SOUTH CENTRE

POLICY BRIEF

No. 18 | May 2015

The Nagoya Protocol: Main Characteristics, Challenges and Opportunities

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Executive Summary

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 entered into force in October 2014. Its provisions clearly reflect the need for countries to set up access and benefit sharing rules and procedures for the Protocol's implementation at the national level. This policy brief aims at describing the main characteristics of the Protocol and highlights the main elements that developing countries need to bear in mind when considering its ratification and subsequent implementation. Importantly, the Protocol's language empowers countries with considerable policy space that should be considered for the design of domestic access and benefit-sharing rules.

I. Introduction

After six years of negotiations, in 2010 the elaboration of an international instrument on access and benefit-sharing was completed, concluding one of the most significant milestones of international environmental law in the last years. From October 2014, 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 is in force.[1]

The Convention on Biological Diversity (CBD) pursues the following three objectives: (i) the conservation of biological diversity, (ii) the sustainable use of its components and (iii) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (article 1 CBD). The Nagoya Protocol progresses in the implementation of the third objective.

The CBD advances the principle of national sovereignty of States over their natural resources. Such recognition resulted in a turning point regarding the legal nature of biological resources, which include

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"genetic resources, organisms or parts thereof, or any other biotic component of ecosystems with actual or potential use or value for humanity" (CBD Article 2). The CBD recognized for the first time that States have the authority to determine access to their genetic resources (CBD Article 15). Prior to the adoption of CBD, plant genetic resources were considered as a heritage of mankind being therefore freely accessible. This view is embodied in the FAO International Undertaking on Plant Genetic Resources (IUPGR) of 1983. Nevertheless, in the FAO context, it later recognized that the concept of mankind's heritage, as applied in the IUPGR, is subject to the sovereignty of States over their plant genetic resources (FAO Resolution 3/91). This concept was also extended in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). That said, the CBD and the ITPGRFA are distinct regimes, as the latter specifically applies to access and benefit sharing of plant genetic resources for food and agriculture.

In addition to legally empowering countries to control access to genetic resources, the CBD also defined two conditions to which access can be subject to, if so desired. These conditions are prior informed consent (PIC) and the establishment of mutually agreed terms (MAT). These conditions are meant to provide a basis for ensuring the third objective of the CBD, the fair and equitable benefit sharing arising out of the utilization of genetic resources. The inclusion of benefit sharing as an objective of the Convention responded to demands by developing countries. While developing countries were being asked to increase commitments to protect genetic resources, they sought to address a perceived historical imbalance whereby, for decades, they were mainly providers of genetic resources that were mainly exploited by and for the benefit of firms and other users in developed countries.

After CBD entered into force, the international community started building steps for the implementation of the first two objectives but not enough efforts were made to effectively implement the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (ABS). This differentiation can be acknowledged through the various initiatives that encouraged countries to establish measurable targets for the conservation of biodiversity and sustainable use of its components, including genetic resources, as well as in the negotiations for the approval of the different Strategic Plans under CBD. However, as regards benefit sharing the main achievement was the approval of the non-binding Bonn guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization (Decision VI/24).

Developing countries were concerned about the misappropriation of their resources, usually known as 'biopiracy'. Consequently, they demanded for an international regime on access and benefit sharing to be negotiated under the CBD in order to advance on the implementation of the Convention's third objective while providing greater legal certainty for users and providers. In this context, countries started a negotiating process that resulted in the adoption and recent entry into force of the Nagoya Protocol.

The Protocol presents opportunities but also challenges. While rules on access and benefit sharing can and should be designed first and foremost at the national level, the CBD and the Protocol provide an important basis of international agreed rules that apply to all providers and users of genetic resources, in all countries that become a Party to the Protocol. Moreover, the flexibility in the language included in the Protocol provides countries with policy space for the design of domestic policies so as to maximise the benefits that arise from its implementation in accordance with local conditions. The vague language of the Protocol in many of its provisions reflects the extent to which compromises needed to be made in the negotiations to reach an agreed outcome. Hence, since the text may allow diverse interpretations, the interpretation of the Protocol should be carefully considered.

This policy brief describes the main characteristics of the Nagoya Protocol and highlights the core elements that developing countries need to bear in mind when considering its ratification and subsequent implementation.

II. What is the aim of the Nagoya Protocol?

The objective of the Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources (see Box 1). It applies to genetic resources under the scope of the CBD and the benefits arising from the utilization of those resources, as well as traditional knowledge (TK) associated with them.

The Nagoya Protocol expands on the obligations of the CBD on access and benefit-sharing (ABS), to effectively create an international ABS system. The Protocol is a detailed roadmap of internationally agreed principles and rules for the access and utilization of genetic resources and associated traditional knowledge. Through its implementation by governments, it is expected to provide users and providers of genetic resources and holders of traditional knowledge in all countries with greater clarity and certainty of what is permissible or not.

Box 1. What is benefit-sharing?

The notion of benefit-sharing finds its roots in the third objective of the CBD that is 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". The CBD in Article 15.7 affirms that each Party must take measures with the aim of sharing, upon mutually agreed terms, 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 country providing such resources. This is at the core of the Nagoya Protocol.

The goal of benefit-sharing is that users of genetic resources effectively share monetary and non-monetary benefits derived from the access and utilization of those resources with the country providing those resources (countries of origin, see box 2).[2] As regards traditional knowledge associated to those resources, benefits should be shared with the communities that are holders of that knowledge in accordance to the measures that need to be taken to this end at the national level (article 5.2 of the Protocol).

Importantly, it clarifies the measures that countries can take to condition access to genetic resources and associated traditional knowledge, and requires commitments, including on tracking and monitoring of the utilization made of genetic resources and associated traditional knowledge, not only by countries that provide genetic resources but also by user countries, even when the latter choose not to regulate access to their genetic resources or associated traditional knowledge.

The fact that in some areas the agreed language of the Protocol is broad, such as in relation to the scope of the provisions of the Protocol covering derivatives, makes it imperative for countries to introduce an adequate interpretation in their domestic legislation. Fortunately, the Protocol allows countries sufficient policy space to define the details of their ABS laws at the national level.

Box 2. Some relevant definitions

The definitions of the CBD (included in article 2 of the CBD) apply to the Nagoya Protocol. In addition, some terms such as "utilization of genetic resources" and "derivatives" are defined in the Protocol.

- **Biotechnology**: "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use"
- **Country of origin of genetic resources**: "the country which possesses those genetic resources in in-situ conditions"
- **Country providing genetic resources**: "the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country"
- **Derivatives**: "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"
- **Genetic material**: "any material of plant, animal, microbial or other origin containing functional units of heredity"
- **Genetic resources**: "genetic material of actual or potential value"
- **Utilization of genetic resources**: "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"

Due to details that the Protocol contains compared to provisions included in the CBD, it is an important guidance for countries that need to design their national ABS legislations. Furthermore, it gives coun-

tries the possibility of prioritising ABS related issues in their national agendas.

On the other hand, countries that already have ABS legislation would need to evaluate to what extent they will have to adapt their existing legislation to the requirements of the Protocol. Moreover, they will need to discuss what the best approach could be in order to use the policy space provided by the Protocol and, subsequently, decide whether to ratify or not.

Box 3. What is prior informed consent?

Prior informed consent means that a user (researcher, firm, etc.) that seeks access to a genetic resource or traditional knowledge associated to the resource needs to receive express acceptance or permission from the country providing genetic resources (whether or not it is the country of origin of the genetic resource), or an indigenous or local community providing traditional knowledge associated to those resources, as may be the case according to national legislation. The consent is materialised through the issuance of a permit for that access. According to the Protocol, each country can decide whether to regulate access to its genetic resources and how to do it.

The Protocol places responsibility on both provider and user countries to take measures so as to ensure that prior informed consent has been obtained previous to the access to genetic resources and/or the associated traditional knowledge, as well as to guarantee the involvement of indigenous and local communities in that process, when relevant.

The Nagoya Protocol includes additional definitions to those found in the CBD, including for the terms "utilization of genetic resources" and "derivatives". Importantly, the inclusion of such definitions clarifies that the Nagoya Protocol includes under the scope of its obligations utilization of genetic resources and their derivatives. The language of "utilization of genetic resources" refers specifically to the conduct of research and development, including their "derivatives", that is, naturally occurring biochemical compounds even when these do not contain functional units of heredity. Activities that fall outside this scope, such as trade in commodities, are not covered. For legal certainty, it will be important that developing countries introduce these definitions in their national ABS legislation.

III. Main obligations for Parties to implement the Protocol

The Protocol clarifies rights and obligations for both providers and users related to the access to genetic resources and traditional knowledge associated with those resources as well as for benefit-sharing and monitoring of the utilization of genetic resources. Some of the main elements are included below.

III.1. Genetic resources

III.1.a. Access

Based on the principle of sovereignty of States over their natural resources, the fundamental provision of the Protocol with regards to access to genetic resources -article 6- states that access shall be subject to prior informed consent, unless otherwise determined by that Party (See Box 3). This means that prior informed consent is an obligation unless a country decides not to require it.

In particular, countries providing genetic resources that require prior informed consent have some obligations to comply with, as follows:

- Domestic ABS legislation, rules and procedures need to provide legal certainty, clarity and transparency, be fair and non-arbitrary
- Information on how to apply for prior informed consent need to be provided as well as a clear and transparent written decision by a competent national authority (in a cost-effective manner and within a reasonable period of time)
- A permit has to be issued at the time of access, as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms (MAT). This will also be notified to the ABS Clearing-House.

These obligations on providers are meant to facilitate the awareness of the conditions/requirements that users need to comply with prior to accessing

genetic resources in each provider country, which might vary from one to the other.

Prior informed consent is directly connected to the establishment of mutually agreed terms (MAT) for benefit sharing in relation to the utilization of genetic resources and/or associated traditional knowledge. MAT means that the conditions for the access and utilization of the resources and/or traditional knowledge, such as the benefits to be shared from the utilization, have been fairly and equitably negotiated and agreed among the Party providing the resource or traditional knowledge holder and the user. Provider countries must establish clear rules and procedures for the establishment of MAT. These terms refer to the conditions of the 'contract' between provider and user, and may include but are not limited to monetary and other forms of benefit-sharing.

While generally access can be conditioned to PIC and MAT, the Protocol includes a reference to some instances that can benefit from *facilitated access* (article 8). These situations include creating conditions to promote research, including through simplified measures on access for non-commercial research purposes as well as paying due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. It also mandates Parties to consider the importance of genetic resources for food and agriculture in implementing its access and benefit-sharing legislation or regulatory requirements.

III.1.b. Fair and equitable benefit-sharing

The Protocol's language on fair and equitable benefit-sharing is based on CBD's provisions on this matter. Nevertheless, it goes beyond the CBD in two specific points. Firstly, as it provides the opportunity that not only benefits arising from the utilization of genetic resources but also those from 'subsequent applications and commercialization' are shared with the provider country (article 5, see box 4). Secondly, it recognises that in some jurisdictions, genetic resources can be held by indigenous and local communities. In these situations, countries need to establish means to ensure that benefits arising from the utilization of those genetic resources are shared with the communities in a fair and equitable manner. Benefits to be shared are both monetary and non-monetary. A non-exhaustive list of possible benefits is included in the Annex of the Protocol. Conditions and mechanisms for benefit-sharing will be based on MAT between provider and user. Thus, the enhancement of institutional and human capabilities to negotiate

Box 4. Derivatives

The issue of derivatives was at the core of the negotiations for the elaboration of the Protocol. While megadiverse countries wanted them to be explicitly included within the Protocol's scope, developed countries pushed for their exclusion. As can be observed in the text, the term 'derivatives' is only used as part of the definition of biotechnology (article 2). However, a joint interpretation of the term 'utilisation of genetic resources' together with that of 'derivatives' can be understood as including derivatives under the Protocol's scope.[3]

Those tensions can be acknowledged, for example, in the 2014 EU regulation on compliance measures for users from the Nagoya Protocol. The regulation, that establishes rules governing compliance with ABS for genetic resources and associated traditional knowledge, states that definitions of the Nagoya Protocol and CBD apply but only some of them have been transcribed into the specific article dealing with definitions (article 3). While the EU included some of the terms already defined in those instruments and also included some additional definitions, it decided to include that of derivative in the Preamble rather than in article 3. Although it has no specific effects, it demonstrates the tensions around the issue of derivatives.

Also, the temporal scope of the Protocol was highly debated. In this regard, the main controversies were based on the need to clarify what accessions would be affected by the need to comply with benefit-sharing rules emanating from the Protocol. Proposals included making a retroactive applicability of the Protocol previous to CBD's entry into force, or retroactivity from 1992 onwards, or applying the traditional interpretation of the principle of non-retroactivity of treaties in accordance with the Vienna Convention (article 28, Vienna Convention on the law of the treaties). The latter is the one that applies for the Nagoya Protocol. This means that while access to genetic resources made before the entry into force of the Protocol are not covered, countries may decide to include in the scope of national benefit-sharing rules any new utilization of those resources.[4]

beneficial conditions is a central issue to be addressed domestically.

III.2 Traditional Knowledge associated with genetic resources

III.2.a. Access and benefit sharing

Access to and utilization of traditional knowledge associated with genetic resources is also a cross-cutting issue throughout the text. Considering the characteristics of traditional knowledge, i.e. the importance of indigenous and local communities as holders of that knowledge, PIC and the establishment of MAT acquire fundamental importance.

Although provisions on TK associated to genetic resources in the Protocol are not as detailed as for the case of genetic resources, the Protocol substantially improves upon the CBD language. Article 7 of the Protocol, in complementing Article 8(j) of the CBD, requires that Parties take measures, as appropriate, to ensure that TK associated with genetic resources that is held by indigenous and local communities is accessed with PIC or their approval and involvement, and that MAT have been established. This applies to both provider and user countries.

The notion of benefit-sharing related to the utilization of associated traditional knowledge (TK) is another element in which the Protocol reinforces CBD's provisions on TK, by reference to the establishment MAT, following PIC. Moreover, while the CBD only expresses the desire for benefit-sharing to exist for the utilization of TK, the Protocol supersedes that provision and sets a concrete obligation.

Article 12 of the Protocol requires consideration to indigenous and local communities' customary laws, community protocols and procedures with regard to associated TK. It is a big step in which the Protocol advances CBD. However, since the article provides some flexibility, each country needs to decide in accordance with its national legislation whether to implement it and how to do it.

It can be challenging but nonetheless it is of great importance for governments to establish effective mechanisms to ensure that PIC and MAT for benefit-sharing are established among providers and users prior to the access, and utilization of TK associated with genetic resources. Challenges include the fact that the traditional knowledge associated to the genetic resource may be found outside the community, e.g. libraries, repositories, and the geographical location of indigenous or local communities, when they are located in remote areas with no easy access and appropriate communication technologies available. In this regard, it is crucial for governments to work together with indigenous and local communities to find viable options to develop a workable system.

The Nagoya Protocol makes no distinction between TK that is well-known outside the indigenous or local community, from TK that is undisclosed or held secret. Thus, it can be understood that PIC and MAT is required for access to any TK associated to GR to be lawful, though countries can define the matter in national legislation.

III.3. Monitoring and Compliance

One of the most important aspects of the Protocol is that it introduces the obligations on monitoring and compliance. It is the first time that an international instrument includes international rules on monitoring and compliance in user countries on access to and utilization of genetic resources and associated TK.[5]

Article 15 and 16 refers to compliance with domestic ABS legislation or requirements regarding access to genetic resources and associated TK respectively. User and provider countries alike have to introduce measures for ensuring that genetic resources or associated traditional knowledge utilized in their jurisdiction have been accessed in accordance with PIC and that MAT have been established, as required by domestic ABS legislation or regulatory requirements of the country providing genetic resources or associated TK, or where indigenous and local communities providing associated TK are located (articles 15, 16).[6]

Importantly, the Protocol requires that associated TK is accessed in accordance with PIC or with the approval and involvement of indigenous and local communities.

The Protocol also mandates Parties to take measures to address cases of non-compliance with domestic

ABS legislation, and that importance of establishing cooperative procedures and institutional mechanisms to promote compliance with the provisions of the Protocol and to address cases of non-compliance.

Parties are also required to monitor the utilization of genetic resources in their territories, as a means to support compliance, and to enhance transparency on the utilization that is being made of genetic resources (article 17). In this regard, the Protocol obliges countries to establish at least one 'checkpoint' that would be able to collect or receive information on prior informed consent, the source of the genetic resources or the establishment of mutually agreed terms. Nonetheless, no list of possible checkpoints is included in the Protocol. To complete this task, countries providing genetic resources can ask for users to provide this information to the national authorities.

In view of the lack of any indicative list in the Protocol, there is flexibility to designate the checkpoint/s that each country considers more appropriate for the effective completion of the tasks. The only indication provided by the Protocol is that checkpoints should be relevant to the utilization of genetic resources, or to the collection of relevant information at any stage of research, development, innovation, pre-commercialisation or commercialisation.

An option that was discussed during the negotiations prior to the adoption of the Protocol was to explicitly mention patent offices, market approval authorities or research funding institutions as checkpoints.[7] Although no agreement was reached for that inclusion, all options are now available for countries' consideration when implementing the Protocol domestically. For instance, in some countries the responsibility is shared between patent offices and environmental agencies. Likewise, considering the characteristics of each country, in those cases in which genetic resources are regulated by the local governments, additional layers of responsibility exist.

Article 17 only refers to utilization of genetic resources, making no reference to monitor the utilization of associated TK. In this regard, additional international instruments could be considered as a complement of the Protocol's provision. One of those complementary regimes can be the elaboration of a(n) international legal instrument(s) to ensure the effective protection of TK, traditional cultural expressions (TCEs) and genetic resources that has been taking place in WIPO.

Compliance and monitoring are closely related issues because effective compliance requires monitoring. It is of vital importance that both user and provider countries increase their capacity to monitor the utilization of both genetic resources and associated traditional knowledge to effectively implement the ABS system. However, it must also be recognized as a challenge that countries face, in particular developing countries, i.e. in cases when the genetic resources were accessed *ex situ*, the associated TK is not directly attributable to a single indigenous or local community, or in the case of genetic resources shared across-borders, it is difficult to establish when and from where the access to the genetic resource was made.

The utilization of genetic resources includes a wide variety of sectors such as pharmaceuticals, food, agriculture, biotechnology or cosmetics and existing differences between them can, and should, be addressed at the domestic level. For example, in sectors such as agriculture it is sometimes difficult to determine the origin of genetic resources. In particular, considering the relevance that the paradigm of plant genetic resources as a common heritage had for that sector and that exchanges of materials throughout the decades have been multiple, the identification of a country of origin can be something challenging. Furthermore, it is frequent that genetic materials utilized for food and agriculture are stored and conserved *ex situ*, in banks such as CGIAR international collections.

To some extent, it can be interpreted that this kind of situations would fall under the global multilateral benefit-sharing mechanism that is under development. However, article 10 only refers to the utilization of genetic resources and associated TK that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent.

Different dynamics characterise the way in which diverse sectors work. But what does it mean in terms of ABS? Some examples of the characteristics of private activities of two sectors that can be subject to comply with ABS legislation are mentioned below.

- Pharmaceutical sector: Some changes are being acknowledged with regard to the way the phar-

maceutical sector conducts research and development.[8] In the recent years, there has been an increase in the demand for microorganisms moving away from the traditional demand for plants.

- Agricultural sector: It is one of the sectors that continue being more dependent on access to genetic resources.[9] Again, the smaller companies are those that require access to public collections since the large ones usually have their own collections of plant genetic resources. However, there is an additional aspect that can affect or regulate the exchange of materials in this sector. In this regard, it is relevant to highlight that the Nagoya Protocol recognises in its Preamble the role of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)[10] of the Food and Agriculture Organization and its multilateral ABS system. In addition, article 4 states that the Protocol shall not apply for the specific genetic resources covered by a specialised international ABS instrument. This means that plant genetic resources for food and agriculture under the scope of the ITPGRFA may be exempted from the establishment of MAT under the Protocol. Therefore, national legislation frameworks should clarify the scope of both agreements so to create a mutually supportive relationship between them.

IV. Intellectual Property aspects in the Nagoya Protocol

The tensions and links that exist between genetic resources, technological capacities and intellectual property have long been recognized in international debates, i.e. Brundtland Report (1987). Whereas the linkages between biodiversity and intellectual property have been expressly recognised in the CBD and the FAO ITPGRFA, processes are underway in other international organisations such as the World Trade Organization (WTO) and World Intellectual Property Organization (WIPO) on the relationship between these two areas. However, no decisions have been adopted so far, i.e. in the WTO discussions on how to create a mutually supportive relationship between the CBD and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the protection of traditional knowledge, and in the WIPO on how to create an effective system of protection for genetic resources, traditional knowledge and traditional cultural expressions.

The controversies around intellectual property (IP) arise due to tensions between the interests of providers; actors that have legal rights to control access to genetic resources and associated traditional knowledge, i.e. indigenous communities, States' institutions, and the interests of users whose activities include research, development and commercialization of genetic resources, including their derivatives. Such tensions arise when genetic resources or associated TK are granted IPR protection. IP rights (IPRs), on the one hand, can serve as a tool to generate economic benefits for the owner of the IPR-protected goods. On the other hand, IPRs exclude third parties from the unauthorized use of the protected good for as long as the period of protection of the IPR lasts, even when a third party may have contributed to the conservation of, or provided important knowledge for the subsequent utilization of the genetic resources.

During the negotiations of the Nagoya Protocol, many developing countries pushed for concrete language on IP. Proposals included to recognize the role of patent offices acting as checkpoints in order to assist in ensuring compliance with national ABS laws, and in particular to introduce a disclosure requirement in patent and other IPRs applications so as to make explicit the country of origin of genetic resources and associated TK and the information contained in the MAT. Other proposals included the use of patent databases to track both the utilization of genetic resources as well as the benefit-sharing obligations declared in the MAT. Although measures concerning IPRs are not directly mentioned in the final text of the Protocol, these can be included as part of the implementation of the Protocol where relevant, for example as part of measures for monitoring and compliance.

It is thus important that in national legislation, countries introduce specific language to designate IP offices as a checkpoint (among other checkpoints, i.e. customs offices) for the purposes of monitoring and compliance with ABS legislation, consistent with article 17 of Nagoya. The function of checkpoints would be to receive information concerning the utilization of genetic resources or their derivatives. This would be done through the mandatory requirement to disclose in a patent or other IPR applications, i.e.

Box 5. First session of the Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol

Following its entry into force on 12 October 2014, the First meeting of the Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol (NP COP/MOP1) was held from 13-17 October 2014 in Pyeongchang, Republic of Korea. The implementation of the Protocol requires many areas to be developed through national legislation while others need to be further strengthened at the international level. In this regard, diverse decisions were adopted in the NP COP/MOP1.

Some progress was made in particular areas in which decisions were adopted. In brief, the following bodies were established:

- Informal advisory committee (IAC) for the implementation of the Access and Benefit-sharing Clearing-house (ABS-CH)
- Compliance Committee
- Informal advisory committee to provide advice to the Executive Secretary on matters related to the assessment of the effectiveness of the strategic framework for capacity-building and development to support the effective implementation of the Protocol

Also, some instruments were adopted:

- Modalities related to the operation of the ABS-CH
- Guidelines for the Interim National Report on The Implementation of the Nagoya Protocol
- Cooperative procedures and institutional mechanisms to promote compliance with the Nagoya Protocol and to address cases of non-compliance
- Strategic framework for capacity-building and development to support the effective implementation of the Protocol

Discussions on a global multilateral benefit-sharing mechanism for situations in which the utilization of genetic resources and associated TK occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent did not lead to any substantive outcome. In contrast, the decision adopted[11] recognises that further discussions are needed to reach a common understanding on this matter.

Concerning the financial mechanism of the Protocol, it was decided that all developing countries, in particular Least Developed Countries, Small Island Developing States and countries with economies in transition, are eligible for funding by the Global Environment Facility (GEF) if: (i) they are parties to the Protocol; or (ii) they are parties to the CBD and provide a clear political commitment towards becoming parties to the Protocol (accompanied by indicative activities and expected milestones submitted in writing to the Secretariat, for up to four years after the Protocol's entered into force).

Some progress was made through the establishment of new institutions that will guide and develop some of the work that needs to be done for the Protocol's implementation. Nonetheless, once these arrangements start delivering concrete outcomes, there will be a better idea of how the implementation is framed at the global level.

plant variety protection applications, the source of the genetic resources or derivatives.

V. Other Obligations in the Nagoya Protocol

The Nagoya Protocol requires that certain institutional arrangements are put in place, particularly to facilitate transparency. Every Party has to designate a national focal point as well as a competent national authority/ies for activities that range from communication with the Secretariat of the Protocol to the implementation of the Protocol itself (article 13). Additionally, it is necessary to make available relevant information for the ABS clearing-house mechanism. This includes legislative, administrative and policy measures on ABS, information on the national focal point and competent national authority/ies and the permits issued at the time of access as evidence of the decision to grant PIC and of the establishment of MAT.

It is worth noting that while the Protocol leaves many areas to be developed at the domestic level, various arrangements still need to take place in the

international arena to provide the necessary basis for an ease implementation. The evolvement of these aspects will mainly take place through the decisions made by the Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol (COP/MOP) that in its first session established some new arrangements to conduct those tasks (see Box 5). As a result, the active participation in the deliberations taking place at the international level is also of striking importance as a means to shape the first steps of this long pathway.

VI. Policy Recommendations

The Nagoya Protocol is an important international instrument on ABS under the CBD. The Protocol came into force when the fifty necessary ratifications of States were achieved in 2010. However, many of the provisions of the Protocol require implementation in national legislation. Thus, countries need to develop and/or revise ABS regulations (and related laws, i.e. IP laws) in accordance to the Protocol and in seeking to materialise the expected benefits of an international regime on ABS that creates more certainty for both providers and users of genetic resources and associated traditional knowledge.

To conclude, some elements are highlighted and recommendations provided to encourage discussions at the national level on what the most appropriate ways to implement the Protocol might be:

- The Protocol does not replace **the need of countries to develop legislation on ABS**.[12] It is rather a basis for its development. Attention needs to be given to the interpretation of the Protocol provisions so as to maximise the policy space provided by them, and in the measures adopted for implementation. A careful review of the countries' interests of both providers and users of genetic resources and associated traditional knowledge is necessary.

- **Dynamics that characterise the exchange of materials within each sector** have to be understood. Some studies[13] indicate that whereas large companies accessed materials in the past and in some cases have their own collections of plant genetic resources, different trends may characterise other resources such as marine and terrestrial microorganisms. This reality, while increasing the difficulties to monitor the utilization of genetic resources and associated TK, also highlights the importance of being conscious about who the targeted actors are in each case so as to design the most appropriate and effective measures.

- Frequently, many governmental agencies are directly or indirectly involved in the implementation of genetic resources related policies. **It is thus imperative that different ministries and departments coordinate and cooperate between them** for the successful implementation of ABS measures.

- It is important for countries providing genetic resources and associated TK to **raise awareness about their domestic ABS rules** so that all potential providers, i.e. indigenous and local communities, gene banks, as well as users are aware of the conditions that they must comply with. Developing countries have to make use of the provisions of the Protocol in this matter.[14]

- **Capacity-building** is central to create an appropriate institutional base for the implementation of the agreement. In particular, to empower providers to negotiate with potential users for the access based on PIC and for the establishment of MAT for benefit-sharing.

- **Developing countries should actively participate in the continued deliberations taking place at the international level** with regards to the implementation of the Nagoya Protocol, provisions where follow-up by the COP MOP is necessary, and related processes in other international fora, particularly the WTO, WIPO and FAO. In particular, experiences of the implementation at the national level should be shared so to facilitate a smooth implementation of the Protocol following its entry into force**.**

Endnotes

1 As indicated in Article 33 of the Protocol, it was necessary that fifty States or regional integration economic organizations ratified the Protocol for its entry into force. To date, it has fifty-seven Parties namely: Albania, Belarus, Benin, Bhutan, Botswana, Burkina Faso, Burundi, Cambodia, Comoros, Côte d'Ivoire, Democratic Republic of Congo, Denmark, Dominican Republic, Egypt, Ethiopia, Europe-

an Union, Fiji, Gabon, Gambia, Guatemala, Guinea, Guinea-Bissau, Guyana, Honduras, Hungary, India, Indonesia, Jordan, Kenya, Lao People's Democratic Republic, Lesotho, Madagascar, Malawi, Marshall Islands, Mauritius, Mexico, Micronesia (Federated States of), Mongolia, Mozambique, Myanmar, Namibia, Niger, Norway, Panama, Peru, Rwanda, Samoa, Seychelles, South Africa, Spain, Sudan, Switzerland, Syrian Arab Republic, Tajikistan, Uganda, United Arab Emirates, Uruguay, Vanuatu and Vietnam.

2 The "country providing genetic resources" and the "country of origin" are two distinct concepts. Both terms are defined in the CBD and those definitions apply for the Nagoya Protocol (See Box 2).

3 Correa, Carlos (2011), Implications for BioTrade of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (UNCTAD/DITC/TED/2011/9), United Nations.

4 Ibid.

5 Although the Protocol refers to Parties in generic terms, the content of the provisions make user countries as important actors for the implementation of articles 15 and 16.

6 For instance, the European Union has recently approved legislation to address the obligations that users of genetic resources and associated TK have under the Nagoya Protocol (For details, see Regulation (EU) No 511/2014).

7 See document UNEP/CBD/COP/10/5/Add.4 (page 27). Available at: http://www.cbd.int/doc/meetings/cop/cop-10/official/cop-10-05-add4-en.pdf

8 Laird, Sarah (2013), Bioscience at a Crossroads: Implementing the Nagoya Protocol on Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: The Pharmaceutical Industry, Montreal: Secretariat of the Convention on Biological Diversity. Available at: https://www.cbd.int/abs/doc/protocol/factsheets/policy/abs-policy-brief-pharma-web2-en.pdf

9 Laird, Sarah and Rachel Wynberg (2012), Bioscience at a Crossroads: Implementing the Nagoya Protocol on Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change, Montreal: Secretariat of the Convention on Biological Diversity. Available at: https://www.cbd.int/abs/doc/protocol/factsheets/policy/policy-brief-01-en.pdf

10 The ITPGRFA has 134 Contacting Parties. The number corresponds to the available information in the ITPGRFA's website as of 1 March 2015

11 See document UNEP/CBD/NP/COP-MOP/1/L.9

12 Cabrera Medaglia, Jorge, Frederic Perron-Welch and Olivier Rukundo (2012), Overview of national and regional measures on access to genetic resources and benefit-sharing: Challenges and Opportunities in Implementing the Nagoya Protocol, 2nd Edition, Montreal: Centre for International Sustainable Development Law.

13 Laird and Wynberg (2012)

14 Chege Kamau, Evanson, Bevis Fedder and Gerd Winter (2010), 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*, pp. 246-262. Available at http://www.lead-journal.org/content/10246.pdf

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