Access to Genetic Resources in Latin America and the Caribbean: implementation of the Nagoya Protocol at a national level

IUCN's Regional Office for South America

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Access to Genetic Resources in Latin America and the Caribbean: Implementation of the NAGoyA Protocol at a National LeveL

Strengthening the Implementation of Regimes of Access to Genetic Resources and Benefit Sharing in Latin America and the Caribbean

Alexandro LAGo CAndeiRA and LuciAnA SiLvestRi

Authors

montseRRAt Rios and ARtuRo moRA

Editors

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Abbreviations and acronyms

(* Acronym has been kept in original Spanish form)

ABS	Access and Benefit Sharing of genetic resources
ACP	African, Caribbean, and Pacific Group of States
Art.	Article
CAN	Andean Community of Nations *
CBD	Convention on Biological Diversity
COMEX	Ministry of Foreign Trade *
CONAGEBIO	National Commission for Biodiversity Management *
COP	Conference of the Parties
DR-CAFTA	Dominican Republic-Central America Free Trade Agreement
FAO	United Nations Food and Agriculture Organization
FTA	Free Trade Agreement
GEF	Global Environmental Fund
GISRS	Global Influenza Surveillance and Response System
GIZ	German Development Cooperation
ICG	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
INBio	National Biodiversity Institute of Costa Rica *
IUCN	International Union for Conservation of Nature
LAC	Latin America and the Caribbean
LMMC	Group of Like-Minded Megadiverse Countries
MINAET	Ministry of Environment, Energy and Telecommunications
MAT	Mutually agreed terms
MTA	Material transfer agreement
NGO	Non-governmental Organization
OCPI	Cuban Industrial Property Office *
OTCA	Amazon Cooperation Treaty Organization *
PCT	Patent Cooperation Treaty
PIC	Previous Informed Consent
PIP	Pandemic Influenza Preparedness Framework
PIP FRAMEWORK	Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits
PMA	Protected Marine Areas
PLT	Patent Law Treaty
RMIB-LAC	Indigenous Women's Network on Biodiversity of Latin America and the Caribbean *
SCAR	Scientific Committee on Antarctic
SCNAT	Swiss Academy of Sciences

SEDEFA	Ecuadorian Society of Forest and Environmental Law*
SPLT	Substantive Patent Law Treaty
TIRFAA	International Treaty on Plant Genetic Resources for Food and Agriculture *
TO	Technical Office
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
UEBT	Union for Ethical Biotrade
UN	United Nations
UNEP	United Nations Environment Programme
WTO	World Trade Organization
WIPO	World Intellectual Property Organization
WHO	World Health Organization

Presentación

El Proyecto Regional "Fortalecimiento de la Implementación de los Regímenes de Acceso a los Recursos Genéticos y Distribución de Beneficios (ABS) en América Latina y el Caribe" (Proyecto Regional-UICN-PNUMA/GEF-ABS-LAC), apoyado por el Fondo para el Medio Ambiente Mundial (sigla en inglés GEF) es una iniciativa ejecutada por la Unión Internacional para la Conservación de la Naturaleza (UICN) e implementada por el Programa de las Naciones Unidas para el Medio Ambiente (PNUMA), en coordinación con el Convenio sobre la Diversidad Biológica (CDB), que tiene como objetivo el fortalecer capacidades para el desarrollo e implementación de regímenes de ABS en la región.

El Proyecto Regional-UICN-PNUMA/GEF-ABS-LAC es complementado por otras dos iniciativas regionales sobre ABS apoyadas por el GEF en África y Asia, porque conjuntamente buscan promover un mejor entendimiento del tercer objetivo del CDB sobre acceso a los recursos genéticos y la distribución justa y equitativa en los beneficios derivados de su uso. Estos proyectos, se encuentran apoyando el marco de trabajo del Protocolo de Nagoya sobre ABS, adoptado en el 2010, así como a la Meta de Aichi 16 del Plan Estratégico para la Biodiversidad 2011-2020.

Durante el Proyecto Regional-UICN-PNUMA/GEF-ABS-LAC se han desarrollado una serie de herramientas prácticas para mejorar las capacidades en el tema de ABS, siendo a través del compartir de experiencias y lecciones aprendidas. Las publicaciones han sido preparadas a partir del conocimiento de varios expertos, provenientes de las autoridades nacionales y regionales, comunidades locales y pueblos indígenas, investigadores, académicos y sector privado, entre otros. Así, se espera una extensa diseminación de los resultados a una amplia gama de actores relevantes en la región de América Latina y el Caribe.

Quisiéramos agradecer a los involucrados en este esfuerzo regional, incluidas las Autoridades y Puntos Focales Nacionales de los ocho países participantes (Colombia, Costa Rica, Cuba, Ecuador, Guyana, Panamá, Perú y República Dominicana), la Organización Mundial de la Propiedad Intelectual (OMPI), así como otras instituciones y expertos que se han unido a este proceso, compartiendo su conocimiento en miras a contribuir al mejor entendimiento sobre este tema fundamental.

Estamos seguros de que las herramientas prácticas desarrolladas en este proyecto regional apoyarán a los países que se encuentran implementando el Protocolo de Nagoya, así como a la Meta 16 de Aichi para la Biodiversidad. Finalmente, quisiéramos alentar la lectura de estas publicaciones, así como la visita al portal del Proyecto Regional-UICN-PNUMA/GEF-ABS-LAC (www.adb.portalces. org), donde se podrá encontrar información clave recogida durante el proceso.

Dr. Braulio Ferreira de Souza Dias
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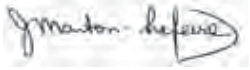

Sra. Julia Marton-Lefèvre
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Foreword

The Regional Project "Strengthening the implementation of Access and Benefit Sharing (ABS) regimes in Latin America and the Caribbean" (Regional Project-ABS-LAC), supported by the Global Environment Facility (GEF) is an initiative executed by the International Union for Conservation of Nature (IUCN) and implemented by the United Nations Environment Programme (UNEP), in coordination with the Convention on Biological Diversity (CBD), to strengthen capacities for the development and implementation of ABS regimes in the region.

This regional project is complemented by two other GEF supported regional projects on ABS in the Asia and Africa regions. Together, these projects aim to promote a better understanding of the third objective of the CBD on access to genetic resources and the sharing of benefits derived from their utilization. The projects are furthermore in support of the framework of the Nagoya Protocol on ABS, adopted in 2010 and Aichi Target 16 of the Strategic Plan for Biodiversity 2011-2020.

A series of practical tools have been developed by the Regional Project-ABS-LAC to improve capacities in the field of ABS through the sharing of experiences and lessons learned. These publications have been assembled from the knowledge of a range of experts (national and regional authorities, indigenous and local communities, researchers, academia and private sector, between others). Extensive dissemination to a broad range of relevant stakeholders in the Latin American and Caribbean region is planned.

We want to thank all those involved in this regional endeavor, including the Authorities and National Focal Points of the eight participating countries (Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, Guyana, Panama and Peru), the World Intellectual Property Organization (WIPO), as well as organizations and experts who have joined this process for sharing their knowledge in the expectation that it will contribute to a solid base for a better understanding of this fundamental topic.

We are confident that the practical tools developed in this regional project help countries implementing the Nagoya Protocol and help achieving Aichi Biodiversity Targets 16. We encourage use of these publications and visits to the project website (www.adb.portalces.org), where key information, collected throughout this process, will be found.

Dr. Braulio Ferreira de Souza Dias
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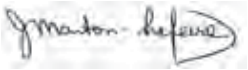

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Introduction

This publication is part of the Cooperation Agreement between the Regional Office for South America of the International Union for Conservation of Nature (IUCN-South) and the Rey Juan Carlos University , which is managed through the UNESCO Chair for Territory and Environment and focuses on developing various components of the GEF Regional Project called "Strengthening the Implementation of Regimes of Access to Genetic Resources and Benefit Sharing in Latin America and the Caribbean" (IUCN-UNEP/GEF-ABS-LAC Regional Project). In this sense, the project seeks to ensure compliance with the principles of conservation, sustainability, equity and justice of the Convention on Biological Diversity (CBD) in relation to the access to genetic resources and the fair and equitable sharing of benefits arising from their utilization (ABS), while considering the protection of their associated traditional knowledge.

The main objective of the IUCN-UNEP/GEF-ABS-LAC Regional Project is to strengthen the capabilities of eight countries in Latin America and the Caribbean to develop and/or comply with the national policy and legal frameworks related to the issue of ABS, namely: Colombia, Costa Rica, Cuba, Ecuador Guyana, Panama, Peru and Dominican Republic. For this reason, the research seeks to identify the critical elements to be considered when it comes to designing, developing, reviewing or updating the national frameworks for ABS, while keeping the adoption and entry into force of the Nagoya Protocol –the latest international instrument adopted in the field– as the central point.

Within this context, it should be noted that the critical elements described in this study reflect the experience gained during the various activities implemented during the Project. This process and its lessons manifest both from the international to the national level, where the overall governance framework of ABS determines the possible and desirable national regimes; as well as from the national to the international, where the success of the national framework of ABS makes it possible to visualize the benefits of the system of global governance thereof. The aforementioned scenario can be observed in a process of dynamic and complex interaction, but its effective application depends largely on the success or failure of national frameworks because many elements are still under discussion or construction, especially at an international level.

In summary, the contributions presented in this work are intended to focus on the critical elements of ABS which are determinant -in the view of the authors- to be successful or fail at promoting the value of genetic resources of a country and the associated traditional knowledge of indigenous and local communities and ensuring the fair and equitable sharing of benefits arising from their utilization. Thus, it is guaranteed that everyone wins: the country, indigenous and local communities, researchers, research institutions, and users; as well as conservation and the sustainable use of biodiversity. In short, it aims to understand what elements must be present or at least be considered in an effective and efficient ABS national framework.

Agaricus sp., Basidiomycota. Rio Lelia, Santo Domingo de los Tsáchilas, Ecuador. © Felipe Campos.

Activities of the IUCN-UNEP/GEF-ABS-LAC Regional Project and context of critical elements

Activities of the IUCN-UNEP/GEF-ABS-LAC Regional Project and context of critical elements

The central activity of the UNESCO Chair for Territory and Environment at Rey Juan Carlos University during the IUCN-UNEP/GEF-ABS-LAC Project can be seen in the description for each of the countries that make up the legal framework for the implementation of the Nagoya Protocol on ABS. In this regard, various capacity building and training activities with other consulting tasks are developed, such as the elaboration of reports assessing the ABS legal frameworks of each country participating in the Project with a view towards the correct implementation of the Nagoya Protocol at the national level or the ad hoc report on the related international instruments.

It should be emphasized that all activities in this research attempt to be in themselves a live an active instrument of communication, interaction and training among the team of the UNESCO Chair and participating members of IUCN on the one hand, and the national focal points of the Project on the other, with the intention to go beyond approaches and theoretical analysis of both the Nagoya Protocol obligations as well as national ABS frameworks. Similarly, it is intended to address the specific concerns raised in the daily implementation of national ABS frameworks with possible solutions and opportunities that the Nagoya Protocol may provide.

In short, all activities seek to address direct demands from different countries through the focal points of the Project, using various training and exchange activities at national level and which are fully adjusted to the needs and the specific situation of each country. The result and the materials of the whole process are available, for the most part, at www.adb.portalces.org.

1. Regional training on ABS contracts

The regional training of the IUCN-UNEP/GEF-ABS-LAC Regional Project on ABS contracts took place in Havana, Cuba, from March 18 to March 22, 2013. The event was attended by 63 participants from all the countries in the project and it included the participation of two deputy ministers, one from Costa Rica and one from Cuba. Also present were: ABS focal points from the countries participating in the project and the competent authorities in the field of protection of traditional knowledge and intellectual property, members of the academia, a few selected regional experts, and representatives of organizations such as the Amazon Cooperation Treaty Organization (ACTO), the German Development Cooperation (GIZ), the CBD Secretariat, the UNEP and IUCN, and members of the UNESCO Chair for Territory and Environment at the Universidad Rey Juan Carlos (Madrid, Spain), with the latter being the event coordinators.

It is important to highlight the multidisciplinary profile of different participants and their high technical capacities, all of which facilitated the dynamics of the event and made it a continuous exercise of participatory construction of different elements due to the broad theoretical and practical knowledge of the participants regarding the issues under discussion. The recognition of the region's experts in the field also stands out as a positive action. Thus, the event conducted a full analysis of the

foundations for the regulation of access to genetic resources and for a fair and equitable sharing of benefits from the rationale of the paradigm shift introduced by the CBD and its the recognition of the sovereignty of countries over their genetic resources, and their search for its value and tools to reverse the technological gap; to the analysis of new control and compliance measures introduced by the Nagoya Protocol. In this review of the situation, the various international instruments and forums related to ABS were put into perspective.

The previously stated scenario and all its elements become visible in the central context of the event which is the "ABS contract", highlighting how this is to some extent "the whole" of the bilateral relationship because both parties clearly specify their terms since it is an agreement governed by the will of the parties with the Law as its principal limit. In this sense, there was a lot of discussion regarding the manner and tools with which to determine the will of the State in a technical and complex issue such as ABS. Special relevance was given to the role that preparation or the development of a national strategy for ABS that clearly establishes the situation of the country, both for biodiversity and for its biotechnology capabilities, so that objectives are achieved through the implementation of a national framework. Participants performed various dynamic practices of contract negotiation and they presented their practical experience in the implementation of their national frameworks and ABS in negotiation.

2. Building national capacities on ABS

During the IUCN-UNEP/GEF-ABS-LAC Regional Project the focal points in each country were supported during various training and exchange activities at a national level, conducted during work meetings with their participation and/or with different departments of public administration to review the draft national report on the ABS regulatory framework. Thus, different national communications and training activities were organized in most countries of the project, such as: national workshops, discussion forums, conferences and lectures, among others. It should be stressed that each national activity was uniquely executed, adjusted in a timely manner to the specific needs and demands of training; and planned in accordance with prior feedback from each focal point of the project, who afterwards remain in possession of all materials used during events. Listed below, in chronological order, are the main activities carried out:

i. Forum on "The Nagoya Protocol: Scope and Benefits for Costa Rica" at the National University of Costa Rica (San Jose, April 23, 2013).
ii. Presentation and discussion on "Access and Benefit Sharing in the global context", held at the Workshop on Access and Benefit Sharing in the framework of the draft Law on traditional cultural expressions, ancestral knowledge and genetic resources of Ecuador (Quito, 25 April 2013).
iii. Presentation and discussion "International Vision and Reality about ABS", held at the Forum on Benefit Sharing and its Relationship among Researchers and Biodiversity Research Centers "(Bogota, April 30, 2013).
iv. National Workshop "Towards the Entry into Force of the Nagoya Protocol on ABS in Panama" (Panama, 21 and May 22, 2013).

v. National Workshop on "Training on ABS in Peru" (Lima, 23, and May 24, 2013).
vi. National Workshop on "Training on ABS in Dominican Republic" (Santo Sunday, May 27, 2013).

3. Legal advice and training on ABS regulatory frameworks in each country

One of the main products of the collaboration between the UNESCO Chair and the IUCN-UNEP/GEF-ABS-LAC Regional Project is the development of eight reports concerning the national regulatory framework on ABS, corresponding to each of the participating countries and their implementation of the Nagoya Protocol. The key objective of each document is to clearly present the content and obligations of the Nagoya Protocol, making it possible to retrospectively evaluate if they are covered in the national frameworks for ABS and, if such is not the case, suggest the elements and way in which these can be incorporated to ensure compliance; thus, three-stages were applied in the process:

i. In the first stage, a draft was elaborated based on the legislation and official documents of the country, subjecting it to comments from the national focal point of the project and to a face to face meeting to exchange views on it, in order to directly understand the circumstances and situations the country and its authorities must face when implementing or developing a national ABS framework.
ii. During the second stage, comments and contributions to the first draft are included, developing a new version of the report which also considers a number of recommendations; so, the manuscript is once again submitted to the review of the national focal points of the project.
iii. During the third stage, the observations to the second version of the document were added, proceeding to finalize and edit each national report to make it available for each of the focal points of the project, who can then use it in their countries for the appropriate ends.

4. Advice on the tools and processes which have relation or impact on ABS national frameworks

The presentation and advice on various international instruments and processes related to ABS or its possible impact on national frameworks is another of the activities carried out during the Project. As such, the objective was to transfer detailed knowledge to the authorities responsible for the national implementation of the Nagoya Protocol in each country, especially on the status of related international instruments and processes to enhance its implementation in each country.

Within this context, it was expected to provide a comprehensive view on the implementation of the Nagoya Protocol, using the existing elements fully while anticipating –at a national level– the pending elements at an international level, as well as within their negotiating positions in these forums. One of the main products of this activity is the Report on International Instruments and Processes Related to ABS.

Cattleya skinneri, Turrialba, Costa Rica. ©Enrique Lahmann, IUCN.

Negotiation and obligations derived from the Nagoya Protocol

Negotiation and obligations derived from the Nagoya Protocol

1. Leadership megadiverse countries and the Regional Group of Latin and the Caribbean in the negotiation and adoption of the Nagoya Protocol

The Implementation Plan of the World Summit on Sustainable Development held in Johannesburg (South Africa) in September 2002, lists in paragraph 42 (0) the need to agree on an international regime for the sharing of benefits arising from the use of genetic resources, taking the Convention on Biological Diversity (CBD) and the Bonn Guidelines as a reference. The importance of the inclusion of this item in the Implementation Plan is significant considering that through Decision VI/24 of April 2002, the sixth meeting of the Conference of the Parties (COP-6) adopted the call Bonn Guidelines, a voluntary instrument that outlines the procedures for obtaining "prior informed consent" (PIC) and for negotiating "mutually agreed terms" (MAT), including an indicative list of monetary and non-monetary benefits.

While the Bonn Guidelines shed some light regarding appropriate measures for supplier States, they did not provide new and effective control measures from the side of the users, and shortcomings were perceived by a group of countries. This group was led by Mexico and in February 2002, they created the Cancun Declaration of the Group of Like-Minded Megadiverse Countries (LMMC). Among the objectives of the LMMC Group is the creation of an international effectively promote the fair and equitable sharing of benefits arising from the use of genetic resources, a political objective they achieved in record time: six months counted from the formal establishment of the group to the adoption of the _ _ Implementation Plan of the World Summit on Sustainable Development in Johannesburg (http://www. cbd.int/doc/meetings/cop/cop-06/information/cop-06-inf-33-en.pdf).

In this scenario, the introduction of the negotiation for an international ABS regime in the international agenda on sustainable development is a success directly attributable to the creation of the LMMC Group, with four of the countries participating in the IUCN-UNEP/GEF-ABS-LAC Regional Project, namely: Colombia, Costa Rica, Ecuador and Peru. The request for the Plan of Implementation of Johannesburg was adopted by the CBD during COP 7 (2004) in Kuala Lumpur (Malaysia). Thus, through Decision VII/19, the ad hoc Open-ended Working Group on Access and Benefit Sharing, is asked to develop and negotiate –in collaboration with the Working Group on Article 8 (j) – an international regime for access to resources and benefit-sharing, considering the effective implementation of Art. 15 and Art. 8 (j) of the CBD. The COP 8 (2006) asked the ad hoc Working Group to continue and complete their work before the COP 10 (2010).

The negotiation process broke the trend of international negotiations relating to the environment _ by successfully meet the established deadlines. The same success was later enjoyed by the Minamata Convention on Mercury with its adoption in 2013, and the Nagoya Protocol was adopted at COP 10 of the CBD. A simple review of the proposals and the negotiation process through numerous documents of working groups and reports of the various COP, became an action that highlights the significant boost and tremendous leadership shown during negotiations by the LMMC Group, which included several countries that are part of the Project of the Group for Latin America and the Caribbean.

The detailed analysis of national ABS frameworks of the countries of the IUCN-UNEP/GEF-ABS-LAC Regional Project –which includes an analysis of the applicable regional regulations– shows that many of the new instruments of the Nagoya Protocol are based or inspired on elements applied in some of these countries, since their mark in the Protocol is recognizable and often part of a regional and/or national legislation.

2. Objectives and obligations of the Nagoya Protocol

The intention to clarify the objectives and obligations of the Nagoya Protocol is simply to establish the basis for articulating critical elements when detailing their contents (Greiber et al., 2012), since they consider the fair and equitable sharing of benefits arising from the use of genetic resources, "thus contributing to the conservation of biological diversity and the sustainable use of its components".

In this context, the third objective of the CBD is reaffirmed and its direct relationship with two other targets, which are confirmed in the rest of the articles as well as in Art. 9. The present study divides the provisions of the Nagoya Protocol on three major areas in order to facilitate its understanding. The three areas are: access to genetic resources and access to associated traditional knowledge; fair and equitable benefit sharing, and compliance measures.

2.1 Access to genetic resources and associated traditional knowledge

With the Nagoya Protocol, regulating the access to genetic resources remains a sovereign decision of the States who –in case they regulate them– must do so through national frameworks that conform to the provisions of Arts. 6 and 8. Access frameworks are pivoting on the Prior Informed Consent (PIC) and the existence of mutually agreed terms (MAT), and it is worth clarifying that in the context of this research they are generally referred to the ABS contract. The Protocol also includes the obligation of issuing a permit certifying compliance with the national framework regarding access to genetic resources and to traditional knowledge, if any, associated with them. This latter shall depend on the scope that each Party decides on for its permits. As such, the national license becomes an international certificate of compliance when it is notified to the Center for the Exchange of Information on ABS Protocol, acting in accordance with the provisions of Arts. 17.2 and 17.3.

One of the biggest news of the Nagoya Protocol from a legal standpoint is the international regulation of the obligations related to the access to traditional knowledge associated with genetic resources that are held by indigenous and local communities and the fair and equitable sharing of benefits arising from their utilization. In itself, this requires that access to traditional knowledge associated with genetic resources that are held by indigenous and local communities remain subject to the PIC or their approval and involvement. Likewise, MAT are established with those who hold such knowledge. In this sense, all of the above should be clearly reflected in the national legislation, since it is demanded as a prerequisite by Art. 16 when regulating compliance measures in the country that uses such knowledge. Therefore, whenever there is traditional knowledge associated with genetic resources held by indigenous and local communities in a country, national rules should be established in order to regulate access to them, otherwise the provisions of Art. 16 may not be applicable.

2.2 Fair and equitable sharing of benefits

The Nagoya Protocol gives greater visibility to the fair and equitable sharing of benefits arising from the use of genetic resources as well as traditional knowledge associated with those genetic resources held by indigenous and local communities, determining the conditions of this distribution through MAT. The Protocol also introduces a list of possible benefits that may relate to benefit sharing, which may be monetary or non-monetary (Art. 5.4) and are detailed in the Annex.

The Protocol emphasizes collaboration and cooperation in scientific and technical research (Art. 23), including access to and transfer of technology for the benefit of developing countries as one of the actions that should be promoted more in this context. Thus, this fact resonates in Art. 15.6 of the CBD which states that "each Contracting Party shall endeavor to develop and carry out scientific research based on genetic resources provided by other Parties ... with the full participation of, and where possible in, such Parties". Article 9 also states that "the Parties shall encourage users and providers to direct benefits arising from the use of genetic resources towards biodiversity and the sustainable use thereof," proving once again the close links which Parties establish among the benefits of the use of biodiversity and their conservation.

2.3 Measures of compliance

Obligations or compliance measures, another innovative area of the Protocol, meet the demands of those who in 2002 called for an international regime to be negotiated which would ensure the fair and equitable sharing of benefits arising from the use of genetic resources. Among the compliance measures, those related to monitoring and control of the use of genetic resources (Art. 17) stand out, as well as the obligation of the Parties to ensure that genetic resources and associated traditional knowledge used within their jurisdiction have been accessed in accordance with the rules of the supplier country. This legal access means that PIC has been obtained and MAT have been negotiated (Arts. 15 and 16), which the user may prove through a single document: the internationally recognized certificate of compliance. Compliance obligations are applicable to all Parties to the Protocol, whether they regulate access to their genetic resources and/or traditional knowledge associated with them or not, which is a feature that differentiates them from the elements discussed above which are more discretionary in nature. This means they would only be used in the case access to genetic resources is regulated or if there are indigenous and local communities in the country.

3. Contribution of the Nagoya Protocol on the issue of ABS: regulations at national and international level

One of the main features that makes the Nagoya Protocol different to other international instruments is the flexibility provided to the Parties, especially when implementing the various obligations it contains. What is considered normal in international regulation on specific environmental issues is the application of a standard set of rules and procedures, in many cases distinguishing between developed and developing countries, which all Parties implement and monitor in the same manner. In the case of

the Protocol, neither measures of access nor measures of control of compliance by users are standardized, because even though "access standards" were discussed during its negotiation, ultimately what Section 6.3 contains is a series of general principles that seek non-discrimination and the granting of a fair handling of requests for access to genetic resources.

The exception to this flexibility is the so-called "access permit" which is compulsory and which, in order to display the expected effects of legality derived from an internationally recognized certificate of compliance, shall have to standardize many elements, and its format shall have to be approved by the Parties to the Protocol. Compliance measures of the Protocol establish an obligation of result, given the fact that countries where genetic resources and/ or traditional knowledge associated to them shall ensure that they are obtained in accordance with the national access framework of the country supplying the resource in question. The Protocol does not say how measures should be, but emphasizes they should be "appropriate, effective and proportionate."

The flexibility of the Protocol allows countries to determine national measures they consider most appropriate and effective to comply with obligations, which may vary from jurisdiction to jurisdiction. In itself, the flexibility is one of the disadvantages of the Protocol, since a variety of measures in different jurisdictions can cause uneven application and effectiveness, undermining the integrity and achievement of its objectives and obligations. For this reason, one can expect that in situations of marked inequality, the Parties have the possibility of resorting to the compliance mechanism provided for in Art. 30 within the Protocol ; so even though the terms and features of this enforcement tool are to be decided during the first meeting of the Parties, it could determine whether specific measures of a Party fully comply or not with the established obligations.

It is likely that in practice, maybe not immediately but in the medium to long term, a formal or informal harmonization of measures for both access to genetic resources and monitoring and enforcement of obligations of users may occur. In fact, some of the latter are already being discussed in other international forums, because harmonization can result from the adoption of common measures at an international level within or beyond the Protocol. Such would be the case of the decision of the World Intellectual Property Organization (WIPO) or the World Trade Organization (WTO) by way of the TRIPS agreement, to introduce the requirement of disclosure of origin of genetic resources and/or associated knowledge in the patent application as a mandatory formal or substantive requirement. The informal harmonization would come through the adoption of the most common and efficient measures used by the Parties as international common practice outside of which the States would have to justify the effectiveness of their actions vis-à-vis with their counterpart.

Another important element which the implementation of the Nagoya Protocol should bring, both nationally and internationally, is to increase legal certainty regarding the exchange of genetic resources and associated traditional knowledge for all stakeholders, be it suppliers or users, countries, indigenous communities or private institutions. The Protocol clarifies the rules to be applied for access, exchange and use of genetic resources and associated traditional knowledge, promoting national frameworks and transparent rules of access, clear and standardized documents of resource legality as well as measures of monitoring and compliance in all countries.

The Protocol will allow for the control and monitoring of genetic resources both nationally and internationally, seeing as biodiversity-rich countries, for instance, are constantly exposing their lack of control when resources leave their jurisdiction, which undoubtedly was one of the main arguments for the negotiation of the international regime on access to genetic resources and benefit sharing. Also, the limited capacity of control and lack of follow-up of genetic resources at the national level is rarely discussed, and becomes a great challenge in biodiversity -rich countries themselves. Therefore, the protocol has a positive effect on the control of genetic resources in the international arena, but it also contributes with an improved control in the most biodiverse countries over the use of genetic resources in their own jurisdiction, because in most cases it was non-existent to date.

A peculiar feature of the Protocol is its contribution to the visibility of indigenous and local communities, particularly in terms of access and use of traditional knowledge associated with genetic resources. In this case, the challenge lies in how the operationalization of the obligations and measures in relation to access to traditional knowledge associated with genetic resources held by indigenous and local communities is implemented. Success will depend greatly on the decisions which indigenous and local communities make, and this means it will be subject to much variability from one country to another.

In short, the Protocol provides an important paradigm shift that for the first time, based on the fact that countries which have bilateral or regional systems of access to genetic resources sponsored by the CBD will receive support to add value to their biodiversity. Countries that exercise their sovereignty over genetic resources and decided or will decide to regulate access to these, will not rely exclusively, as they have so far, on the control and compliance measures established within their jurisdiction, because as of the entry into force of the Protocol, they will be able to monitor the use of genetic resources in other countries that are Parties. With this internationalization of the system through the monitoring of genetic resources and the compliance with national ABS frameworks in jurisdictions in which they are used, effective and proportionate penalty measures can be used for users who breach the legislation of the supplier country.

The paradigm shift should have an immediate effect on the national frameworks for ABS, which will have to abandon the restrictive and defensive protection approach on access to these, something that is physically difficult to undertake. As such, it would be assumed that extended control provided to third countries by the Protocol should be decreased, particularly in the area of user control in the points closest to the procurement of benefits. For this attribution, one must consider second generation national access frameworks, which are dynamic and efficient and can determine the best valorization of their resources as a real incentive, both for the development of their scientific and innovation capacities, as well as for conservation and a sustainable use of biodiversity, thus becoming a true element of sustainable development for the country.

Gallery forest in the Napo River, Chingana ravine, Peru. © Jorge Celi, Michigan State University.

Critical elements for the National Implementation of the Nagoya Protocol

Critical elements for the national implementation of the Nagoya Protocol

The development of the IUCN-UNEP/GEF-ABS-LAC Regional Project enables the detection of a number of critical elements for the implementation of the Nagoya Protocol, which should be provided for within a national framework on ABS so that it can be considered successful and capable of: promoting the valorization of the genetic resources of a country and the associated traditional knowledge in the hands of indigenous and local communities; ensuring the fair and equitable sharing of benefits arising from the use; fostering the development of the capacities of the national biotechnology sector based on research, and complying with international law.

In this context of the Nagoya Protocol, some elements that must be present or must at least be considered in an effective and efficient national ABS framework have been defined. For this reason, access to genetic resources and the sharing of benefits arising from their utilization must effectively contribute to the conservation of biodiversity as well as to the sustainable use of its components and the sustainable development of the country.

1. Integrating the Nagoya Protocol into ABS national frameworks

Integrating the Nagoya Protocol into national ABS frameworks is critical, since though it may seem so obvious as to be unnecessary, the reality analyzed within the context of the IUCN-UNEP/GEF-ABS-LAC Regional Project is emphatic in this regard. None of the national ABS frameworks of the countries in the Project met, at the time of analysis, all the obligations stated under the Nagoya Protocol. However, it should be noted that all countries are in the process of designing, reviewing or updating their national ABS framework, having yet to integrate an adaptation to comply with or observe the obligations under the Protocol. Furthermore, considering the current situation of the eight countries which are part of the Project, only Guyana and Panama have ratified the Nagoya Protocol and the rest have only signed it, with the exception of Cuba who has yet to do so.

In this scenario of the Nagoya Protocol, some cases are discussed which face a situation caused by the disconnection between the ratification process and the parallel process of adoption, development or update of national frameworks. All these activities. All these actions are, in many cases, conducted at the same time with very limited interaction with other government agencies or no interaction whatsoever. The lack of clarity on the ratification processes and on how they are configured seems to have a negative influence in some countries of the Project, including those who have signed the Protocol and lead its negotiation but, due to unknown internal reasons, seem like they will not become a part thereof.

Nowadays, the challenge is that even without considering the cause, there is a great risk that the review or the current development of frameworks, if ultimately adopted, fail to meet the Nagoya Protocol. This is because, in some cases, once it has ratified or adhered to the Protocol, the country in question must immediately -upon approval- review their national ABS frameworks to comply. The situation is somewhat peculiar in the case of several countries in the project, because they are active during the negotiation of the Protocol but sometimes their national frameworks inspire new measures and obligations, which do not require many changes for their adaptation and compliance.

The ABS regulation at the national level is complex, often controversial, has poor visibility in relation to other environmental problems, and there are few people who can fully manage it. This is what makes it rare to deal with the need or the opportunity for the creation, development or modification of such regulations. Due to this circumstance, effectiveness is required to seize the opportunities that arise, especially among technicians and political /technical decision makers, since most chances are that such opportunities will take considerable time to repeat themselves, which is why countries that manage to modify environmental standards in a period of less than five years are rare. In itself, it is a critical situation when a country starts a process of designing, reviewing or updating their national ABS framework, requiring the various elements to be ensured as well as the new legal reality determined by the Nagoya Protocol, with the exception being a country where there is a formal decision not to adhere.

In the time during which national reports of the project were elaborated –from May to September 2013– three countries had specific ABS legislation at a regional level (Colombia, Ecuador and Peru), mainly through Decision 391 (1996) and Decision 486 (2002) of the Andean Community of Nations (CAN). In relation to Decision 391, it should be noted that the Committee on Genetic Resources of CAN decided to initiate a review process in November 2012, with the objective of updating it with the experience gained over the last 15 years of practice in Member Countries. However, this fact does not necessarily include changing text to as provided in the Nagoya Protocol among its objectives a priori.

In the case of the three countries which have specific national development legislation on ABS – namely Colombia (1997), Ecuador (2011) and Peru (2009), when the first reports were produced, Colombia was in an advanced stage of the process of reviewing its regulations with four decrees in the making, two of them approved and two pending in the following order:

i. Decree No. 1375 of June 27, 2013, through which biological collections are regulated.
ii. Decree No. 1376 of June 27, 2013, through which the permit for harvesting wild specimens of biological diversity for the purposes of non-commercial scientific research is regulated.
iii. Draft Decree through which access to genetic resources is regulated.
iv. Draft Decree through which the permit for harvesting wild specimens of biodiversity for environmental studies required in the environmental licensing process is regulated.

Neither of the two decrees approved, nor the two decrees in process of public consultation, consider or incorporate a priori obligations of the Nagoya Protocol, since their goal in the initial stage of their development was just adjusting and updating these procedures nationally. In Ecuador, ABS regulations came after the adoption of the Nagoya Protocol, with Executive Decree No. 905 being signed on October 3, 2011, because when the country signed the instrument, its regulations did not incorporate all the elements provided.

In Peru, national ABS regulations are adopted at the end of 2008 (Ministerial Resolution 087-2008-MINAM subsequently endorsed by Decree No. 003-2009-MINAM), so it does not meet some of the provisions of the Nagoya Protocol. However, the country is in the process of updating it through the revision of Decree No. 003-2009-MINAM and the development of regulations for Law No. 27811 which establishes a Protection Regime for the Collective Knowledge of Indigenous Peoples Linked to Biological Resources, a process in which we will have the opportunity to incorporate new obligations and provisions.

Two other countries of the Project, Costa Rica (2003) and Panama (2006), had a specific ABS regulatory framework before the Nagoya Protocol, though it was evident it needs adjustments and specific developments, for instance regarding compliance measures. Moreover, Panama ratified the Nagoya Protocol and, therefore, it already has a compliance obligation as soon as it enters into force. Ultimately, Cuba, Dominican Republic and Guyana have general biodiversity and research rules that can be applied generally to ABS issues, providing advanced drafts for the purposes of specific rules, though at the time of analysis they did not fully comply with the provisions of the Nagoya Protocol.

2. Politically prioritizing ABS at national level

One of the main reasons for the lack of integration of the Nagoya Protocol compliance in the processes of design, review or update of national ABS frameworks in most countries of the Project, is their low profile in terms of politics at a national level. In this regard, it is recommended to improve the connection and coordination between foreign or international policies and the domestic policies of the countries in the Project. , This is considering that many of them successfully lead international negotiations of the Protocol, both in Latin America as well as in the alliance of LMMC. However, upon the attainment of an international instrument such as the Nagoya Protocol, when its application enters the national level it seems to vanish in a few of those countries. In honor of the truth, it should stand out that this political barrier caused by invisibility, the low internal importance and limited political interest in an issue as complex as ABS, is not a problem exclusively linked to the countries of the project but it is common in all the countries which are a part of the CBD, with no difference between developed and developing countries.

Lack of interest or political unawareness becomes, in most countries, an impassable barrier against which ABS national focal points collide and can do little, although they have staff whose technical ability as reflected in project execution is remarkable and even outstanding where consolidated national frameworks exist. All countries of the Project are going through complex situations, though perhaps the best example is the case of the Draft Sectoral Law on Biodiversity of the Dominican Republic, whose development appears as part of the General Law on Environment and Natural Resources (Law No. 64) of 2000, which is still pending approval and has been discussed for several years. Thus, this important loophole greatly limits the possible development of an ABS national framework.

The lack of political leadership is paving the way to disinformation or misinformation regarding the Nagoya Protocol and its implementation at national level. During the implementation of the Project, the limited knowledge of some sectors of the public administration is manifest and, in some cases, it is used for establishing opposing currents which have even rallied the sponsorship of environmental NGOs. In themselves, these statements emphasize either the negative elements, not included in any serious analysis of the Protocol, or the incomplete elements. For this reason, real political leaders are who take on ABS as a national priority, conveying a clear structure of its elements in order to build new national frameworks based on reality and not on assumption or science fiction are required.

3. Understanding, Implementing and Coordinating international Negotiation Instruments related to the Nagoya Protocol at a national level

The Nagoya Protocol is an instrument for the implementation of the provisions on access and benefit sharing of the CBD (Art. 4.4), though it has a number of limitations that must be considered for its successful implementation. Decision X/ 1 of the Conference of the Parties of the CBD, through which the Nagoya Protocol is adopted, recognizes that the International Regime on ABS consists of the: CBD, the Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, complementary instruments which include the International Treaty on Plant Genetic Resources for Food and Agriculture and the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization.

At an international level, three issues which affect or may affect the national implementation of the Nagoya Protocol stand out: its limitations regarding the scope, application and relation to other forums, as well as to any other instruments of precision in terms of points for monitoring and compliance measures. Therefore, analyzing the situation requires analyzing and knowing both existing and future instruments, such as international forums in which these complementary elements of the international regime and the Nagoya Protocol are negotiated.

3.1 Limitations in the field of genetic resources outside national jurisdiction

The Nagoya Protocol, as its Art. 3 explicitly stipulates, applies to the genetic resources comprised within the scope of Art. 15 of the CBD and the benefits arising from the utilization of such resources. Similarly, it applies to traditional knowledge associated with genetic resources within the scope of the CBD and the benefits arising from the utilization of such knowledge. In this regard, Art. 4 of the CBD states that its provisions "shall apply in relation to each Contracting Party, in the case of components of biological diversity, in areas located within the limits of its national jurisdiction" (Greiber et al., 2012). Therefore, it is assumed that genetic resources that are beyond the national jurisdiction of States Parties to the CBD are outside the scope of Art. 15 of the CBD and the Nagoya Protocol; such as marine genetic resources that are outside the jurisdiction of States and genetic resources of Antarctica.

3.1.1 Marine genetic resources

Marine genetic resources beyond national jurisdiction are vital for the Nagoya Protocol and in particular to the countries of the IUCN-UNEP/GEF-ABS-LAC Regional Project, as they are coastal States and given the fact they currently lack national regulation they constitute a big exit route. Therefore, the ideal situation is the establishment of a legal regime on marine genetic resources beyond national jurisdiction. This means 64% of the ocean surface, equivalent to 50% of the space of the globe, because it internationally reaffirms the principle of ABS since it is coherent and consistent with the requirements of access and benefit sharing of national frameworks. Thus, a system of joint research and scientific cooperation and technology transfer must be consolidated to reverse the current situation, which is perfectly portrayed by the 10 countries which together account for 90% of patents

on marine genetic resources, with 70% of these being located in three countries (Arnaud-Haond, Arrieta and Duarte 2011).

The request contained in Item 32 (c) of the Plan of Implementation of the World Summit on Sustainable Development in Johannesburg in 2002 and related to the establishment of Marine Protected Areas (MPAs), including areas beyond national jurisdiction, was presented to the General Assembly of the United Nations (UN) at its 59th Session (2004) and an Ad Hoc Open-ended Informal Working Group was created and "commissioned to study conservation and sustainable use issues related to marine biodiversity beyond areas of national jurisdiction "(Item 73, Resolution A/59/24, www.un.org/Depts/dhl/resguide/r59sp.htm). In 2006, since the first meeting the Working Group focused on two main issues: 1) the creation of Marine Protected Areas (MPAs) and 2) the legal *status* of marine genetic resources in areas beyond national jurisdiction. With regards to the second issue, the debate is reported to have opposing views between those who believe the legal status of marine resources should be applied vs. those who believe they should be treated as heritage of humanity.

After several years of working with little progress on the issues discussed above, during the World Summit on Sustainable Development 2012 (Rio +20), it is worth highlighting its final decision of taking on the commitment to address as urgent the issue of conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction, particularly deciding on the elaboration of an international instrument within the framework of the Convention on the Law of the Sea before the end of the sixty-ninth session of the General Assembly in 2015 (Paragraph 162, A/RES/66/288 , www.un.org/es/sustainablefuture/). Currently, the Working Group is developing the various elements in that field, the parameters and the feasibility of an international instrument under the United Nations Convention on the Law of the Sea, and plans to hold two meetings in 2014 and the beginning of 2015 with the objective of complying with the objectives of the Rio +20 Conference.

3.1.2 Antarctic genetic resources

The special characteristics of the Antarctic ecosystem make it difficult for its lack of regulation to be used as an exit route for genetic resources, especially in the case of tropical or subtropical countries of the Project. Thus, only Ecuador and Peru are parties to the Antarctic Treaty and its development instruments, while Colombia and Cuba are "not Consultative Parties" with a status similar to that of observers.

Antarctica and its regulation constitutes a unique case in having a somewhat vague legal status, because it is an area beyond national jurisdiction and with a number of countries that have a claim to sovereignty over its territory. The main international instrument by which this continent is regulated is the Antarctic Treaty (1959), which includes both the land area covered by ice as well as the seas that surround it further south of 60 degrees south latitude. A Protocol on Environmental Protection (1991) is being contemplated.

The management of Antarctica is based on the common goals of the countries that are Party to the Antarctic Treaty, using this space "exclusively for peaceful purposes" (Art. 1), as well as preserving the freedom of research and scientific cooperation. In addition, an exchange of available scientific results (Arts. 2 and 3) is maintained, which presupposes an important sharing of benefits since these results are freely available to other researchers and for any particular research conducted in this area.

It should be clarified that the issue of access to genetic resources and the fair and equitable sharing of benefits arising from their utilization, is not explicit neither in the Antarctic Treaty nor in the Environmental Protocol. For this reason, it was first discussed in 1999 by the Scientific Committee on Antarctic Research (SCAR), and was taken up again in 2005 and when it became clear that there is very limited related information (Lohan and Johnston 2005).

In 2009 and 2013, the Committee deals again with the subject of Resolution 6/2013 of the Antarctic Treaty, reaffirming that it is the appropriate instrument to address and manage bioprospecting and members are prompted to report these type of activities performed under their national legislation. Basically, the objective established is to facilitate the understanding and evaluation of these activities, while looking for ways to improve the exchange of related information through the possible adaptation of an electronic system for information exchange.

3.2 Specialized ABS forums

When analyzing the issues that are beyond both the CBD and the Nagoya Protocol because they go beyond their scope of application and even affect them, the existence of specialized agreements on ABS at an international level becomes salient. Thus, specific regulation of certain genetic resources based on their characteristics or special needs is required, and the application of differentiated regulations has been suggested. In principle, the Protocol applies to all genetic resources under the sovereignty of the Parties which they wish to regulate. So, one could say that, as development instruments, both the CBD and the Protocol are general in nature in terms of the regulation for genetic resources internationally.

The Protocol provides for the existence of specific international agreements governing ABS, since in Art. 4 establishes a relationship with international agreements and instruments and it includes principles of international law which are applicable to these situations. So if any specialized international ABS instruments existed or are developed, the specialized agreement would prevail over the general agreement, applying only to the parties involved provided that "it is consistent with and not contrary to the objectives of the Convention and this Protocol "(Art. 4.4).

3.2.1 International Treaty on Plant Genetic Resources for Food and Agriculture

Plant genetic resources play a decisive role for since no country is self-sufficient and they all depend on the genetic diversity of crops from other countries and regions. In this sense, and open exchange of genetic resources for food security becomes essential for the fight against hunger and poverty (http://www.planttreaty.org/es). The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) of the United Nations Food and Agriculture Organization (FAO), adopted in 2001 and in force since June 2004, nowadays brings 131 Parties together (http://www planttreaty.org/content/contracting-parties-treaty) which in turn belong to the CBD, and five of them are part of the IUCN-UNEP/GEF-ABS-LAC Regional Project, namely: Costa Rica, Cuba, Ecuador, Panama and Peru.

are part of the IUCN-UNEP/GEF-ABS-LAC Regional Project, namely: Costa Rica, Cuba, Ecuador, Panama and Peru.

The main distinguishing element of ITPGRFA versus the ABS system of the CBD is the Multilateral System of Access and Benefit Sharing, applicable to plant genetic resources for food and agriculture covered under Annex I. Thus, a standard contract called Material Transfer Agreement (MTA) which includes the stipulated conditions is set forth. For this reason, all countries participating in the project must determine how to regulate access to their in situ plant genetic resources for food and agriculture since the Treaty is expected to be applied nationwide. The analysis of the national ABS frameworks in the countries of the project shows a tendency to exclude national access regulations, particularly in the ITPGRFA signatory countries, leading to a legal loophole that should be regulated.

At the international level, the ITPGRFA is in harmony with the CBD, but the development of the Nagoya Protocol may result in certain challenges or opportunities. One of the key points would be to clarify to what extent the mechanisms of control and monitoring of the Nagoya Protocol, which are absent in the ITPGRFA, apply or not to the plant genetic resources that the latter covers. Therefore, total homogeneity and compatibility of the two systems is necessary to avoid exit doors in national ABS frameworks.

3.2.2 Commission on Genetic Resources for Food and Agriculture

Nowadays, a series of very relevant genetic resources for food security stand out, so the Commission on Genetic Resources for Food and Agriculture of FAO that developed the ITPGRFA continues working. Thus, the Commission at its thirteenth regular session in April 2011, decided to adopt the Nagoya Protocol and recognize "the special nature of agricultural biodiversity, its distinctive features and its problems in need of clear solutions" (CGRFA-13/11, www.fao.org/docrep/meeting/024/mc192s.pdf). Also, the Commission invites countries to study and evaluate how to adopt legislative measures, administrative measures or policies on ABS, which are sectoral approaches that allow for a differentiated treatment of: different sectors or subsectors of genetic resources for food and agriculture; different genetic resources; different activities or purposes for which those activities are conducted (Paragraph 57, CGRFA-13/11, www.fao.org/docrep/meeting/024/mc192s.pdf) .

Within this context, the creation of a special technical working group on access and benefit-sharing as related to genetic resources for food and agriculture (2012) apparently implies proposing the development of other specialized instruments for different genetic resources for food and agriculture different from those which are phytogenetic. By this principle, it was never expected that during the fourteenth regular session of the Commission it would be decided that "it was premature to negotiate one or more international agreements on access and benefit sharing in relation to genetic resources for food and agriculture" (Paragraph 39, CGRFA-a4/13, www.fao.org/docrep/meeting/028/mg538s.pdf).

The Commission chose to develop "Draft elements to facilitate the national implementation of access and benefit-sharing in different sub-sectors of genetic resources for food and agriculture"; assuming that such draft elements will constitute "voluntary instruments to help the governments of countries and not new international instruments on access and benefit sharing" (Paragraph 40.xv, CGRFA-a4/13, www.fao.org/docrep/meeting/028/mg538s.pdf).

3.2.3 Framework for Sharing of Influenza Viruses, Access to Vaccines and Other Benefits. Preparing for Pandemic Influenza.

In Art. 4.2, the Protocol stipulates that "due diligence shall be given to ongoing work or practices which are useful and pertinent under such international instruments and relevant international organizations, provided that they are supportive and not contrary to the objectives the Convention and this Protocol". All countries in the IUCN-UNEP/GEF-ABS- LAC Regional Project are part of the World Health Organization (WHO), which in 2011 adopted the "Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits. Preparing for Pandemic Influenza" known as PIP, an acronym which stands for "Pandemic Influenza Preparedness Framework" (Resolution of the World Health Assembly 64.5, http://apps.who. int/gb/ebwha/pdf_files/WHA64-REC1/A64_REC1-sp.pdf).

The PIP framework should be considered when implementing national frameworks for ABS as it has been stipulated in Art. 8b of the Nagoya Protocol, instrument that indicates the commitment of countries with their national frameworks when it mentions that "due attention should be given to cases of present or imminent emergencies that threaten or harm human, animal or plant health". Likewise, in such cases the expeditious access to genetic resources is provided for. Compliance with this provision refers to the application of national access procedures in emergency situations, especially to national influenza centers or specifically approved laboratories. Rapid transmission of genetic resources makes the provisions for the sharing of benefits of the PIP Framework.

The objective of the PIP Framework is "to improve the level of preparedness and response to pandemic influenza and strengthen the protection against pandemic flu by improving and strengthening the Global Influenza Surveillance and Response System (GISRS) of the WHO, aiming to have a fair and transparent system that is equitable, efficient and effective, in order to have equality in: i) the sharing of H5N1 and other influenza viruses with pandemic potential for human beings and ii) the access to vaccines and other sharing of benefits (World Health Assembly Resolution 64.5, http://apps. who.int/gb/ebwha/pdf_files/WHA64-REC1/A64_REC1-sp.pdf).

The PIP Framework provides a specific exchange system of these viruses and the main obligation of Member Countries , through their National Influenza Centers and Other authorized laboratories, is to "rapidly and systematically provide PIP biological materials obtained from all cases of human infection with H5N1 and other influenza viruses with pandemic potential for humans, whenever feasible, to the WHO Collaborating Centre on Influenza or to a reference laboratory for H5 chosen by the Member Country of origin" (World Health Assembly Resolution 64.5, http://apps.who.int/gb/ebwha/pdf_files/WHA64-REC1/A64_REC1-sp.pdf).

The resolution includes two models of MTA as well as the implementation of a traceability and notification mechanism based on an electronic system to monitor the movement of PIP biological materials in real time (World Health Assembly Resolution 64.5, http:// apps.who.int/gb/ebwha/pdf_files/WHA64-REC1/A64_REC1-sp.pdf). With regard to the system of "benefit sharing in the context of preparing for a pandemic flu," a range of information and services are expected to be generated which include, among others: antiviral drugs and vaccines against H5N1 as well as drugs for treating other viruses with pandemic potential for humans; the transfer of knowledge and technology; the establishment of a reserve of H5N1 vaccine, and related equipment which initially would have 150 million doses. The monitoring and evaluation of the implementation of the framework will take place at the World Health Assembly, which establishes an Advisory Group to monitor the functioning of GISRS and provide guidance to strengthen it. The Framework and its Appendices, which include the MTA models will be reviewed in 2016 to propose the relevant revisions to the World Health Assembly in 2017 (http://apps.who.int/ gb/ebwha/pdf_files/WHA64-REC1/A64_REC1-sp.pdf).

3.3 Forums related to checkpoints and measures of compliance

One of the main contributions of the Nagoya Protocol is producing a paradigm shift at an international level through what is known as "enforcement measures", in which the flexibility provided by the Parties to this denomination stands out since these do not have a specific checkpoint or specific measures of compliance, but at the same time it is implemented effectively and with relevant results in the utilization of genetic resources. If understood broadly or loosely, flexibility could lead to an uneven application of the obligations of the Protocol and, in relation to the part pertaining to measures of compliance, it could also lead to the impossibility of proper monitoring and control of the use of the genetic resources at an international level. In this sense, the Protocol should be formally or informally harmonized in the issues of monitoring (checkpoints) and compliance mechanisms, even applying other international instruments.

Intellectual property rights are always at the center of the origin of ABS regulation, so the two international forums dealing with international regulation are discussing the possible modification of these instruments to include the disclosure of origin of genetic resources or associated traditional knowledge held by indigenous and local communities as a new formal requirement, either for patentability or patent applications. The current deadlock which exists in the matter, has been manifested in both forums and demands a reflection of how to successfully fill these gaps in the international sphere through national ABS frameworks.

3.3.1 World Trade Organization

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the first multilateral agreement. It originated from the Uruguay Round and was part of the "single package" of creation of the World Trade Organization (WTO) (Jeffery 2002). In itself, TRIPS is the expression of the bargaining power of developed countries in the WTO and their willingness to impose greater enforcement of intellectual property rights in other countries or, in other words, impose a part of the price that developing countries had to pay for their incorporation into the single package of the WTO.

Maskus (2000) mentions the positive and negative effects that intellectual property rights can have in the development processes of countries and concludes that "the modern systems of intellectual property rights by themselves are not enough to ensure an effective technology transition. Instead, they must be part of a broader coherent set of complementary policies that maximize the potential of property rights in order to generate dynamic competition rather and not monopolies. These policies include the strengthening of human capital and skills acquisition, promoting flexibility in the organizational structure, ensuring a high degree of competition in domestic markets and developing a system of transparent, non-discriminatory and effective competition.

The Uruguay round confirmed the expansionary effect the trading system has towards other areas such as services and intellectual property rights, clarifying that the so-called "single package" means that in order to be a Party of the system, a country must participate in all agreements. The TRIPS agreement has relevance for ABS issues, because it firstly considers the importance of pharmaceutical companies in its negotiation and in the provisions of Art. 27 concerning patentable subject matter. Also, Art. 27, Paragraph 3 establishes exceptions for the patentability that Member Countries may apply, so that especially their review process is based on the discussion of ABS issues in the TRIPS agreement. In this regard, Gad (2003) believes that the involvement of transnational corporations and associations of producers and their interaction with governments during the elaboration of the TRIPS demonstrates that there is an elite of powerful actors which join the State in the management of global economy.

The Ministerial Declaration at the opening of the Doha Round, adopted on November 14th, 2001 (WT/MIN(01)/DEC/1), adds some considerations to the aforementioned topics, as it includes a broad additional mandate for the TRIPS Council to address issues related to ABS and the CBD, given its priority status for developing countries. Thus, Paragraph 19 states the following: "We instruct the Council of the TRIPS –when carrying out their work program, even within the framework of the examination considered in Paragraph 3 b) of Art. 27, pertaining to the examination on the application of TRIPS provisions set forth in Paragraph 1 of Art. 71 and the work pursuant to the compliance with Paragraph 12 of this Declaration– to examine, among other things, the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Paragraph 1 of Art. 71. In carrying out this work, the TRIPS Council shall be governed by the objectives and principles of the Arts. 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension. "

In this scenario, India raises the need to amend Art. 29 of the TRIPS agreement, which refers to the "conditions imposed on patent applicants" (http://www.wto.org/spanish/docs_s/ legal_s/27-trips.doc), applying the requirement of disclosure of origin of genetic resources in patent applications along with PIC and MAT. Also, if the invention utilizes traditional knowledge, the consent of those communities or what they called the Keating Information Transfer Agreement (2005) is needed. The last proposal to amend Art. 29 was presented in the month of April 2011, and was made by the delegations of Brazil, China, Colombia, Ecuador, India, Indonesia, Kenya (on behalf of the African Group), Mauritius (on behalf of the African, Caribbean and Pacific Group, ACP), Peru and Thailand (http://www.wto.org/spanish/tratop_s/trips_s/art27_3b_s.htm). At the same time, it must be said that six of these countries, namely: Colombia, Cuba, Ecuador, Guyana, Peru and Dominican Republic, are participating in the IUCN-UNEP/GEF-ABS-LAC Regional Project.

In summary, it has been reported that many developed countries have exploited the idea that TRIPS would produce an increase in technology transfer, stimulating the economic situation in developing countries, recognized as recipients; but the reality is that it is has been confirmed that there is a tendency to promote the importation of biotechnological products without its corresponding processes (Venbrux 2005). Interestingly, one of the elements of success in the creation of the WTO's so-called "single package", is exerting a negative pressure on the negotiations of the Doha Round, which began in 2001 and whose term was three years, but has been ongoing for over 12 years. In addition, it becomes clear that this blocking of international trade negotiations resulting in the proliferation of bilateral free trade agreements promoted by the major trading powers, represented by the United States, the European Union and Japan, and its impact can be seen in the national ABS frameworks.

3.3.2 World Intellectual Property Organization

The World Intellectual Property Organization (WIPO) was established in 1970 with the entry into force of the Convention of 1967, when the organization is created, establishing their relationship with the CBD and the Nagoya Protocol on the issue of biotechnology and its relation to biodiversity . All countries participating in the IUCN-UNEP/GEF-ABS-LAC Regional Project are Part of WIPO, and most participate in the Patent Cooperation Treaty (PCT) except for Guyana, and none are signatories of the Patent Law Treaty (PLT). WIPO has discussed for some years modifying the application procedures for intellectual property, requiring the disclosure of origin of genetic resources and/ or their associated traditional knowledge.

In this context, WIPO has three areas that address matters related to the CBD and the Nagoya Protocol: the Standing Committee on Patents, the Working Group on Reform of the Patent Cooperation Treaty (PCT) and the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). The first was created in 1998 to set priorities, allocate resources to ensure continuity of the work of the WIPO on Patents, negotiate the Patent Law Treaty (PLT) and be the forum for discussion of the Substantive Patent Law Treaty (SPLT). The third, was established during the General Assembly of WIPO in 2000, as its topic does not fit into any of the conventional branches of intellectual property law. In the case of the PLT, it was adopted on June 1, 2000 and it entered into force on April 28, 2005 (Keating 2005).

The first proposal to establish the requirement for disclosure of origin in patent applications related to ABS was presented in Colombia, in the Standing Committee on Patents in 1999 and had the support of a large group of developing countries. However, it led to the Working Group on Biotechnological Inventions, when it called for the First Meeting on Intellectual Property and Genetic Resources, the predecessor of the current IGC. When analyzing the above situation, it is reported that even with the distance between the Patent Cooperation Treaty and the ABS issue there are several proposals in the Reform Working Group. So, an example is Switzerland with his repeatedly presented proposal since 2003, but with strong opposition from the United States and Japan, and another case is the European Union that presented its proposal to reform the Treaty, opting to channel it through IGC.

After several years of discussion with limited progress in this area, in 2009 it was decided by the Member Countries of WIPO at the General Assembly, that the IGC start negotiations in order to "reach an agreement on one or several international legal instruments ensuring the protection of genetic resources, traditional knowledge and traditional cultural expressions." In this way, a two-year term was granted which was extended twice, most recently in the General Assembly of WIPO in September 2013 and covering the period of 2014-2015. For this reason, the IGC has to forward the text to reach the General Assembly in 2014 in order to decide whether to hold a diplomatic conference (http://biodiversity-l.iisd. org/news/wipe-assembly-renews-igc-mandate/).

It is noteworthy that WIPO produced some useful products for its members, such as the "Traditional Knowledge Toolkit", submitted in November 2012 (http://www.wipo.int/export/sites/www/tk/en/documents/pdf/tk_toolkit_31662_es_bv_Final_merged.pdf). Likewise, since 2004 WIPO has run the "Guide to intellectual property aspects of the access to genetic resources and equitable benefit-sharing Project, which is currently at an advanced stage. As a whole, it has a database of agreements and its various models, all related to biodiversity access and benefit sharing and related information, as well as information focusing on the aspects of intellectual property (http://www.wipo.int/ tk/en/databases/contracts/).

At the present , several elements are under discussion in the IGC more attention is being dedicated to everything related to the introduction of the requirement for disclosure of origin of genetic resources and /or associated traditional knowledge, and there is a strong conflict between countries seeking to introduce it as a fourth requirement for patentability and those who do not accept any obligation for disclosure of origin, accepting it only if it is essential to the criteria of novelty and non-obviousness (http://www.wipo.int/edocs/mdocs/tk/es/wipo_grtkf_ic_25/wipo_grtkf_ic_25_6.pdf).

Placing research and national scientific institutions at the center of ABS national policy

Placing research and national scientific institutions at the center of ABS national policy

Biodiversity-rich countries wishing to benefit from ABS should put it at the center of their strategies and/or national frameworks to ensure the development of their national biotechnology industry, promoting the capacities of endogenous human talent related to this subject matter as well as placing financial resources. In practice, this means that the strategies and policy frameworks for ABS should, among other things, prioritize measures in the agreements such as: access and technology transfer, cooperation and scientific collaboration, participation of national researchers in joint projects or conduction of all the possible stages of research within the country. In short, the objective is to recover the provisions of Arts. 15.6, 16 and 19 of the CBD and place them a central element of any national ABS system.

The message mentioned above may again seem obvious, but experience shows that expectations are focused on monetary benefits which are not generally accomplished, turning those related to access to and transfer of technology, such as collaboration and scientific cooperation into something minor or secondary in the system. Therefore, it becomes necessary to build a national framework with a primary focus on the native research institutions and their researchers, with one of the main benefits being to locally assimilate the various stages of the biotechnology value chain, because the contribution of genetic resources as raw material without any added value is low in these processes, particularly for the conservation and sustainable use of biodiversity.

Most national ABS frameworks consider national research institutions in their procedures, but their true integration is still pending so that these systems can become their tools, thus contributing to the country and its development. In this sense, a true joint ABS strategy is required, which must be built on the status of biodiversity and the potential of genetic resources of the country, while considering the national reality of institutions dedicated to conservation, particularly ex situ; research and biotechnology. When the reality of local research and its relation to the biodiversity of the country is known, the negotiation of specific ABS agreements can produce the desired results for the consolidation and development of the sector.

In addition to all that has been previously stated, a third element must be added: the status and potential of traditional knowledge associated with genetic resources held by indigenous and local communities. The strategy in this regard provides a valuable start point from which to build and develop the objectives and tools of a national ABS framework, encouraging and truly integrating the different worlds, and it can also be applied to deal with all the issues involved more appropriately with the aim of achieving joint objectives.

As for ABS procedures, they must be as consistent as possible with the work of the researcher and the reality of research projects. The government sector is responsible for regulating and managing the environmental procedures associated with ABS, and must prepare in order to better understand the steps and stages of implementation of research projects, so that the procedures may conform to the activities and bureaucratic burdens or excessive controls may be avoided.

the activities and bureaucratic burdens or excessive controls may be avoided. Similarly, the researcher must understand the basis of the ABS system and the reason for administrative intervention, assuming that it is an opportunity and a tool to create value since research channels and absorbs most of the benefits at a national level.

Within this context, it must be remembered that the relationship between the environmental regulator and the researcher is not as integrating and fluid as it should be, and the relationship between the researcher and indigenous and local communities is not usually better. Again, it is advisable for the ABS national strategy to facilitate a meeting point in which both sectors recognize and understand each other, finding synergies that enhance the recognition of the important role that each of them play, as well as the importance of working together. Thus, it seems logical to reflect on the importance of the role that the scientific sector has or may have in the valorization of traditional knowledge associated with genetic resources held by indigenous and local communities, which is a role which many researchers seem to be extremely skeptical about at present.

All national ABS frameworks analyzed during the implementation of the Project contain references to research and integration as part of the process of access and benefit sharing. However, none seems to successfully integrate that element in the end. In this situation, the exception of Costa Rica stands out since the country channels the application of ABS through a research institution: the National Biodiversity Institute of Costa Rica (INBio).

The best example of success as a country is Costa Rica, with its research center created and implemented to absorb and channel the distribution of benefits arising from the utilization of genetic resources, which are invested in conservation and sustainable use of its rich biodiversity. In addition, the model is very clear and has been working for years because INBio, which was created in 1989, operates a national framework for ABS which is one of the least protectionist with its research centers, at least in terms of access requirements for foreigners. In fact, in practical terms, the only thing that it requires non-national researchers is to appoint a resident in the country as legal representative, through the mandatory registration at the Technical Office (OT) of the National Commission for Biodiversity Management of Costa Rica (CONAGEBIO).

The vast majority of countries in the Project regulate access to their genetic resources through administrative procedures, considering only research institutions in the country for the role. This is the reason why, in fact national systems are not designed to receive progress reports and ultimately promote the development of biotechnology in the country, but rather often impose unnecessary and unaffordable burdens. Countries use different ways to incorporate the participation of national research institutions or researchers into the access Project. The first, is incorporating research institutions or national researchers into the different activities of the Project as a condition for access. Precisely, this is the case of Decision 391 of the CAN, pertaining to specific ABS procedures of Colombia, Ecuador and Peru, or the Executive Decree No. 25 of 2009 in Panama. Some countries, such as Peru, not only deal with the requirement of participation of national research institutions in the project, but also grant them a control and monitoring capacity on access to genetic resources.

1. Establish measures for effective and efficient implementation

One of the major advances introduced by the Nagoya Protocol at national and international level, is that it allows monitoring and control over genetic resources beyond the jurisdiction of the country that supplies and regulates the access. Basically, the Protocol refers to measures that all parties, especially the "users" of genetic resources, intend to adopt in order to ensure that their use within their jurisdiction will be conducted in accordance with the national legislation of the supplying Party.

In this context, the Nagoya Protocol stipulates that "each Party shall adopt legislative, administrative or policy measures to ensure that genetic resources utilized within their jurisdiction have been accessed in accordance with the PIC and the MAT, as specified in the national legislation on access and benefit sharing of the other Party "(Art. 15.1). Likewise, Art. 16.1 provides for the same obligation for traditional knowledge associated with genetic resources. So, for this control to exist, it is essential that for the supplier Parties of genetic resources or traditional knowledge to regulate them.

Legislative, administrative or policy measures lead to the adoption and designation of at least one control or checkpoint (Art. 17), which "must be relevant to the use of genetic resources, or the collection of relevant information" [Art. 17.1 (iv)]. In practice, this means that each Party shall establish a control point, for instance the National Patent Office, where anyone wishing to apply for a patent is required to submit a Certificate of Compliance. The Parties (States users) may also require such information to be disclosed, requesting funding for research, publishing scientific papers, whose content is based on research development and analysis of genetic resources obtained in a third country; or registering certain products that need this requirement prior to their release to the market or to the request from the national ABS focal point.

At control points, the users of the resource must show that they obtained their Certificate of Compliance, which in turn proves that there is a PIC and MAT; and therefore that national legislation complies with the supplier country. The certificate is issued at a national level in the country where access occurs and has international value once the country of access communicates this to the Information Sharing Mechanism on ABS. Article 17.3 specifies that this internationally recognized certificate "will serve as proof that the resource it refers to was accessed in accordance to a PIC and that MAT have been established, which will become the new basic documentation to go along with genetic resources and that must be submitted in the control or checkpoints.

In cases when a there is no Certificate of Compliance because the supplier country had not yet issued it at the time of access or because access in the country was not or is not regulated, the presentation of the PIC, if available, will be enough. If no documentation were available, a user statement regarding the origin will be required. The checkpoint will be obliged to submit the required information to the competent national authorities, to the country of origin and to the Information Sharing Mechanism on ABS. In this regard, it is worth pointing out that the information generated in the control points will be available both directly from the user country, from the supplier country, and it will be available centrally at the Center for Information Exchange on ABS of the CBD, where this new international system will be located to generate greater transparency and legal certainty regarding the exchange of genetic resources and associated traditional knowledge.

Other documents produced within the framework of Project explain the possible ways to implement Arts. 15, 16 and 17 of the Nagoya Protocol, referring to developments that some users or regions such as Norway, Switzerland and EU countries are conducting to meet the requirements of control and compliance measures (Cabrera Medaglia 2013). In this case, measures in the Project countries currently exist which already work as checkpoints or compliance measures; many of which serve as inspiration for the development of the Nagoya Protocol; and on certain issues, they simply require small changes and adjustments to be fully in line with its provisions.

The Nagoya Protocol, as stated before, has some flexibility; but it requires a formal or informal process of harmonization of its measures. In this regard, and given the fact that many of the countries of the IUCN-UNEP/GEF-ABS-LAC Regional Project are leading the demands for certain measures, it is recommendable that they not wait for the user countries to determine such measures according to their standards. In fact, the countries in the Project which are also rich in biodiversity, should organize themselves to facilitate examples of effective control points, as well as compliance measures that serve as standard for others, because in this way they may even require third parties for access to genetic resources based on the principle of reciprocity.

1.1 Andean Community

Do to their membership in the Andean Community and their consistent implementation of Decision 391 and Decision 486, the three Andean countries of the Project –Colombia, Ecuador and Peru– have a checkpoint and compliance measures on the use of their genetic resources and the associated traditional knowledge held by indigenous and local communities. Supplementary Provision Three of Decision 391, establishes its checkpoint at "national offices competent in the matter of Intellectual Property" stipulating that they "shall require the applicant to give the registration number of their access contract and a copy thereof as a condition prior to the granting of the rights concerned, when they are certain or have reasonable evidence that the products or processes whose protection is being requested have been obtained or developed from genetic resources or derivates from any of the Member Countries of origin" (CAN 1996). Being a regional standard, it adopted an identical approach to that of the Nagoya Protocol nearly 15 years later, applying such provision not only to national genetic resources but to "genetic resources or byproducts from ... any of the Member Countries" (CAN 1996).

The Second Supplementary Provision of Decision 391 also states that "Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this Decision "(CAN 1996). So with this second part, this provision would be complying with the checkpoint, exercising the measures provided for in Arts. 15.1, 15.2, 16.1 and 16.2 of the Nagoya Protocol; as it applies a penalty by not granting rights –mainly intellectual property rights– to genetic resources obtained illegally, although it may also address others. Additionally, it anticipates cases of default, in which "... the Member Country

affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents". (CAN 1996) This clause enables the member country to have access to justice abroad for violation of its regulations on access to genetic resources. In this way, it would be in compliance with the provisions of Arts. 15.3 and 16.3 of the Nagoya Protocol.

Decision 486 of September 14th, 2002 on the common regime of intellectual property, supplements this in Art. 26 by stating that in the application for a patent one must submit, among other things, a copy of the access contract when the products or processes, for which a patent is sought, are obtained or developed from genetic resources or derived from any of the Member Countries of the Andean Community (Paragraph h). In relation to traditional knowledge, the decision establishes a similar obligation to require the submission of a copy of the license or authorization of use of the traditional knowledge of indigenous, Afro-American and local communities in the Member Countries when the products or processes, for which protection is sought, are obtained or developed from the knowledge originating in any of the Member Countries (Section i). Compliance with these articles is checked during the evaluation process for the patent application (Art. 38).

In the two cases referred to above, the scope of Art. 26 includes genetic resources of the country and all Member Countries of the Andean Community, as well as the traditional knowledge of indigenous, Afro-American and local communities living in this territory. The scope of Decision 486 is extensive and expressly applies to traditional knowledge, with the obligation to certify their origin and legal use in patent applications, strengthening Decision 391 that generally refers to "the associated intangible components" and establishing another compliance measure in Art. 75 stating that:

> "The competent national authority may, either ex officio or at the request of a party, and at any time, declare a patent null and void, where:
>
> g) when pertinent, the products or processes in respect of which the patent is being filed have been obtained and developed on the basis of genetic resources or their byproducts originating in one of the Member Countries, if the applicant failed to submit a copy of the contract for access to that genetic material;
>
> h) when pertinent, the products or processes whose protection is being requested have been obtained or developed on the basis of traditional knowledge belonging to indigenous, African American, or local communities in the Member Countries, if the applicant has failed to submit a copy of the document certifying the existence of a license or authorization for use of that knowledge originating in any one of the Member Countries".

Finally, Art. 3 of Decision 486 states that: " The Member Countries shall ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities. As a result, the granting of patents on inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law".

As of today, even though the regional legislation is complete, with Decision 391 dating back to 1996 and Decision 486 to 2000, a concrete application of national standards in the three countries of the Project that belong to the Andean Community is needed. This can perhaps due to the lack of information of patent cases that were not granted or invalidated because they lacked proof of the legality of access to genetic resources and / or traditional knowledge; so, when the patent is based on a development based on these, it could be an indication of the absence of real implementation of national standards. In itself, this latter assumption should be considered with extreme caution since confirming it requires having sufficient information.

Firstly, the complete adjustment of all measures to align with the provisions of the Nagoya Protocol requires a particular terminology and documentation, with the main document required for checkpoints being the Compliance Certificate recognized internationally, and alternatively, the PIC and MAT, or the ABS contract. \ . Secondly, the scope of regulation should be extended, and go from being applicable to genetic resources from any of the countries of the Andean Community, as well as to the traditional knowledge of indigenous and local communities in their territory, to being applicable to genetic resources from any of the countries which are Parties to the Nagoya Protocol and to traditional knowledge of indigenous and local communities in their territory. Finally, information on the use of genetic resources which is collected in intellectual property applications should at least be sent to: the Party of the Nagoya Protocol, which is who grants the PIC and to the Center for Information Exchange on ABS of the CBD.

1.2 Costa Rica

Costa Rica is a pioneer since 1998, when it established in Art. 80 of the Biodiversity Act (Law No. 7788) the mandatory requirement for both the National Seed Office as well as the Registers for Intellectual and Industrial Property to consult with the TO of the CONAGEBIO with regards to innovations involving components of biodiversity. In Art. 80, it is also stipulated that consultations "must always provide the certificate of origin issued by the Technical Office of the Commission and the prior informed consent", meaning that in the patent application requirements the records offices should demand that petitioners provide that information. The scope of this provision is reduced to the Costa Rican genetic resources and, given the current context, its scope should be extended to all genetic resources from other Parties to the Nagoya Protocol.

The big problem with the above provision, is in its existence within the Biodiversity Law without ever been incorporated and implemented in their own procedures of intellectual property. In December 2008, the government enacted Decree No. 34958-COMEX MINAET, approving the Regulation for Art. 80 of the Biodiversity Act. However, it was later overturned by the Constitutional Chamber of the Supreme Court through Decision No. 2012-17058 of December 5, 2012, when it considered that during its processing, "the right of participation of indigenous peoples was violated, in detriment of the Law in the Constitution and more specifically of Convention No. 169 of the WTO and the Convention on Biological Diversity." Therefore, we can conclude that since the creation of Art. 80 of the Biodiversity Law, enacted in 1998, there is no mechanism to date in practical terms for monitoring and control, nor are there any compliance measures on the use of genetic resources in Costa Rica.

1.3 Cuba

The situation in Cuba is a peculiar case study with regard to compliance measures, as it is common to find provisions in biodiversity regulations which refer to provisions that become nothing more than mere principles of the system, but have no real practical application and no procedures for the incorporation of intellectual property, as is the case of Costa Rica. In analyzing the situation in Cuba, it is just the opposite, because their biodiversity rules have Resolution No. 111/96 of the Ministry of Science, Technology and Environment of November 28th, 1996 which provides regulations on biodiversity, but when analyzed it states nothing about it and it is the rules on intellectual property that exercise control, applying them to genetic resources of any country and becoming a reference source on the subject.

The recent legislation on intellectual property, adopted through Decree-Law No. 290/2011 concerning Inventions and Industrial Designs, states the documentation that must be attached to a patent application in Art.26:

> "j) copy of the prior express authorization for access to biological material, issued by the competent authority in accordance with the laws in force on the matter when the invention relates to such material, including genetic material and its parts or byproducts coming from Cuba, or present in domesticated and cultivated species in the country;
>
> k) statement that expresses that the biological material to which the invention relates, has not been obtained in the Republic of Cuba, in which case the applicant shall indicate what is the country of origin and source of biological material and the traditional knowledge associated with such material, as well as the prior informed consent for access;"

The novel contribution of the legislation relates to the control of the access to Cuban biological material, in Paragraph j; and to material from third countries, in Paragraph k; with the Decree-Law referring to biological material and traditional knowledge in this last case. In this regard, it is surprising not to find the protection of traditional knowledge associated to Cuban genetic resources included in Section k, pertaining to this matter, a point that should be clarified with the patent department, given the fact that the system currently offers greater a priori protection for traditional knowledge coming from third countries than that which it offers for the knowledge held by the local communities in Cuba.

The terms of the text referred to above must be adjusted to align with the Nagoya Protocol, requesting the Cuban Office of Industrial Property (OCPI) for an internationally recognized certificate of compliance for the genetic resource in question. Also, environmental regulations or the OCPI itself shall arrange for the communication of documentation since, once collected, it is the Center for Information Exchange of the Nagoya Protocol, as well as the Party who grants the PIC pertaining to those resources in accordance with the provisions of Art 17.1.a.iii of the Nagoya Protocol, which is in charge of that communication. Likewise, in Art. 31 of Decree-Law No. 291/2011 on the Protection of Plant Varieties, pertaining to applications, it stipulates the following:

> "f) when the plant variety is derived from an initial plant material originally from the territory of the Republic of Cuba or is present in species which are domesticated and cultivated in the country, a copy of the document attesting the express written consent for access to such starting material or materials, issued by the competent authority, in accordance with current legislation on the subject;

> g) if the case were opposite to the provisions stated in the prior paragraph, when otherwise as provided in the preceding paragraph, a statement will be required that expresses that the material which is the starting source of the plant variety has not been obtained in the territory of the Republic of Cuba, and that a PIC has been obtained prior access."

In the case of Sections f and g, the text has to be adjusted to the new documents provided for in the Nagoya Protocol, complying with the requirement of an internationally recognized certificate and the communication of this information to the Center for Information Exchange of the Nagoya Protocol as the Party that granted the PIC. The requirements of the two regulations are formal, so a failure to incorporate them may result in not proceeding with the substantive examination. This means that the application could be considered as abandoned, but in no case are these requirements grounds for refusing the patent. Cuban legislation, even with necessary adjustments pending, becomes an excellent example of how to introduce the specific requirements of intellectual property by operating through patent applications and a nationwide checkpoint in accordance with the Nagoya Protocol.

2. Design and establish clear models for ABS contracts

Under the framework of The IUCN-UNEP/GEF-ABS-LAC Regional Project, the importance of the contract is emphasized because it is the tool which regulates every detail of the particular ABS bilateral relationship, and it is mentioned in this research in general way in order to cover all possible forms of MAT, and to forge the agreements and specific conditions to be applied in a bilateral or multilateral relationship. Thus, a contract is a voluntary agreement between two or more parties intended to produce legal effects, which bases its relevance in the clauses the law creates among the signatories. The principle of autonomy determines the content of the contract, and its only limit is respect for applicable Law, morality and public order; so, the parties can agree on what they want, provided that such conditions are not against the Law. Therefore, two basic elements of the contract are displayed, with the case of ABS being of particular attention regarding several of the above elements, namely: respect or applicable Law and the will of the parties.

International standards do not set excessive limits or details for an ABS contract, although the Nagoya Protocol itself explicitly includes some items, many being based on national ABS frameworks in several countries of the project and on the experience in implementing them. For example, Art. 6.3.g Nagoya Protocol stipulates that ABS contracts be written and include dispute resolution clauses, benefit-sharing (including intellectual property rights), subsequent use by a third party and change in intention, if there were any. In relation to the Dispute Resolution Art. 18.1 includes specific provisions on ABS contracts that determine "the jurisdiction to which all processes will subject any dispute resolution; the applicable law; and/or options for alternative dispute resolution, such as mediation or arbitration."

Within this context, Art. 17.1.b of the Nagoya Protocol highlights the importance of information sharing and the ability to include clauses in ABS contracts that determine how this exchange will happen and how often. Also, the article considers that the existence of model clauses may facilitate both the processes of negotiating contracts, as well as the results to be obtained because it encourages

Parties to develop model clauses or even establish contractual models (Art. 19). Also, ABS contracts determine the specific conditions which define access and benefit sharing in a country with national ABS frameworks. The contract will be lawful, it shall respect and introduce the specific conditions laid down in national ABS frameworks, especially in countries with national frameworks in which the structure of the contract and many of its provisions have been established. In such cases, it is considered that the Nagoya Protocol encourages the creation of a simplified procedure to provide access for scientific research purposes, which is reflected nationally in a different model of contract.

In national ABS frameworks, even in the most detailed ones, it will normally not be established in closed form, with specific provisions and percentages, the conditions for benefit sharing because there is a scope for them to be determined in each particular case, applying the will and discretion of the parties. Normally, the clearer and more precise the will of both parties in establishing the conditions of the ABS contract, the greater the assurance that its terms will be met. Thus, the elements that will be considered and configuring the will of the country's institutions, become responsible for negotiating the conditions of the ABS contract, and become the basis for building the model nationwide.

Most existing national ABS frameworks in countries of the IUCN-UNEP/GEF-ABS-LAC Regional Project have references to the contract as a central element, because it establishes the specific conditions of each specific relationship. For this reason, some apply the minimum elements that this tool should contain. The most advanced countries in the implementation of ABS establish models of individual contracts, because they help to visualize the type of relationship and the conditions which are expected to be covered by this regulation. Thus, Costa Rica and Peru are described as examples, since they are already developed models used as the basis for certain provisions of the Nagoya Protocol.

2.1 Andean Community

Some days after the adoption of Decision 391 in July 1996, the Andean Community adopted Resolution No. 415 and adopted the reference ABS contract model. The document, rather than a reference model for an access agreement in itself, is a series of points that should be included in every ABS contract to be implemented in the region, thus leaving it to member countries to develop more concrete models of valid contracts for their jurisdiction. In fact, several of the items on this reference model, for instance regarding dispute resolution (Law and Jurisdiction), are listed in the Nagoya Protocol and this is proof that these elements are a source of inspiration, nearly 15 years later, for certain provisions of this tool (Arts. 6.3.g y 18.1).

2.2 Costa Rica

The case of Costa Rica, as mentioned earlier, stands out as the country with one of the most comprehensive national frameworks for ABS and with long experience in its practical implementation, becoming a reference for many of its aspects. The legal framework for ABS in Costa Rica is remarkable due to three instruments: Law No. 7788 of Biodiversity of 1998; Executive Order No. 31514 of 2003,

through which the general rules for access to genetic and biochemical biodiversity resources and elements; and Executive Order No. 33297 of 2007, which amends the Regulation for Access to Genetic and Biochemical Elements and Resources from Biodiversity in ex situ conditions.

Executive Order No. 33297 is characterized because it completes the ABS system because in its Annexes, it introduces models of MAT for institutions ex situ (Annex I), a model for a framework agreement on access to genetic and biochemical resources and elements from biodiversity (Annex III) and a code of conduct for access to genetic and biochemical resources and elements from biodiversity (Annex II). Again, Costa Rica with its national ABS framework, anticipates and inspires elements which are contained in the Nagoya Protocol in Art. 19 (model contract clauses) and Art. 20 (codes of conduct, guidelines and best practices and/or standards).

Another contribution to the ABS scenario, is highlighted in the CONAGEBIO through its TO, who developed the forms for the procedures stipulated by the Law, such as the access registration and application, among others, which are available on its Web site (www.conagebio.go.cr). In the referring to PIC, the "contract guide for developing PIC and MAT for access to genetic and biochemical resources of items or elements from biodiversity or associated traditional knowledge" stands out. It is basically an access agreement model that the TO operates; the difference between it and the reference model of the Andean Community –which is a general list of items to include in access contracts– is that the guide is a contract model that can be used directly because it introduces detailed and concrete information about the parties and about the material to be accessed as well as the specific conditions for access and benefit sharing. As such, the document is relatively simple and takes the provisions stipulated in the national ABS framework into account in 18 clauses, among which certain provisions stand out, such as those pertaining to the following areas: project characteristics; access site, material to which access is sought, and permission of the owner; pricing of samples and benefit sharing. It also takes into account information and technology transfer, the requirement to pay up to 10% of the research project and up to 50% of the profits (which obviously should be detailed in each case, as well as everything else mentioned above) and the obligation to keep a record of the origin of the material in any activity or publication.

3. Ensure that free trade agreements do not affect national ABS frameworks

Ensuring that free trade agreements do not affect national ABS frameworks, becomes one of the least obvious and most critical points of this study, as it relates to the state of negotiations on disclosure of origin in the context of the TRIPS of the WTO and its importance is manifest in the general blockade to international trade negotiations in recent years within the context of the WTO, causing the big trading powers like the United States and the European Union to embark on bilateral negotiation with third countries in free trade agreements (FTAs).

In the two countries of the Project that have complete and advanced national ABS frameworks, such as Costa Rica and Peru, there has been an impact on these instruments when there is a negotiation and implementation of a FTA with the United States of America. The impacts reveal a lack of integration of public bodies responsible for ABS, particularly in the national delegations negotiating these agreements. Also, there is little or no influence or presence of environment institutions in the

trade negotiations, confirming that international principles and aims of sustainable development continue to be ignored when such negotiations move along purely economic parameters to move only in purely economic parameters such negotiations.

Within this context, the use of United States -as the world's economic power- of bilateral trade mechanisms which obviously adopt strategies to advance national positions on matters which are still debated in the international arena, has become evident. Regarding this situation, one can analyze the case for the possibility of including disclosure of origin as a formal or substantial requirements in applications for intellectual property rights, especially patents. In this sense, it becomes a priority to consider the particular circumstances of individual countries on future FTA negotiations, as in the case of Costa Rica and Peru.

3.1 Costa Rica

For a starter, it is valuable to remember that Costa Rica is one of the pioneers in the field of ABS and its national framework is composed of different standards, making it one of the most complete and effective internationally. In the ABS system Rica to key piece is expressed in Biodiversity Law No. 7788 (1998), which in 2010 obtained important international recognition by getting the first "Gold Award" at the "Future Policy Awards") for its excellence in achieving the principles contained in the CBD.

One of the great innovations of the Biodiversity Law No. 7788 is the mandatory requirement, established in Art. 80 pertaining to consultation with the TO of CONAGEBIO, of both the National Seed Office and the Registers of Intellectual and Industrial Property in relation to innovations in which elements of biodiversity are involved . Thus, the consultations "will always provide the certificate of origin issued by the Technical Office of the Commission and the prior informed consent", meaning that in the requirements for patent applications, offices and records should demand petitioners to provide this information because, given that it is included in a law, it must become operational by developing the corresponding rules or regulations in intellectual property procedures.

The requirement of Biodiversity Law No. 7788 is developed from a specific regulation, Decree No. 34958-COMEX MINAET, thus approving the Regulation to Art. 80 of the Biodiversity Law. The name of this Decree is peculiar because it has the heading of the Ministry of Environment, Energy and Telecommunications (MINAET) and that of the Ministry of Foreign Trade (COMEX), reflecting the fact that its development and approval covers a necessary foreign trade requirement for the adoption of the Dominican Republic-Central America-United States of America FTA (CAFTA-DR) in hand with Costa Rica..

The second peculiarity of Decree No. 34958-COMEX MINAET is that even when it regulates and develops the provisions in Art. 80, after analyzing its content it can be concluded that the real objective is to leave it without any practical effect. Subsequently, this decree is annulled by the Constitutional Chamber of the Supreme Court, through its Decision No. 2012-17058 of December 5th, 2012, concluding that its processing violated _ "the right of participation of indigenous peoples in detriment of the Law of the Constitution and more specifically of Convention No. 169 of the WLO and the Convention on Biological Diversity. "Today, the development of the regulations of Art. 80 of the Biodiversity Law continues, after over15 years; and it is still pending and unlikely to move forward because there is an FTA with a business partner that it would be inconvenient to go against.

3.2 Peru

In analyzing the case of Peru, the approval of its ABS regulations under development and implementation with the Andean regulations made by Decision 391 and Decision 486 must be noted, being implemented by way of Ministerial Resolution No. 087-2008-MINAM, which has been ratified and elevated to Supreme Decree No. 003-2009-MINAM. Similarly, Law No. 27811 for specific traditional knowledge is developed because it establishes the system of protection of the Collective Knowledge of Indigenous Peoples Derived from Biological Resources.

Regarding checkpoints and control, by applying compliance measures the Peruvian legislation executes the provisions of the Third Complementary Provision of Decision 391, by stipulating that the registration process of "patents, industrial design, plant varieties, drugs, nutraceuticals, cosmetics and certified seed, corresponding to products which have used genetic resources or traditional knowledge of which Peru is a country of origin , the presentation of the corresponding access agreement or the certificate is required "(Fifth Complementary Provision , Supreme Decree No. 003-2009-MINAM of Peru). Thus, the penalties for non-compliance apply in accordance with the provisions of Decision 391 (Second Complementary Provision) and Decision 486 (Arts. 38, 26, 27 and 75) and they consist of: the non-recognition of rights, including intellectual property, if genetic resources and/or traditional knowledge were accessed in violation of the Decision; and the absolute nullity of a patent when the copy of the access contract is not submitted during the process. The same is mandated by Law No. 27811 in relation to traditional knowledge, requiring a copy of the license agreement to grant the patent. Failure to comply will be cause for refusal or invalidity of the patent (Second Supplementary Provision, Law No. 27811 of Peru).

The penalties mentioned above are lessened through the rules adopted to implement the Trade Promotion Agreement signed between Peru and the United States, eliminating the non-recognition of intellectual property rights, as well as the invalidity of the patent or refusal. In this sense, Law No. 29316 of January 13, 2009 is applied to modify, incorporate and regulate various provisions to implement the Trade Promotion Agreement signed between Peru and the United States of America, since in Art. 8 it contains a new amendment to Legislative Decree No. 1075 of June 27th, 2008 which approves the Complementary Provisions to Decision 486 of the CAN when establishing the Common Intellectual Property Regime in Art. 120A.

Article 120A stipulates that failure of a patent applicant to comply with the requirement of the contract referred to in Art. 26, literal h) for genetic resources and literal i) for traditional knowledge of Decision 486; and developed in the Art. 20 (access contract) and Art. 21 (accessory contract) of the Regulation on Access to Genetic Resources (Supreme Decree N º 003-2009-MINAM) will result in fines; compensation; fair and equitable sharing of benefits including distribution of royalties, and / or other monetary or non-monetary measures; technology transfer and capacity building and authorizations for use. So, all this is true as long as genetic resources and / or traditional knowledge originating from Peru are involved. Similarly, the Second Supplementary Provision of Law No. 27811 is amended by Art. 13 of Law No. 29316, so when a patent related to products or processes produced or developed from the knowledge held by an existing collective in Peru, the competent authority shall request a copy of

the license agreement. The breach of this requirement is no longer as it was originally provided for in the Second Supplementary Provision of this Law, because the refusal or invalidity of the patent application applies, thus fulfilling the penalties.

By keeping important sanctions concerning the refusal or invalidity of the patent as established by Decision 391; the non-recognition of intellectual property rights; and Decision 486, with the invalidity of the patent or denial thereof, when contracts for access to genetic resources and/or traditional knowledge are not submitted; in Law No. 27811 itself pertaining to traditional knowledge, for the purposes of the license agreement, these are removed and replaced, thus limiting the adoption of standards for the implementation of the FTA between Peru and the United States to pecuniary sanctions or sanctions of another type. So, even though Peru is one of the countries that supports the introduction of an Art. 29 in the context of the TRIPS Agreement of the WTO at an international level with the intention of introducing the mandatory disclosure of origin of genetic resources or traditional knowledge associated as a patentability requirement, it appears that there is a Trade Promotion Agreement with United States which prevents them from nationally implementing that which they call for changing internationally.

4. National ABS frameworks in Latin America and the Caribbean: challenges for the implementation of the Nagoya Protocol

The experience and lessons learned from the implementation of the IUCN-PNUMA/GEF-ABS- LAC Regional Project; particularly in relation to the revision and update of the legal ABS frameworks , reveal seven currently critical elements for the nationwide implementation of the Nagoya Protocol, which can be applicable not only to the region but to many other countries. In itself; the seven critical elements are directly or indirectly interconnected and they shape, condition or limit the effective implementation of the Nagoya Protocol.

The first critical element contrasts the importance and priority that the negotiation and adoption of the Nagoya Protocol had for many countries in the Project, exemplified by the leadership exercised in these processes; versus the political abandonment that it suffers when the time comes to properly implement it nationwide. The remarkable technical capacity and experience of the countries of the region in the design and development of tools for the implementation of ABS at a national level –reflected in the fact that their regional or national regulations have directly inspired most of new the elements and obligations of the Nagoya Protocol– clashes against the wall of political invisibility on this issue, which becomes the greatest obstacle to progress in the national implementation of the Protocol.

The second critical element refers to the lack of integration of the obligations and derivative instruments of the Nagoya Protocol, which can be observed in national processes for reviewing and updating national ABS frameworks. Thus, even though the vast majority of countries in the region are implementing processes for updating and reviewing their national ABS frameworks, it appears that none of these regulatory projects fully integrates or takes up these new international rules. Precisely, the disconnect between the ratification process and the updating of national frameworks involves a delay in the national implementation of the Nagoya Protocol and is a guarantee so that –in case they are approved behind their back- the processes must be reviewed again almost immediately for approval.

The third critical element is the knowledge, implementation and coordination at national level of certain instruments and negotiations related to the Nagoya Protocol. Despite being the main international mechanism on ABS, this instrument is not alone and there are other important international forums on various subjects such as food, health care, intellectual property and high seas, to cite the most relevant and diverse, which should develop schemes or additions to the Nagoya Protocol. Therefore, it is necessary to develop second generation national regulatory ABS frameworks that fully incorporate the vision of the Protocol and combine it with the efficient and comprehensive implementation of other international instruments.

The fourth critical element is placing research at the center of national ABS policy again, not as the main door out, but as a valorization of the country's genetic resources and as a main channel for a fair and equitable sharing of benefits to support the development of the biotechnology sector. In addition, the main paradigm shift of the Nagoya Protocol is the first real and effective internationalization, by establishing checkpoints and compliance measures in all parts of the ABS Protocol.

The fifth critical element refers to the importance of clear ABS contract models at a national level which provide guidance and legal certainty for suppliers and users. The development of these models, helps public authorities in the country to negotiate contracts and have clear parameters, since they can feel confident that their actions are in accordance with the law. It also facilitates the access to the genetic resource for the interested parties, and it helps them understand and assume a priori the terms that this negotiation will set forth. The combination of the interests of conservation and sustainable use of biodiversity and those of development, should be reflected in the standard contracts and the type of benefits that the country in question anticipates or expects from each project of access to genetic resources.

The sixth critical element is the implementation of measures of compliance of the Nagoya Protocol, reflecting its correct and full integration into national ABS frameworks for their importance in the paradigm shift and true internationalization. The Protocol also internationalizes the monitoring and control of genetic resources through compliance measures, but does not standardize them. This is why countries need to secure them in practice. Today, the trend of countries considered as suppliers of genetic resources is to wait for user countries to implement their compliance measures, understanding that the latter are pushing to lower the standard that is being built. If supplier countries put the measures in place, they should set an example in their national ABS frameworks with the control and protection that their genetic resources will receive in third countries, particularly through what is offered in their own country.

The seventh critical element refers to the negotiation of bilateral free trade agreements in a way they do not affect the national ABS frameworks. The blockage of trade liberalization negotiations at the international level, usually encourages the big trading powers to continue that liberalization through bilateral or multilateral free trade agreements. Some of these powers are characterized by their strong positions in relation to ABS, using the negotiations of these treaties to assert their positions. This is why, it is necessary for other countries to address these negotiations with conviction and determination in their positions, so that FTAs are not affected when approved.

Nowadays, countries that regulated access to their genetic resources were alone in the implementation and enforcement of their national ABS frameworks, seeking to protect their genetic resources and, often closing their doors to prevent loss. One of the main open doors for access, and therefore of exit of genetic resources is research, which has for many years suffered the consequences of controlling and restrictive national frameworks. The Protocol gives countries that supply genetic resources an instrument at national and international level to monitor the use of their genetic resources, so second generation national ABS frameworks should clearly reflect this paradigm shift and not be so focused protection of resources but rather its valorization. In short, the approach of the seven critical elements ensures a proper national implementation of the Nagoya Protocol and the development of national ABS frameworks as an active tool for the sustainable development of the country.

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Access to Genetic Resources in Latin America and the Caribbean:
implementation of the Nagoya Protocol at a national level

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