

**IMPLEMENTATION OF ACCESS AND BENEFIT SHARING AND THE  
NAGOYA PROTOCOL IN LATIN AMERICA AND THE CARIBBEAN:  
CURRENT SITUATION, LEGISLATIVE AND POLITICAL CHALLENGES 3  
YEARS AFTER ITS ENTER INTO FORCE.**

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## **IMPLEMENTATION OF ACCESS AND BENEFIT SHARING AND THE NAGOYA PROTOCOL IN LATIN AMERICA AND THE CARIBBEAN: CURRENT SITUATION, LEGISLATIVE AND POLITICAL CHALLENGES 3 YEARS AFTER ITS ENTER INTO FORCE.**

During the drafting process of the Convention on Biological Diversity (CBD), the negotiation of the provisions on sharing of benefits derived from the utilization of genetic resources (ABS), were conceived as necessary for the incorporation of traditional issues in the field of biodiversity<sup>2</sup> (conservation and sustainable use). However, there is widespread recognition - particularly among developing countries - that full compliance with the Third Objective of the CBD (fair and equitable distribution of benefits) has yet to materialize or at least not to the extent that was expected.<sup>3</sup> Some of the reasons for this perception are<sup>4</sup>:

Frustration due to the scarce economic and non-economic benefits (monetary and non-monetary) derived from bioprospecting projects and the implementation of ABS initiatives and partnerships more generally.

The difficulties in finding cost-effective legal solutions to address cases of illegal access, misappropriation or "biopiracy" - at the country and community levels, and especially in Latin America, Asia and Africa, - within the framework of national ABS legislation or in the context of intellectual property law. Cases such as Maca in Peru have frequently been cited, among many others, as justification for reforming the operation of intellectual property rights systems, especially patents, which are one of the main causes of claims about misappropriation or biopiracy.

Also, although the CBD establishes obligations for the Parties to take measures to fairly and equitably share the benefits from the utilization of genetic resources (Article 15.7), prior to the conclusion of the negotiations of the Nagoya Protocol only developing countries had issued regulations on ABS. The nations where pharmaceutical, biotechnological, cosmetic or agricultural companies operate (largely developed countries) had not promulgated the corresponding regulations to ensure the sharing of benefits and comply with their legally binding international obligations. The absence - or limited presence - of the so-called "user country measures" has been criticized as one of the reasons for the high transaction costs and the highly controlling nature of the current access legislation. The importance of such measures<sup>5</sup> is highlighted by the cross-border nature of ABS's business

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<sup>2</sup>Cfr Gloyka, L., Burhenne-Guilmin, F. y Synge, H, *A Guide to the Convention on Biological Diversity*, UICN, Gland, Switzerland y Cambridge, U.K., 1994

<sup>3</sup>Cabrera Medaglia, Jorge and Lopez Silva Christian, *Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty*. IUCN, Bonn, 2006

<sup>4</sup>See Cabrera Medaglia, Jorge, *El Régimen Internacional de Acceso y Distribución de Beneficios: Elementos, progreso y recomendaciones*, UICN, Quito, 2006

<sup>5</sup>Cfr. Barber, Charles, et al, *User Measures: options for developing measures in User Countries to implement the access and benefit sharing provisions of the Convention on Biological Diversity*, UNU/IAS, Japan, 2003, Godt, Christine, *Enforcement of Benefit-sharing duties in User Countries* y Isozaki, Hiroji, *Enforcement of ABS agreements in*

relationships<sup>6</sup> and the inadequacy of national laws and regulations when samples, information or associated traditional knowledge on genetic resources are transferred out of the country that provided them. This lack of "user measures" was one of the driving forces behind the negotiation of the Nagoya Protocol and for establishment of "compliance measures" (see Articles 15-18 of the Protocol). Now, several developed countries have enacted regulations to implement the Protocol, incorporating "compliance measures" to support the legislation of the provider countries (see examples in the ABS-Clearing House [www.cbd.int](http://www.cbd.int), particularly those established by member countries of the European Union<sup>7</sup>, Norway and Switzerland)

ABS relationships are characterized by the lack of trust between the various actors involved in these processes. This is an unfavorable context for the development of negotiations, both for international level agreements between countries and for smaller scale contracts between providers and users of genetic resources and associated traditional knowledge.

In response to these difficulties in the proper implementation of the Convention's ABS objectives, and after more than six years of negotiations and four years since its adoption in the 10<sup>th</sup> Conference of the Parties to the Convention in 2010, the Nagoya Protocol became fully effective in October 13 of 2014, when it was ratified by 50 countries. As of February 2018, approximately 104 nations are Parties to the Protocol.

The Nagoya Protocol (NP)<sup>8</sup> represents a milestone in the search for legal and political solutions regarding the use of genetic resources (GR) and the fair and equitable sharing of benefits derived from their utilization as well as the traditional knowledge (TK) associated with these resources. The NP responds to long-standing demands from developing countries, including several in Latin America and the Caribbean. It presents great challenges and opportunities- especially in a region with high biological and cultural diversity

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User States, ambos en Kamau, Evanson y Winter, Gerd, Genetic Resources, Traditional Knowledge and the Law. Solutions for benefit-sharing, Earthscan, 2009.

<sup>6</sup>Cfr. Young, Tomme, *Genetic Resources and Utilization of Genetic Resources: a legislative view*, documentopresentado al Taller Internacional de Expertos sobre Acceso a Recursos Genéticos y Distribución de Beneficios, Cuernavaca, México, Octubre del 2004.

<sup>7</sup> For example, the European Union has regulated these measures through Regulation No. 511/2014 of the Council's Parliament of April 16, 2014 (and other supplementary instruments developed). Subsequently, the EU has developed other complementary measures to facilitate the application of the legal framework.

<sup>8</sup> On the Protocol see: Mathias Buck, and Clare 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*" (2011) 20 RECIEL; Union for Ethical Biotrader, *Nagoya Protocol on Access and Benefit Sharing*, Technical Brief, 2010; GurdialNijar, "*The Nagoya Protocol on Access and Benefit-Sharing of Genetic Resources: analysis and implementation options for developing countries*" South-Centre, Research Paper No. 36, march 2011; Sebastian Oberthur and Rosendal Kristin ( eds) *Global Governance of Genetic Resources: Access and benefit sharing after the Nagoya Protocol*, Routledge Research in International Environmental Governance, 2013; Thomas Greiber et al, *Explanatory Guide on the Nagoya Protocol*, IUCN Legal Paper No. 32, Bonn, 2012; Evanson Kamau, Bevis Fedder and Gerd 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*" (2011) 6(3) Journal of Environment and Development; Meyer, Hartmut et al, *Nagoya Protocol on Access to Genetic Resources and the Equitable Sharing of Benefits Arising from Their Utilization: Background and Analysis*, Berne Declaration and Third World Network, 2013 y Cabrera Medaglia Jorge, La implementación del Protocolo de Nagoya en ALC: retos y desafíos. CISDL, Montreal, Diciembre del 2015

and important scientific capacities, albeit with disparities in capacities - to generate a sustainable use of genetic resources and associated traditional knowledge. Its objective is the "fair and equitable sharing of the benefits arising from the utilization of genetic resources, including through appropriate access to genetic resources and through the appropriate transfer of relevant technologies, taking into account all rights over these resources and technologies and through appropriate financing, thus contributing to the conservation of biodiversity and the sustainable use of its components"<sup>9</sup> The NP contains a high degree of ambiguity and flexibility in its main components, possibly because this was the only way to reach an agreement on its content. These flexibilities also involve challenges for translating the text provided in the NP into national actions. Among other aspects, the NP covers the following issues: scope of application; relationship with other international agreements and instruments; fair and equitable sharing of benefits; access to genetic resources; access to traditional knowledge associated with genetic resources; special considerations; contribution to conservation and sustainable use; traditional knowledge associated with genetic resources; cross-border cooperation; compliance with the ABS and associated TK frameworks of the provider countries; monitoring the use of genetic resources; model clauses and codes of conduct; capacity building; public awareness; and transfer of technology and cooperation and administrative and institutional components of the agreement.

Since its entry into force, two Meetings of the Parties (known as COP / MOP) have been held, which have addressed aspects such as: capacity building; awareness raising, model clauses and codes of conduct; the multilateral mechanism for the sharing of benefits (need and possible modalities); operation of the clearing house mechanism (ABS-CHM); compliance with the Protocol; reporting; relationship with other bodies of the Convention; financing and mobilization of resources; and the impact of "genetic information digital"<sup>10</sup> on the objectives and principles of the Protocol, among others.<sup>11</sup>

Three years after its entry into force and almost eight years since its adoption, the following analysis reviews the main features of the current drafting, design and implementation of the ABS legal frameworks in the region, excluding the English-speaking Caribbean countries<sup>12, 13</sup>.

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<sup>9</sup> Nagoya Protocol on Access to Genetic Resources and Benefit-sharing, article 1.

<sup>10</sup> Decision XIII / 16 of the COP decided to establish a process to consider the implications of Digital Sequence Information (Genetic information) on the objectives of the CBD, including the establishment of an Ad Hoc Expert Group and the elaboration of a Technical Report. Similarly, the COP-MOP of the Nagoya Protocol, Decision 2/14, referred to the analysis of the implications of the use of Digital Genetic Information on the objective of the Protocol. The respective decisions would be taken at COP XIV and COP-MOP 3. See the Report prepared by the Experts and the comments received by the countries and other organizations at [www.cbd.int](http://www.cbd.int)

<sup>11</sup> See on these issues the web of the Protocol where there are references to the Decisions, processes and activities in progress. <https://www.cbd.int/decisions/np-mop>

<sup>12</sup> For the case of 8 English-speaking Caribbean countries, a GEF Project executed by the International Union for the Conservation of Nature (IUCN) is being implemented, which includes capacity building and the development of national regulatory frameworks, among other actions, called, "Advancing the Nagoya Protocol in Countries of the Caribbean Region". Also, between 2012 and 2014, the "Strengthening the Implementation of ABS in Latin America and the Caribbean" Project, which covered 8 nations, was executed (IUCN / UNEP).

**Increased cooperation for the drafting or amendment of ABS regulatory frameworks, capacity building, and awareness-raising at the different levels.** The adoption of the NP constituted a milestone in generating capacity building initiatives that usually include: the elaboration or amendment of regulatory frameworks, the building or improvement of capacities of the different actors - including non-governmental organizations, research centers and universities, the private sector and local communities and indigenous peoples, the promotion of the bio-community (often called biocultural) protocols mentioned in the NP, and support for concrete research and development projects that seek to generate new products and processes derived from the use of genetic resources or associated traditional knowledge. These have been financed mainly by the Global Environmental Fund (GEF) and the German Cooperation Agency (GIZ) and cover regional projects such as<sup>14</sup> the ABS Program in Central America and the Dominican Republic (known as ABS / CCAD / GIZ program) and the UNDP project “Strengthening of Human Resources, Legal Frameworks and Institutional Capacities for the Implementation of the Nagoya Protocol” (known as the “Global ABS Project”) which includes 25 countries, 6 from the region (Honduras, Panama, Colombia, Ecuador, Uruguay and the Dominican Republic). At the national level, projects have been developed, already completed, or are close to completion, in Mexico, Guatemala, Costa Rica, Panama, Colombia, Peru, Brazil, Ecuador and Argentina, among others. This set of initiatives should contribute significantly to the development and reform of ABS regulatory frameworks, one of the critical steps for the effective implementation of the CBD and the Protocol.

**Launch of initiatives to establish regulatory frameworks in ABS.** In terms of legislation, some ABS regulations have been in place since 2010, though in most cases they are not in full compliance with the NP. There are several drafts and regulatory initiatives underway. The most relevant examples are:<sup>15</sup>

- Mexico: based on legal instruments and pre-existing institutional competencies, 6 national competent authorities (NCA) have been appointed to carry out the

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<sup>13</sup> At the international level, some actions have been taken to share experiences of possible national implementation, see the Report of the "International Symposium on Domestic Measures to Implement Obligations Under the Nagoya Protocol". Summary Report, United Nations University, Tokyo, March 8, 2012 and more recently the Dialogue promoted by the government of Germany on national measures carried out on the Island of Vilm in August 2017 available at the NP web site.

<sup>14</sup> See for a description until 2016 of the most important capacity-building activities, the document prepared by the Secretariat of the Convention on Biodiversity, Overview of capacity-building and development initiatives providing direct support to countries for the implementation of the Nagoya Protocol, UNEP / CBD / NP / COP-MOP / 2 / INF / 6 of October 31, 2016.

<sup>15</sup> This is not an exhaustive list of the actions undertaken post-Nagoya. Resolutions or administrative measures have been omitted e.g. that designate a body as NCA to issue permits or others of similar nature, such as the generation of technical manuals. Likewise, in subsequent sections of this document, specific measures taken by the countries on particular topics are addressed. See on this point Cabrera Medaglia, Jorge, Diagnosis of the regulatory frameworks of ABS and contractual experiences in the member countries of ALADI, Aladi, Montevideo, 2018 and Ruiz, Manuel, Access to genetic resources and fair and equitable sharing of benefits : political and regulatory framework in Central America and the Dominican Republic; CCAD / GIZ, El Salvador, 2016.

procedures (including processing applications) and take the respective decisions on access in conformity with their legal frameworks. There is a draft General Biodiversity Law approved by the Senate in December 2017, currently pending adoption by the Chamber of Deputies, that regulates ABS and associated traditional knowledge and a specific, detailed regulation on ABS driven by the Inter-Secretarial Group created in 2015 is planned for the future in order to implement the Protocol;

- Guatemala: based on existing legal provisions, access permits have been granted (notified to ABS-CHM and became the internationally recognized certificate of compliance) and a Biodiversity Law that would contain detailed ABS regulations is being prepared;
- Honduras: a draft - in early stages of drafting - of the Biodiversity Law that would contemplate issues related to the NP is being worked on;
- El Salvador: a specific chapter of ABS within the draft regulations of the Wildlife Conservation Law has been formulated and a national policy on the matter is being prepared. It is expected that El Salvador will have specific regulations once the Nagoya Protocol has been at the national level;
- Costa Rica: already had a regulatory framework in place prior to the NP adoption, has promulgated a regulation (Decree No. 39341 of 2016) to establish the sanctioning procedure on ABS that is provided by the Biodiversity Law of 1998, and has established an electronic platform for the processing of different access requests, among other actions;
- Nicaragua: although the Biodiversity Law No. 807 of 2012 was approved after the NP adoption, the ABS provisions - in general - do not incorporate many of the innovations required by it, possibly due to the fact that different drafts of the Law have been discussed for many years before;
- Panama: several ABS provisions of Law No 41 (General Law of the Environment) were reformed by Law No. 25 of 2015 and the country is reviewing the Decree No. 25 of 2009 on ABS to adapt it to the Protocol. Consultation workshops were held at the end of 2017;
- Ecuador: after the adoption of the NP, numerous secondary legislation has been issued that includes, among other provisions of relevance: Regulation No. 905 of 2011 on access to genetic resources that implements Decision 391; Resolution No. 034 that regulates the procedure for signing Framework Contracts for Access to Genetic Resources of February 2015; Resolution No. 99 of 2012 that creates the Public Registry of Access Applications; and Ministerial Resolution No. 024 of March 9, 2016, which regulates the delegation of the signature or subscription of the Framework Contracts to the Undersecretary of Natural Heritage. Subsequently, some general ABS provisions were incorporated in the

Organic Code of Environment (COA) to ratify the sovereignty of the State over genetic resources, clarify the separation between rights over biological material and rights over genetic material, and determine the strategic nature of GR for national development and point out some limitations for access activities (articles 72 to 74, articles 24.7 and 30 paragraphs 4, 5, 6 and 10). The Organic Code of the Social Economy of Knowledge, Creativity and Innovation (COESC), under Title VI, regulates more precisely the subject of traditional knowledge associated with genetic resources and gives new competences to the Secretary of Education, Science, Technology and Innovation (SENESCYT); and the Integral Organic Code of Criminal Law of 2014, article 248 (crimes against the resources of the national genetic patrimony). Finally, through the Executive Decree, No. 245 of 2014, the National Institute of Biodiversity (INABIO) is created under the Ministry of Environment, which currently has the authority to negotiate access contracts for commercial purposes. At this time, the regulations of the COA and COESC are in preparation that should update the ABS regime of the norm No. 905;

- Brazil: one of the countries that has implemented important modifications to its national regulations, primarily through the promulgation - after several years of discussions - of an ABS Law: No. 13123 of 2015 that entered into force on November 17 of that year and of its regulations Decree No. 8772 of May 11, 2016. Also, some internal operating provisions of the administrative structures created by the Law have been provided for. Additionally, other regulations have been issued, among them, Resolution No. 1 of 2016 that approves the Model Material Transfer Agreement, and Resolution No. 2 of 2016, that establishes Rules and Procedures for Modification of the terms of Distribution of Benefits notified in the SisGen. The latter - the electronic system provided for the registration, notification and authorization of the various activities covered by the Law and Decree 8772 - was officially launched on November 6, 2017. So far, many registrations and product notifications have been included in the SisGen.
- Chile: the country is in the process of approving ABS policies that act as regulatory frameworks for the Ministry of Agriculture entities that manage genetic resources. Currently, only the National Institute of Agricultural Research of 2014 exists;
- Argentina: Resolution No. 226 of 2010 of the Secretariat of Environment and Sustainable Development establishes the regime of access to genetic resources and the registration of access to genetic resources (applicable to cases of import and export of genetic resources) and the regulation of scientific research in national parks No. 81/2016 of May 2016. It contains some general references to the PIC of indigenous communities and the sharing of benefits and the subscription of Material Transfer Agreements in the case of commercial use of

genetic resources. Several provinces have partially regulated this issue and progress has been made in the drafting of an ABS Law proposal<sup>16</sup>;

- Uruguay: the Ministry of Housing, Land Planning and the Environment recently (November 30, 2017) approved, by way of resolution No. 1844/2017, a general interim procedure for the processing and decision making of access requests. The country is expected to develop a specific ABS regulation in the context of work of the UNDP Global ABS Project;
- Dominican Republic: Sectorial Law on Biodiversity No. 333-15 was approved in 2015 and includes many ABS rules. Based on this, a specific regulation and a national policy on this subject were finalized (approved by resolution No. 0002/2018 of January 15, 2018).

**Treatment of basic and commercial research.** It is also possible to identify a tendency to facilitate non-commercial research (as established by the NP in its article 8(a)), by means of its exclusion from the scope of the access regimes or through the use of simplified instruments. This change towards facilitating access in cases of non-commercial research has occurred in countries such as Peru, Colombia and Ecuador through framework contracts.

Colombia: controversies have arisen about the scope of application of the ABS regime and in particular about its impact and relationship with other research schemes on biological resources. Through Resolution No. 1348 of 2014 and Resolution No. 1352 of 2017, the activities that constitute access to genetic resources and their derived products are defined. On the other hand, Decree No. 1076 of 2015 compiling pre-existing regulatory standards indicates that basic research activities involving systematic, ecology, evolution and molecular biogeography activities do not constitute access to genetic resources and do not require the respective access contract. These exclusions had been previously contemplated, especially by decree No. 1376 of 2013.

Ecuador: Article 2 of Regulation No. 905 provides as a scope of ABS: genetic resources of which the Ecuadorian State is a country of origin, its by-products, its associated intangible components, and the genetic resources of migratory species that for natural causes are found in its territory. Excluded are: The uses of genetic and biological material for scientific purposes such as systematics, taxonomy, conservation, evolution, population biology, biogeography and phylogeography. Research projects for such purposes must be supported by a University, Museum or Herbarium or any other duly recognized center and **sign a framework contract**. This subscription is regulated in detail by means of Resolution No. 034 cited and its 2016 amendment. However, due to the provisions of COESC, SENESCYT would be the institution in charge of providing basic research permits on

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<sup>16</sup> The country has a Genetic Resources (Plant) Committee created by Decree No. 151/95. In the context of its work, a Draft Law on Access to Genetic Resources (dated 2012) has been prepared, which in general does not take into account most of the innovations and provisions of the NP and should be revised to adapt it to the provisions of this international instrument.

biological and genetic resources (framework contracts) and INABIO in cases of access for commercial purposes.

Peru: at least for certain cases of access to genetic resources, in accordance with decrees No. 18-2015-MINAGRI and 19-2015-MINAGRI, the activities of basic taxonomic research of **flora and fauna**, related to molecular studies with taxonomic, systematic, phytogeographic, biogeographic, evolutionary and conservation genetic resources, among other non-commercial research, **will be approved through research permits or authorizations** and not through access contracts.

In general, a similar trend seems to be found in some of the regulatory proposals mentioned above, but for now it is not clear to what extent and how they will be reflected in the final texts approved by the respective Assemblies, Ministries or Executive Powers. This seems to respond to the criticisms of the research sector regarding the excessively restrictive access systems on research, especially that of a basic nature.<sup>17</sup> On this point, it has been criticized that the application of the access regimes has made basic research by nationals difficult and some modification proposals have been made.<sup>18</sup> In any case, a critical aspect becomes the regulation of the "change of intention" from non-commercial to commercial. In most legislations this aspect is not previously determined.

**Legislative processes related to TK in the medical field.** There are parallel processes of issuing legal norms related to indigenous, traditional or ancestral medicine (or sometimes on free prior informed consent as is the case of Panama) that establish regulations that complement - sometimes not without some ambiguity and duplicity - the provisions on ABS and associated TK included in ABS frameworks. This is the case in Panama (Law on Free, Prior and Informed Consent of Indigenous Peoples and the Law of Traditional Indigenous Medicine both of 2016), Bolivia (Law of Ancestral Medicine of 2013), and Nicaragua (Law of Traditional Ancestral Medicine of 2011), among others<sup>19</sup>, where the harmonization of these provisions with the new rules of ABS that emerge or pre-existed constitutes a major challenge, to avoid inappropriate fragmentation of the legal framework. In this sense, it will be necessary to align new and emerging legal frameworks with the preexisting ABS schemes in order to build a coherent functioning system.

**Emergence of new approaches.** The excessive control of access/research activities that the ABS legal systems of the region have followed is facing some limited alternatives

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<sup>17</sup>Nijar, Gurdial et al, The Implementation Of Nagoya ABS Protocol for research sector: experience and challenges, in International Environmental Agreements: Politics, Law and Economy, disponible en [www.link.springer.com](http://www.link.springer.com)

<sup>18</sup> See, for example, the study by Nemogá et al, The Biodiversity Research in Colombia. Proposed adjustments to the Access Regime to Genetic Resources and Derivative Products and to the Andean Decision 391 of 1996, National University of Colombia, Bogotá, 2010 and Biber-Klem, Susette et al Access and Benefit Sharing in Latin America and the Caribbean: a science- policy dialogue for academic noncommercial research, Background document, November 2013.

<sup>19</sup> In Venezuela, something similar happens with the Cultural Heritage of Indigenous Peoples Law of 2009 and the Organic Law of Indigenous Peoples and Communities of 2005, but they predate the PN.

and approaches. Such is the case of the Brazilian regulations, where an example of the change of emphasis from the control of access to the control of results and commercialization (products and marketable materials) can be identified. Even research and development does not require any permission or registration and only becomes mandatory in cases of achieving or reaching certain milestones, such as publication of results, registration of products or intellectual property applications. The benefits should only be paid or negotiated in the event that there are final products and in the agricultural case of reproductive material to be marketed and not before, fixing predetermined percentages of monetary benefits: 1% and 0.75% of the annual net income in the case of non-monetary benefits in which case it becomes necessary to submit an agreement for the sharing of benefits. Only in the case of the use of traditional knowledge or genetic patrimony in hands of indigenous peoples, local, and farmer communities it is mandatory to obtain and register the Prior Informed Consent before initiating the access activities. The obligation to share benefits rests with the individual or company that performs the respective manufacture or marketing of the product or material, regardless of how it was developed, e.g. if the genetic resources or associated traditional knowledge were previously accessed by third parties (article 17 paragraphs 2 and 3). The licensing and transfer of intellectual property rights operations does not generate the obligation to distribute benefits (Article 17, paragraph 4).<sup>20</sup> With respect to the distribution of monetary and non-monetary benefits, this should be done from the commercial exploitation of a final product or reproductive material as defined by the regulations (article 2). In this way, the Registry in the System does not immediately generate the obligation to agree with monetary or non-monetary benefits, but it arises only from the point of the existence of some forms of commercial exploitation. This constitutes an important difference of the Brazilian system with respect to other legal systems that usually require negotiating mutually agreed terms from the beginning of the procedure, which are incorporated in the respective access contracts or similar instruments. The regulation indicates that a product is considered final if it is ready for use by a consumer. Likewise, in the cases of agricultural activity, the reproductive material is considered as the final product (article 2).

**Use of contracts - especially for basic research cases -as a fundamental mechanism to determine the fair and equitable distribution of benefits.** The use of contracts and material transfer agreements - this last one especially in the case of agricultural genetic resources conserved *ex situ* - continues as the main instrument for the fair and equitable sharing of benefits in the regulatory frameworks issued in the post-Nagoya era, even if some attempts have been made to put in place other approaches such as the use of Funds - such as the case of the Brazilian Law of ABS or Law No. 27811 of 2002 on the Protection of Collective Knowledge of Indigenous Peoples of Peru, but this precedes the Protocol - which are intended to channel the benefits more broadly. However, implementation through contracts has increased and there are practical experiences in several countries in the region. For example, in the Dominican Republic, 6 contracts have been

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<sup>20</sup> Henry Philippe Ibanez of Novion and Letícia Piancastelli Siqueira Brina, Brazilian National implementation of access and benefit-sharing, to submission to the International Workshop on Access and Benefit-Sharing for Genetic Resources for Food and Agriculture, Rome, January 2018.

signed but only one for access for commercial purposes; Panama<sup>21</sup> is in the process of negotiating several requests for commercial contracts and has granted about 10 licenses for the use of traditional knowledge protected by Law No. 20 of 2000 and its regulations (on registration of traditional knowledge); Peru uses some 85 access contracts all for basic research; Colombia with approximately, 150 such contracts, has about 6 for commercial purposes; Ecuador has 73 Framework Agreements, all of which are non-commercial; Venezuela, with over 8 such contracts by 2015; and Brazil with 295 such contracts from 2000 to 2015.<sup>22</sup> In other countries, the regulatory system does not provide for direct contracts between the NCA and users, but between the users and the providers. This is the case in Costa Rica, where more than 500 access permits have been issued since 2004, mostly for non-commercial purposes but also for bioprospecting and one for economic development in 2016. One issue to be highlighted is that the texts and information on the contractual agreements and the outcomes and results derived from the implementation of the contracts is not always easily accessible. Further, although, it is mentioned in several regulations, the establishment of permit registers or contracts in practice do not operate or do so in a limited way.

**Strengthening ABS negotiation capacities and supportive instruments.** Linked with the above discussion regarding the negotiation of benefits (contracts), in countries with some kind of regulation development this constitutes an important challenge, especially in the case of commercial access. This is the case although there are also benefits that can be associated with non-commercial access, especially - but not only - of a non-monetary nature.<sup>23</sup> This is reflected in the development of drafts and supportive instruments to determine the benefits, especially those associated with royalties, direct payments, milestone payments, but also non-monetary payments. For example, in Colombia, a Toolkit and Methodological Route for the valuation of genetic resources and the negotiation of benefits were developed in 2017. This text, not yet official, aims to guide the negotiation of monetary and non-monetary benefits in access contracts. In Ecuador, work is being done on a resolution proposal that includes percentages of benefit sharing, especially in the case of monetary benefits. These actions are related to the emphasis placed by some countries in the strengthening of human teams to negotiate contracts or in the elaboration of model clauses

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<sup>21</sup> Panama has notified more than 10 permits all for basic research to ABS-CHM but it is not clear if in some cases there are pre-existing contracts. Previous contracts had been concluded, especially in the context of research projects supported by the International Cooperative Biodiversity Groups (ICBG), see Cabrera Medaglia, Jorge, Case Study of ABS of Panama, IUCN, Quito, 2013.

<sup>22</sup> 2018 information mentions more than 2600 authorizations and 295 benefit-sharing contracts. See Henry Philippe Ibanez de Novion and Leticia Piancastelli Siqueira Brina, Brazilian National implementation of access and benefit-sharing, submission to the International Workshop on Access and Benefit-Sharing for Genetic Resources for Food and Agriculture, Rome, January 2018.

<sup>23</sup> As indicated in the case of the recent Brazilian legislation, a different approach has been adopted, standardizing the percentages of monetary benefits (1 percent with possible reductions in the cases of sectoral agreements with producers and the government) and 0.75 in the case of non-monetary benefits, referring to some of the activities that would entail such benefits. In the case of those monetary items, the amounts corresponding to the percentage of net annual sales must be paid to the Benefit Sharing Fund established by the Law.

or contracts that facilitate the negotiation and decision-making processes. Additionally, Project Promoted by UNCTAD in Peru is another such example.<sup>24</sup>

**Compliance measures (according to PN) and verification points poorly addressed.** The PN determines in articles 15 (for genetic resources) and 16 (for associated traditional knowledge, although in this case it is qualified "as appropriate")<sup>25</sup> the obligation to issue appropriate, effective and proportional measures to ensure that the genetic resources or associated traditional knowledge used within of its jurisdiction have been accessed in accordance with prior informed consent and mutually agreed terms have been established as specified in the legislation or regulatory requirements of access and benefit sharing of another Party.<sup>26</sup> In addition, they must adopt appropriate, effective and proportional measures to address situations of non-compliance with these measures. Cooperation is also required - as far as possible - in cases of infringements of the national legislation of the provider country, cooperation that, for example, can be carried out through the National Competent Authorities and the National Focal Points. What these measures will be is not spelled out, but they may require proof of legal access for different activities and the corresponding sanctions (civil, criminal, administrative) if such proof does not exist. Article 17 requires the designation of at least one check point to fulfill the functions indicated therein and to support monitoring and compliance with the utilization of GR.

Overall, these different obligations which designate check points and compliance measures have been complex for the countries of the region to the extent that only two of the Parties (as of December 2017) have reported them to the ABS-CHM: Peru and the Dominican Republic. Even for countries with experience - at least theoretical - in the use of intellectual property offices as check points - without calling them check points - for domestic or regional uses of genetic resources or associated TK (for instance, the Andean Community or Panama) the official designation of same has been slower than expected. Exceptionally, there are provisions to implement the NP compliance system in the recent ABS regulation of the Dominican Republic of 2018 which prohibits the use of genetic resources or associated traditional knowledge by users located in that country that have been obtained in contravention of the provider's access regulations whenever the country is member of the NP (Article 28). Another partial example can be found in the provisions of Cuba's intellectual property legislation. The Decree Law 290/2012 on protection of inventions stipulates the requirement of disclosure of the origin of biological material when it is involved in the patent application (in force since April 2012) and Decree Law 291/2012

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<sup>24</sup> This initiative, funded by UNCTAD, aims to support the construction of capacities to negotiate access contracts related to biotrade activities and the elaboration of possible models.

<sup>25</sup> In this regard, Lago, Alejandro, A study on options for the implementation of checkpoints and a system for monitoring the utilization of genetic resources and its compliance under the Nagoya Protocol, 2014, available in the ABS-CHM of the CBD.

<sup>26</sup> Additionally, Article 18 establishes some measures that the Parties must take, including providing access to legal remedies in cases of non-compliance with the Mutually Agreed Terms (mainly contracts). In this case it would seek to prevent misuse more than misappropriation, although sometimes these two aspects overlap. The article also requires action in relation to access to justice (whose scope is not entirely clear) and for the mutual recognition of foreign arbitration decisions, the latter aspect regulated, among others, by the New York Convention of 1958.

on protection of plant varieties also establishes this requirement for this type of intellectual property. Cuban patent law establishes a requirement for linking ABS and IPR applications, both for the case of the use of Cuban genetic resources (subsection J), and for foreigners (subsection K). The Patent Law expressly requires in Article 26(J) and (K), that as part of the documents to be submitted with the application, a copy of the prior and express authorization of access to biological material, issued by the competent authority, must be included when the invention it refers to said material, including the genetic material and its parts or derivatives from which Cuba is a country of origin or that is present in species domesticated or cultivated in the country (subsection J). Further, **a statement indicating the country of origin and the source of the biological material and associated traditional knowledge and the prior informed consent to access is required**(subsection K).

The aforementioned difficulty could be due to coordination issues for the establishment of these check points and for the development of the procedures to be followed for its operation, considering that in many cases these are bodies or entities that belong to non-environmental fields, such as intellectual property rights, product registrations or public funding for research.

**Synergistic implementation of the international ABS regime.** The main "hard law" instruments related to ABS are the CBD, the NP and the International Treaty of Plant Genetic Resources for Food and Agriculture or ITPGRFA or IT.<sup>27</sup> The relationship between the NP and the IT is covered by Article 4, particularly in paragraph 4 of the Protocol.<sup>28</sup> In such cases, the NP shall not apply to a Party that is also a member of the specialized instrument,<sup>29</sup> but only with respect to the specific genetic resources covered by the

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<sup>27</sup> It is also important to mention the World Health Organization since the latter approved in 2011 a "Framework for the exchange of influenza viruses and access to vaccines and other benefits" (known as the PIPF for its acronym in English). Some have indicated that this could be conceptualized as another international instrument specialized in ABS (limited to the case of the H5N1 virus and other influenza viruses) or that it can be considered a useful practice or work developed by the World Health Organization. The definition of the concept of "international instruments" for the purposes of article 4 of the PN is currently under analysis. COP-MOP II Decision 2/5, which "... requests the Executive Secretary, within the of paragraph 4 of Article 4 of the Protocol and subject to the availability of resources, conduct a study on the parameters that could be used to specify what constitutes a specialized international instrument of access and benefit-sharing, and what would be a possible process to recognize a instrument of this type ... " On the PIPF see [who.int/gb/ebwha/pdf\\_files/WHA64/A64\\_17\\_R5-en.pdf](http://who.int/gb/ebwha/pdf_files/WHA64/A64_17_R5-en.pdf). See on this aspect Wilke, Marie, The World Health Organization's Pandemic Influenza Preparedness Framework as a public health resources pool, in Kamau and Winter (eds) op cit.

<sup>28</sup> Article 4 paragraph 4 establishes the prevalence of IT among countries that are part of it and of the NP under certain conditions and limitations:

- a) for the resources covered by the specialized instrument.
- b) for the Parties of both instruments (for example, a non-IT country will apply the CBD and PN rules unless the national design of its ABS measures provides a treatment for the different PGRFA based on its own assessment)
- c) for the purpose of the aforementioned instrument (food and agriculture in this case)

<sup>29</sup> The point becomes particularly relevant since IT has around 144 parts and the NP about 104. Therefore, a set of countries (among them, Mexico, Colombia, Dominican Republic) are not part of IT. In principle they would apply the bilateral regime and approach of the NP and the CBD, unless they have decided - for a strictly

specialized instrument and for its purposes (in this case, food and agriculture).<sup>30</sup> Subject to some conceptual and legal clarifications, it is clear from the reading of the NP that it supports the operation of the Multilateral Access System (SML) of the IT and would entail the countries that are members of both instruments creating "legal space" for the operation of this special ABS regime, subject to respecting the specific considerations of article 4.4 itself. To date, some countries have exempted from the ABS system the multilateral IT regime (such as Ecuador and Peru) or expressly indicated that in the case of international ABS instruments these will be applied for the resources and purposes covered (Brazil). However, steps have also been taken to establish "positive norms" such as the Memorandum of Understanding signed between CONAGEBIO (National Commission for Biodiversity Management of Costa Rica), the IT Focal Point (National Seed Office) and the National Genetic Resources Commission (CONAREFI) regarding the interpretation of the scope of the ABS regime developed under the CBD (the Biodiversity Law and related decrees) and that of the IT. Likewise, in Peru<sup>31</sup> and Guatemala<sup>32</sup>, proposals have been made, with the support of international organizations and projects, for mechanisms or administrative coordination procedures to synergistically implement both international instruments.

**Emerging issues: the so-called digital genetic sequences.** Discussed within the framework of the CBD and the NP and in other forums<sup>33</sup>, such as the World Health Organization, the FAO Commission on Genetic Resources for Food and Agriculture and the International Treaty that have agreed on different processes to elucidate the treatment of the "digital genetic sequences", terminology on which there is no consensus at this time. These pose challenges to the scope of application of access rules, monitoring the utilization of genetic information, and for the fair and equitable sharing of benefits, among issues. To date, Brazilian legislation should be highlighted. For the specific determination of the scope of application, the different definitions contemplated in the Brazilian Law must also be used (article 2). Regarding the Genetic Heritage, it also includes **the genetic information** of plants, animals or microorganisms, including metabolites. This conceptualization would cover not only the tangible or physical component (molecules, genes or substances) but also the intangible or information taken from samples, which would extend the legal system to the "genetic information" beyond the physical samples, for example, included in databases. Although there are no guidelines or practice on this point, the regulation to the Law requires

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national consideration, without being obliged to do so - to give a different treatment to the Plant Genetic Resources for Food and Agriculture.

<sup>30</sup> For an exhaustive analysis of the relationship between the NP and the ITPGRFA, see Cabrera Medaglia Jorge et al, The Interface between the Nagoya Protocol on ABS and the ITPGRFA at the international level, FNI Report 1/2013, Norway 2013.

<sup>31</sup> Sigüenías, Manuel et al, The Implementation of the International Treaty of Plant Genetic Resources for Food and Agriculture in Peru, INIA and Bioversity International, Lima, 2012.

<sup>32</sup> See Lapeña, Isabel, Vázquez-Francisco and Say Eduardo, The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) in Guatemala. Process of Implementation of the Multilateral System of Access and Distribution of Benefits, Bioversity International, Guatemala, December 2014.

<sup>33</sup> The process for negotiating a legally binding instrument for the Areas Beyond National Jurisdiction has also considered the issue of access and sharing of benefits in the case of "in silico" resources, that is, information and not physical samples.

registration in the SisGen when the use of the genetic patrimony is made through access to "in silico" sources. Possibly, the drafting of ABS frameworks will consider these challenges at the time of their design and to try to build the corresponding capacities to interpret and implement regulatory frameworks that cover the digital sequence information<sup>34</sup>.

### **Conclusions:**

The LAC countries have undertaken actions in recent years to improve their regulatory frameworks and build capacities among the different actors for their effective implementation. The Nagoya Protocol has undoubtedly served as a catalyst to rejuvenate efforts and initiatives in this field.

We must expect that the outcome of these waves of projects and national efforts be translated at the end of the day into concrete ABS relationships that generate new opportunities for innovation, improvement of the quality of life of the local people and for the conservation of biodiversity.

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<sup>34</sup> See, with respect to the notion of genetic resources as natural information, the book by Ruiz, Manuel, Genetic resources as natural information, Peruvian Society of Environmental Law, Lima, 2016.