capacity building (Article 22) and technology transfer, collaboration and cooperation are provision aiming to promote and facilitate the implementation of the Protocol. The provisions 26 to 36 deal with institutional, procedural and administrative matters. In Article 30, the so-called "enabling clause" invites the COP serving as the meeting of the Parties, at its first meeting, to consider and approve procedures and mechanisms to promote compliance with this Protocol.

3.2 The Intergovernmental Committee Work Programme

In Nagoya, the CBD COP10 established an Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the Intergovernmental Committee). The Intergovernmental Committee was created "to finalize those elements that did not form part of the negotiation of the Protocol itself, but that are required in order to bring to operation the Protocol on entry into force."[119] COP10 has foreseen two meetings of the Intergovernmental Committee before COP11 to be held in India in October 2012.

At its first meeting in June 2011, the Intergovernmental Committee will consider (i) the modalities of operation of the ABS Clearing-House; (ii) Capacity-building; (iii) Awareness raising; (iv) Compliance. At is second meeting to be held in April 2012, the Committee will consider the (i) budget; (ii) financial mechanism; (iii) resource mobilization; (iv) rules of procedure for the Conference of the Parties; (v) agenda for the first meeting of the Conference of the Parties; (vi) the need for and modalities of a global multilateral benefit-sharing mechanism; (vii) continued consideration of items taken up at the first meeting of the Intergovernmental Committee, as needed. As stated by Buck and Hamilton, "whilst some elements could potentially be finalized after the Protocol entry into force, others must be adopted at the first meeting of the Parties in order for the Protocol to operate effectively. It remains to be seen whether two meetings will be sufficient to enable full consideration of all those issues. A stock-taking will likely to be needed at CBD COP11 in India in October 2012."[120]

3.3 Signature, Ratification and Entry into Force

The Protocol is open for signature at UN Headquarters in New York from 2 February 2011 to 1 February 2012. Only Parties to the CBD may sign and ratify the Protocol. The Nagoya Protocol will only be legally binding only for Parties to the CBD that decide to sign and ratify it. If Parties to the CBD do not sign and ratify the Protocol, they will however remain bound by the overarching

[119] M. Buck, C. Hamilton, supra note 70, p.61.
[120] Ibidem, p.61.

CBD rules and principles. Non-Party to the CBD has thus first have to ratify the Convention before being entitled to become a Party to the new Protocol. [121]

It is important to properly understand the difference between signature, ratification and entry into force. The signature of a treaty is "an act by which a State provides a preliminary endorsement of the instrument."[122] The Signature does not result in any positive legally binding obligation. Nevertheless, it indicates the State's intention "to examine the treaty domestically and consider ratifying it. While signing does not commit a State to ratification, it does oblige the State to refrain from acts that would defeat or undermine the treaty's objective and purpose."[123] At this writing, Bangladesh became the 41st State Party signing the Protocol.[124]

"Ratification" is an "act by which a State signifies an agreement to be legally bound by the terms of a particular treaty. To ratify a treaty, the State first signs it and then fulfils its own national legislative requirements."[125] The CBD Secretariat clarifies the implications ratification process on its website: "Parties to the Convention that sign the Nagoya Protocol before the closing date for signature may then proceed to take steps at the domestic level that would lead to depositing their instruments of ratification, acceptance or approval with the Depositary. Those Parties to the Convention that may not be able to sign the Nagoya Protocol by 1 February 2012, but still wish to become Parties, may accede to it by depositing an instrument of accession with the Depositary. Ratification, acceptance, approval and accession have the same legal effect. The relevant instruments represent an expression of explicit consent, at the international level, by a State or regional economic integration organization to be legally bound by the Nagoya Protocol. They are signed either by a Head of State, Head of Government or by a Minister for Foreign Affairs."[126]

As stated by Article 33.1, the Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification. Pursuant to Article 33.2, the Protocol shall

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[121] Interestingly, Art. 24 provides that "the Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-House." This is particularly relevant as the United States are not a Party to the CBD and cannot ratify the Protocol without first joining the Convention.

[122] Unicef, 'Definition of Key terms used in the *UN Treaty collection*", found at: <http://www.unicef.org/crc/files/Definitions.pdf > last accessed 6 September 2011.

[123] Ibidem.

[124] CBD Secretariat, 'Signatories to the Nagoya Protocol', found at <http://www.cbd.int/abs/nagoya-protocol/signatories/> last accessed 6 September 2011.

[125] Unicef, supra note 122.

[126] CBD Secretariat, 'Becoming a Party'; found at < http://www.cbd.int/abs/becoming-party/ > last accessed 6 September 2011.

enter into force for a State that ratifies the Protocol after the deposit of the fiftieth instrument on the ninetieth day after the date on which that State deposits its instrument of ratification. Experiences with the entry into force of international environmental treaties have shown that between 22 and 30 months are necessary for 50 countries to ratify.[127] And Buck et Hamilton to calculate " if one would apply a similar timescale to the Nagoya Protocol, it may take approximately three-and half years for the Protocol to enter into force, possibly prior to CBD COP12."[128]

[127] The CBD was opened for signature in May 1992 and entered into force on 29 December 1993, 90 days after the 30th ratification. The Cartagena Protocol was adopted on 29 January 2000 and entered into force on 11 September 2003, ninety days after the deposit of the 50th instrument of ratification.
[128] M. Buck, C. Hamilton, supra note 70, p.61

4 Scope of the Protocol, a better defined playing field

An effective and legally certain ABS scheme largely depends on a clear delimitation of its scope, especially since it directly determines the rights and obligations of Parties. Article 3 states that "the Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilisation arising of such resources."[129] Section 1 clarifies the application *ratione materiae* of the Protocol. Subsection 1 highlights the main characters of the definitions of "utilization of genetic resources" and "derivatives." Subsection 2 explains the four major substantive limitations of the Protocol's application field. Section 2 presents the geographical and temporal limitations of the ABS scheme. Section 3 concludes by analysing the impact of the Protocol scope on its functionality.

4.1 Material scope

4.1.1 Analysis of the definitions of "utilization of genetic resources" and "derivatives"

As highlighted in Part 1, a major weakness of the ABS framework laid down by the CBD is its particularly vague theoretical basis. None of the three steps of ABS (access to genetic resources, utilization, and benefit-sharing) were defined by the Convention or in any official decision of the COP. The Convention only provides a highly unpractical definition of genetic resources which led to many different and often contradictory interpretations, both in national legislation and international fora. In the Protocol, the definition of genetic resources remains as was used by the Convention. The draftsmen decided to obviate the conceptual disagreement and focus the new regime on "utilization of genetic resources." The definitions of "derivatives" and "utilization" were considered as a hot and crosscutting issue as their usage have influence over the whole scheme. The term of "utilization" and its alternative forms (used, use, utilized, etc) are directly applicable in the provisions concerning the scope (Article 3), benefit-sharing (Article 5), access (Article 6), conservation and sustainable use (Article 9), the global benefit-sharing mechanism (Article 10), Traditional knowledge and genetic resources (Article 12), compliance (Article 15, 16) and Monitoring (Article 17). It is also indirectly relevant to compliance with MAT (Article 18), model clauses (Article 19), codes of conduct (Article 20), capacity (Article 22) and technology transfer

[129] Art. 3 also states that the Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilisation of such knowledge. As aforementioned, this aspect of the Protocol is not studied in this research.

(Article 23). The functionality of the whole scheme thus largely depends of a legally sound formulation. Article 2 of the Nagoya Protocol reads as following:

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

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

(e) "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity."

The activities and resources covered by the "utilization" notion were the object of fierce discussion and the definition deserves further attention. According to article 2 of the Protocol, "utilization" relies on Research and Development on the genetic and/ or Biochemical composition of genetic resources. Research and Development, a well-established term, refers to "creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications. R&D is a term covering three activities: basic research, applied research, and experimental development."[130] "Utilization" covers all the R&D activities along the innovation chain *i.e.* the study, use and development following the collection *in-situ* or *in situ conditions* of a genetic resource.

Subsequent applications and commercialization stages seem not to be covered by the definition. Article 5 on Benefit-sharing advocates for this interpretation as it relates to "utilization

[130]OECD Factbook 2008: 'Economic, Environmental and Social Statistics', found at: <http://titania.sourceoecd.org/vl=3997450/cl=19/nw=1/rpsv/factbook/070101.htm> last accessed 6 September 2011. According to the same Factbook, "Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view". "Applied research is also original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective." "Experimental development is systematic work, drawing on existing knowledge gained from research and/or practical experience, that is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed."

of genetic resources as well as subsequent applications and commercialization" (and thus considering them as distinct steps in the valuation chain). This is noteworthy since "obligations of Parties under article 15 and 17 of the Protocol to take 'user measures' only apply to the utilization of genetic resources as defined in Article 2 (c) of the Protocol, whereas benefit-sharing for 'subsequent applications and commercialization' will need to be pursued on the basis of contractual rights."[131] It remains to be seen how clear-cut the distinctions between the R&D steps and the applications and commercialization stages will appear in the practice. Importantly, "the point where an innovation is moved from development to commercialization" is included in the activities covered by the utilization trigger.[132]

Furthermore, with regards to the resources covered by the definition, the question was whether "utilization" would cover R&D activities on derivatives.[133] The answer given by the Protocol is incontestably positive. In the Protocol, the R&D constituting "utilization" focuses on "genetic and/or biochemical composition of genetic resources" and includes the application of biotechnologies. In the definition, "biochemical composition" refers to "derivatives." The wording "and/or" suggests that R&D on biochemical composition of genetic resource can alone constitutes "utilization." The explicit inclusion of "biotechnologies" provides further confidence as regard the inclusion of derivatives. Indeed, it means "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use" (emphasis added). It is thus certain that derivatives are included in the ABS international regime through the definition of utilization.

As such, the definition of derivatives has little real utility. For purpose of legal certainty, it solves the controversy surrounding the meaning of the term and could serve as model for domestic legislation. According to the definition of article 2.3, "derivatives may be described as non-modified chemical components other than DNA or RNA, but formed by the organism's metabolic processes. (…) Derivatives in this context, for example, may constitute active biological components found in the collected plant material, but that have yet to be modified and used in technological applications."[134] In other words, as stated by Casas, "they are compounds, extracts or

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[131] M. Buck, C. Hamilton, supra note 70, p.53.
[132] Ibidem, p.54.
[133] For reminder, derivatives often constitute the basis for profitable commercial utilization; they are however not covered by the CBD framework since they are devoid of functional units of heredity. See para 2.1.3.1.
[134] L. Glowka, supra note 68, p.45.

secretions that occur as a natural expression of the genetic material and are a result of a metabolic process."[135] The expression "naturally occurring" is of crucial importance. It serves to exclude from the definition "the products that are derived or synthesized from genetic or biochemical resources through human intervention."[136]

4.1.2 Resources Covered by the ABS international regime

The application *ratione materiae* of the international regime is delimited in four different manners.

First of all, the COP10 decision adopting the Protocol expressly excludes human genetic resources.[137] Secondly, Article 4 on the "relationship to other international instrument" also delimits the material scope. Article 4.2 states that the "Protocol does not prevent the development and implementation of other relevant international agreements, including specialized access and benefit-sharing agreements, provided that they are supportive and do not run counter to the objectives of the Convention and this Protocol." In other words, the Nagoya Protocol applies to all types of genetic resources-including pathogens- and all potential utilization of such resources, unless covered by a specialized regime which does not run counter to the CBD objectives. Currently, the International Treaty on Plant and Genetic Resources for Food and Agriculture (ITPGRFA) is the only specialized regime. The Protocol does however not preclude the development of other such regimes in the future. Article 4.4 specifies that the resources covered by a specialized regime are only excluded from the Nagoya framework for the purposes pursued by the said regime. This means the Nagoya Protocol would for instance apply to resources covered by the ITPGRFA which are not used for food and agriculture but for cosmetic or pharmaceutical goals.

Thirdly, like Article 15.3 of the CBD, the Protocol repeats in several provisions that "the genetic resources being provided by a Contracting Party are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention." As explained in paragraph 2.1.2.1, this limits the scope of ABS in two different ways. On the one hand, it only entitles those two categories to benefit from the ABS rights. Hence, materials held in ex-situ collections do not give rights to ask

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[135] J. Cabrera Medaglia, C. Lopez Silva, supra note 26, p.39.
[136] Ibidem, p.39.
[137] CBD COP 10, Decision X/1, UNEP/CBD/COP/DEC/X/1, 29 October 2010, section I, para.5.

for PIC at the expense of the countries of origin. On the other hand, it also implies that "material in *ex situ* collection collected prior to the entry into force of the CBD does not come within the reach of benefit-sharing claims on the basis of article 5.1 of the Protocol."[138]

Lastly, "utilization" also serves to identify the resources covered by the ABS international regime. According to Burton, "*utilisation* means that all in-situ collection situations are covered *i.e.* – if the resource is collected for the given purpose in the Protocol, then subsequent study, use and development of all biological functions of the material collected are covered by the grant of prior informed consent (PIC) and mutually agreed terms (MAT) provisions of the Protocol."[139] By tying the identification of genetic resources to the intention to pursue R&D activities, it is clear that commodities or products are beyond the scope of the regime and do not need to be accessed through the PIC and MAT processes. When biological resources are collected for the purpose of bulk use, there is no intention to create knowledge and take advantage from the gene sequences of the resources collected.[140]

As explained in the previous subsection, the Nagoya Protocol resolves the issue of derivatives by including them in the scope of the ABS scheme through the definition of "utilization." From a legal point of view, the way the Protocol is dealing with derivatives is however far from straightforward. Beside Article 2, derivatives are not explicitly mentioned in any other operative provisions. Further explanations are needed in order to properly understand the inclusion of derivatives in the ABS scheme. The ABS international regime continues to focus on material collected *in-situ* or in *in-situ conditions*. Pursuant to article 6, if a Party decides to require PIC and MAT for its genetic resources and adopts the necessary measures in order to do so, "access to genetic resource for their utilization" shall be given according to PIC and MAT. This wording seems to indicate that there must be functional units of heredity in the material accessed. If derivatives are purified from functional units of heredity, they are thus "non-genetic resources" and do not need to be accessed through a specific PIC authorization under the international regime.[141] The inclusion of derivatives is still tied to the collection *in-situ or* in *in-situ conditions* of a genetic

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[138] M. Buck, C. Hamilton, supra note 70, page 52.
[139] G. Burton, 'Derivatives: "Utilisation of Genetic Resources" Solving an old problem, presentation at the IDDRI conference, "Towards the effective implementation of the Nagoya Protocol on ABS - Legal, policy, practical challenges and contributions to the sustainable development agenda-", Paris 3 February 2011, personal note.
[140] This was a crucial concern to developed states throughout the negotiations.
[141] See in this sense H. Meyer, quoted by TWN, 'Mixed Reactions on New Access and Benefit-sharing Treaty', <http://www.biosafety-info.net/bioart.php?bid=649> last accessed 6 September 2011.

resource. The definition of utilization should thus not be interpreted as implying that derivatives removed from their genetic material and kept, for example, in bank genes need be accessed through specific PIC/MAT under the Protocol. However, purified extracts are already the outcome of R&D activities and necessarily derivates from a material containing functional unit of heredity.[142] Therefore, if the original material collected in situ at the basis of the purified extract is within the ABS scope and if so agreed by the parties in the MAT concluded at the time of access, benefit-sharing can also be due for the benefits arising from the subsequent utilization, applications and commercialization steps of those derivatives.

4.2 Geographic and temporal scope

Pursuant to article 3, the Protocol applies "to genetic resources within the scope of Article 15 of the Convention and to the utilization of such resources." This explicit reference to Article 15CBD limits the geographical scope of the Nagoya Protocol. Since the latter provision solely applies to Genetic Resources within the reach of sovereign rights of a State Party, the new Protocol does not cover genetic resources collected beyond national jurisdiction such as in the high seas or collected in the Antarctic Treaty Area. The inclusion of resources found in areas beyond national jurisdictions seems in addition incompatible with the way ABS is constructed. Indeed, in such case: who would be entitled to grant PIC and establish a MAT for such resources?

The Protocol remains tacit on its application *ratione temporis*. This silence can be explained by the lack of consensus on the issue.[143] It is commonly agreed that the Protocol should not have retroactive effects. However, some countries argue that the non-retroactivity principle would not

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[142] Production of derivatives is included in the illustrative list of activities constituting "utilization of genetic resources" provided by the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches (GLTE). Non- exhaustively, this list covers "genetic modification, biosynthesis (use of genetic material as a 'factory' to produce organic compounds), breeding and selection, propagation and cultivation of the genetic resource in the form received, conservation, characterisation and evaluation, sequencing genes or genomes, production of compounds naturally occurring in genetic material (extraction of metabolites, chemical synthesis of DNA segments and production of copies)." (CBD ABS Working Group, 'Report of the meeting of the group of legal and technical experts on concepts, terms, working definitions and sectoral approaches', UNEP/CBD/WG-ABS/7/2, 2008, p.10). Importantly, it is also important to note that functional units of heredity "are found in virtually all cells and cell types and in many other parts of organisms." (Ibidem, p.6).

[143] Three different application fields were proposed during the negotiations. From the narrowest to the most extended scope, it was suggested that benefits sharing obligations should be due (1) only for GR/TK accessed after the entry into force of the NP (2) for continuing and new uses of GR/TK acquired after CBD entry into force where no benefit-sharing agreement had been established in accordance with the CBD (3) for continuing and new uses of GR/TK accessed after the entry into force of the CBD. Throughout the whole negotiation process, there was a strong opposition between developing countries advocating for the largest scope and developed nations calling for the narrowest.

preclude the application of the Protocol to new or continuing uses of genetic resources accessed post CBD but prior to the entry into force of the Protocol.[144]

To answer questions on the temporal scope of treaties, Article 28 of the Vienna Convention on the Law of International Treaties is the relevant provision of International law. It establishes the basic rule of non-retroactivity and reads as follows: "Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party."[145] Article 28 was worded in such a manner "in order to allow for cases where the very nature of the treaty rather than its specific provisions indicates that it is intended to have certain retroactive effects."[146] In public international law, the principle of non-retroactivity relates to the juridical effect states intend to devote to agreements they conclude. The principle of non-retroactivity is not a peremptory norm of international law since the temporal scope of a treaty ultimately depends on the intention of parties.

It is commonly agreed that neither the CBD nor the Nagoya Protocol explicitly express the intention to produce certain retroactive effects. ABS retroactivity is not "otherwise established" and the very nature of those agreements does not either suggest the intent to produce retrospective effects. Therefore, it is clear that the Nagoya Protocol will apply *ex futuri* and after its entry into force. Consequently, the Protocol does not "bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party."[147] In other words, genetic resources or Traditional Knowledge accessed before the date of the Protocol' entry into force "cannot retroactively be made subject to PIC requirements. Likewise, any benefits obtained before that date cannot retroactively be subjected to a benefit-sharing obligation."[148] However, as stated by Chege Kamau et al., it could be argued that

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[144] According to the African Group, "there is a moral obligation to share benefits arising from continuing uses of material accessed before the protocol's entry into force, and the protocol should "encourage" such benefit-sharing; and there is a legal obligation to share benefits arising from new uses of such material, possibly through a multilateral mechanism.." (Jungcurt et al., 'CBD COP 10 highlights Monday, 25 October 2010', Vol. 9 No 540 *Earth Negotiation Bulletin* (26 October 2010), Available at: <http://www.iisd.ca/biodiv/cop10/> last accessed 6 September 2011.
[145] Vienna Convention on the Law of Treaties, supra note 52, Art. 31.
[146] Yearbook of the International Law Commission, 1966, Vol. II, pp. 212-13.
[147] Vienna Convention on the Law of Treaties, supra note 52, Art. 31.
[148] E. Chege Kamau, B. Fedder, G. Winter, 'The Nagoya Protocol on Access to Genetic Resources and Benefit-sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?', 6/3 Law, Environment and Development Journal (2010), p. 246, found at <http://www.lead-journal.org/content/10246.pdf> last accessed 6 September 2010.

"the generation of benefits after that date is a new act in terms of Article 28 of the Vienna Convention, or that the holding of the genetic resource or traditional knowledge is a situation which has not ceased to exist."[149]

Even if they are not *per se* excluded of the scope by the non retroactivity principle, it is the author's view that future uses of GR accessed between the dates the CBD and the Nagoya Protocol entered into force are not covered by the new regime. First of all, the fact that the text does not specify how to address those situations seems to indicate that there was no "meeting of minds" of the Parties in favour of their inclusion. Foremost, such modulation of the temporal application field would not be compatible with the way ABS is envisioned. ABS targets new collection of genetic resources *in-situ* and is seen as a sort of contractual exchange, access being linked to benefit-sharing.[150] As stated by Buck and Hamilton, "the main operational provisions of the Protocol (Article 5 on benefit-sharing, Article 6 on access, and Article 15 on compliance) all relate to genetic resources provided by a Party to the Protocol on the basis of its domestic access and benefit-sharing legislation or regulatory requirements."[151] Logically, benefit-sharing obligations cannot be due if genetic resources were accessed prior to the entry into force of the Protocol. The entry into force will thus determine the application *ratione tempori* of the new Protocol.[152]

4.3 The global multilateral benefit-sharing mechanism

Article 10 is incontestably the "surprise" of the Protocol. It appeared in the text of the "package deal" agreed upon one night before the end of the COP. It calls upon parties to "consider the need for and modalities of a global multilateral benefit-sharing mechanism" to address "transboundary situations" and "situations for which it is not possible to grant or obtain prior informed consent." Furthermore, the benefits shared through the global mechanism would be used to support the conservation and the sustainable use of its components globally. The existence and the features of the mechanism still need to be agreed upon by the Parties and figures at the agenda of the next COP meeting.

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[149] Ibidem, p.255.
[150] This linkage between access to genetic resources and the fair and equitable sharing of the benefits arising from the utilization of such resources is *expressivis verbis* acknowledged by para. 8th of Protocol' preamble.
[151] Buck, C. Hamilton, supra note 70, p.57.
[152] See section 3.3.

The establishment of a global multilateral benefit-sharing mechanism was informally proposed in July 2010 by the African Group "as a way out of the protracted discussions on temporal and geographical scope in particular."[153] If a global mechanism would be created, African Parties expressed readiness to retract some of their claims, such as application of the Nagoya Protocol to pre-CBD accessed materials or its application to areas outside national jurisdiction. Article 10 reflects some of the aspirations of the African group. Worded in particularly loose language, the Article however, clearly falls short as "the provision only establishes a procedural obligation on the parties to "consider the need for and modalities of a global multilateral benefit-sharing mechanism."[154] According to Buck and Hamilton, "without prejudging the necessary discussion by Parties to the Nagoya Protocol on the need for such a mechanism, it is important to realize as a starting point that any such mechanism would be voluntary, supplementing the legally binding provisions of the Nagoya Protocol."[155]

Excessive speculations seem largely premature since the existence and properties of the mechanism still need to be negotiated during the next COP/MOP and/or Interim Committee.[156] However, several interesting features are worth mentioning. The mechanism would function on a multilateral basis and thus differs from the bilateral contractual-based approach adopted by the CBD and the Nagoya Protocol. The concept is clearly inspired by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Adopted in 2003 under the aegis of the FAO, this treaty set up "the multilateral system for access to and use of plant genetic resources for food and agriculture." It has yet to be seen to what extent a similar system could be transposed into the CBD context and whether it would constitute a significant value addition. Secondly, the fund would promote biodiversity conservation on a global basis and not only nationally. Lastly, the meaning being attributed to "situations for which it is not possible to grant or obtain PIC" is also very unclear. It seems that the provision may cover *i.a.* "the use of genetic resources obtained '*ex*

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[153] M. Buck, C. Hamilton, supra note 70, p.57.
[154] Buck and Hamilton further posits that "the wording of Art. 10 was not negotiated but proposed by the Japanese COP 10 presidency as part of its compromise proposal and accepted as such by all the Parties." (M. Buck, C. Hamilton, supra note 70, p.57).
[155] Ibidem, p.60.
[156] The wording of Art. 10 "Parties" refers to the Parties to the Nagoya Protocol and not to Parties to the CBD. Therefore, the consideration on the need for establishing the mechanism can not be undertaken before COP/MOP1 of the Nagoya Protocol, meaning that all preceding deliberations under the Intergovernmental Committee have little real significance. It will only be known at COP/MOP1 whether or not all Parties support the establishment. (M. Buck, personal communication, 2011).

situ' (outside their place of origin) or in a manner not compliant with the CBD."[157] Continuing and new uses of genetic resources acquired between the entry into force of the CBD and the Protocol' entry into force could also be included in the ABS through the creation of the global multilateral benefit-sharing mechanism. It remains to be seen whether or not genetic resources found in areas beyond the jurisdiction of sovereign states (e.g. Antarctica or the high seas) may be covered by the global multilateral benefit-sharing mechanism.[158]

4.4 Impact of the scope on the functionality of the ABS regime

Under the Protocol, the scope of ABS international regime is better defined, significantly expanded and limited in several ways. Substantively, it focuses solely on the utilization of genetic/biochemical composition of genetic resources collected *in situ* or *in situ conditions*. The inclusion of derivatives in the scope of the Protocol should not be underestimated. According to Buck and Hamilton, it increases "its economic value to provider countries by least twenty-fold."[159] Temporarily, in the absence of explicit contrary intention, the Protocol only covers post-Nagoya accessed genetic resources. Geographically, the Protocol only applies to genetic resources collected within states national jurisdiction. A global multilateral mechanism may also be created to cover the resources which are not covered by the Protocol. To conclude this chapter, it seems relevant to give three observations on the influence of this scope on the functionality of the ABS scheme.

First of all, the definition of utilization is crucially important in the Nagoya Protocol since it "informs the scope of the main operational provisions."[160] The functionality of the whole scheme thus largely depends on a legally sound formulation. There are reasonable grounds to believe that the definition will provide such legal certainty. While some scholars and the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches (GLTE) recommended complementing the descriptive definition with an indicative list of activities explicitly covered by the notion, such an approach was not followed by the negotiators. The definition adopted by the Protocol, formulated in scientific terms, was indeed considered as

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[157] ICTSD, 'CBD Clinches ABS Protocol in Nagoya', *Bridges Trade BioRes*, Vol. 10, No 20, 8th November 2010, found at: <http://ictsd.org/i/news/biores/94075/ > last accessed 6 September 2011.
[158] It has to be clarified whether those resources, beyond the scope of the Protocol, may be covered by a mechanism created by the same Protocol. To the author, this asymmetry in scope seems problematic and the question calls for a negative answer.
[159] Buck, C. Hamilton, supra note 70, p.58.
[160] Ibidem, p.57.

comprehensive enough to cover all the activities potentially capturing valuable genetic resources through R&D.[161] The scientific definition presents the advantage of fitting better with the dynamic character of genetic resources and, unlike a list, does not need to be updated and reviewed with the evolution of techniques and knowledge.[162] Furthermore, such a list can provide legislative guidance and help countries in establishing their national legislation, especially in case it is not crystal clear whether an activity should be consider as utilization of genetic resources or not.

As stated by Tvedt and Rukundo, "utilisation can easily be seen to be the basis for a functional system."[163] Utilization becomes the central element of the ABS concept, the link between the concept of genetic resources and the sharing of benefits. Focusing on the purpose underlying the access to biological material presents four main advantages. First of all, it significantly reinforces the theoretical basis of the ABS concept.[164] As such, the definition of utilization does not explicitly settle the plurality of interpretations of the "genetic resource" notion. Nevertheless, it strongly suggests "a practical basis for grounding the concept of genetic resources- genetic resources are not simply the biologically encoded information in species (nor the specific cellular material containing this information), but they are tied to utilization – realization of the value of the functional units of heredity."[165] Secondly, "utilization" captures the dynamic dimension of the genetic resources definition and will evolve with the scientific and technological developments.[166] Thirdly, "utilization" is an activity. It is therefore easier to define in practical terms and can be, most of the time, externally identified. It constitutes a more concrete foundation than an "intention" for designing a legal scheme and it has thus a better potential be a legally enforceable basis. Lastly, utilization has the advantage that it "captures both the uses of genetic information as well as that of naturally occurring compounds, and reflects genetic resources and derivatives in a single definition."[167]

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[161] Burton, personal communication, 2011.
[162] This is of particular value added as biotechnology is a particularly quickly evolving field of R&D.
[163] M. Tvedt, O. Rukundo, supra note 80, p.14.
[164] As highlighted in para. 2.1.2.1, the definition of Genetic Resources is however not the only conceptual problem of the ABS mechanism.
[165] M. Tvedt., T. Young, supra note 8, p. 81.
[166] As stated by Schei and Tvedt, "there is however a dilemma and a contradiction between on the one hand leaving a definition dynamic and flexible, at the same time as it is understood in a manner which creates legal certainty and thus is enforceable." (P. Schei, M. Tvedt, '*Genetic Resources' in the CBD: The Wording, the Past, the Present and the Future*, FNI Report 4/2010. Lysaker, FNI, 2010, 24 p.)
[167] J. Jungcurt et al., supra note 110.

The adoption of the "utilization" approach is the major change incorporated in the new framework and constitutes a significant value added for the ABS regime. It has the potential to provide the necessary legal certainty the scheme requires by determining the resources and activities both user and provider legislation should cover. By tying to the definition to a certain list of activities, the Nagoya Protocol strongly suggests to Parties that the intention of leading R&D should become the primary focus of their legislation. This means the concept of genetic resources can be consistent through all the steps of the ABS process. Under the Protocol, Parties will design their measures implementing their compliance and monitoring obligations by identifying the activities generating benefits from the utilization of genetic resources. In the meantime, provider countries should also focus their legislation on the activities and situations covered by the utilization trigger. If implemented in a uniform way, "utilization" could become the cornerstone of a functional scheme.

Secondly, in my view, the possibility to create specialized regimes compatible with the objectives of the Protocol offers appropriate flexibility. In the future, it may appear relevant to develop a specialized regime if a new legal instrument is better suited to deal with the specificities of a certain type of genetic resources; to leave such an option is therefore positive in itself. Nevertheless, in my opinion Parties should be particularly cautious with the use of "tailor-made" regimes. The Nagoya Protocol was built to be the primary basis to deal with genetic resources at an international level and therefore already offers substantial manoeuvring space. The Protocol's requirements are formulated in general terms, which are susceptible to modification for specific situations to be regulated. As such, each new specialized framework increases the risk of overlaps, gaps and contradictions within the international regime. Unreasonable use of specialized regime could therefore end up defeating the future effectiveness of the Protocol.

Thirdly, the Protocol does not expressly address how situations falling outside its scope should be addressed. Limiting the applicability of the Protocol in several ways makes it necessary to ascertain whether or not the resources are within the scope of the regime. The effectiveness of the ABS regime will ultimately depend upon Parties' ability to ensure that these limitations are overcome. To avoid benefit-sharing obligations, unscrupulous users may pretend to have freely accessed biochemical compound in a gene bank, or genetic resource in an ex-situ collection or outside the geographic scope. In particular the temporal limitation may be particularly problematic for the future effectiveness of the regime. The resources accessed before the entry into force of the

Protocol seems to be uncovered. The problem is that it may take several years between access and successful utilization. When arriving at a checkpoint without certificate, unscrupulous users may pretend to have accessed the resources before the entry into force of the Protocol.[168] There is a need for clear rules and procedures for addressing those situations. Though non-expressly imposed by the Protocol, it is the author's view that users claiming to utilize a genetic resource not covered by the ABS international regime should be required to demonstrate they are legally operating outside the scheme.

[168] As explained in section 7.2, in order to increase the monitoring of the utilization of genetic resources, the Protocol foresees the creation of a system of "checkpoints" and of "internationally recognised certificate of compliance."

5 Access to genetic resources: finding the equilibrium between State' sovereignty and legal certainty

As explained in the first chapter, a functional ABS international regime does not require a full harmonization of all aspects of the access legislation. For being potentially effective, it is however necessary that the needs for certainty of user and user country are duly taken into account. The present chapter presents the provisions of the Protocol relevant to "access to genetic resources", their relationship with other Articles and their impact on the functionality of the ABS system.

5.1 "Appropriate" regulated access:

Article 6 is the main provision of the Protocol defining what constitutes an "appropriate access to genetic resources" in the meaning of Article 1.[169] Article 6.1 reads as follows: "In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party."[170] For "appropriate" access to genetic resources, the Protocol builds on the main three elements laid down by article 15.1 and 15.3 of the CBD, namely the sovereignty-based approach and the use of PIC and MAT. It reaffirms State's sovereign authority to determine whether, how and under which conditions genetic resources within their jurisdiction can be accessed through PIC.[171] Though the purpose of ABS is to facilitate access for environmental sound uses, it seems that Parties may still decide to deny the access to their genetic resources. In addition, the modalities, terms and conditions on the sharing of the benefits need to be agreed in contractual agreements, the MAT.[172]

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[169] Art. 1 states that "the objective of the Protocol is the fair and equitable sharing of the benefits arising from the utilization, including by appropriate access to genetic resources (…)." This part of Art. 1 is a *verbatim* reproduction of Art.1 of the CBD.

[170] Though Art.15 of the CBD is recalled by para. 3 of the Preamble, two operative provisions mention it explicitly. In Art.3, the reference is used to define the temporal scope. In Art. 5 on benefit-sharing, the reference to art. 15.3 and 15.7 serves to confirm that benefit-sharing is based on MAT. Interestingly, Art. 15 of the CBD is not expressly mentioned in Art. 6 of the Protocol.

[171] For reminder, as highlighted in section 5.2, Art 6 is without prejudice to facilitated access for non-commercial research and expeditious access for pathogens as provided for in Art. 8 (a) and (b).

[172] This aspect is further developed in subsection 5.1.4 and chapter 6.

Article 6 also recalls that covering its national genetic resources by the ABS scheme is a faculty and not an obligation. Parties can decide submitting the access to (part or the totality of) their genetic resources to Prior Informed Consent but can they also choose give up their ABS rights. As stated by Chege Kamau, "many states – and in particular the industrialized states which normally appear on the user side – may opt for free access to their genetic resources and traditional knowledge."[173] Like article 15.3 CBD, Article 6 repeats that only the Party providing genetic resources is entitled to ABS rights.[174] While the CBD does not "directly call for any kind of direct governmental measures,"[175] the Protocol requires the adoption of such specific law as a precondition to require PIC. In addition, access law of Parties requiring PIC must now also respect several general principles and requirements. The following sections briefly present these obligations and their linkages with other provisions of the Protocol.

5.1.1 General principles for the design of access legislation

Article 6.3 (a) of the Protocol imposes the Parties to provide for clear, transparent and legally certain domestic access and benefit-sharing legislation or regulatory requirement. Article 6.3(b) calls the Parties to provide for fair and non-arbitrary rules and procedures on accessing genetic resources. In the author's view, two other general principles should also be respected when shaping the access regulatory measures. On the one hand, Parties shall take into account Article 9 which calls them to encourage parties to ABS agreements to direct the sharing of the benefits towards biodiversity conservation and sustainable use of its components. On the other hand, though not explicitly mentioned in article 6, Parties shall take into account article 15.2 of the CBD which call the Parties to "endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other contracting Parties and not to impose restrictions that run counter the objectives of this Convention."[176]

Importantly, the "fair and non arbitrary" provision should not be interpreted as precluding the establishment of any kind of difference. Under the Protocol, more favourable treatments are not

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[173] E. Chege Kamau et al., supra note 148, p. 260.
[174] See section 4.1.2 on Resources covered by the ABS regime for the exact meaning of this expression and the situations it excludes.
[175] S. Batthy, T. Young, supra note 56, p. 23.
[176] Art. 15 of the CBD is not expressly mentioned in Art. 6 of the Protocol but is recalled by para. 3 of the Preamble. Interestingly, two operative provisions opt for an explicit mention of Art. 15 of the CBD. In Art.3, the reference is used to define the temporal scope. In Art. 5 on benefit-sharing, the reference to art. 15.3 and 15.7 serves to confirm that benefit-sharing is based on MAT.

prohibited as long as the distinctions are operated upon objective, reasonable and legally-based grounds. For instance, provider national law could "give preference to users that commit to the standards of an "ABS Certification System" or specified/approved voluntary codes of conduct."[177] In the same way, provider countries could also favour national users, users operating in countries Party to the CBD or users "which have made specific commitments, to help avoid lawsuits or claims for misappropriation or biopiracy."[178] It could also be argued that the fair and non-arbitrary clause should be interpreted as prohibiting a long term exclusive exploitation of a genetic resource when this exclusivity runs against the environmental objectives of ABS.[179]

5.1.2 Process certainty in regulated access

The Protocol is very elaborate on process certainty. As aforementioned, Parties need to provide for clear, transparent and legally certain domestic access and benefit-sharing legislation or regulatory requirement. In addition, Article 6.3 also requests Parties to provide for information on how to apply to PIC and to establish clear rules and procedures for requiring and establishing MAT. The requirements of article 6 must be read in combination with article 13, and 14. Article 13 imposes the Parties requiring PIC to create National Focal Points (NFP) responsible to make available information on procedures for obtaining prior informed consent and establishing mutually agreed for both genetic resources and TK. The NFP has also the task of granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

The creation of NFP is also complemented by the establishment of an ABS sharing Clearing House Mechanism (CHM) as a means for sharing information on ABS. The CHM shall provide access to information made available by each Party relevant to the implementation of this Protocol. Without prejudice to the protection of confidential information, the information to be communicated by the Parties shall include legislative, administrative and policy measures, information on the NFP and the competent national authority or authorities, permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of MAT.

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[177] J. Cabrera Medaglia, C. Lopez Silva, supra note 26, p.60.
[178] Ibidem, p. 60. This also illustrates how access legislation and user measures can be mutually supportive.
[179] V. Koutsiouris, personal communication, 2011.

Given that it may be difficult for some countries to develop the institutional and legal infrastructures necessary for effective access legislation, Article 22 provides that "Parties shall cooperate in the capacity building, capacity development and strengthening of human resources and institutional capacities to effectively implement this protocol in developing country Parties, in particular the least developed countries and small island developing States. Capacity building and development may address *i.a.* capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing."

5.1.3 Evidence of PIC

Article 6.3 also stresses the importance of establishing evidence that the access requirements have been met. It calls Parties to "emit a clear and transparent written decision by a competent national authority, in a cost- effective manner and within a reasonable period of time" and to issue, at the time of access, "a permit or its equivalent as evidence of the decision to grant PIC and of the establishment of MAT and notify the Access and Benefit-sharing Clearing-House accordingly." Once the permit or its equivalent is issued by the NFP and made available to the CHM, it shall constitute an internationally recognized certificate of compliance (Article 17.2 and 17.3). In this respect, Article 17.4 provides minimum information that the internationally recognized certificate shall include when it is not confidential, namely "(a) Issuing authority; (b)Date of issuance; (c)The provider; (d)Unique identifier of the certificate; (e)The person or entity to whom prior informed consent was granted; (f)Subject-matter or genetic resources covered by the certificate; (g) Confirmation that mutually agreed terms were established; (h)Confirmation that prior informed consent was obtained; and (i)Commercial and/or non-commercial use." The "permit or its equivalent" issued by the NFP at the time of access shall thus at the least contain the aforementioned information.

5.1.4 Contract certainty

Article 5(1) confirms that benefit-sharing shall only be achieved through MAT *i.e.* on a contractual basis.[180] The establishment of clear contractual rights and obligations is crucial for the enforcement of the MAT across jurisdictions.[181] In this context, Article 6.3 (g) calls the Parties to

[180] See chapter 6.
[181] A basic principle of contract law is indeed that agreements can only be enforced if they are "sufficiently definite." See e.g. T. Young, 'Applying Contract law to ABS', in S. Bhatti et al., (eds.), *Contracting for ABS: The Legal and*

provide for "clear rules and procedures for requiring and establishing MAT. Such terms shall be set out in writing and may include, *inter alia:* (i)A dispute settlement clause; (ii)Terms on benefit-sharing, including in relation to intellectual property rights; (iii)Terms on subsequent third-party use, if any; and (iv)Terms on changes of intent, where applicable." Several other Provisions provide guidance on the content and functioning of the MAT.

Article 6.3 (g) is to be read in combination with Article 18.1 of the Protocol relative to compliance with MAT. This latter provision calls the countries regulating access to their genetic resources to encourage users and providers to include provisions in MAT to cover, where appropriate, dispute resolution including (a) the jurisdiction to which they will subject any dispute resolution processes, (b) the applicable law and/or (c) options for alternative dispute resolution. In addition, Article 17.1(b) and (c) (Monitoring) oblige the Parties to encourage users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements, and to encourage the use of cost-effective communications tools and systems.[182]

The development of model clauses (Article 19 and Article 14.3 (b)) is seen as a key measure to enhance the effectiveness of the ABS regime. Article 19 states that "Parties shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for MAT. The COP/MOP is mandated to periodically take stock of the use of these clauses." Simply put, model clauses are standardized contractual agreements parties to an ABS transaction may decide to utilize for part or in totality. Such templates may present multiple advantages in the ABS context. Model clauses recognize "the specific conditions and existing practices of different uses and users of genetic resources but also avoid some of the biggest problems associated with the contractual approach such as legal uncertainty and complexity, high administrative burdens for monitoring and compliance as well as prohibitively high transactions

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Scientific Implications of Bioprospecting Contracts, IUCN Environmental Policy and Law Paper No. 67, The ABS Series, p.3.

[182] Art. 17.1 (b) and (c) are user side measures. However, since MAT is normally concluded at the time of access, these measures will need to be primarily implemented in the legislation of Parties regulating access to their genetic resources. The relevance of placing such obligation in the provisions devoted to user measures is that all Parties are obliged to implement them. For reminder, Parties may decide waiving their access obligations by making their resources freely accessible.

costs."[183] The willingness to utilize such standardized agreements may considerably increase if "all CBD countries in the regime specifically state that agreed 'model clauses' are automatically valid and enforceable in their respective national courts."[184]

5.2 Non-commercial research and pathogens

The requirements of article 6 must be read in combination with Article 8(a) and 8 (b). Pursuant to article 8(a), in the development of their ABS legislation, Parties shall "create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research." In accordance to article 8(b), in the design of their ABS legislation, Parties shall also pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries." Article 8(b) confirms that Pathogens are covered by the international ABS regime. However, it also do clarify that "the general framework for access and benefit-sharing of genetic resources set out in Articles 5, 6, 15, 17 and 18 of the Protocol does not apply in the same way to [those] genetic resources (…) as it does to other genetic resources."[185]

5.3 Impact of access requirements on the functionality of the ABS regime:

The design of clear, fair and legally certain access regulations is a *sine qua non* condition for a functional scheme. Access legislation has so far often consisted in trying to ensure an excessively strict control over national genetic resources. Taking due account of the impossibility to materially control the movement of genetic resources, the new regime suggests that access should rather focuses on favoring the access to users willing to comply and participate in the conservation effort.

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[183] S. Täuber, 'Contract Standardisation as an Instrument for Access and Benefit-Sharing under the Convention on Biological Diversity A Governance Analysis of Transactions with Genetic Resources', found at <http://hss.ulb.uni-bonn.de/2011/2579/2579.pdf> last accessed 6 September 2011.

[184] M. Tvedt, T. Young, supra note 20, p.24.

[185] M. Buck, C. Hamilton, supra note 70, p. 59. The issue of pathogens is not further studied in this research as it does not affect *per se* the functionality of the Protocol. For a comprehensive overview of the controversy, see WHO, *Documentation: Pandemic influenza Preparedness*, 2009, found at < http://whqlibdoc.who.int/publications/2009/9789241547680_eng.pdf>, last accessed 6 September 2011.

[186] Building on the Bonn Guidelines, the Protocol therefore stresses that the exercise of States' sovereign rights in designing access regulation may not run against the needs for certainty of users and user countries.[187]

In order to do so, the Protocol moves towards so-called "international access standards"; a set of minimum requirements provider countries have to incorporate in their access legislation. The Protocol now imposes as precondition for Parties requiring PIC to adopt "the necessary legislative, administrative or policy measures, as appropriate." This means that in case no specific legislation regulating the access is adopted, provider countries will not be entitled to require other countries to activate the application of their compliance measures as regard the utilization of the said resources. In addition, the Protocol imposes a set of general principles and obligations that Parties requiring PIC must respect while establishing their domestic access legislation.

The importance of these minimum requirements should not be overlooked. They may provide guidance for interpretation in case disputes arise between parties to a MAT agreement or between Parties at international level.[188] Furthermore, it remain to be seen how and to which extent user country may decide not to activate their compliance measures undertaken pursuant to Article 15 in case a domestic access regulatory measure is in contradiction with those minimum obligations. This last hypothesis is particularly sensitive since it would imply that the user country is assessing the "appropriate character" of the contested legislation *vis-à-vis* the aforementioned rules and principles. This could result in major clashes between Parties and significantly affect the fragile trust' feeling the Nagoya Protocol contributed to rebuild. It is therefore the author's view that only a "manifest breach" may constitute a basis for user country to dismiss the application of his compliance obligations. The assistance of an international independent actor to be determined may also allow to objectivate the debate and decrease the contentious character of such an issue. On the other hand, if default with the minimum access requirements can lead user country to refrain from applying their compliance measures, in the author's view, the flipside of this "standard access"obligation is that user countries will need to carry on appropriate and effective actions to

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[186] See para. 2.1.3.2.
[187] The principles laid down by the Protocol are largely similar to the principles and recommendations of the Bonn guidelines presented in footnote 99 (see subsection 2.2.1). The major difference is however that this time, the general principles are legally binding.
[188] "Compliance", Art. 30. of the Protocol.

ensure providers' rights in case these requirements are fulfilled. As regard the criteria of the "access standard" properly speaking, several observations deserve to be highlighted.

First of all, the Protocol makes clear that ensuring process certainty is pivotal for a functional scheme. In order to make explicit what can reasonably be expected, Parties will need to identify the relevant laws and authorities, provide information and guidance regarding the resources covered by the national law, the application process, its timing, milestones and potential role played by the various stakeholders during the PIC process. The provider country also needs to provide for clear rules and procedures for requiring and establishing MAT. The law dealing with ownership of genetic resources, legal protection given to the parties, etc. should also be clearly established. Provisions on how to deal with transfer of accessed resource to third-party and change of intent would also be significant value-added. All those law does not need to be harmonized in the ABS context but for the functionality of the regime, should be easily identifiable.

The establishment of Competent National Authority is seen as a crucial measure in this respect. According to many experts, the establishment of a centralized focal point is "the critical element for running a PIC system."[189] The "lack of institutional and technical capacity for resolving the request for PIC at the legal administrative and technical matters"[190] has been stigmatized as a major problem of provider-side measures. As stated by Perault, "a recent study also indicates that questions frequently exist about how to convey the information needed to make informed decisions and about how, when, and from who consent should be obtained."[191] A well performing authority disseminating and coordinating access information may significantly improve the predictability of the provider legislation. This should in turn reduce the transactions costs for private parties, increase their confidence in the scheme and reduce biopiracy.[192] Appropriately, the Protocol therefore identifies legal and institutional development as a key area of capacity building. At the international level, the CHM will act as an internet-based centralized portal and will play an important role for

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[189] K.-J. Ni, supra note 101, p. 266.
[190] Ibidem, p. 267.
[191] A. Perault, 'Prior Informed Consent and Access and Benefit-sharing: Recognition and Implementation, Prior Informed Consent from Theory to Practices', in *Disclosure Requirements: Ensuring Mutual Supportiveness Between the WTO TRIPs Agreement and the CBD*, IUCN (Gland) and ICTSD, 2006.
[192] As argued by Jeffery «the establishment of competent national authorities and the appropriate focal point to coordinate and disseminate access information may also serve to discourage biopiracy, some of which may owe its existence to frustration in obtaining relevant information as opposed to deliberate intention to avoid obtaining PIC." (M. Jeffery, Bioprospecting: 'Access to Genetic Resources and Benefit-Sharing under the Convention on Biodiversity and the Bonn Guidelines', *Singapour Journal of International and Comparative Law*, Vol. 6, 2002, p. 799).

increasing transparency of access measures and to bring to operation the "internationally recognized certificate."[193]

Secondly, the Protocol also underlines that the establishment of PIC evidence have a crucial role in a functional regime. A clear decision or permit attesting of the fulfillment of the ABS requirements provides to bioprospectors further confidence in the reliability of the system. On the other hand, together with process certainty, such permits or its equivalent are also necessary to enable user countries to adopt their monitoring and compliance measures to (Article 15 and 17). As stated by Buck, "the predictability and enforceability of user-measures under article 15 of the Protocol rests on steps taken by provider countries to anchor the chain of information in their jurisdiction at the time of access, which is particularly important if PIC is to apply not only to gene sequences but also to any biochemical contained in material accessed under Article 6 of the Protocol."[194] In addition, in the author's view and to the extent possible, legal evidence should also be issued for resources freely accessed in order for the user to be able to demonstrate that he is legally operating outside the ABS system.

Thirdly, contract certainty is not substantively regulated under the Protocol and is still a matter to be dealt at national level. It is upon basis of domestic laws that users and providers will continue to define in their particular transactions the exact scope and nature of the rights they acquire, the obligations associated with those rights; and defining an endpoint in their contractual relationship. Most importantly, the Protocol does not address expressly the nature and ownership questions of genetic resource, a major problem in the ABS implementation so far.[195] Each country will thus have to determine the legal status of its genetic resources and ensure that parties in ABS transactions share a clear common view on this issue.[196] In order to foster contractual certainty of ABS transactions, the Protocol nevertheless foresees for Parties the possibility to develop model clauses. These could become a key mechanism for an effective scheme. Standardization of agreements may significantly reduce transactions costs and enhances legal certainty. Model clause also provides for flexibility and can take into account the specificities of each uses. On the other

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[193] See T. Kantai, supra note 43.
[194] M. Buck, C. Hamilton, supra note 70, pp. 57-58.
[195] See para. 2.1.3.2.
[196] As stated by Laird and Wynberg, "the extent to which ownership and/or legal status of genetic resources is resolved at the national level plays a key role for those seeking access to genetic resources and PIC. Where there is legal clarity with respect to ownership of genetic resources, ABS arrangements are more easily facilitated"(See S. Laird, R. Wynberg, supra note 26).

hand, as any standardized instrument, model clause may also result in "race to the bottom" of the requirements and an appropriate balance of rights and obligations between the parties must be conserved.[197]

Fourthly, beside the requirements described above, Parties still dispose of significant leeway for designing their domestic scheme. Parties should design their access regulation by focusing on the "utilization of genetic resources." Activities constituting "utilization of genetic resource" should thus serve as the basis for their legislation and persons engaging in such activities, the targeted beneficiaries. Parties should remain particularly pragmatic in adapting the requirements of the Protocol to their national realities, bearing in mind the needs for certainty of user and user countries. Importantly, the Protocol constitutes minimal measures countries have to transpose in their national legal order. Stricter measures can be imposed as long as they respect the general principles laid down by the Protocol. Parties may require "further authorisations besides the ABS regime, such as a licence for research, entering into national parks, the collection of produce from forests, seas, etc. It is suggested that in such cases procedures should be streamlined in order not to deter researchers and increase transaction costs."[198] The enforcement of such additional measures by other countries may however appear complicate or even voluntary.

Lastly, the functionality of the scheme could have been severely affected if no special provision was recognizing the pivotal role of non-commercial research in supporting biodiversity conservation. Burdensome access processes constitutes an impediment for non-commercial research, especially due to the high number of transactions achieved each year. However, basic research initially accomplished with a pure scientific goal "can often lead to discoveries of substances and knowledge with commercial potential. Furthermore, the intent and ambitions of the original researcher may change from publication to patenting and licensing; or a private company may use the research publication and specimens as a starting point for commercialisation."[199] Therefore, as reflected by article 8(a), simplified access needs to be balanced by appropriate contractual clauses, monitoring and compliance measures. It will belong to the Parties to define nationally which measures will constitute simplified access, which activities may be viewed as non-commercial, etc.

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[197] See S. Täuber, supra note 183.
[198] E. Chege Kamau et al, supra 148, p. 260.
[199] M. Tvedt, O. Rukunnko, supra note 80, p.12.

6 Fair and Equitable Benefit-sharing: A contractual matter

The functionality challenge of the benefit-sharing aspect is twofold. First of all, it raises the question on how to ensure that the benefits shared in the ABS context are actually used to promote biodiversity conservation and sustainable use of its components. The second challenge relates to difficulty determining what should be a "fair" and "equitable" sharing of benefits. Section 1 examines how the new Protocol deals with the fair and equitable sharing of the benefits. Section 2 shed some lights on the functionality challenges of the benefit-sharing aspect of the ABS concept.

6.1 The Fair and equitable sharing of the benefits under the Protocol

Article 5 of the Protocol stipulates that "benefit-sharing arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources, in accordance with Article 15.3 and 15.7 of the CBD. Such sharing shall be upon Mutually Agreed Terms." By explicitly referring to article 15.3 and 15.7 CBD, Article 5.1 of the Protocol confirms that the sharing of benefits arising form the utilisation and subsequent applications and commercialization need to be pursued through MAT (*i.e.* upon basis of contractual rights). The reliance of the ABS system on MAT has important consequences.

First of all, under the Protocol, MAT remains the unique legal vehicle on which to proceed to fair and equitable sharing of the benefits arising from the utilization of genetic resources. The conclusion of such contractual agreement is a precondition for sharing of benefits: there is no other legal basis for a provider to obtain such sharing and only the conclusion of a MAT entitles the provider to enforce ABS rights. If no contract is signed with the user at the time of access, the provider cannot go directly to court and ask the judge to proceed *ex aequo et bono* to the fair and equitable sharing of the benefits. In all hypotheses, a MAT will first need to be concluded. It is only if the user does not comply with the terms and conditions set out in the MAT that provider may try to enforce its ABS rights in accordance with the modalities defined by the parties.[200]

[200] It is however possible to imagine domestic access frameworks establishing default MAT conditions that apply whenever no contract negotiation takes place. The activity of accessing in situ genetic resources in absence of a negotiated MAT would be characterised in national law as articulation of the will to accept the default MAT conditions. (M. Buck, personal communication, 2011).

Secondly, in accordance with Article 15, provider may be helped by the user country in concluding a MAT with non-compliant user. Importantly, the latter provision does not impose a "self-standing obligation of user states to ensure benefit-sharing."[201] The user country may thus not proceed or be requested to proceed to fair and equitable sharing of the benefits. In accordance with Article 15, the user country will, however, need to take effective, appropriate and proportionate measures to address those situations for example by ensuring a MAT is established or that the provider and user agree on a forum to settle their dispute.

Thirdly, even if there is no self-standing obligation, there is nevertheless an overarching obligation of each Party to ensure fair and equitable benefit-sharing. Article 5.3 states that "each Party shall take legislative, administrative or policy measures, as appropriate, to implement paragraph 1" (*i.e* the fair and equitable sharing of benefits upon MAT). According to Buck and Hamilton, the exact regulatory content of this provision is unclear: "it seems to confirm more specific obligations of Parties under the Protocol rather than to establish additional ones."[202] To the author, Article 5.3 has to be seen as recalling the overarching obligation of Parties under Article 15.7 CBD to adopt the necessary measures "with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources." Article 5.3 then underscores that specific user side measures each Party needs to undertake in accordance with the Protocol, and in particular pursuant to Articles 15 to 18, must *in fine* be striving at the achievement of this overarching objective.[203] This also suggests that if measures adopted in accordance with Article 15 to 18 do not succeed in ensuring the fair and equitable sharing of benefits through MAT, other measures may be necessary to implement this overarching obligation.[204]

Article 5 provides further guidance on benefit-sharing obligations. Article 5.1 makes clear that the sharable benefits are to be understood broadly. On the one hand, MAT can include benefits

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[201] M. Buck, C. Hamilton, supra note 70, p. 53.
[202] Ibidem, p. 53.
[203] Nothing in the text of Art. 15 to 18 of the Protocol suggests such an overarching obligation to ensure the "fair and equitable" sharing through MAT.
[204] It may also be argued that Art. 5.3 is implemented if Parties undertake faithful implementation of their obligations under Arts. 15 to 18 of the Protocol. Otherwise, Art. 5.3, which is an unspecified obligation of result, would systematically result in non-compliance of user countries. This may also disturb the balance between provider and user obligations. (M. Buck, personal communication, 2011).

from a large panel of activities, namely the "utilisation of genetic resources as well as subsequent applications and commercialization." The meaning of the word "subsequent" may sound confusing. It seems to indicate the presence of a clear consequential link between the R&D and the applications and commercialization. Furthermore, the Protocol also confirms that the benefits shared may be very different in nature. The Annex of the Protocol, a *verbatim* reproduction of the Appendix II of the Bonn Guidelines, illustrates this diversity by providing a long list of monetary and non-monetary benefits which may be shared through MAT.

6.2 Impact of benefit-sharing requirements on the Functionality of the ABS regime

For the functionality of the ABS international regime, the challenges as regard the benefit-sharing obligation are twofold. First of all, it raises the question on how to ensure, or at least promote, that the benefits shared in the ABS context are actually used to promote biodiversity conservation and sustainable use of its components. Under the Protocol, this seems to be potentially achieved in two different ways. On the one hand, Parties requiring PIC will need to design their access legislation in a way that encourages parties to ABS agreements to arrange the sharing of the benefits in a manner supporting those two goals (pursuant to Article 9). On the other hand, the direction of the benefits towards the ABS end-goals is one of the issues that will need to be promoted by Parties through their awareness raising obligation (Article 21).

The second impact of the benefit-sharing provision on scheme functionality relates to the difficulty determining what a "fair" and 'equitable' sharing of benefits is. Until very recently, minimal attention had been paid to what is now called the "valuation problem of ABS."[205] Under the CBD and the Nagoya Protocol, the valuation is based on individual negotiation between the parties involved in a specific transaction. According to Tvedt, "due to a number of reasons, including e.g. unequal negotiating power and market failures, such a contractual approach to valuation does not necessarily lead to a fair and equitable result and value of genetic resources."[206] On a practical basis, the valuation problem refers to the extreme complexity "to calculate the relative contribution from genetic resources to the commercialised end product."[207] The valuation

[205] M. Tvedt, 'Elements for Legislation in User Countries to Meet the Fair and Equitable Benefit-Sharing Commitment', *Journal of World Intellectual Property*, Vol. 9, No 2, 2006, p. 192.
[206] Ibidem, p.194.
[207] Ibidem, p. 198.

problem is not totally ignored by the Protocol. In the 10th paragraph of the preamble, Parties recognize the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources. Pursuant to Article 22.4, one of the key areas that capacity building and development may address is the capacity to negotiate mutually agreed terms. Article 22.5 (b) and (e) further specifies that this may include measures to promote equity and fairness in negotiations, such as training to negotiate mutually agreed terms and the development and use of valuation method.

7 Compliance: "the core of the core"

In the context of this research, "compliance" refers to the need to ensure that users of genetic resources comply with domestic legislation on ABS (Article 15 and 16) and with the MAT they conclude with the provider (Article 18).[208] Ensuring "user compliance" consists in making sure that users fulfil their ABS obligations, namely that (i) genetic resources utilized are legally accessed through PIC authorization, (ii) a MAT is concluded with the provider to organize the utilisation of the said resource and the sharing of the benefits in a fair and equitable manner and (iii) users are complying with the terms and conditions set out in the MAT. In order to ensure "user compliance", Parties will need to adopt laws (i) requiring the user of foreign genetic resources to respect the benefit-sharing obligation imposed by other countries and (ii) authorizing the provider of a foreign genetic resource to seek remedies against non-compliant users operating within their jurisdiction. The adoption of user side measures is pivotal for the functionality of the ABS international regime, especially since it often has the most direct impact on the users' behaviour. To the author, given the prohibitive complexity of a purely mandatory approach, the international regime should however not impose excessive regulatory burdens on user countries and allow for the creation of an incentive based paradigm.[209]

Two basic situations of non-compliance need to be distinguished in the ABS context. First of all, the user can utilize a foreign-origin genetic resource for which no PIC was granted and no MAT established at the time of access. Secondly, the user may also have legally accessed a genetic resource through PIC and MAT but may not be compliant with the implementation of the said contract. Under the Protocol, three provisions specifically address the "user-side measures" aiming to ensure the protection of the ABS providers' rights.[210] Article 15 (Compliance with ABS domestic legislations) addresses the first hypothesis of non-compliance whereas Article 18 (Compliance with Mutually Agreed terms) deals with the second situation. Lastly, Article 17 deals with monitoring the utilization of genetic resources.

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[208] Though this meaning is widely accepted in the ABS debate, it obviates from the traditional signification of the term in international law. In the latter context, "compliance" refers to the obligation of States to comply with their duties under the CBD and the Nagoya Protocol (Art. 30), including with their obligations under Arts. 15, 16 and 18. This later aspect is however not analysed in the present research.

[209] See chapter 1.

[210] For remainder, Art. 16 on "compliance with domestic legislation on ABS from traditional knowledge associated with genetic resources" is beyond the scope of this study.

Before a more in-depth analysis of the user-side measures, there are two preliminary remarks are of particular relevance. First of all, it is not possible to waive the obligation to adopt user measures and all Parties are obliged to implement Articles 15 to 18 of the Protocol. Secondly, it is important to recall that user-side measures ultimately need to achieve the overarching obligation of ensuring a fair and equitable sharing of the benefit through MAT provided in Article 5.1 and 5.3 of the Protocol.[211]

7.1 Compliance with Domestic legislation or regulatory requirements on ABS

Pursuant to Article 15.1, user country shall take the appropriate, effective and proportionate measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with PIC and that MAT was established as required by the domestic ABS legislation or regulatory requirements of the other Party. Article 15.2 also requires the Parties to take appropriate, effective and proportionate measures to address situation of non compliance. Article 15.3 obliges the user country to cooperate, as far as possible and as appropriate, to collaborate in cases of alleged violation of domestic ABS legislation referred to in paragraph 1.

Article 15 of the Nagoya Protocol significantly fleshes out the obligations of Parties under Article 15.7 CBD.[212] First of all, as stated in section 6.1, the Protocol does not impose user states to ensure benefit-sharing. Thus, the user country may not proceed or be requested to proceed to fair and equitable sharing of the benefits if a user is utilizing a genetic resource for which no MAT was concluded at the time of access. In accordance with Article 15.2, the user country will need to take effective, appropriate and proportionate measures to address those situations for example by ensuring that a MAT is established or both the provider and the user agree on a forum to settle the case. The obligation "as far as possible" and "as appropriate" to cooperate in case of alleged violation must also be viewed in the same perspective *i.e.* as striving for the successful conclusion of a MAT[213]. It is worth mentioning that the exact meaning and regulatory content of Parties' obligation to "address" situations of non-compliance is unclear.

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[211] See section 6.1.

[212] For reminder, as highlighted in para. 2.1.2.2, Art. 15.7 was mainly worded in term of results countries should endeavour to reach and did not provide with concrete measures to implement user-side measures.

[213] As previously highlighted, provider country may foresee default MAT applicable in case no contract was signed at the time of access.

Secondly, "utilization" of genetic resources also triggers the compliance obligations. These shall therefore focus on R&D activities on genetic resources within the scope of the international regime.[214] With regard to the activities covered, user legislation will as a result include commercial as well as non-commercial research.

Thirdly, Article 15 is written in rather general terms and offers Parties considerable flexibility to implement their user obligations. It does not specify the type of measures (legislative, administrative and/or policy) user countries need to adopt, as long as they are appropriate, effective and proportionate. The verb "provide" in Article 15.1 also seems to lay the emphasis on the results to achieve rather than the manner employed to reach them. This flexibility is justified by the necessity of Parties to adopt the measures they estimated best suited to their national realities. These can be mandatory and/or incentivized. In addition, such modularity will allow to better coping with the specificities of the wide range of economic activities covered by the new framework. As highlighted in subsection 4.1.1, activities constituting utilization of genetic resources are very different in character; effective measures for one sector may be clearly inappropriate for another. This importance of adopting a tailor-made approach and favouring the use of soft law instruments is also underscored by Article 20 of the Protocol. The latter provision requires Parties to encourage the development, update and use of voluntary codes of conducts, guidelines and best practices and/or standards in relation to ABS.

Fourthly, the wording of Article 15.1 is largely similar to the wording of Article 6.1 of the Protocol. This emphasizes that the implementation of user measures is largely dependent on decisions adopted at the time of access, especially the issuance of a permit or its equivalent. The wording of Article 15 of the Protocol is however slightly different as it refers to resources which have been accessed in accordance with the requirements of "the other Party." Unlike in Article 5.1, 6.1 and 23, Article 15.1 of the Protocol departs from the language based on Article 15.3 CBD according to which "the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention." This difference of wording in fact confirms the binding character of the "international certificate of compliance" established by Article 17 of the Protocol.

[214] See subsection 4.1.1.

Pursuant to Article 17.3, the certificate shall serve as evidence that the genetic resources which it covers have been accessed in accordance with PIC and that MAT have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing PIC. Consequently, user countries have no right or obligation to verify the origin of the genetic resources utilized if a certificate issued by "the other Party" attests that said resource was legally accessed. This seems rather logical as it is precisely the goal of a certificate of compliance to ascertain that a genetic resource was legally accessed in a specific country. To allow or oblige a Party to track the genetic resource back to its country of origin would *de facto* defeat the purpose of a certificate and thereby impose an unnecessary burden upon the user country.[215] Furthermore, the legally binding character of the certificate also means that users in possession of such certificate are assumed to be compliant with their ABS obligations and shall be protected from biopiracy accusations.[216]

Fifthly, as explained in section 5.3, it remains to be seen how and under which conditions a user country may refrain from undertaking measures if access legislation does not fulfil the minimum access requirements spelled out in Article 6.3.

7.2 Monitoring the utilization of genetic resources

During the negotiation, a highly contentious issue related to whether the general requirement of Parties to undertake user measures established by Article 15 should be complemented by more specific obligations to monitor users and/or the utilization of genetic resources within their national jurisdiction.

On the one hand, in the view of many developing countries, user compliance can only be achieved if the utilization of genetic resources is sufficiently overseen by the user country. Therefore, Parties should agree to create an "internationally recognized certificate of compliance" and establish "checkpoints." The country providing a genetic resource would issue a certificate attesting that the said resource has been legally accessed in accordance with the PIC requirements

[215] Country where a user is operating cannot be expected to actively seek clarification on whether or not the implicit sovereignty claim of a Party that acts as "provider" of specific material is justified or not. For instance, in case Brazil provides material that originates in Peru to a French user, this may result in a dispute over sovereignty claims between Brazil and Peru. However, it should not result in a dispute between Peru and France, where material is being used. (M. Buck, personal communication, 2011)

[216] The certificate and its uncertainties will be studied in subsection 7.2.2.

and that a MAT was established. Then, the user should be requested by the user country to present the certificate at various "checkpoints" *i.e.* to authorities situated at critical stages of the value-adding chain and charged with controlling the legality of the utilization of genetic resources, including on basis of the information transmitted in the international certificate. Developing countries in particular insisted on the obligation to appoint the patent office as a mandatory "checkpoint" while research funding agencies, customs authorities and market approval offices were other proposed options.[217]

On the other hand, "industrialized countries challenged the proposed system of checkpoints/ disclosure obligations/certificate of compliance as inflexible, costly and ineffective in identifying instances of biopiracy. A few Parties categorically rejected any mention of disclosure obligation in patent applications and patent offices as checkpoints, which is consistent with their positions in the WTO/TRIPS to oppose an eventual amendment of Article 27.3(b) of TRIPS by a mandatory disclosure requirement."[218] Article 17 of the Protocol reflects a delicate political compromise between developing and developed countries. The approach of "checkpoints" (Article 17.1) and "certificate of compliance" (Article 17.2 to 17.4) is conserved but the Protocol introduces significant flexibility and does not contain any reference to "disclosure requirement" or "patent office."

7.2.1 Designation of checkpoints:

To support compliance, Article 17.1 requires Parties to take measures, as appropriate, to monitor and to enhance transparency concerning the utilization of genetic resources. The measures to be undertaken under Article 17.1 shall include the designation of one or more checkpoints, encouraging parties to a MAT to include provisions to share information on the implementation of such terms, encouraging the use of cost-effective communication tools and systems. As this

[217] The disagreement over the mandatory designation of patent office as checkpoint can only be properly understood in view of its close relationship with a longstanding and sensitive issue in the International Property Rights regime. Under the WTO, over the last 15 years, developing countries have consistently been arguing that Art. 27.3 (b) TRIPS should be amended so "to require patent applicants to disclose one or more of the following: the source and origin of any genetic material and/or any related traditional knowledge used in a claimed invention; evidence of prior informed consent (PIC) from the competent authority of the country of origin; and evidence of fair and equitable benefit-sharing."
[218] M. Buck, C. Hamilton, supra note 70, p. 54.

wording suggests, this list of measures is non-exhaustive but the examples provided are mandatory.[219]

The Protocol provides further details pertaining to the role which the checkpoint(s) Parties have to appoint and the features they contain. Article 17.1 (a) (i) states that "checkpoints designated would collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources. Pursuant to Article 17.1 (a) (ii), Parties are obliged to require users to provide the relevant information at a designated checkpoint and to take the appropriate, effective and proportionate measures to address situations of non-compliance. Article 17.1 (a) (iii) clarifies that such information, including from internationally recognized certificates of compliance when available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing house as appropriate. Pursuant to Article 17.1 (a) (iv), checkpoints must be effective and should have functions relevant to the implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, inter alia, any stage of research, development, innovation, pre-commercialization or commercialization.

Several observations are necessary to properly understand the regulatory content of Article 17 of the Protocol. First of all, Article 17.1 does not impose an obligation of tracking the resources utilized or to report on the utilization activities within its national jurisdiction, as proposed in previous drafts. "Tracking" refers to the process of following the physical movement and use of genetic resources (and their derived products) throughout the whole chain of research and development (i.e. from the collection in-situ to the product commercialization). As stated by Ruiz Muller and Lapeña, 'monitor' means "to verify that the uses being given to these resources and products are reflected in and are permitted by the original ABS contracts (or subsequent contracts) and national laws under which research and development are undertaken."[220] Importantly, utilization also defines the scope of Parties' monitoring duties.

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[219] The obligation to "encourage" in Art. 17.1 (b) and (c) is however clearly not an obligation of result but should rather be seen as an obligation of effort.
[220] M. Ruiz Muller, I. Lapeña, supra note 93.

Secondly, as explained by Buck and Hamilton, "the text purposefully avoid the use of the words 'disclosure' or 'disclosure requirement' and suggests rather indirectly that a disclosure requirements at designated checkpoints could play a role in the implementation of Article 17.1 (a). However, this is left to the discretion of Parties."[221] For ABS to be functional, the international community will need to harmonize the relationship between the IPR regime and the CBD. To the author, this seems to reflect the idea that the Nagoya is not a single magic bullet addressing all the ABS problems in one shot and that discussion will need to be pursued under other fori, including the TRIPS, to ensure a smooth relationship with various interlocking framework of international law.

Thirdly. it is unclear to the author what the use of the conditional tense "would" stands for in Article 17.1 (a) (i).[222] In the same provision, the wording 'collect or receive' introduces flexibility on how checkpoints 'would' operate. On the face of it, it seems that Parties may be giving a rather limited role to checkpoints in order to fulfil their obligations of Article 17. Indeed, the latter merely foresees that checkpoints will gather relevant information to monitor and enhance transparency about the utilization of genetic resources. This suggests that there is no obligation for designated checkpoint (s) to verify that the relevant information indicates that the utilization is compatible with the terms of the initial or subsequent ABS transactions. In other words, Parties are not obliged to meet their monitoring obligation by means of checkpoint(s). Interpreted in this way, a checkpoint solely enhancing transparency fulfils the requirements of Article 17 of the Protocol and Parties may decide to achieve their monitoring duties in totally different ways (for example, through a system of Audit or by imposing self-monitoring obligations on companies).[223]

Fourthly, in Article 17.1 (a) (iii), the choice of the word 'including' indicates that the 'international certificate of compliance' is not the exclusive source of information for Parties to ascertain whether genetic resources utilized were lawfully accessed. In the same provision, the

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[221] M. Buck, C. Hamilton, supra note 70, p. 55

[222] To the author, there seems to be a contradiction between Article 17.1 (a) (i) and (ii). Point (ii) seems to make compulsory what (i) makes flexible. Point (ii) states that "the information specified n the above §" shall (emphasis added) be provided to a designated check point "according to its characteristics."

[223] This sharing of responsibilities in terms of monitoring is also suggested by Laird and Wynberg, "Because of complexities of identification and capacity constraints, it is unlikely that countries presently can effectively and comprehensively regulate, or groups can adequately track and monitor, the use of resources they provide to users. This stresses the importance of building monitoring capacity amongst parties, ensuring their commitment to agreements and to transparent and fair transactions, and establishing on-going and long-term partnerships. Such approaches are vital to ensure that the use of material can be monitored and benefits down the road assured." (S. Laird, R. Wynberg, supra note 29).

reference to the protection of confidential information is seen as crucial for developed countries. To the author, it is a valid concern that the activities of economic operators may require certain essential information not to be disclosed. It should however be kept in mind that the functionality of the Protocol relies for a large part on an enhanced transparency; therefore, the choice not to disclose information should remain the exception rather than become the rule.

Lastly, the added value and legal soundness of Article 17.1 (a) (iv) seems rather dubious. As observed by Buck and Hamilton, "the notion that checkpoints 'must be effective' already flows from the chapeau of Article 17.1 and 17.1 (a) (i) of the Protocol. Furthermore, the non-obligatory list of stages to collect 'relevant' information goes beyond the substantive scope of the obligation in the chapeau to Article 17.1 ('utilization of genetic resources'), which suggests that some of the collected information might indeed be irrelevant for implementing Article 17 of the Protocol."[224]

7.2.2 Certificate of compliance:

Articles 17.2 to 17.4 deal with the elaboration of the "internationally recognized certificate of compliance." Article 17.2 states that a permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing House, shall constitute an internationally recognized certificate of compliance. As stated by Buck and Hamilton, this wording "leaves it unclear whether the simple act of registration in the ABS CHM elevates a domestic permit or equivalent to the status of an internationally recognized certificate of compliance or whether the registered information itself constitutes the internationally recognized certificate of compliance. In the latter case, the internationally recognized certificate of compliance would be distinct from the domestic permit or equivalent."[225]

As highlighted earlier in this research, Article 17.3 consecrates the legally binding effect of the certificate; by doing so, it precludes States from tracking the genetic resource back to the 'Other Party' and protects the user in its possession from being accused of biopiracy. Article 17.4 contains a list of minimum information which must be included in the certificate. As Buck and Hamilton state it, "contingent to the interpretation of Article 17.2, this list will either result in a minimum harmonization of domestic permits or equivalents or it could be implemented by providing a

[224] M. Buck, C. Hamilton, supra note 70, p. 54.
[225] Ibidem, p.54.

common format for registering information on domestic permits or equivalents in the ABS CHM."[226]

7.3 Compliance with Mutually Agreed Terms

Article 18.2 obliges Parties to ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from MAT.[227] Pursuant to Article 18.3, each Party shall take effective measures, as appropriate, regarding (a) access to justice; and (b) the mutual recognition and enforcement of foreign judgements and arbitral awards.

Article 18 contains the obligation to ensure the availability of administrative and legal remedies enabling the provider to protect the ABS rights he acquired in a MAT. In a nutshell, it is legally feasible to proceed to the cross-border enforcement of an ABS contract. In addition, different remedial options might be suited to address ABS claims brought by providers. In the ABS context, the provider claiming user non-compliance will however be confronted with "two primary challenges: (i) the challenges of costs, access to information and evidence gathering which are common to all commercial parties who are not located in the country in which the action is being taken; and (ii) the challenge of making certain that the contract is sufficiently clear and specific to enable a court, arbitration or other remedial action to come to an unambiguous decision. There are many factors relating to ABS which suggest that the Parties may need to have access to special measures and protections in order to use national remedial laws and processes, including the fact that many source countries and traditional communities will lack the funds, expertise and ability to engage in a protracted action in another country seeking redress from an entity which is probably better funded, more familiar with the relevant legal system, and better positioned to participate in legal action."[228]

As already shown in this research, the Protocol tries to cope with the second challenge by putting the emphasis on contract certainty. The coverage of the first aspect by the Protocol is less evident. The obligation to ensure that an opportunity to seek recourse is available seems not to imply an obligation of assistance. According to some delegates, Article 18.3 (a) 'access to justice' is

[226] Ibidem, p.54.
[227] As already shown in section 5.3, Art. 18.1 provides that Parties shall encourage providers and users to include provisions in their MAT to cover dispute resolution.
[228] T. Young, supra note 30, p.182.

said to refer to the UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters ('Aarhus Convention').[229] The legal consequences of this reference in the Protocol are still to be explored. More specifically, it has yet to be seen whether and to which extent Article 18.3 could be interpreted as requiring Parties to provide legal, technical and/or economical assistance in order to enforce compliance with MAT.

7.4 Impact of the Compliance Provisions on the functionality of the ABS regime

The Protocol stresses the importance of adopting user measures for an effective and legally certain ABS regime and, for the first time, explicitly recognizes that contractual provisions and providers legislation alone are markedly inadequate tools for a functional ABS regime. Several remarks seem to be relevant to properly understand the content and importance of the user measures under the new framework.

First of all, Article 15 of the Protocol defines the responsibilities of user countries, namely to provide that PIC was granted and that a MAT was established at the time of access. Article 17.1 of the Protocol clarifies that there is an obligation to verify, as appropriate, that the utilization is in conformity with the terms defined in the MAT and to enhance transparency regarding the utilization of genetic resources within its national jurisdiction. Disputes concerning the implementation of MAT shall be dealt with Article 18 of the Protocol. Though it is particularly difficult to assess with precision at this time of writing, the actual distribution of tasks seems to be a reasonable compromise in terms of functionality. According to Chege Kamau et al., the fact that "the enforcement of the benefit-sharing is left to contractual means, with all the difficulties of forum, litigations costs, and prosecution of titles (…) constitutes a major disappointment for the provider side."[230] As shown in the previous section, even if the contract certainty aspect of the MAT is improved, it will remain very challenging to proceed to their cross-border enforcement. The provider should clearly be assisted in ensuring that the enforcement of their rights is possible and it is unclear whether or not this is the case under the Protocol. Nevertheless, to the author, it would have been unrealistic to require user countries to ensure the due implementation of all MAT transactions. It must be acknowledged that it is practically unfeasible and excessively onerous to

[229] UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters ("Aarhus Convention"), Aarhus, 25 June 1998. See e.g. G. Nijar, supra note 116, 2011.
[230] E. Chege Kamau, supra note 148, p.262.

oblige user country to assess each individual ABS transaction, determine whether the terms are fair and equitable and eventually force users to comply with their ABS obligations. To the author, the clear definition of limited but implementable obligations has a better potential for effectiveness than excessively broad and ambitious requirements that are impossible to realize in practice.

Secondly, user measures are much less elaborated than the provisions on access; they are also foremost formulated in terms of result rather than developing concrete means to meeting those requirements. Parties thus dispose of all necessary discretion to focus their action on creating the conditions to favour compliance and develop incentive for economic operators to enter into ABS relationships.[231] In my view, the fact that the Protocol leaves significant flexibility with regard to the measures to be adopted undoubtedly highlights the extents to which user measures constitute the most challenging part of the Protocol to be implemented. It also reveals that countries will need to be creative in designing totally new legal frameworks, supported by an arsenal of mutually interactive incentive based and mandatory implementation measures. Those difficulties should not be overlooked. Parties should start reflecting as soon as possible on how user measures could best operate. The value adding chain of the various sectors covered should be analysed in order to identify how user compliance should best be supported. Economic operators should be associated to the regulatory process so to make sure that the measures enacted fit with the needs and characters of the specific sector of activities. At international level, Parties should closely collaborate and share knowledge, experience and best practices.

Thirdly, Articles 15.2 and 17.1 (a) (ii) of the Protocol state that each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance. The Protocol does not specifically provide further guidance on how exactly situations of non-compliance should be managed. For Parties, two closely interconnected challenges have to be addressed. On the one hand, Parties will have to determine whether or not genetic resources utilized for which no certificate is presented are within the scope of the Protocol. Secondly, it also raises the question of potential sanctions for non-compliance or non-disclosure of the origin of the genetic resources utilized. This is crucial for the scheme integrity since, as observed by Young, so far "one of the most important gaps that prevent further progress towards ABS functionality is the loophole by which users who do not know or disclose the source country of the resources they are using are

[231] It may be argued that the lack of identified user-side measures lessen the legal functionality of the ABS scheme. (M. Tvedt, supra note 17).

not required to engage in any benefit-sharing or substitute activity. Even more than the practical unenforceability of ABS contracts, the failure to adopt user measures to close this gap has rendered ABS a very ineffective system, and closed many options for increasing its effectiveness."[232]

Fourthly, Article 17 of the Protocol attests of the resistance of/to the mandatory approach. The demands of developing countries have been significantly watered down in terms of means to achieve the monitoring duties. However, in terms of results, the obligations 'to monitor and enhance transparency' are clear and sufficiently precise to be implemented. The system of checkpoints and internationally recognized certificate of compliance remains rather undetermined. In particular, the exact role and features of the latter is still largely undefined. To the author, this is nevertheless not so problematic. As observed by Cabrera Medaglia and Rukundo, the precise design of the internationally certificate of compliance, "unlike some other outstanding issues in the Protocol, (…) might take shape only at a later stage and during the actual implementation."[233] Indeed, only the practical implementation of the whole regime will show how the certificate can best operate.

[232] M. Tvedt, T. Young, supra note 8, p.130.
[233] J. Cabrera Medaglia, O. Rukundo, 'Monitoring compliance: Disclosure requirements and the international certificate', *Environment and Natural Resources Programme,* Vol. 4, No. 3, 2010, found at: <http://ictsd.org/i/environment/87118/> last accessed 6 September 2011.

General Conclusion:

This research aimed to evaluate the potential for effectiveness of the legal framework laid down by the Nagoya ABS Protocol. It was assumed that a functional ABS regime could only be achieved by; (1) providing the necessary legal certainty, while (2) allowing for shifting towards incentive based user compliance, and (3) ensuring that the scheme serves the environmental developmental goals it pursues. To find out whether the Nagoya Protocol may constitute a legally sound basis for a functional ABS regime, the strengths and weaknesses of four main elements were assessed. The choice of functionality as analytical concept was motivated by the will to be objective, critical and constructive; it allowed me to focus on the legal soundness of the new framework and underscoring the interdependence between its main provisions. This conclusion briefly summarizes the main teachings to be drawn from the present analysis.

The Protocol is a new and standalone legally binding international instrument for the implementation of the access and benefit-sharing provisions of the Convention on Biological Diversity. It has been so far signed by 41 countries and is expected to be in force early 2014. Once into force, the Protocol will become the primary legal framework dealing with the access to genetic resources at international level. It however does not preclude the adoption of specialized regimes, provided that they are supportive and do not run counter to the objectives of the Convention and the Protocol.

The Protocol reproduces the same fundamental *quid pro quo* underlying the ABS' conception in the CBD, access being the counterpart of benefit-sharing. At the core, the new instrument is built on the assumption that an effective ABS regime can only be achieved if Parties encourage users willing to participate in the conservation effort by favouring access to genetic resources but also by creating incentives to enter into ABS contracts. The Protocol develops a better common understanding on the manner ABS should operate and lays down a set of basic principles and processes Parties will need to implement in their domestic legal order. It relies on the same four main elements of the CBD framework; State sovereignty over their genetic resources, PIC, MAT, and user measures, but significantly fleshes out on how these building blocks should interact for an effective ABS regime.

Under the Protocol, the scope of the ABS international regime is better defined, significantly expanded and limited in several manner. Temporarily, in the absence of explicit contrary intention, the Protocol only covers post-Nagoya accessed genetic resources. Geographically, the Protocol only applies to genetic resources collected within a state's national jurisdiction. 'Utilization of genetic resource' constitutes the major theoretical breakthrough and becomes the cornerstone of the ABS concept. It considerably extends the playing field of the regime by including utilization of derivatives of resources collected *in situ*. Foremost, the utilization trigger has the potential to provide the necessary legal certainty the scheme requires by determining the resources and activities both user and provider legislation should cover. With this meaning, the concept of genetic resources can be consistent throughout all the steps of the whole ABS concept. The Protocol however does not expressly indicate how situations falling outside the scope should be addressed. The effectiveness of the ABS regime will ultimately depend upon Parties' ability to ensure that these limitations are overcome.

Building on the Bonn Guidelines, the Protocol stresses that the exercise of States' sovereign rights in designing access regulation may not run against the needs for certainty of users and user countries. Access legislation therefore evolves towards so-called "international access standards"; a set of minimum requirements provider countries have to incorporate in their access legislation. The Protocol is particularly elaborated on process certainty, but rather elusive with regard to contract certainty, a matter which will need to be dealt mainly at national and transactional level. The establishment of National Focal Point is seen as a crucial provider measure. The Protocol also counts on the elaboration of tools and guidance to increase the certainty and enforceability of MAT, especially the development of model clauses. Lastly, the Protocol calls Parties to establish facilitated access measures for non-commercial research activities.

Benefit-sharing will still occur on the basis of contractual rights *i.e.* through MAT. ABS contract remains the unique legal vehicle to proceed to fair and equitable sharing of the benefits arising from the utilization of genetic resources. If no contract is signed with the user at the time of access, the provider cannot directly go to court and ask the judge to proceed *ex aequo et bono* to the fair and equitable sharing of the benefits. In all hypotheses, a MAT will first need to be concluded. Parties have an overarching, but no self-standing obligation to ensure the fair and equitable sharing of the benefits arising from the utilization of foreign genetic resources within their national jurisdictions. Dispute arising from the implementation of MAT will need to be dealt with in

accordance with the modalities foreseen by the parties to the transaction in the said MAT. The Protocol also calls the Parties to ensure the necessary linkages between benefit-sharing and the developmental environmental ABS objectives.

The emphasis on user side measures is another major change of the new framework. It explicitly recognizes that contractual provisions and provider legislation are alone markedly inadequate tools for a functional ABS regime. Parties need to ensure that PIC was granted and that MAT was established at the time of access. They also have a rather vaguely worded obligation to monitor and enhance transparency on the utilization of genetic resources within their national jurisdictions. The Protocol foresees the creation of a still largely undetermined system of checkpoints and internationally recognized certificate of compliance. Like in the CBD, user side measures are defined in terms of result rather than listing specific actions to reach them. The Protocol therefore leaves room for developing an incentives based ABS paradigm. Parties dispose of all necessary discretion to focus their action on creating the conditions to favour compliance and develop incentives for economic operators to enter into ABS relationships. A Pivotal, but highly complex challenge; the ability of Parties to fulfil the user side obligations will ultimately determine ABS effectiveness, since it has the most direct impact on a large majority of users.

Interestingly, beside these key operational provisions, several Articles encourage the creation of policy and legal mechanisms aiming to support and improve the effectiveness of the new regime. In particular, the use of soft laws and tailor made instruments is a singular characteristic of the Protocol. Development of model clauses, codes of conducts, industry standards, etc. will play a crucial role for the successful implementation of the new framework. Awareness raising and capacity building are more traditional obligations of international law but also have an important task to fulfil in this respect.

The new framework laid down by the Nagoya Protocol is still a ‘work in progress’. Important issues for its operation are still to be resolved by the Intergovernmental Committee, some of it before entry into force. In particular, “Compliance of Parties with their obligations under the Protocol” (Article 30) will require special attention as it often constitutes the major Achilles’ heel of

international environmental law.[234] International cooperation will also be needed to bring to operation the international aspects of the new framework, such as the CHM or the internationally recognized certificate of compliance. These are expected to play a key role for the successful implementation of the ABS regime and attests that a more active role needs to be endorsed by the CBD institutions.

It is clear that not all problems affecting ABS functionality have been resolved in the Nagoya Protocol. In particular, the relationship with the IPR regime and all the contradictions in the legal life cycle of genetic resources have not been resolved. Some theoretical deficits will also continue to undermine the ABS concept. As aforementioned, it was however clear that the Nagoya ABS Protocol could not be the single magical solution addressing all the ABS problems in one hit. Further international work will be needed to ensure the internal and external soundness of the new ABS regime.

Concretely, Parties must now prioritize implementing the Protocol's obligations in their domestic legal orders. The very abstract character of the framework and the lack of experience at international level will incontestably raise a number of challenges, especially for user side measures. Parties will need to be realistic, creative and pragmatic when designing their national measures. Cooperation and coordination at international level will be required for Parties to design and implement mutually supportive legislation. Awareness raising and participation of all relevant actors are also crucial for the elaboration of an effective ABS regime and respecting the rights of all concerned stakeholders.

Legally speaking, in the author's view, the provisions of the Protocol analysed in this research seems to indicate that the new framework should not be seen as a "master of creative ambiguity."[235] The text is worded in flexible and general terms but contains mostly clear requirements which should not lead to divergent interpretations.[236] The Protocol is also impregnated with the traditional debilitative language of international law, such as "as appropriate", "as far as

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[234] Art.30 of the Protocol, not studied in the present research. For more information, see e.g. S. Beyerlin, B. Wolfrum, *Ensuring Compliance with Multilateral Environmental Agreements. A Dialogue between Practitioners and Academia*, Martinus Nijhof Publishers, Leiden/Boston, 2006.
[235] S. Jungcurt et al, supra note 2.
[236] Art. 17 on Monitoring constitutes the exception to this statement and is, indeed, creatively ambiguous.

possible", "proportionate", "encourage", "endeavour", etc. Clearly, this loose and flexible language may jeopardize the successful implementation of Parties' obligations.

Nevertheless, the flexibility and general character of the provisions are also justified by the very wide spectrum of situations to be covered. It is therefore not so surprising that "the negotiations have often led to agreements on principle rather than on real operational rules."[237] Parties have specific national realities and juridical culture. The economic activities regulated are also dramatically different. As expected by Laird, "it is likely that only a broad framework that ensures uniformity of principles and consistency in approach is possible. This generic framework could then be elaborated in different, and flexible, ways for different sectors, types of research (e.g. academic *vs.* commercial, discovery *vs.* development and commercialization), and scales."[238] This remark of Laird, in my view, highlights the "*raison d'être"* of the new framework: it is aiming to develop a platform for collaborative partnerships in R&D in the field of biodiversity conservation.

Overall, the Nagoya ABS Protocol constitutes an important step towards the implementation of the ABS objective of the CBD. One year after the epic failure of the United Nations Framework Convention for Climate Change COP 10 in Copenhagen, it considerably restores the reputation of environmental multilateralism. It shows that the international community is able to overcome deep North-South differences to cope with major global environmental issues. Even if many practicalities remain to be defined, the new framework has potential to achieve the ABS objective of the CBD and thereby contribute to equity, sustainability and biodiversity conservation. If successfully implemented, ABS may develop to be a key instrument in the global governance of biodiversity conservation. Despite all the challenges faced, the negotiation phase of the ABS international regime came to a relatively successful end in Nagoya. The implementation phase has now started, countries and the international community must "switch gears" [239] and concretize the new framework into an on the ground reality.

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[237] R. Billé et al., supra note 5, p.89.
[238] S. Laird, R. Wynberg, supra note 29.
[239] T. Kantai et al., supra note 43.

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Annexes:

ANNEX I: LIST AND BIOGRAPHY OF THE PEOPLE INTERVIEWED

ANNEX II: THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF THE BENEFITS ARISING FROM THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY

ANNEX I: LIST AND BIOGRAPHY OF THE PEOPLE INTERVIEWED

The author tried to take the care to interview people with various interests and position in the debate (civil society, scientific community, political actors). It is worth mentioning that the author did not manage to organise a meeting with a representative of the economic sphere. **Importantly**, the opinions expressed by the persons interviewed do not necessarily reflect the views of the institutions or employers they represent.

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Biographical Statement (found at <http://unu.edu/faculty/geoff-burton>, last accessed 6 September 2011)

Geoff Burton is a Senior Fellow of the UNU Institute of Advanced Studies. He provides expert policy and practical advice to various countries on domestic and international on access and benefit-sharing (ABS). He is a contributing author to Genetic Resources, Traditional Knowledge and the Law – Earthscan, August 2009. He is also the author of numerous papers and presentations on ABS and Traditional Knowledge: most recently delivering conference papers in 2009 in Japan, China, and Brazil. In December 2009 in Jakarta, he chaired the inaugural UNU-IAS ABS Business and Science Dialogue. As the UNU-IAS Fellow, Mr. Burton also champions the cause of taxonomy and biodiversity internationally.

Mr. Burton was formerly Australia's Competent National Authority on Access and Benefit-sharing under the Convention on Biological Diversity (CBD) and Australia's lead negotiator on ABS issues from 1999 to 2006. In 2005, he co-chaired the first round of negotiations within the CBD on the development of an international regime on genetic resources. Within Australia, he developed national ABS policy and law and oversaw its implementation.

Mr. Burton was also policy advisor to the Australian Prime Minister's Science Engineering and Innovation Council Reference Group on Biodiscovery that led to the establishment of the Atlas of Living Australia. In 2008, he conducted a feasibility study on the establishment of a tropical biodiversity and evolution centre for the government of Australia's Northern Territory and Charles Darwin University.

Mr. Matthias Buck
Head negotiator of the EU Commission for the Nagoya ABS Protocol; M. Buck joined the Cabinet of Environment Commissioner Potočnik in January 2011,
European Commission

Mr. Hugo-Maria Schally
Head of Unit International Agreements and Trade,
Directorate-General Environment,
European Commission

Mr. Vassilis Koutsiouris
Desk Officer for ABS,
Directorate-General Environment,
European Commission

François Meienberg,

The Bern declaration,

The Berne Declaration is a Swiss non-governmental organization with 20'000 members. Through research, public education and advocacy work, it has promoted more equitable, sustainable and democratic North-South relations since 1968.

ANNEX II: THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY,

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

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

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

Recalling further Article 15 of the Convention,

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

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

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

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

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

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

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

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

Recognizing that an innovative solution is required to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Have agreed as follows:

ARTICLE 1

OBJECTIVE

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

ARTICLE 2

USE OF TERMS

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

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

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

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

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

(e) "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

ARTICLE 3

SCOPE

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

ARTICLE 4

RELATIONSHIP WITH INTERNATIONAL AGREEMENTS AND INSTRUMENTS

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

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

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

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

ARTICLE 5

FAIR AND EQUITABLE BENEFIT-SHARING

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

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

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

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

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

ARTICLE 6

ACCESS TO GENETIC RESOURCES

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

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

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

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

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

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

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

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

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

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

(i) A dispute settlement clause;

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

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

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

ARTICLE 7

ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

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

ARTICLE 8

SPECIAL CONSIDERATIONS

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

(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified

measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;

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

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

ARTICLE 9

CONTRIBUTION TO CONSERVATION AND SUSTAINABLE USE

The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

ARTICLE 10

GLOBAL MULTILATERAL BENEFIT-SHARING MECHANISM

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

ARTICLE 11

TRANSBOUNDARY COOPERATION

1. In instances where the same genetic resources are found *in situ* within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.

2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

ARTICLE 12

TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

1. In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.

2. Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.

3. Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:

(a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;

(b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and

(c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.

4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

ARTICLE 13

NATIONAL FOCAL POINTS AND COMPETENT NATIONAL AUTHORITIES

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:

(a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;

(b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and

(c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

The national focal point shall be responsible for liaison with the Secretariat.

2. Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.

5. The Secretariat shall make information received pursuant to paragraph 4 above available through the Access and Benefit-sharing Clearing-House.

ARTICLE 14

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE AND INFORMATION-SHARING

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.

2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant

to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:

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

(b) Information on the national focal point and competent national authority or authorities; and

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

3. Additional information, if available and as appropriate, may include:

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

(b) Model contractual clauses;

(c) Methods and tools developed to monitor genetic resources; and

(d) Codes of conduct and best practices.

4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

ARTICLE 15

COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

ARTICLE 16

COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING FOR TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.

2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

ARTICLE 17

MONITORING THE UTILIZATION OF GENETIC RESOURCES

1. To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:

(a) The designation of one or more checkpoints, as follows:

(i) Designated checkpoints would collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate;

(ii) Each Party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance;

(iii) Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;

(iv) Check points must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization.

(b) Encouraging users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements; and

(c) Encouraging the use of cost-effective communication tools and systems.

2. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.

4. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

(a) Issuing authority;

(b) Date of issuance;

(c) The provider;

(d) Unique identifier of the certificate;

(e) The person or entity to whom prior informed consent was granted;

(f) Subject-matter or genetic resources covered by the certificate;

(g) Confirmation that mutually agreed terms were established;

(h) Confirmation that prior informed consent was obtained; and

(i) Commercial and/or non-commercial use.

ARTICLE 18

COMPLIANCE WITH MUTUALLY AGREED TERMS

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:

(a) The jurisdiction to which they will subject any dispute resolution processes;

(b) The applicable law; and/or

(c) Options for alternative dispute resolution, such as mediation or arbitration.

2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

3. Each Party shall take effective measures, as appropriate, regarding:

(a) Access to justice; and

(b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.

4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.

ARTICLE 19

MODEL CONTRACTUAL CLAUSES

1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

ARTICLE 20

CODES OF CONDUCT, GUIDELINES AND BEST PRACTICES AND/OR STANDARDS

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.

ARTICLE 21

AWARENESS-RAISING

Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues. Such measures may include, *inter alia*:

(a) Promotion of this Protocol, including its objective;

(b) Organization of meetings of indigenous and local communities and relevant stakeholders;

(c) Establishment and maintenance of a help desk for indigenous and local communities and relevant stakeholders;

(d) Information dissemination through a national clearing-house;

(e) Promotion of voluntary codes of conduct, guidelines and best practices and/or standards in consultation with indigenous and local communities and relevant stakeholders;

(f) Promotion of, as appropriate, domestic, regional and international exchanges of experience;

(g) Education and training of users and providers of genetic resources and traditional knowledge associated with genetic resources about their access and benefit-sharing obligations;

(h) Involvement of indigenous and local communities and relevant stakeholders in the implementation of this Protocol; and

(i) Awareness-raising of community protocols and procedures of indigenous and local communities.

ARTICLE 22

CAPACITY

1. The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations. In this context, Parties should facilitate the involvement of indigenous and local communities and relevant stakeholders, including non-governmental organizations and the private sector.

2. The need of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition for financial resources in accordance with the relevant provisions of the Convention shall be taken fully into account for capacity-building and development to implement this Protocol.

3. As a basis for appropriate measures in relation to the implementation of this Protocol, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition should identify their national capacity needs and priorities through national capacity self-assessments. In doing so, such Parties should support the capacity needs and priorities of indigenous and local communities and relevant stakeholders, as identified by them, emphasizing the capacity needs and priorities of women.

4. In support of the implementation of this Protocol, capacity-building and development may address, *inter alia*, the following key areas:

(a) Capacity to implement, and to comply with the obligations of, this Protocol;

(b) Capacity to negotiate mutually agreed terms;

(c) Capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing; and

(d) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources.

5. Measures in accordance with paragraphs 1 to 4 above may include, *inter alia*:

(a) Legal and institutional development;

(b) Promotion of equity and fairness in negotiations, such as training to negotiate mutually agreed terms;

(c) The monitoring and enforcement of compliance;

(d) Employment of best available communication tools and Internet-based systems for access and benefit-sharing activities;

(e) Development and use of valuation methods;

(f) Bioprospecting, associated research and taxonomic studies;

(g) Technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable;

(h) Enhancement of the contribution of access and benefit-sharing activities to the conservation of biological diversity and the sustainable use of its components;

(i) Special measures to increase the capacity of relevant stakeholders in relation to access and benefit-sharing; and

(j) Special measures to increase the capacity of indigenous and local communities with emphasis on enhancing the capacity of women within those communities in relation to access to genetic resources and/or traditional knowledge associated with genetic resources.

6. Information on capacity-building and development initiatives at national, regional and international levels, undertaken in accordance with paragraphs 1 to 5 above, should be provided to the Access and Benefit-sharing Clearing-House with a view to promoting synergy and coordination on capacity-building and development for access and benefit-sharing.

ARTICLE 23

TECHNOLOGY TRANSFER, COLLABORATION AND COOPERATION

In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol. The Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, in order to enable the development and strengthening of a sound and viable technological and scientific base for the attainment of the objectives of the Convention and this Protocol. Where possible and appropriate such collaborative activities shall take place in and with a Party or the Parties providing genetic resources that is the country or are the countries of origin of such resources or a Party or Parties that have acquired the genetic resources in accordance with the Convention.

ARTICLE 24

NON-PARTIES

The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-House.

ARTICLE 25

FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism of the Convention shall be the financial mechanism for this Protocol.

3. Regarding the capacity-building and development referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need of developing country Parties, in particular the least developed countries and small island developing States among them, and of Parties with economies in transition, for financial resources, as well as the capacity needs and priorities of indigenous and local communities, including women within these communities.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed countries and small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building and development requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and other resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

ARTICLE 26

CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 29 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its Annex, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat and held concurrently with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held

concurrently with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

ARTICLE 27

SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may serve this Protocol, including upon a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any such decision shall specify the tasks to be undertaken.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by Parties to this Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

ARTICLE 28

SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

ARTICLE 29

MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals and in the format to be determined by the Conference of the Parties serving as the meeting of the

Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement this Protocol.

ARTICLE 30

PROCEDURES AND MECHANISMS TO PROMOTE COMPLIANCE WITH THIS PROTOCOL

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under Article 27 of the Convention.

ARTICLE 31

ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, four years after the entry into force of this Protocol and thereafter at intervals determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, an evaluation of the effectiveness of this Protocol.

ARTICLE 32

SIGNATURE

This Protocol shall be open for signature by Parties to the Convention at the United Nations Headquarters in New York, from 2 February 2011 to 1 February 2012.

ARTICLE 33

ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after the deposit of the fiftieth instrument as referred to in paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

ARTICLE 34

RESERVATIONS

No reservations may be made to this Protocol.

ARTICLE 35

WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from this Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

ARTICLE 36

AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol on the dates indicated.

DONE at Nagoya on this twenty-ninth day of October, two thousand and ten.

Annex I

MONETARY AND NON-MONETARY BENEFITS

1. Monetary benefits may include, but not be limited to:

   (a) Access fees/fee per sample collected or otherwise acquired;

   (b) Up-front payments;

   (c) Milestone payments;

   (d) Payment of royalties;

   (e) Licence fees in case of commercialization;

   (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;

   (g) Salaries and preferential terms where mutually agreed;

   (h) Research funding;

   (i) Joint ventures;

   (j) Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:

   (a) Sharing of research and development results;

   (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;

   (c) Participation in product development;

   (d) Collaboration, cooperation and contribution in education and training;

   (e) Admittance to *ex situ* facilities of genetic resources and to databases;

   (f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;

   (g) Strengthening capacities for technology transfer;

   (h) Institutional capacity-building;

   (i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;

   (j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;

   (k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;

   (l) Contributions to the local economy;

   (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;

   (n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;

   (o) Food and livelihood security benefits;

(p) Social recognition;

(q) Joint ownership of relevant intellectual property rights.

Annex II

WORK PLAN FOR THE INTERGOVERNMENTAL COMMITTEE FOR THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING OUT OF THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY

A. ISSUES FOR CONSIDERATION BY THE INTERGOVERNMENTAL COMMITTEE AT ITS FIRST MEETING

1. The modalities of operation of the Access and Benefit-sharing Clearing-House, including reports on its activities (Article 14, paragraph 4).

2. Measures to assist in the capacity-building, capacity development and strengthening of human resources and institutional capacities in developing countries, in particular the least developed countries and small island developing States amongst them, and Parties with economies in transition, taking into account the needs identified by the Parties concerned for the implementation of the Protocol (Article 22).

3. Measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues (Article 21).

4. Cooperative procedures and institutional mechanisms to promote compliance with the Protocol and to address cases of non-compliance, including procedures and mechanisms to offer advice or assistance, where appropriate (Article 30).

B. ISSUES FOR CONSIDERATION BY THE INTERGOVERNMENTAL COMMITTEE AT ITS SECOND MEETING

5. Development of a programme budget for the biennium following the entry into force of the Protocol.

6. Elaboration of guidance for the financial mechanism (Article 25).

7. Elaboration of guidance for resource mobilization for the implementation of the Protocol.

8. Consideration of rules of procedure for the Conference of the Parties serving as the meeting of the Parties to the Protocol (Article 26, paragraph 5).

9. Elaboration of a draft provisional agenda for the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (Article 26, paragraph 6).

10. The need for and modalities of a global multilateral benefit-sharing mechanism (Article 10).

11. Continued consideration of items taken up at the first meeting of the Intergovernmental Committee, as needed.
