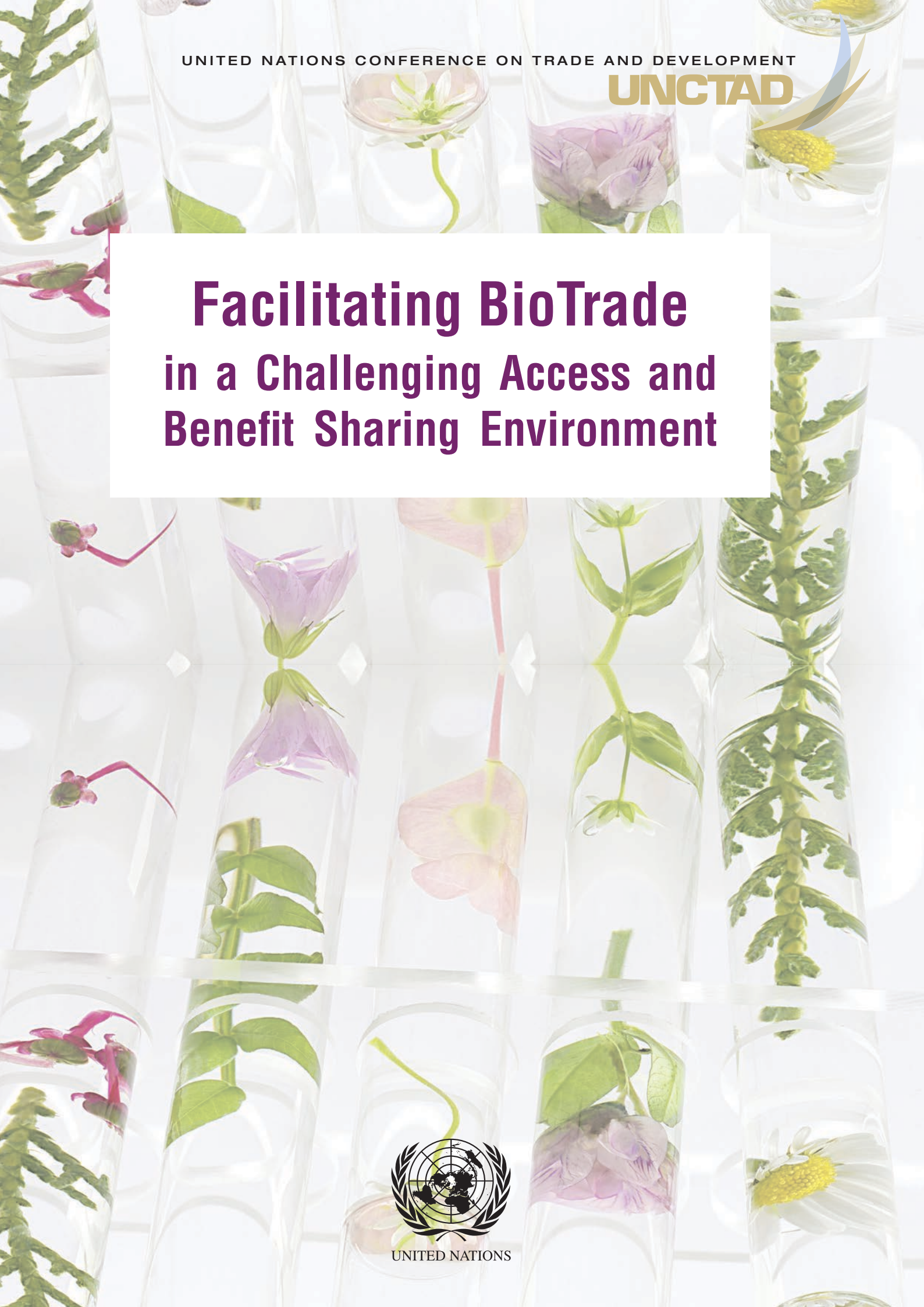

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Facilitating BioTrade in a Challenging Access and Benefit Sharing Environment

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This is an unedited publication.

Acknowledgements

This scoping study was prepared by Manuel Ruiz Muller, Director of Biodiversity, Director and Principal Researcher International Affairs and Biodiversity Program of the Peruvian Society for Environmental Law (SPDA) in cooperation with Veronique Rossow, Head of Research and Development of PhytoTrade Africa and David Vivas Eugui, Legal Officer (UNCTAD) under the guidance of Bonapas Onguglo Head a.i, at the Trade, Environment, Climate Change and Sustainable Development Branch, Division on International Trade in Goods and Services, and Commodities (DITC) UNCTAD. Mariona Cusi, Technical Expert, UNCTAD, also provided substantive inputs and orientation. Case studies were prepared by Maria Julia Oliva (UEBT), Veronique Rossow (PhytoTrade Africa) and Balakhrishna Pishupati (UNEP).

Additional comments to the scoping study were provided during an UNCTAD Expert Peer Review Meeting on the implementation of the Nagoya Protocol and its impact over certain aspects of BioTrade, held on 24 of November 2015, in Geneva, Switzerland by the following experts: Paolo Bifani (Former UNEP staff and Professor at the UAM), Marco D´Alessandro (FOEN), Nicolas Guigas, (SECO), Claude Hemio (Former World Bank staff), Lorena Jaramillo (UNCTAD), Harmut Meyer (GIZ), Viviana Muñoz (South Centre), Valerie Normand (CBD Secretariat), María Julia Oliva (UEBT) and Nguyen Thi Dang Thu Cuc (BCA, Viet Nam). All presentations and information about the Expert Peer review can be found at: http://unctad.org/en/pages/MeetingDetails.aspx?meetingid=953.

We also thank to Vanessa Ingar (BioTrade Coordinator), Emma Rivas (Biotechnology Specialist) and Dora Velásquez (Access and Benefit Sharing Specialist) from the Ministry of the Environment from Peru (MINAM) for their comments.

The formatting of this document and the cover page design was done by Rafe Dent and Lirong Zang, UNCTAD.

UNCTAD gratefully acknowledges the support of the Swiss State Secretariat of Economic Affairs (SECO) for the third phase of the BioTrade Facilitation Programme (BTFP III), under whose framework this scoping study was prepared.

Guillermo Valles
Director
Division on International Trade in Goods and Services, and Commodities
31 May, 2016

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Acronyms

ABS	Access and benefit sharing
BCA	Biodiversity Conservation Agency
BHB	Bosque Húmedo Biodiverso
BTFP	BioTrade Facilitation Program
CAF	Andean Development Corporation
CBD	Convention on Biological Diversity
CITES	Convention on International Trade of Endangered Species of Wild Fauna and Flora
COCOMACIA	Consejo Comunitario Mayor de la Asociación Campesina Integral de Atrato
CSD	Commission on Sustainable Development
EU	European Union
FAO	United Nations Food and Agriculture Organization
FOEN	Federal Office for the Environment of Switzerland
GEF	Global Environment Facility
GIZ	German Federal Enterprise for International Cooperation (Gesellschaft für Internationale Zusammenarbeit)
IGC	Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IP	Intellectual property
ITPGRFA	FAO International Treaty on Plant Genetic Resources for Food and Agriculture
LMMC	Group of Like-Minded Megadiverse Countries
MINEPDED	Ministry for Environment, Nature Protection and Sustainable Development
MAT	Mutually agreed terms
MDG	Millennium Development Goals
MTTI	Ministry of Tourism, Trade and Industry of Uganda
NTFP	Non-Timber Forest Products
OTCA	Organization of the Amazon Cooperation Treaty
PIC	Prior informed consent
R&D	Research and Development
REDD	Reduced Emissions through Degradation and Deforestation
SDG	Sustainable Development Goals
TK	Traditional knowledge
UAM	Universidad Autónoma de Madrid
UEBT	Union for Ethical BioTrade
UNCED	United Nations Conference on the Environment and Development
UNCTAD	United Nations Conference on Trade and Development
UNCCD	United Nations Convention to Combat Desertification
WIPO	World Intellectual Property Organization

EXECUTIVE SUMMARY

Legal uncertainty, lack of clarity and administrative inaction are not a good recipe to facilitate sustainable biodiversity businesses. With the entering into force of the CBD Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, there is a new opportunity to improve the synergies for access to genetic resources and benefit sharing (ABS) in the context of BioTrade, and in turn contribute to legal certainty on this particularly important matter in regards to sustainable use of biodiversity. Though historically BioTrade has moved in the realm of sustainable biodiversity businesses, particularly with biological resources and certain ecosystem services, questions remain regarding when and how genetic resources become part of BioTrade and most importantly, whether ABS policy and legal frameworks are applicable or not.

The Nagoya Protocol on Access and Benefit Sharing is a new multilateral environmental agreement under the CBD, seeking to clarify definitions, issues of scope and coverage of ABS, and specific actions by user and provider countries of biodiversity resources. The rapid implementation of the Protocol within the European Union and Switzerland is placing considerable pressure on providing countries to adjust, develop and implement effective and efficient ABS frameworks at the national level to be consistent with the Protocol and also benefit from it.

Implementing the Protocol in regards to BioTrade will require guidance as to how BioTrade and ABS positively interact and generate complementarity. When and how ABS requirements may be applicable to BioTrade is key to creating the enabling policy and regulatory environments. This scoping study offers an overview of some of the key issues and connections between BioTrade and ABS under the framework of the Nagoya Protocol, the challenges faced by interested actors and suggestions of ways to address them, including in terms of interpretation, implementing policies and legal reforms. Examples, figures and case studies are used to clarify some of the points raised and suggestions on the way forward.

1. INTRODUCTION

The relationship between BioTrade[1] and ABS continues to challenge policy makers, entrepreneurs, communities, project managers and academics alike. Since its launching in 1996 under UNCTAD´s "BioTrade Initiative", BioTrade has demonstrated the importance of multiple forms of conservation and sustainable-use of biodiversity and ecosystems oriented businesses. The key challenge is to clarify how BioTrade can take into account mandatory ABS principles, in accordance with the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.[2]

In parallel and often with limited interaction, BioTrade projects, businesses and ABS frameworks, have expanded in many regions and countries. A definite answer to the quintessential question of "do ABS laws or regulations apply to my BioTrade project or business activity" remains elusive. National ABS frameworks are often unclear as to whether certain BioTrade activities are covered under their scope. As a result, legal uncertainty often prevails in regard to clarity of applicable ABS norms and regulations, exclusions, obligations, rights and benefit sharing criteria.

The Nagoya Protocol is the most recent addition to a complex international, regional and national "ABS architecture" which defines how and under what conditions genetic resources and biochemicals can be accessed and utilized – with potential implications on BioTrade.[3]

This scoping study offers an overview of the challenges faced and options available to implement BioTrade and ABS principles under the CBD and the Nagoya Protocol in a coherent manner. It further provides examples of how these challenges are being addressed. The study gives an overview of the current state-of-the-art discussions and issues in order to facilitate a better understanding of how to manage the interphase between BioTrade and ABS in practice.

This scoping study is one output of the BioTrade Facilitation Programme's third phase (BFPT III), which seeks to "mainstream BioTrade in relevant multilateral, regional and national processes and strengthen the policy and regulatory environment for BioTrade sectors. This will allow key stakeholders (governments and companies) to take advantage of policy options and strategies available for BioTrade sectors".

1.1 A brief overview of BioTrade and its developments

BioTrade seeks to promote trade and investment in biodiversity products and services to further sustainable development and reduce poverty in line with the three main objectives of the CBD: conservation of biodiversity, sustainable use of its components and benefit sharing from the utilization of genetic resources. But what is BioTrade exactly and when does it take place? A common definition, promulgated also by UNCTAD, is that BioTrade are "*activities of collection, production, transformation, and commercialization of goods and services derived from native biodiversity under the criteria of environmental, social and economic sustainability*".[4] Such BioTrade activities projects cover sectors such as food and agriculture; natural ingredients for cosmetics and pharmaceuticals; ecotourism; fashion accessories and handicrafts; and sustainable trade in wildlife. In BioTrade activities, the emphasis is on the *process,* with distinct stages or phases[5]; the use of native biodiversity[6] and the way of doing business, catering for social, environmental and economic sustainability. Often, entrepreneurs and businesses are engaged in sustainable biodiversity-based enterprises without necessarily knowing the details about the CBD, BioTrade or the Nagoya Protocol.

Through inspiration from national BioTrade programs and practitioners, a common set of agreed Principles and Criteria and approaches were developed by UNCTAD in 2007.[7] Of particular relevance to the BioTrade – ABS connection[8] is Principle 3 on benefit sharing and Principle 7 on clarity about rights (see Box 1). These Principles go beyond the Nagoya Protocol, but are certainly relevant to ABS. BioTrade Principles and Criteria are of voluntary nature and can also take the form of private standards or simply be a part of the corporate social responsibility strategy of a company or group of companies.

Under Principle 3, benefit sharing is not limited to genetic resources as established in Article 1 of the CBD. Instead, *benefit sharing also applies to the use of biodiversity in much broader terms*.[9] This may include not only genetic resources, but also biological resources as defined by the CBD as well as environmental and ecosystem services.[10] Other Principles and Criteria address land rights, compliance with international and national legislation, protection of intellectual property and recognition of traditional knowledge (TK) of indigenous peoples

Box 1: BioTrade Principles 3 and 7 and the respective Criteria on benefit sharing, access to genetic resources and traditional knowledge

Principle	Criteria
3. BioTrade activities which involve the commercialization of genetic resources are linked to the benefit sharing objective of the CBD. Equitable benefit sharing also arises in the context of **sustainable use of biodiversity**. Benefit-sharing is therefore also important in activities dealing with **biological resources**, which form the vast majority of BioTrade activities.	3.1 The organization should interact and involve actors along the whole value chain, where possible. This reduces asymmetries and ensures **negotiation of fair and equitable monetary and non-monetary benefits**, especially by weakest links along the value chain. 3.2 **Income should be generated along the value chain**, by contributing to the position of value-added products in the market, under transparent conditions, as a condition for benefit sharing. 3.3 **Information and knowledge of target markets** should be made available and shared among actors, to enable access to market opportunities.
7. **Clarity about rights of access** is very important. Only then can long-term investments be made or corresponding management measures be implemented to ensure sustainability. At the same time, clarity on this issue means that the **responsibilities of each actor can be clearly established**.	7.2 Access to **biological and genetic resources f**or sustainable use **should be subject to prior informed consent**. The CBD requires access and distribution of benefits in relation to genetic resources. In such cases, the consent of all relevant national authorities in the provider country should be obtained. These cases are normally regulated by national legislation, in line with the CBD. 7.3 Access to **traditional knowledge** should be granted only where **prior informed consent has been verified.** Where traditional knowledge is used, the organization should follow all regulations and their established procedures to ensure that the rights of the actors providing this knowledge are recognized, including **the right to prior informed consent of all relevant stakeholders, such as indigenous and local communities**, as appropriate and subject to domestic law. **Traditional knowledge should be valued and rewarded in the appropriate manner.**

Note: This is a summary prepared by the authors. Highlights have also been added by the authors.

and communities as substantial inputs in BioTrade activities and projects.

Actors along the BioTrade value chain may include indigenous people, farmers or communities as providers (often) of raw biological materials; collectors and intermediaries that gather and transport bulk quantities of materials; researchers; processors and transformers; distributors and, ultimately, traders. They are part of a process which is also subject to national and international regulations that will apply at different stages, including extraction, collection, sometimes bioprospecting activities, processing and commercialization.

Over time, and with support from UNCTAD in collaboration with national, regional and international partners, progress has been made in defining the concept of BioTrade and supporting a wide range of technical cooperation activities, projects, and businesses around the world.[11] BioTrade Programmes,[12] collaboration with relevant conventions such as the CBD and the Convention on the International Trade in Endangered Species of Wild Fauna and Flora (CITES), BioTrade congresses,[13] the emergence of the Union for Ethical BioTrade (UEBT),[14] as well as a considerable body of literature and studies, have helped cement the presence and influence of the BioTrade.

There is need to differentiate in practice BioTrade activities with capital "T" from biotrade with the "t" in small letters. The first only occurs when the economic actors involved, practitioners and specific projects apply the BioTrade Principles and Criteria as established by UNCTAD and its partner organizations. The second could be understood as the trading of biodiversity products and services without necessarily applying sustainability criteria including trade in commodities.

1.2 The international foundations for BioTrade: the CBD and other forums

The initial BioTrade Principles (on conservation, sustainable use and benefit sharing) match and respond to the objectives of the CBD, *with the difference that the benefit sharing principle extends to the utilization of biodiversity, including the species and ecosystems levels, rather than to genetic resources only*. In this context, UNCTAD, through its BioTrade Initiative, works closely with the CBD to establish positive synergies. This is manifested in various CBD COP Decisions that have provided a framework to engage BioTrade in activities related to business involvement and incentives to further enhance biodiversity conservation, sustainability and benefit sharing.[15]

Other international forums and instruments recognize the role BioTrade could play in promoting conservation, sustainable development and benefit sharing. The United Nations Commission on Sustainable Development (CSD) has stressed the need to develop incentives that stimulate conservation and sustainability and support improvements in biodiversity markets. BioTrade acts as a medium to implement the United Nations Millennium Development Goals (MDG) on reconciling the goals of environmental sustainability with development needs of the poor, which rely extensively on biodiversity to survive.[16] These goals were replaced by a set of new *Sustainable Development Goals* (SDG), Transforming Our World - the 2030 Agenda for Sustainable Development. The new global goals include specific references to the conservation of biodiversity as an integral dimension towards sustainable development.[17] More specifically target 15.6 of the SDGs calls upon the international community to *"Promote fair and equitable sharing of the benefits arising from the utilization of genetic resources and promote appropriate access to such resources, as internationally agreed".*

In addition, various international agreements, including CITES, the United Nations Convention on Wetlands of International Importance, especially as Waterfowl Habitat (RAMSAR Convention, 1971) and the United Nations Convention to Combat Desertification (UNCCD, 1994), also provide a policy framework that BioTrade can support. Under discussions and negotiations on climate change and Reduced Emissions through Degradation and Deforestation and the role of conservation, sustainable management of forests and enhancement of forest carbon stocks in developing countries (REDD+) schemes, BioTrade

Box 2: The Goals of the Aichi Biodiversity Targets

- **Strategic Goal A:** Address the underlying causes of biodiversity loss by mainstreaming biodiversity across government and society.
- **Strategic Goal B:** Reduce the direct pressures on biodiversity and promote sustainable use.
- **Strategic Goal C:** To improve the status of biodiversity by safeguarding ecosystems, species and genetic diversity.
- **Strategic Goal D:** Enhance the benefits to all from biodiversity and ecosystem services.

may also contribute with projects and initiatives.[18] The World Intellectual Property Organization (WIPO) and its ongoing process to develop an international regime for the protection of TK under the International Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), could also be relevant in the future as to how BioTrade activities relate to the use of TK. Finally, in 2010, parties to the CBD adopted the Strategic Plan for Biodiversity including the Aichi Biodiversity Targets for the 2011-2020 period. These targets (see Box 2) also offer a solid policy and legal guidance to implement BioTrade related activities as part of their conservation, sustainability and benefit sharing goals.

BioTrade is well positioned to promote sustainable trade and investment in biodiversity-based products and services as provided under global goals and policy framework of different institutions involved in biodiversity use and conservation.

Key messages

Benefit sharing under BioTrade adds to the concept of ABS under the CBD and Nagoya Protocol. BioTrade is a voluntary scheme and a process, often reflected in a value chain, respecting a series of Principles and Criteria developed by UNCTAD, where the sustainable use of native biodiversity and benefit sharing along that value chain stands out as critically important. Due to its broad scope, BioTrade activities are subject to a set of complex, albeit supportive, international frameworks (CBD, CITES, RAMSAR, WTO agreements, etc.) and national regulations. BioTrade is increasingly and explicitly recognized in international forums as an enabler of sustainable businesses, initiatives and projects.

2. UNDERSTANDING HOW AND WHEN ACCESS AND BENEFIT SHARING RULES UNDER THE NAGOYA PROTOCOL APPLY TO BIOTRADE ACTIVITIES

2.1 How do access and benefit sharing provisions affect BioTrade?

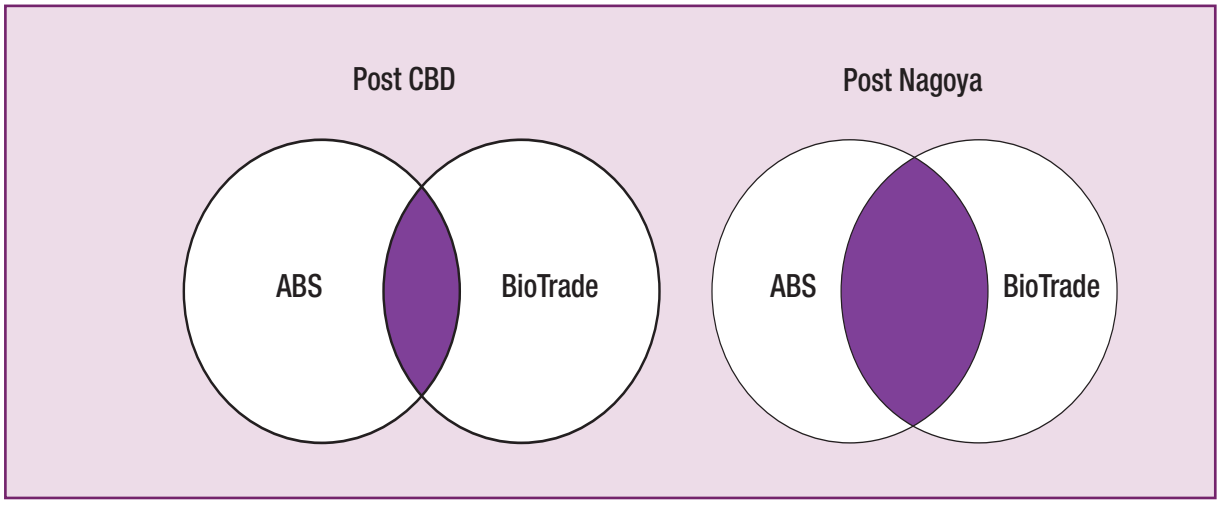
Under the CBD, the Nagoya Protocol and national ABS frameworks, ABS obligations may apply to distinct *phases or stages* in BioTrade value chains.[19] Generally, when genetic resources are utilized[20] (e.g. through biotechnological R&D), the person or institution undertaking these activities would need to comply with existing ABS regulations and procedures and be aware that the benefit sharing obligation has been triggered. This may include R&D on the biochemical composition of genetic resources (e.g. a natural occurring biochemical compound), also classified as "derivatives" under the Protocol,[21] and depending of the national implementing legislation.

Under almost all ABS national regulations, a national competent authority will negotiate an ABS contract which reflects mutually agreed terms (MAT) and then issue a permit or an authorization, which would normally reflect Prior Informed Consent (PIC). Sometimes, when TK is involved or access to genetic resources is sought from indigenous peoples or local communities' lands, parallel agreements may also be required, often following customary law and principles, again depending on national legislation. *Ad hoc* agreements (e.g. material transfer agreements) may also be needed if genetic resources or biological samples are sought from *ex situ* facilities (e.g. a seed bank or a botanical garden).

In this regard, ABS regulations and procedures may be different from the regulatory framework under which the overall BioTrade Initiative was initiated and operates in.[22] Quite often, the boundaries between BioTrade and ABS *per se* are subtle and have to be analyzed on a case-by-case basis. For instance, a BioTrade project may involve the use of Non-Timber Forest Products (NTFP), such as the Brazilian nut in the Amazon, and require a concession and permit to proceed under regulations from a forestry ministry or department. Likewise, a project may involve collecting kernels from the Argan tree in Morocco, which might also require authorizations from the agriculture or environment ministries. Yet another example may be *Bixa orellana* (achiote), collected in the Amazon for its processing as a natural dye or food ingredient, which would fall under a classic BioTrade activity and almost certainly require a permit under the agriculture or environmental sector.

For any of these examples, if a company decided to undertake a new line of R&D to identify specific molecules which it then used and incorporated into a pharmaceutical, cosmetic or other product, ABS frameworks would almost certainly apply. Then, a different set of obligations and procedures may need

Figure 1: Broadening intersection between access and benefit sharing and BioTrade



Source: UNCTAD (2016).

to be met, possibly –depending on specific national frameworks involving a different set of State entities and authorities. In this regard, it must be kept in mind that R&D is not only basic science but applied science and when linked to commercial objectives it also includes product and services development.

Figure 1 shows how the intersection possibilities between ABS and BioTrade may have grown as part of the broader scope and coverage that the Nagoya Protocol (and many national frameworks) are proposing. This is due to the Nagoya Protocol's references to research and development on 'biochemical' composition of genetic resources and to 'derivatives' as naturally occurring biochemical compounds.

Under UNCTAD's BioTrade Principle 3, benefit sharing is not so much "triggered" but rather reflected in the process. Monetary and non-monetary benefits need to be shared and distributed along the value chain when biodiversity is used. Most of the projects and businesses that fall under the scope of BioTrade are based on the direct utilization and processing of *biological* resources, along a value chain.[23] For example, activities include trade in native grains or fruits or the sourcing of known natural ingredients for existing natural pharmaceuticals. Furthermore, the reference to "biodiversity" in Principle 3 also allows other situations and circumstances to be addressed under BioTrade. These may include, for instance, payment for ecosystem conservation schemes or ecotourism activities based on their biodiversity potential and values. So far, most BioTrade activities have been usually centered on the use and transformation of biological resources or derived products as inputs for a wide range of industries and trades, as well as in sustainable tourism.

2.2 The rationale for the Nagoya Protocol

The Nagoya Protocol is the result of developing countries realizing the insufficiency and partial ineffectiveness of national ABS legal frameworks in securing benefit sharing. By the year 2000 there were already a few, albeit highly scrutinized, examples of ABS legislation and regulations that were being applied with limited success.[24] As early as 2002, calls were being made for an international regime on ABS that could ensure equitable and fair benefit sharing and that would shift certain burdens and responsibilities regarding the realization of benefit sharing to *user* countries.[25]

2.3 How will the Nagoya Protocol provisions affect BioTrade?

Arguably, the first important political milestone towards the adoption of the Nagoya Protocol was the Cancun Declaration of the Group of Like-Minded Megadiverse Countries in 2002, where its members[26] expressed their "*concern over the limitations of various international instruments to protect effectively the legitimate interests of the countries of origin of biodiversity*" and called for the "*creation of an international regime to effectively promote and safeguard the fair and equitable sharing of benefits arising from the use of biodiversity and its components. This regime should contemplate, inter alia, the following elements: certification of the legal provenance of biological materials, prior informed consent and mutually agreed terms for the transfer of genetic material, as requirements for the application and granting of patents, strictly in accordance with the conditions of access agreed by the countries of origin*." An important specific reference was also included in the Plan of Implementation of the World Summit on Sustainable Development (2002) with a call to "*negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising from the utilization of genetic resources*."[27]

The Nagoya Protocol could affect BioTrade-related activities in three ways. First, the Protocol reflects the original interests of biodiversity rich countries in placing certain obligations and responsibilities on countries that utilize and undertake R&D on genetic resources. This means that user countries need to adopt measures to ensure that users under their jurisdiction respect ABS requirements of provider countries. There may be a centralized check point or different sectors such as customs controls, phytosanitary or health-safety authorities, and intellectual property (IP) offices may become check points were compliance related requirements are implemented. This may have consequences in regards to BioTrade value chains when R&D or commercialization of BioTrade products takes place in user countries.

Secondly, the coverage of the Nagoya Protocol can be interpreted "in cascade" by linking the definitions of "utilization of genetic resources", "biotechnology",

Box 3: Case study on BioTrade and ABS: A natural blue colorant derived from *Genipa americana*

Description: Ecoflora Cares is a Colombian company developing and producing natural colors and ingredients for the cosmetics and food industries. It has been widely recognized for its innovative and sustainable use of Colombia's biodiversity, sourced through partnerships with indigenous peoples and local communities. One of the flagship colors of Ecoflora Cares is a natural blue colorant for food applications, developed and extracted from the fruit of Genipa americana, in the Colombian tropical rainforests. It provides a natural alternative to indigotine, an artificial colorant used in food (and also in blue jeans).

Interface between BioTrade and ABS: Ecoflora Cares' work with Genipa americana responds to its aim to enhance the sustainable use of Colombia's biodiversity by increasing the added value of its natural resources. In that context, sourcing, research, development and commercialization activities linked to this project have always been framed by UNCTAD's BioTrade Principles and Criteria. Ecoflora Cares is also a member of the UEBT since 2009.

As a result, the company developed the supply chain in collaboration with local communities, with the support of local NGOs working on ethical sourcing of natural ingredients. It also has in place a biodiversity management system that integrates the Ethical BioTrade principles in the supply chain. Finally, it has taken various measures to support fair and equitable sharing of the benefits from sourcing activities, including the creation a community entrepreneurial initiative.

These efforts towards ethical sourcing of biodiversity have established a solid basis for Ecoflora Cares' compliance with requirements on access to genetic resources in Colombia. It has secured various permits and agreements for the utilization of Genipa americana, based on the legal framework established by Andean Decision 391 and implementing rules. In 2011, Ecoflora Cares received a permit for non-commercial research and development on natural colorants from the fruit of Genipa americana. In 2013, the company concluded a series of agreements on sharing of monetary and non-monetary benefits with local communities. Finally, in 2014, the Ministry of Environment and Sustainable Development of Colombia subscribed a contract with Ecoflora Cares, authorizing the commercial use of Genipa americana as the basis for a natural a colorant.

Lessons learnt: Where companies committed to BioTrade engage in R&D, the experience on issues linked to conservation and sustainable use of biodiversity and fair and equitable benefit sharing constitute a solid basis for compliance with ABS requirements. For example, companies working in the BioTrade context tend to have higher awareness of the importance and procedures of ABS, as benefit sharing is already part of the principles and criteria of BioTrade. Such understanding is important when it is necessary to navigate complex administrative procedures. Moreover, the partnerships with local communities may facilitate consultations and equitable trade practices may enhance and complement benefit sharing agreements.

Source: UNCTAD and UEBT (2016) based on information from Ministry of Environment and Sustainable Development of Colombia, Fondo para la Acción Ambiental y la Niñez (2015).

and "derivatives". This enables the inclusion of biochemicals, which are, in many instances, key inputs and products in BioTrade activities, particularly in the foods, cosmetics, nutraceutical and natural medicine sectors.

Thirdly, the Nagoya Protocol is not self-executing. Countries need to develop national laws, regulations and administrative measures to implement its obligations. Many of the effects of the Nagoya Protocol will also depend on how well ABS frameworks are developed nationally and operate in practice. For compliance measures to be effective, provider

countries or countries of origin will need to have in place national ABS frameworks that are operational and ensure legal certainty for actors involved in BioTrade value chains. Box 3 provides an example of how the Nagoya Protocol may affect a BioTrade business in practice.

Key messages

Depending on how national ABS frameworks define their scope, distinct phases in BioTrade value chains may be affected by their provisions. BioTrade benefit sharing is broader than ABS since it applies to all biodiversity, including species and ecosystems. Benefit sharing along a BioTrade value chain varies considerably from case to case, in terms of the monetary and non-monetary dimensions that may be present. The Nagoya Protocol was, in essence, developed to contribute to legal certainty and to safeguard the interests of providing countries through action in user countries. However it shoul dbe noted that all countries are both users and providers. The Nagoya Protocol has a broad scope in practice which, depending on national implementation, may cover a range of BioTrade activities and products. The Nagoya Protocol is not self-executing. Compliance measures will only be effective if providing countries define and implement their national ABS and/or BioTrade regulatory frameworks.

3. NATIONAL ACCESS AND BENEFIT SHARING REGULATORY FRAMEWORKS AND BIOTRADE: THEIR RELEVANCE FOR USERS AND PROVIDERS

Though considerable attention has been paid to a new set of initiatives regarding compliance (stimulated by the Nagoya Protocol), measures will only be effective in as much as countries of origin or provider countries have in place legislation that is clear, transparent and, most importantly, applicable and enforceable. So, if countries of origin do not have in place *effective* national legislation or regulations to implement the Nagoya Protocol, measures implemented in user countries may have no effect. There may be different interpretations of the utilization of genetic resources (GR) by provider countries but users will need to comply with the ABS requirements of provider countries. Box 4 below shows some samples of scope and coverage in national ABS frameworks. Some of these frameworks are pre-Nagoya Protocol so may need to be adjusted to adequately respond to its new obligations.

As Box 4 demonstrates, some BioTrade activities may be affected by ABS legislation as progress is made along the value chain. But legislations also vary

Box 4: Samples of regulatory trends in scope and coverage in ABS frameworks in provider countries applicable to BioTrade: examples in the Andean Community, African Union, Brazil, Costa Rica, India, South Africa, Kenya, Ethiopia, Peru and Viet Nam

Law or regulation	Specific provision(s)
Andean Community Decision 391 (1996)	**Article 1 (Definitions). Derived product:** A molecule, a combination or mixture of natural molecules, including ***crude extracts*** of live or dead organisms of biological origin derived from the metabolism of living beings. **Article 3 (Scope).** This Decision is applicable to genetic resources for which is the Member Countries are the countries of origin, to their ***derived products …***
Law 7788. Biodiversity of Costa Rica (1998)	**Article 7 (Definitions) 1.** Access to biochemical and genetic elements: Action of obtaining samples of wild or domesticated elements of biodiversity, in ex situ and in situ conditions, and of associated knowledge, for the purpose of basic research, ***bioprospecting or economic exploitation.*** **3. Bioprospecting:** The systematic search, classification and research for commercial purposes of ***new sources of chemical compounds, genes, proteins, microorganisms, and other products with potential or actual economic value, which are found in biodiversity.***
Biodiversity Act (2002) and Rules (2004) in India	**2. Definitions.** (f) "commercial utilization" means ***end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention***, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping; Chapter II. Regulation on ABS 3.1. No person referred to in sub-section (2) shall, without previous approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for ***research or for commercial utilization or for bio-survey and bio-utilization.***

Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, Kenya, (2006)	**Part I.2 Definitions:** "Access" means ***obtaining, possessing and using genetic resources conserved, whether derived products and, where applicable, intangible components, for purposes of research, bioprospecting, conservation, industrial application or commercial use;*** benefit sharing" means the sharing of benefits that accrue from the utilization of genetic resources;
Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006 Ethiopia (2006)	**General provisions, 2.** "Access" means the collection, acquisition, transfer or use ***of genetic resources*** and/or community knowledge; Scope: This Proclamation ***shall apply on access to genetic resources found in in situ or ex situ conditions and community knowledge.***
Order No. 18, biodiversity law in Viet Nam (2008)	**Article 3.29 (Definitions)** Access to genetic resources: means activities of i***nvestigating and collecting genetic resources for research and development and production of commercial products.*** **Article 44.1 (Sustainable Development of Species)** The conditional ***exploitation of wild species in nature*** must comply with the law on forest protection and development, the law on fisheries and other relevant laws.
Supreme Decree 002-2009-MINAM, ABS regulation on Peru (2009)	**Article 4 (Scope).** The regulation applies to genetic resources of which Peru is a country of origin, its ***derived products,*** intangible components and genetic resources of migratory species … Article 5 (Exclusions). ***Excluded from this regulation are: e) Activities which imply the exploitation of non-timber natural resources used to produce natural products (nutraceuticals and functional foods).***
African Union (AU) Strategic Guidelines for for the Coordinated Implementation of the Nagoya Protocol on Access and Benefit Sharing (2015)	9. AU Member States as countries of origin or as countries having acquired genetic resources in accordance with the Convention on Biological Diversity resolve that ***prior informed consent is required for access to their genetic resources*** and that such genetic resources ***shall only be utilized as authorized with their prior informed consent and specified in mutually agreed terms […]*** 22. African Union Member States shall in their domestic legislation require that mutually agreed terms specify provisions for the fair and equitable sharing of benefits arising from ***the utilization of genetic resources, including naturally occurring biochemical derivatives, as well as subsequent applications and commercialization of derivatives and products resulting from utilization of genetic resources and associated traditional knowledge.***

Amendments to the Biodiversity Act No. 10, on bioprospecting and ABS in South Africa (2015)	**Chapter 1. (Definitions). 1. Biotrade:** Means the buying and selling of ***milled, powdered, dried, sliced or extract*** of indigenous genetic or biological resources for further commercial exploitation. (Application of these regulations). 3.1. These regulations apply to (a) commercial or industrial sectors that utilize a***ny indigenous genetic and biological resources for biotrade or for research, application or development*** of drugs, complementary medicines nutraceuticals, industry enzymes, food flavors, fragrances, cosmetics, emulsifiers, oleoresins, colors, extracts and essential oils.
Law 13.123 on ABS in Brazil (2015)	**Article 1. (General provisions).** This law applies to rights and obligations related to: IV. the economic exploitation of the ***final product*** or reproductive material derived from the genetic patrimony … V. fair and equitable benefit sharing related to the economic exploitation of the final product or reproductive material derived from the genetic patrimony … **Article 2.I. (Definitions).** Genetic patrimony: information of genetic origin of plant, animal, microbial or other species, including ***substances originated from the metabolism of living beings.***

Note: Except in the case of the South African, Viet Nam and African Union, translations of the legal texts are non-official. Highlights are included by the authors.

considerably from country to country. In Peru, for instance, there is an exception in the ABS framework for activities involving utilization of non-timber forest products (NTFP) when they are used in the production of nutraceuticals and functional foods.[28] In Costa Rica, bioprospecting applies to any type of research over a broad range of biodiversity components for the purpose of commercial exploitation. In South Africa, ABS regulations clearly cover BioTrade-related activities such as using natural ingredients in products formulation and also for research and development inputs for various industrial sectors. India on the other hand, has developed a broad and all-embracing ABS legislation, which applies to all activities that use biodiversity components (including biological resources) for whatever purpose intended, including commercialization. Brazil also applies ABS principles to activities which may result in the commercial exploitation of products derived from genetic resources. Brazil has shifted from a system which focused on the access phase, to a system that places the emphasis on the benefit sharing aspects. These examples include situations that may be of common occurrence along the BioTrade value chain processes.

Key messages

Most ABS regimes vary considerably worldwide in terms of their scope and coverage, as well as their administrative and procedural elements. Compliance measures in the Nagoya Protocol will be more effective if countries of origin or providers have clear and operational ABS regimes in place, including precise definitions of what may or not be covered under their scope. This has considerable implications on certain BioTrade activities as in many cases they will be covered by ABS legislation, which is of mandatory application. Some countries with pre-Nagoya ABS legislation may need to revise their regulations in order to better align them with the new definitions and obligations under the Nagoya Protocol and provide further clarity on the interphase between ABS and BioTrade-related activities. Countries without ABS legislation will inevitably be required to regulate ABS if they want other Parties to the Nagoya Protocol to adopt compliance measure within their jurisdictions. The use of regional approaches for the implementation of the Nagoya Protocol can support the management of shared resources, reduce transaction costs and harmonize standards.

4. SETTING SOME BOUNDARIES AND COVERAGE

4.1 Definitions and examples

To assess the potential impacts of ABS and the Nagoya Protocol on BioTrade-related activities, understanding definitions and scope is essential. Within the margins provided by the CBD and the Nagoya Protocol, it is still the responsibility of Contracting Parties to define exactly how boundaries of ABS requirements are set to cover various R&D and commercialization activities. National biodiversity or ABS authorities have the responsibility of providing coherent interpretations and implementation of regulations. Lack of and inconsistent responses, excessive delays and unclear responses and guidance will contribute to potential projects, businesses and entrepreneurships being cancelled or lost to other countries.

The scope of BioTrade projects, on the other hand, is very broad, comprising biodiversity related activities and conservation, sustainable use and benefit sharing at its different phases and regarding different components – from specimens to ecosystems. Understanding where

Box 5: Understanding the coverage and scope of the Nagoya Protocol

The Nagoya Protocol	Examples of BioTrade-type activities potentially related to the Protocol provisions
Scope of the Protocol (Article 3): The Protocol shall apply to **genetic resources** within the scope of **article 15** of the Convention [CBD] and to the benefits arising from the **utilization of such resources.** This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and benefits arising from the utilization of such knowledge.	• Accessing and undertaking R&D on extracts of medicinal plants, or identifying an active compound from a plant or microorganism. • Obtaining TK from an indigenous community and using it to orient and guide initial phases of R&D processes (e.g. regarding use, characteristics, and dosages of medicinal plants).
Utilization of genetic resources (Article 2): Conduct **research and development on the genetic and/or biochemical composition of genetic resources,** including through the application of biotechnology as defined in article 2 of the Convention.	• Undertaking R&D on specific, isolated compounds and natural extracts of maca (*Lepidium meyenii*), uña de gato (*Croton lechleri*), and hercampuri (*Gentianella alborosea*), medicinal plants sourced from the Amazon and Andes. • Undertaking research on different extraction processes regarding a plant extract, leading to potential compositional variations. An example may be *Centella asiatica* extracts whose compositions vary depending on the source, extraction process and harvesting practices. • Plant or animal breeding using biotechnology.
Biotechnology (Article 2): Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.	• Any biotechnology process which is using enzymes to lyse the plant cells and allow separating hydrophilic and lipophilic fractions from kernels, leaves, seeds, etc. • The action of specific enzymes (e.g. elongase, desaturase) that will transform the naturally occurring composition of a vegetable oil to give a different fatty acid profile. • Insect reproduction or genetic modification for pest control. Extraction processes and analysis of compositions.

Derivative (Article 2): **A naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.**	• Triglycerides (vegetable oils such as Argan oil, Marula oil, etc.). • Phospholipids of cell membranes (fractions of vegetable oils. • Saps (Aloe Vera juice for example). • Secondary metabolites (e.g. Polyphenols).
Fair and equitable benefit sharing (Article 5.1): In accordance with article 15, paragraphs 3 and 7 of the Convention, **benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization** shall be shared in a fair and equitable way with the Party providing such resources or a Party that acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms. "	• Providing money and capacity building to communities or other actors along the value chain, when commercial success of a product generates income and resources. • Involving national researchers in upstream research and development. • Co-authoring research papers or publications with national researchers. • Sharing the results of research with local authorities or local and indigenous communities.
Fair and equitable benefit sharing (Article 5.2): Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring **that benefits arising from the utilization of genetic resources that are held by indigenous and local communities,** in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.	• Establishing through law or regulation community funds to distribute benefits or compensate indigenous or local community from accessing and using their genetic resources or natural resources in their lands and territories. • Providing in a law or regulation that communities participating in a bioprospecting project receive non-monetary benefits as part of the projects, including through training, supporting local infrastructure development, providing with free products derived from the accessed and used resources, etc. • Developing national legislation which recognizes biocultural or community protocols as tools to empower and support benefit sharing at the local level, or utilize soft IP tools such as geographical indications and collective marks may be options to capture culture and local values.
Fair and equitable benefit sharing (Article 5.3): To implement paragraph 1 above, **each Party shall take legislative, administrative or policy measures,** as appropriate.	• Enacting a law, regulation, strategy, plan of action or administrative measure which addresses benefit sharing dimensions.

Note: This is a non-exhaustive list of policy/measure related and practical examples: there may be many more ways to consider implementing Nagoya Protocol provisions.

BioTrade-related activities and ABS (and Nagoya Protocol provisions) overlap or intersect can be quite a challenge, as seen from Box 5.

The examples provided in Box 5, may be helpful to understand where the Nagoya Protocol and BioTrade-related activities may converge. Some BioTrade activities or phases, especially when involving access to and the utilization of genetic resources and biochemicals (e.g. through R&D for product development) will almost certainly fall under national ABS frameworks and thus, under the Nagoya Protocol. On the other hand, trade in commodities or the direct sale of biological resources (e.g. dried fruits or seeds) or even certain processed foods (e.g. meat, bottled juices, food preparations) would seem to be outside the scope of ABS. However, in some cases such as in India or Brazil, this seems not to be the case.

In strict legal terms, although there are various options for interpretation of what may be covered by the Nagoya Protocol, subject to national legislative developments and definitions, one line of thought, and through a "cascade type interpretation" of the Protocol,[29] considers that its scope extends not only to genetic resources *per se*, but to biochemicals as well. The use of traditional or modern biotechnology in research and product development is an indication that the activity may be covered by the Protocol. For instance, this may imply undertaking R&D in regards to DNA strands, RNA, isolated genes or complete genomes or biochemical compositions of genetic resource (e.g. some derivatives).

In the case of biochemicals in general, this would include R&D undertaken in regards to various classes of molecules as a result of metabolisms related to genetic expression. This may include simple and complex mixtures of molecules such as resins, saps, oils, hemoglobin, enzyme or antibodies.

To expand on these examples, enzymes and their related biological activities are widely used in industry. Research can be conducted to change the composition of a naturally occurring protein to obtain some specific peptides. It can also be used to change the composition of a vegetable oil or to digest some molecules (e.g. pectine) in some fruit pulps. Tellingly, in these cases no genetic resources or DNA are involved, only the derivative biochemical. Hereby lies the importance of the expansive scope of the Protocol and of many national ABS frameworks.

While the "cascade interpretation" (noted earlier) is not a universally accepted, it may be helpful for the purpose of providing a coherent interpretation of the Nagoya Protocol when dealing with dynamic sectors, where there is an evolution in the treatment and use of materials and samples.

4.2 What does each of these elements mean for BioTrade businesses?

In accordance with the Nagoya Protocol, and as seen in the examples in Box 5, there may be a considerable set of activities under BioTrade which may warrant ABS-induced benefit sharing arrangements under implementing laws and regulations. As indicated above, if R&D of any kind, including through the use of biotechnology, is applied at some point of the BioTrade value chain in regards to genetic resources, biochemicals and, depending on the case, also derivatives, [30] the actor participating in that particular phase of the value chain may need to comply with this legislation and follow ABS procedures. This may be foreseen *ex ante* in the project or product development phase. This could also occur as R&D is undertaken and progresses over time. If the latter was the case there may also be a need to negotiate or re-negotiate ABS conditions.

BioTrade projects or businesses need to be aware and prepared to address the transaction costs these circumstances may entail in terms of time spent going through administrative procedures, possible legal counsel costs, fees, etc. Regulators need also to be aware that they may get informal questions of coverage and application of ABS laws even before a formal request is made. Regulators may need to explore options for introducing preliminary assessments before an activity or a formal request is made in order to avoid investment "chilling" effects whether by national or foreign users.

4.3 How are genetic resources, biochemicals and derivatives used by the industry and in R&D?

The natural interactions between humans and genetic resources have been transformed by many industrial sectors into a wide range of consumer products. Curiosity, inventiveness and sectorial needs have led to research in order to assess the required claims (e.g. nutritional compositions or specific physiological properties such as anti-oxidant, anti-inflammatory

activities, or blood pressure regulation). In many cases, research has been inspired by TK from ancestral medicinal practices which exist all over the world. Examples include the Ayurveda or Yogi tradition in India, the traditional Chinese medicine or TK from ancestral Amazon communities.

Depending on the ultimate purpose for acquiring genetic resources, biochemicals and/or derivatives, additional research activities may need to be conducted at certain stages of the value chain, in order to ensure the safety of consumers, prior to commercialization. This is particularly true within the European Union and Switzerland, and other industrialized countries, where companies selling raw materials, ingredients or more advanced products are facing various levels of regulatory obligations other than ABS ones, linked to the industrial sector where they operate.

In the cosmetic and personal care industry, where products are articles intended to be "*applied to the human body [...] for cleansing, beautifying, promoting attractiveness, or altering the appearance*",[31] plants and their derivatives are an endless sources of inspiration and, as such, innovations. Mostly under extract forms, cosmetic ingredients are developed to provide formulators with tools to achieve the most successful cream, lotion, lipstick, etc. A wax, naturally present on a leaf, can become the key ingredient in a "long-lasting" lipstick if its composition demonstrates film-forming properties. An indigenous flower can be used for its skin magnifying properties, illustrated by the natural beauty of local populations (e.g. Tahiti and the Tiaré flower).

The composition of one fruit oil, traditionally used to heal wounds, can be further assessed, and then used in cosmeceutical formulas. Besides the performance angle of the research process, each actor in the value chain has its own legal obligations to comply with other relevant regulation such as Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)[32] or the European Union regulation on cosmetics[33]. This implies building a comprehensive knowledge of the biochemical composition and related safety of the ingredient prior entering the European Union market with commercial quantities. The information generated has a level of confidentiality, which prevents its free access by any other stakeholder without some forms of commercial agreements.

In the food industry, the research process is somehow more straightforward, and leads to an outcome that can easily be used by all stakeholders involved in the same value chain. In the main user markets (European Union and North America), no importer can use any ingredient if it is not approved for such application (e.g. the 2015 Novel Food[34] in the European Union, Generally Recognized as Safe (GRAS)[35] in the United States). Therefore, and prior to any commercial activity, the use of a genetic resource or biochemical for the purpose of food use will require compositional and safety tests. In general terms, once such approval is validated, it remains available under simple conditions to other importers of the same product.

Additional research steps may be conducted for sector-specific performance claims. Depending on the nature of the material that will be evaluated (e.g. whether it's a fruit, or an extract of such fruit), the research outcome will freely benefit the entire value chain (fruit), or will remain the property of the user who has applied its know-how to the raw material to add its own value to the extract. The food supplements sector mimics more and more the food sector process, with a regulated environment that moves towards similar safety constraints

In the pharmaceutical industry, the purpose and related R&D process is to some extent and in some dimensions "simpler" than that of the food sector: less actors are involved in the value chains, extraction or purification processes are always applied to the natural resource and there is compulsory research (physiological effects as well as safety assessment) and proprietary know-how (i.e. confidential) applied at various research steps. However, discoveries and innovations through R&D processes may or may not lead to commercial activities. Processes take years to be completed and the overall use of the natural resource (e.g. a genetic resources or compound) may be limited to identifying a naturally occurring active molecule, which will then be chemically synthesized.

Significantly, costs in R&D are in the billions of dollars and it often takes a decade before a useful product is ready for commercialization. Conversely, the herbal medicine "sub-sector", which these past years has also become highly regulated in users countries, mainly focuses on raw materials and the TK associated to their use. This R&D process decreases timeframes between access and utilization and relies highly on providers' TK.

These three sectorial uses of genetic resources or biochemical compounds have quite different ways of

operating and thus different links with BioTrade and ABS principles. They also require very different levels of financial investments from actors seeking access and utilization. Sources of biological and genetic resources also vary considerably among sectors. In some instances, *ex situ* sources may be more relevant than *in situ* or cultivated sources.

Moreover, the value addition that can be generated when the resource travels along the value chain and its final use varies drastically among sectors. Highly dependent upon the results obtained from the performance-oriented research (e.g. functional or active properties), this value addition (and possible profits to be generated) is also limited by the investment made by most users for the safety-related research which is compulsory in many user countries. These differences in the value chains and R&D process need to be considered by policy makers and regulators when negotiating and drafting regulations, as well as negotiating access or benefit sharing contracts.

Lastly, another important issue when looking at industry practices is the type of uses given to samples that may "evolve" along the value chain or may be transferred or shared among researches, universities, *ex situ* centers, etc. Research and development processes are dynamic and constantly changing. Thus, R&D over a particular genetic resource, biochemical and/or derivative may lead to new lines of research or product development that were originally not planned or even envisioned, often years down the research process.

In these situations, new provisions of the Nagoya Protocol, regarding the internationally recognized certificate of compliance (for traceability and legal certainty purposes), checkpoints and other measures for compliance will be particularly important.[36]

4.4 What do regulators need to consider when receiving access applications?

Regulators processing applications need to be fully cognizant about the exact scope and coverage of their *national* ABS frameworks. As is the case, legislations vary regarding what may be covered or not under ABS. National ABS frameworks are the first step under which to evaluate whether an ABS application or contract may or not be necessary. Administrative practice will also be critical to define the scope and coverage. When such frameworks are not clear and coherent, these can lead to complex and uncertain situations such as that shown in Box 5.

For instance, if the processing of and trade in biological resources and biochemicals are covered by the national ABS legislation, it is almost certain that most BioTrade activities will be subject to ABS. But if ABS frameworks and practices are limited to access and the utilization of genetic resources as foreseen in the Nagoya Protocol, the probability of affecting BioTrade businesses is much lower.

Certain BioTrade projects and enterprises offer, even up-front, some indication on whether ABS legislation may have a bearing on them. For example, when biotechnology is involved, or when the R&D product/output to be generated derives from biodiversity or genetic resources, and whether or not there is intellectual property (IP) involved (particularly patents and plant breeders rights[37]), may offer guidance as to coverage by the Nagoya Protocol and whether ABS frameworks are applicable or not.

The coverage of national ABS laws and regulations in various countries around the world varies considerably and may continue changing as they adapt to the Nagoya Protocol´s provisions. None of these regulatory examples makes an explicit reference to BioTrade *per se*, but may have implications on specific BioTrade projects and businesses if there is utilization or R&D undertaken over biochemicals or genetic resources during the value chain or if some of the indications suggested above are met.[38]

Key messages

National policy makers need to develop clear ABS frameworks. Clarity in scope, coverage and definitions is a first and critical step in ensuring effective and efficient ABS regimes. Regulators also need to apply and implement these in reasonable and coherent manner. This seems very logical and straightforward but it is often not followed in practice. BioTrade activities often fall under the scope of NTFP legislation dealing with biological resources. But they may also fall under ABS and the Nagoya Protocol framework, depending on how countries adjust to its scope and coverage flexibilities. There are no examples of an all-encompassing or embracing law or regulation for BioTrade activities" yet. In some cases, the use of biotechnology to assess a gene, an active compound or a molecule

is an indication that ABS frameworks may be applicable. Likewise, intellectual property rights (IPRs) or the product output itself may provide useful indications regarding ABS application. R&D processes vary considerably among sectors and are often very dynamic and may change course along the chain. Genetic resources and biochemicals become part of a very complex value and R&D chain with technological innovation dramatically changing these from their original, natural form. Each sector has its own specificities in terms of safety, regulatory requirements and confidentiality. Traceability "backwards" from a finished product to its ingredients' origins is not necessarily obvious, especially in multi-stakeholder value chains or transboundary genetic resources and derivatives.

5. THE BENEFIT SHARING CHALLENGE

Under normal circumstances, in any enterprise or business, monetary benefits *are* shared in one way or another along the value chain, often responding to market price and demand forces. This is the nature of doing business. Different actors along the value chain will be paid, profits made and taxes will probably be collected by the State. But the CBD and the Nagoya Protocol were not referring to this type of "regular" benefit sharing. Even to this day it is still not clear what exactly is meant by "fair and equitable" benefit sharing.[39] What is obvious is that benefit sharing in the context of ABS and BioTrade means "something more", additional or extra to what under normal circumstances may be negotiated in a commercial agreement or transaction.

The BioTrade Principles and Criteria offer some guidance as to how this "additionality" in benefits may be enabled and facilitated through providing information, especially to community providers (to strengthen negotiating positions), generating income along all phases of the value chain, as well as awareness by actors about potential and existing market opportunities. Under BioTrade, benefit sharing is more process oriented than a single act or moment in the value chain. Actors then become prepared to demand and participate in an equitable and fair benefit sharing scheme. For this to materialize, participation of communities in business planning, continued technical and legal assistance, monitoring and reporting are all tools to facilitate communities informed involvement in the benefit sharing process.

In the case of the Nagoya Protocol and ABS overall, benefit sharing is triggered by the utilization of genetic resources. Utilization means research and development on the genetic or biochemical composition of genetic resources. This implies that any research and development on genetic resources and biochemicals should share benefits in some way. At a research stage, in practice, this may imply the distribution of non-monetary as well as monetary benefits.[40] Thereafter, if commercialization takes place, usually monetary benefits will need to be shared according to the terms of the original ABS agreement(s). Depending on national ABS frameworks, benefits will be often negotiated and shared with the State. These will be generally defined in a contract, permitting or fund/taxing system. But indigenous and local communities, particularly when their genetic resources within their territories or associated TK are involved, may also be entitled to benefits. This will depend on national ABS frameworks. The Nagoya Protocol includes an annex that describes the types of monetary and non-monetary benefits that may be considered by national legislation and/or specific ABS projects and initiatives.

There may be circumstances when, as part of a BioTrade project, ABS obligations are triggered either by the specific utilization of genetic resources and biochemicals or the commercialization of a resulting product. This may also be deemed an "additional" benefit sharing situation within the BioTrade value adding chain.

Figure 2 shows an illustration on how a BioTrade value chain may evolve, where specific uses of genetic resources or application of biotechnology are involved and therefore trigger additional benefit sharing – to that of the overall BioTrade value chain. In this particular example, BioTrade activities usually go from the sourcing stage **(phase 1)** were materials are harvested, collected and stocked; to a processing phase **(phase 2)** were materials are transported, transformed and processed; to a research and product development phase **(phase 3)** were specific R&D takes place and, finally to the manufacturing of a final product and commercialization phase **(phase 4)** were sales and marketing occur. Within this process, there may be particular instances (phase 2 and / or phase 3) when specific R&D takes place which triggers access and benefit sharing obligations.

When products are sold at phase 1 (e.g. raw materials such as fruits or nuts), they are most likely to be directly processed *in situ* or by the buyer or a buyer further down the value chain. The intention of a buyer may be diverse. If the intention is simply further processing and manufacturing under known methods, there is not risk of triggering ABS[41] as a price for the raw material has been already paid.

BioTrade products could be sold after phase 2 when a certain level of processing and manufacture has already occurred (e.g. direct sale of essential oils), without the need for R&D. In such cases, Nagoya Protocol provisions would not be triggered.

If there were an intention to undertake R&D during phases 1 and 2 of the value chain, such an activity would trigger ABS regulations. Phase 3 represents further value addition on the ingredient obtained at

Phase 2. It should be considered as R&D and therefore be fully covered by ABS regulations.

If further R&D occurs over genetic resources and their biochemical at a later stage of the value chain, even if it was not initially anticipated, ABS frameworks should also respond to this new circumstance since there would then be a change in intention and use. This may even include cases when resources leave the providing country. It is important to note that in practice value chains are not linear and the sample may change, so the different phases of the value chain (see figure 2) may be undertaken by different actors. Depending on the law of the provider and user countries, the level of responsibility in the value chain may fall primarily on the hands of the actor(s) "utilizing" the genetic resources and the biochemicals.

This basically means that whoever undertakes R&D has a responsibility on ensuring the legality of the access and the activity even if in a different country. However, other actors may also be accountable under due diligence obligations under regional or national regulations, since they need to be aware of what they are actually buying and selling and which are the conditions for use of each sample received as it travels throughout the value chain.

The need to consider ABS may occur at specific stages in the BioTrade value chain. National legislations and regulations will need to provide guidance as to how actors at that particular stage will comply with ABS requirements and how benefits will be shared and among whom. For instance, benefits may only be possible downstream along the value chain (e.g. at

Figure 2: Illustration of benefit sharing along the BioTrade value chain phases

Source: UNCTAD and PhytoTrade Africa (2016).

the commercialization stage) and when many other actors may have also participated in the process. Will then benefits be shared upstream and reach the community if this were the case? Or who will negotiate the ABS agreement? At what point will the State and the users share benefits? What happens when R&D is undertaken outside the country providing the original genetic resource and benefits generated outside national jurisdiction? To address these and other complex questions, case by case solutions and accumulation of experience will be required.

An option considered for example in the recent ABS Brazilian law (see Box 4), is to establish a funding mechanism with fixed "royalty" or payments, under which monetary benefits can be distributed, especially to stakeholders such as farmers, indigenous peoples or communities. The main advantage of this option is that it precludes often complex ABS negotiations and the analysis of the value chain to identify where and when ABS contracts may be required. The main difficulty under this option will be how to determine the value of the "royalty" to be paid. The Brazilian law looks at global sales, which may be difficult to determine in practice, particularly in the case of multinationals. Other options may include a share of "after tax" income generated by key users or a "special value added tax" on biodiversity based products. These and other creative options for benefit sharing need to be explored as they may reduce transaction costs and timeframes regarding prior informed consent and contract negotiations, which are usually key concerns for businesses.

Finally, due to increasing regulatory constraints, particularly about safety, traceability throughout the value chain, together with the reliability of shared information, have become strategic selection criteria for users in BioTrade, who also have the responsibility to place consumer products on the markets. Any uncertainties about sourcing or about legal duties, including ABS obligations, can lead to the collapse or liabilities over a BioTrade project or an enterprise.[42] Value chains remain long and complex, with various intermediaries whose activities could potentially trigger ABS obligations while adding their own value to the resource or product. Moreover, where products are made of multiple ingredients, the need for reliability, transparency and availability of information increases exponentially. But, at the same time, as a business endeavor, confidentiality needs by different actors along the value chain may also have an effect on information availability.

In the case of ABS, the Nagoya Protocol, in its Article 14, established the ABS Clearing House[43] as a means for sharing of information related to ABS, and it requires Parties to make available to the ABS Clearing-House the following information: national focal points and competent national authorities, ABS legislative, administrative and policy measures, and permits or their equivalent issued at the time of access.

Under the Nagoya Protocol rules, if a permit or its equivalent is granted for accessing genetic resources within a BioTrade project or phase, the country issuing the permit is required to make it available to the ABS–CH. The permit or its equivalent then becomes an internationally recognized certificate of compliance as provided in article 17.2 of the Protocol.[44]

5.1 Monetary and non-monetary benefits

"Benefit sharing" both in the context of BioTrade and access to genetic resources dimension, is somewhat novel and *additional* to classical commercial relationships, where each actor of the value chain focuses in making the most profitable business out of what is acquired and produced. Benefit sharing can take many forms and be expressed in money and non- money terms. In BioTrade, it is the perception of the value brought to the receiver of the benefits that defines its actual value. In most cases, monetary benefits arise at different stages of the value chain but are the highest during the final commercialization phase of the natural resource or product, when all the value has been added.

As an essential element in the value chain, each actor is supposed to receive a compensation or payment for services or the products provided. In an ideal scenario, each actor should reach a profitable stage in the value chain development process. Prices are based on mutually agreed terms (often contractual), where the needs of the buyers are aligned with the sellers' offer specifications. Hence, parties have the capacity to negotiate to the best of their respective interest. This is regular business practice and responds to market forces, but can also be positively influenced by fair trade principles, good business practices, sustainability criteria, exclusivity contracts, local employment and value addition preferences, as well as other considerations that are at the core of BioTrade enterprises seeking to improve asymmetries in relations amongst actors in the value chain.

Particularly in the case of monetary benefit sharing, both in classical commercial or industrial ABS and BioTrade projects (with some nuances),[45] money *needs* to be generated. The commercial success of a product will determine how much monetary benefits can be shared upstream, among researchers and/or communities, farmers or whoever provided materials for the R&D process, including *ex situ* centers.

However, there may also be other indirect benefits depending on the nature of the business or project. They can be "in kind" (i.e. non-monetary), such as equipment to improve a process or to improve quality control. They can also be "intangible", under the form of knowledge sharing (training, building capacity at the local level, improving production methods, diversification of products, developing marketing strategies, identifying new market opportunities, etc.). These forms of non-monetary benefits could potentially create and strengthen local capacities, which could then result in more favorable conditions to place negotiating parties at similar level of strengths to protect their respective commercial interests. These types of benefits could also lead to adding more value locally, placing the seller at a higher stage in the value chain.

Key messages

Fair and equitable benefit sharing in classical access to genetic resources projects and BioTrade responds to something more than a commercial transaction or market driven negotiation result. Benefit sharing obligations under the Nagoya Protocol are triggered at the moment of utilization of genetic resources, biochemicals or any component that may be covered by national ABS frameworks. In a BioTrade value chain, an ABS situation may imply an additional sharing of benefits than that calculated along the value chain, for a specific phase of that value chain. In BioTrade, benefit sharing is process oriented and a series of conditions are suggested under the Principles and Criteria to facilitate it. Fairness and equity dimensions are still blurred and need further analysis. However, BioTrade Principles and Criteria are targeted at enabling conditions that facilitate and support equity and fairness along the value chain. Benefits along a value chain can be extremely varied and diverse, from direct payments, to funding mechanisms, to non-monetary forms of benefits. Non-monetary benefits could be incentive based as a means to value and revalue biodiversity. Legal uncertainty is the main reason for inhibiting projects and business or making enterprises in BioTrade and ABS collapse altogether. "Benefits" does not always mean "profits" and, therefore, direct taxing systems could affect competitiveness.

6. PIC AND MAT PRINCIPLES: EXISTING APPROACHES AND OPTIONS FOR BIOTRADE

Benefit sharing, prior informed consent (PIC) and mutually agreed terms (MAT) are at the core of the international ABS frameworks of the CBD, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the Nagoya Protocol. They also inform national legal and regulatory schemes for ABS.

Generally, PIC reflects, within an administrative procedure, the acceptance of State authorities and in some cases indigenous peoples for ABS activities to take place. In regard to MAT, these terms invariably translate into bilateral agreements or contracts under which ABS conditions are specifically defined and which bind the State and other actors involved in ABS, depending on the specifics of legislation or regulations. Whether explicitly or implicitly and elaborated in more or less detail, all existing ABS policy and legal frameworks are based on these two principles.

According to BioTrade Principles and Criteria, BioTrade projects and businesses apply, more broadly, the basics of PIC (consent) and MAT (agreement) principles along the value chain. This is particularly so when indigenous people participate as providers of genetic or biological resources and any related TK.

BioTrade projects and businesses operate on the basis of contracts, permits, authorizations or even material transfer agreements (as shown in the case study in Box 6). Certainly, if a utilization of genetic resources and biochemicals arise along the value chain, the application of ABS principles will be mandatory according to national ABS legislation and regulations.

Options for MAT and PIC vary considerably across national legislation. Sometimes, MAT and PIC are required simultaneously from the State and providers of genetic or biological resources. In other cases, an agreement from the State's competent authority will suffice to legitimize the use of genetic and biological resources. Sometimes, if required by law, a specific agreement that reflects MAT and PIC will be needed from indigenous people and local communities when their TK is accessed and used. With the entry into force of the Nagoya Protocol and the European Union Directive for the implementation of the Protocol (511/2014 EU) clear and unequivocal MAT and PIC will become important, as part of a set of measures which may be evaluated as a condition to enter the European Union.

It should be noted that in the particular case of BioTrade projects or business arrangements, the type of PIC and MAT obtained may be different than the one required by the national ABS laws. In this sense, policy makers and regulators should consider ways in which PIC and MAT within BioTrade projects, businesses and enterprises, can become regularized or validated through simple and practical administrative procedures for the purposes of the ABS law. Future regulations should seek to recognize the type of PIC and MAT already agreed under a BioTrade project as "sufficient" for the purposes of fulfilling ABS regulations without a need to undertake new PIC and MAT, even if it implies fewer direct benefits for the State. Such an approach would allow continuation of businesses, employment and value addition and at the same time fulfill the spirit of ABS regulatory objectives.[46]

Key messages

Under the Nagoya Protocol, the minimum legal requirements for access to genetic resources are PIC and MAT – often granted by and negotiated with a State entity. This will be expressed as a permit, material transfer agreement, authorization and/or access contract. National ABS legislations around the world vary considerably as to how PIC and MAT are expressed and materialized. BioTrade already incorporates PIC and MAT under its principles, which could make it easier for the fulfillment of ABS requirements. However, the type of PIC and MAT and the actors granting it may be different than the one required by the national ABS law. Regularization and recognition of PIC and MAT under BioTrade projects could enable continuation of business, employment and value addition.

Box 6: Case study on BioTrade and ABS: Imports of fresh plants from Namibia to Europe

Summary of the project/business: A farm in Namibia, already producing and selling a few plants for herbal supplements in the European Union and the United States, is willing to expand its activity and offer to other markets. They have looked at another endemic plant, easy to reproduce, whose sap is known for its skin healing properties. Only few extraction methods are locally accessible to them in order to develop their own extract. Eager to enter the cosmetic industry with an innovative and competitive ingredient, they've requested support to their trade association (PhytoTrade Africa). In the project design, it was decided to try various extraction methods they could possibly outsource.

After further investigation, a process was identified as being relevant for their project. An SME providing the required services was identified and contracted in the European Union in order to conduct the extraction trials and related analytical work. Several kilograms of fresh plants were to be imported in order to run the various extraction tests.

BioTrade and ABS considerations: Namibia is a party to the Nagoya Protocol since 2014. National ABS measures are in place, and while the law is still under discussion, retroactivity on utilization of ex-situ collection pre-Nagoya could potentially become part of the national ABS law. For this specific project, to anticipate on possible ABS obligations arising in the development process, and because the recipient of the fresh plants is in the European Union, a Material Transfer Agreement (MTA) for commercialization purposes was signed by PhytoTrade Africa on behalf of the farm. In this document, the purpose for the transfer of material was explicitly described "compositional and activity research on the material for potential product development". However, no further details were provided on the processes to be tested. The farm granted a research permit for the exact same purpose as this written in the MTA. A non-disclosure agreement and contract were signed with the European Union-based SME providing the services.

Prior to the physical import, and further to the European Union's Council Directive 2000/29/EC, PhytoTrade Africa contacted the Competent Authorities to comply with the due diligence of importing fresh plants. The outcome was shared with the farm so they could apply for the corresponding Export Phytosanitary certificate.

Fresh plants were traveling with the original copy of an Export Phytosanitary certificate. This document was then used by the customs at the first point of entry within the European Union. To clear the material, a statement from the importer was required and had to mention the outcome of the due diligence under the 2000/29/CE, the plant name, the imported plant parts, the name of the importer, the contact details of the final destination and the intended use.

After three unsuccessful attempts due to logistics problems which resulted in the destruction of the plants, several kilograms of fresh plants had finally reached their final destination.

Main lesson: This case illustrates the need to look at both provider and user ABS regulations (in Europe). It also shows the importance of fulfilling obligations for international trade and export to Europe (i.e. due diligence), where customs or other institutions could become a check-point. The case is also interesting because it involves the use of a MTA as a means of securing MAT, which anticipates on the potential ABS duties arising in this BioTrade process, and requires an export phytosanitary permit to ensure legal export of fresh material to Europe, highlighting the pragmatic potential of developing a "one-stop-shop" approach in providing countries.

Source: UNCTAD and PhytoTrade Africa (2015). See BioTrade for Biodiversity project approved at: http://phytotrade.com/news/biotrade-for-biodiversity-project-approved-2/). Names of the actors in this case study have been kept confidential.

7. COMPLIANCE MEASURES AND THEIR IMPLICATIONS FOR BIOTRADE[47]

The rationale for the development of compliance measures (often also referred to as "user measures") is based on the fact that countries of origin, relying on their national ABS legislation only, have limited possibilities to ensure that their interests in benefit sharing can be effectively realized. Once genetic resources leave national jurisdictions, monitoring their use and enforcing ABS contractual obligations becomes highly problematic, especially along a complex R&D value chain which may include, for example, subsequent transfers or biological or genetic resources, or related innovations.[48] Ensuring compliance with ABS legislative and regulatory requirements also becomes a challenge. These are some of the reasons why some ABS frameworks have taken a defensive and restrictive regulatory approach, even though there is an often overlooked principle in the CBD which calls for access to be facilitated - under certain boundaries.

Article 15.7 of the CBD offers the legal foundation for developing compliance or user measures by establishing that:

"*Each Contracting Party [**both users and providers**] shall take legislative, administrative or policy measures, as appropriate, […], with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources […]*". [Highlight is from the authors]

Article 15.7 stresses that actions are also needed from Contracting Parties that are *user countries* to ensure realization of the benefit sharing objective of the CBD. Initial proposals and ideas concerning "user measures" were received with reluctance, open opposition and did not receive much support from developed nations in the 1990´s.[49] However, by the time the Bonn Guidelines had been approved, user measures were a firmly established part of policy and conceptual discussions regarding ABS.

Examples of user measures originally focused on developments in or adjustments to IP (patent and breeders rights) laws and regulations to support defensive protection of biodiversity and TK. The Bonn Guidelines included a specific section on measures which could be implemented from the user side to support realization of benefit sharing, compliance with PIC and MAT, etc.[50] Ironically, user measures were actually first developed and implemented in *provider* countries.[51]

The Nagoya Protocol has further refined and made mandatory a series of compliance measures which are, taking into account that countries are *both* users and providers, especially important for developed countries in terms of legal certainty and developing countries in terms of benefit sharing and safeguarding their interests in genetic resources (and TK).[52]

As a response to obligations under the Nagoya Protocol, the European Union has adopted the Directive for the implementation of the Protocol (511/2014 [EU]) which is the first comprehensive compliance oriented framework and offers guidance on how member states may go about in making the Protocol work in practice, particularly in regards to users under their jurisdictions.

Users in these countries are required to exercise due diligence to ascertain whether genetic resources have been accessed in accordance with relevant legal and regulatory mandates. For instance, e*x situ* collections may be registered if they comply with certain standards and exercise due diligence in regards to management and transfers of genetic resources from their collections. Designated checkpoints may also contribute to implementation of the Nagoya Protocol. Checkpoints must be effective and collect or receive information from users at, inter alia, any stage of research, development, innovation, pre-commercialization or commercialization. Possible checkpoints can be public funding institutions (for example when researchers apply for funds and are required to ensure that they have the right documentation in order to undertake their research activities over genetic resources). Other possible checkpoints are: the competent national biodiversity authority in the user country; research institutions subject to public funding; publishers and entities engaged in the publication of research results related to the utilization of genetic resources; intellectual property offices; and/or authorities who regulate or grant the authorization for the selling of products in the market.

Apart from these measures, both in the European Union and other countries around the world, "defensive protection" through IP procedures (particularly patents), are also becoming, de facto, a

Box 7: A sample of regulatory trends in user countries (European Union, Norway and Switzerland) which may be applicable to BioTrade

Regulation (EU) No. 511/2014 on compliance measures for users of genetic resources under the Nagoya Protocol (2014)

Whereas (21):
With a view of implementing the Nagoya Protocol, **all users** of genetic resources and traditional knowledge associated with genetic resources should exercise due diligence to ascertain whether genetic resources and traditional knowledge associated to genetic resources have been **accessed in accordance with applicable legal and regulatory requirements** and to ensure that, where relevant, **benefits are fairly and equitable shared.** In that context, competent authorities should **accept internationally-recognized certificates of compliance as evidence that the genetic resources covered were legally accessed and that mutually agreed terms were established** for the user and utilization specified therein.
Whereas (23):
The due diligence obligation should apply to **all users** irrespective of their size, including micro, small and medium-sized enterprises. This Regulation should offer a range of measures and tools to enable micro, small and medium-sized enterprises to comply with their obligations at an affordable cost and with a high level of legal certainty.

Article 2.1 (Scope):
This Regulation **applies to genetic resources** over which States exercise sovereign rights and to **traditional knowledge associated to genetic resources** that are accessed after the entry into force of the Nagoya Protocol for the Union. It also **applies to the benefits arising from the utilization of such genetic resources and traditional knowledge** associated with genetic resources.

Article 4.3.a (Obligations of users):
For the purpose of paragraph 1, users shall s**eek, keep and transfer to subsequent users: the internationally-recognized certificate of compliance,** as well as information on the content of the mutually agreed terms relevant for subsequent users.

Article 5 (Register of collections) 5.1:
The Commission shall establish and maintain a register of collections within the Union ("the register") […]

Article 5.3
In order for a collection or a part of a collection to be included in the register, a collection shall demonstrate the capacity to: a) apply standardized procedures for **exchanging samples of genetic resources** and related information with other collections, and for **supplying samples of genetic resources** and related information to third persons for their utilization i**n line with the Convention and the Nagoya Protocol.** b) supply genetic resources and related information to third persons for their utilization only **with documentation providing evidence that the genetic resources and related information were accessed in accordance with applicable access and benefit sharing legislation or regulatory requirements** and, where relevant, with mutually agreed terms.

Article 7 (Monitoring user compliance):
1. The member States and the Commission shall request all recipients of **research funding involving the utilization of genetic resources and traditional knowledge** associated with genetic resources to declare that they exercise due diligence in accordance with Article 4.

Patent Act of Norway, Act No. 9 of 1967 on patents, as amended in 2015	**Section 8 b.** If an invention concerns or uses biological material or traditional knowledge, **the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country).** If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained. If the providing country is not the same as the country of origin of the biological material or the traditional knowledge, **the application shall also state the country of origin.** The country of origin means for biological material the country from which the material was collected from its natural environment and for traditional knowledge the country in which the knowledge was developed. **If the national law in the country of origin requires that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.** If the information set out in this subsection is not known, the applicant shall state that.
Patent Act of Switzerland, as amended in 2012	**Article 49.a.II.** Information on the source of genetic resources and traditional knowledge. 1. **The patent application must contain information on the source**: - **of the genetic resource** to which the inventor or the patent applicant had access, provided the invention is directly based on this resource; - **of traditional knowledge of indigenous or local communities** of genetic resources to which the inventor or the patent applicant had access, provided the invention is directly based on this knowledge. 2. If the source is unknown to the inventor or the patent applicant, the patent applicant must confirm this in writing. Note: This is a side note to article 49.a but highly relevant for the purpose of the example.
Federal Act on the Protection of Nature and Cultural Heritage in Switzerland (amended in 2014)	**Article 23n 76, 1 (Due diligence requirement):** Any person who in accordance with the Nagoya Protocol utilizes genetic resources or derives benefits directly from their utilization (users) **shall apply due diligence** appropriate to the circumstances to ensure that: **a. the resources have been accessed lawfully; and b. mutually agreed terms for the fair and equitable sharing of the benefits have been established.** **Article 23o 77 (Notification requirement):** Notification of compliance with the due diligence requirement must be given to the FOEN **before market authorization has been obtained or, if such authorization is not required, before the commercialization** of products developed on the basis of utilized genetic resources.

Note: Highlights are by the authors. There are other countries in Europe, including Belgium, Sweden, France, The Netherlands and Germany, which have included similar provisions in their legislation, linking ABS to IP. These are not all official translations.

check point where legitimate uses of genetic resources and biochemicals can be verified before granting of exclusive rights.

Another important aspect of compliance measures may be the link with national regulation of the provider country. Under Article 15 (Compliance with Domestic Legislation or regulatory Requirements on ABS)[53] and Article 16 (Compliance with Domestic Legislation or regulatory Requirements on ABS for TK)[54] of the Protocol, users countries are required to adopt measures to ensure that national legislation in provider countries is complied with within their jurisdictions. Furthermore, Parties are required to adopt measures to address situations of non-compliance and cooperate in cases of alleged violations.

This means that a user country may limit its responsibility regarding verification only in regards to countries that have a national law or mechanism in place to verify the legality of the flows of resources from third countries (i.e. they also have measures in place as users). It is also important to note that the Nagoya Protocol implementing regulations in the European Union and Switzerland do not have a retroactive effect. This means that they will only apply to Post-Nagoya situations.

All of these measures have two main effects. First, they ensure legal certainty for both providers and users. Second, and most importantly, provider countries are obliged not only to enact ABS legislation but to ensure it is operational, including through PIC, MAT, benefit sharing and, through the issuance of a permit or its equivalent at the time of access which is mandated by the Nagoya Protocol. Only through effective actions and measure both by users and providers will the Nagoya Protocol be realized.

Key messages

Compliance measures are becoming more common. The implications for BioTrade practitioners are that they need to respect ABS requirements of provider and user countries alike. It is also important that all Parties to the Protocol are considered as both potential providers and users of genetic resources and TK and need to comply with all obligations. Typical compliance related measures may include defensive measures through the IP system (and patent procedures in particular) and due diligence requirements. Parties are now establishing checkpoints to facilitate the monitoring of the utilization of the genetic resources through the value chain and implement Article 17 of the Protocol. For example the European Union and Switzerland are rapidly advancing by adopting regulations and developing guidelines to implement compliance measures under the Nagoya Protocol. The flip side of user measures is the need for effective and efficient national ABS frameworks in provider or export countries.

8. INDIGENOUS PEOPLE, LOCAL COMMUNITIES AND BIOTRADE: CHALLENGES AND OPTIONS IN APPLYING CBD AND NAGOYA PROTOCOL PRINCIPLES AT THE LOCAL LEVEL

All existing BioTrade projects and businesses relate to some extent to indigenous people and local communities along the value chain. This often happens at initial stages where biological materials are sought and required. Sometimes, TK is also used to further support and complement research and development. In some cases, TK defines good practices and methods of production and processing even if scientific evidence doesn't exist to support or validate its effectiveness.

Consent and agreements with indigenous people and local communities, as well as local authorities, legitimize interactions and define the form and type of benefit sharing which will take place. In practice, PIC and MAT often take place within regulatory vacuums where no specific normative guidance is provided.

In some countries such as Costa Rica, Peru and Panama, or in regional blocs such as the African Union, there is specific legislation in place pertaining to TK protection. Experience with BioTrade projects shows that trust is constructed among users and communities as projects or businesses develop. BioTrade Principle 7 offers some guidance in this regard. The use of TK must be subject to PIC from indigenous people or communities when accessed and used as part of adding value to the value chain. Box 8 offers an example of a BioTrade enterprise where medicinal plants with traditional uses are being industrialized and commercialized in Viet Nam.

Box 8: Case study on BioTrade and ABS: Medicinal plants in Viet Nam

Description: Traphaco SaPa is a Viet Namese company specializing in the sourcing of natural ingredients for the Traphaco Group, the largest traditional medicine producer in Viet Nam. The Traphaco Group conducts research and development of food, cosmetics and pharmaceutical products from herbal plants. It has hundreds of internal research projects, as well as collaborations with government institutions, including to explore and develop the gene pool of valuable medicinal plants in Viet Nam, including Dioscorea persimilis (a type of yam) and Coix lacryma-jobi (commonly known in English as Job's tears).

Interface between BioTrade and ABS: Traphaco SaPa is responsible for implementing the Traphaco Group Green Plan Project, which focuses on improving practices for the sourcing, research and development of medicinal plants. To advance these objectives, Traphaco SaPa became a member of the Union for Ethical BioTrade (UEBT) in 2014. As a UEBT member, Traphaco SaPa is working on mechanisms to ensure monitoring of the prices paid to producers and to systematize the support given to producers on local development and capacity building. It is also reviewing its practices to integrate Ethical BioTrade requirements on biodiversity-based research and development.

For example, with the support of the Helvetas BioTrade project, Traphaco SaPa focused on improving practices for the Ampelopsis cantoniensis supply chain. This is a medicinal herb described in many scientific books and journals in Viet Nam and now used as a herbal medicine to treat gastric and intestinal inflammation. The Helvetas BioTrade project conducted an assessment of the socio-economic aspects and a mapping of the actors of the supply chain, which served as the basis for improving practices. Traphaco SaPa developed a mechanism to build a more direct dialogue with the collector groups, supporting their organizational mechanisms, technical training and capacity development. Traphaco SaPa now has agreements in place, both with collector groups and local authorities linked to ethical BioTrade practices.

Traphaco SaPa has also received training on concepts and requirements linked to access to genetic resources and fair and equitable benefit sharing (ABS). As a result, it is in contact with the Biodiversity Conservation Agency of Viet Nam to follow the implementation of a 2008 Biodiversity Law and the development of new rules and procedures on ABS, as part of Viet Nam's commitments as a Party to the Nagoya Protocol.

Lessons learnt: This case study shows how business engagement in BioTrade increases their awareness of ABS and facilitates eventual compliance with ABS requirements. Another important point is the role of traditional knowledge in research and development of new natural ingredients. This project did not include direct relationships with traditional knowledge holders. This may be due to the traditional knowledge related to these plants being widely used, known and shared throughout Viet Nam, which would make it difficult to define legitimate holders and potential benefit recipients for this traditional knowledge.

Source: UNCTAD and UEBT (adapted from http://ethicalbiotrade.org/helvetas-Viet Nam-interview-with-rik-kutsch-lojenga-executive-director-uebt/), Helvetas Viet Nam BioTrade Project (https://Viet Nam.helvetas.org/en/activities/projects_in_Viet Nam/biotrade/), Traphaco Group (http://www.traphaco.com.vn/en/product/phamaceutical/herbal-tonic-products).

To support the implementation of the Nagoya Protocol in respect of TK, the Protocol suggests some instruments through which TK may be protected. Community or biocultural protocols, customary practices and model contractual provisions may be options that countries could consider. In the case of TK which may be widely disseminated and distributed among communities and across jurisdictions, the Protocol also provides an avenue to address this specific situation under the context of transboundary cooperation. [55]

Key messages

Some examples exist of effective national TK protection frameworks. Most of the time, under BioTrade, uses of TK are governed under MAT (contracts) with communities whose TK is being accessed and used. Often, widely shared, known and disseminated TK makes it difficult to identify a single, legitimate holder of the TK. The Nagoya Protocol offers considerable guidance and includes substantive provisions regarding TK protection (e.g. through PIC and community protocols), benefit sharing (e.g. through MAT) and compliance aspects.

9. THE ROLE OF INTELLECTUAL PROPERTY AND CERTIFICATION IN BIOTRADE

BioTrade projects and businesses around the world use different forms of IP to protect innovations and promote the marketing of their products (see Box 9). The most common tools are patents and trademarks. The existence of patent and breeders rights directly obtained or based on genetic resources and biochemicals implies "utilization" under the Nagoya Protocol. It is almost impossible to generate new inventions or new plan varieties over genetic resources and biochemicals without some level of access to the physical material and some level of R&D, unless information accessed was already transferred into genetic information or chemical or biochemical formulas.[56]

UNCTAD developed a Handbook on the Convention on Biological Diversity and the Nagoya Protocol: Intellectual Property Implications that provides an in-depth analysis of the interaction between the IP regime and the new obligations under the Protocol[57]. This guidance should be considered for assessing the use of IP tools when engaging in BioTrade.

In many cases of BioTrade, some form of certification or social/market recognition scheme is used to highlight the reputation of the sustainable product or process. These tools vary widely in their objectives and are mainly voluntary, but can be summarized in terms of providing an advantage or value added to a product or process which is then appreciated by the market and consumers (see Box 10).

Box 9: When does IP "kick in"?

BioTrade and other biodiversity-based project or business	IP used and subject matter protected	Phase of the project or business in which IP was sought
Aldivia (France): www.aldivia.com	Trademarks (e.g. Ubuntu) covering its range of ethically sourced ingredients – the ethic claim being substantiate by a charter	Commercialization
Aldivia (France): www.aldivia.com	Patent (FR2883003A11, jointly filled by Aldivia and PhytoTrade Africa) on a discovery made on a derivative fraction	After research and before commercialization
Hersil SAC (Peru): www.hersil.com.pe	Under its trademark, "Schuler", it commercializes ointments and dietary supplements	Prior to commercialization
Peruvian Seaweed (Peru): http://www.pswsa.com/	A natural molecule, extracted from marine algae, named under the trademark "Marintec", and identified through its biotechnology division, has bioactive natural compounds which are being used in a wide range of products.	Prior to commercialization

Key messages

IP plays a key role both in BioTrade and more classical ABS projects. Innovations often require IP protection and marketing strategies also often make use of IP tools. Certain forms of certification, for BioTrade processes and products in particular, are also important to promote products along the value chain as a means to gain market share and convince consumers.

Box 10: Certification, standards and mark schemes relevant to BioTrade

Tool	Objective
Union for Ethical Biotrade (UEBT) www.ethicalbiotrade.org	UEBT is an international, non-profit association that promotes the "Sourcing with Respect" of ingredients that come from biodiversity. Ethical BioTrade advances sustainable business growth, local development and biodiversity conservation. UEBT members, which include companies sourcing natural ingredients for food, cosmetics and pharmaceuticals, commit to the Ethical BioTrade Standard, which is based on the BioTrade principles and Criteria.
FairTrade (Fair Trade Labelling Organization International) www.fairtrade.net	FairTrade is an international organization which sets standards which seek to: ensure that producers receive prices that cover their average costs of sustainable production; provide an additional Fairtrade Premium which can be invested in projects that enhance social, economic and environmental development; enable pre-financing for producers who require it; facilitate long-term trading partnerships and enable greater producer control over the trading process; set clear core and development criteria to ensure that the conditions of production and trade of all Fairtrade certified products are socially, economically fair and environmentally responsible.
Fair Wild www.fairwild.org	Through the FairWild Standard and Certification System for the sustainable management and collection of wild plants, the FairWild Foundation promotes the sustainable use of wild-collected ingredients, with a fair deal for all those involved throughout the supply chain.
Fair for Life www.fairforlife.net	The Fair for Life Social & Fair Trade Certification Programme offers operators of socially responsible projects a solution for brand neutral third party inspection and certification in initial production, manufacturing and trading. It combines strict social and fair trade standards with adaptability to local conditions. The system is designed for both food and non-food commodities (like cosmetics, textiles or tourist services).
Forest Stewardship Council (FSC) www.fsc-uk.org/what-is-fsc.73.htm	FSC is an international NGO dedicated to promoting responsible forestry. FSC certifies forests and NFTP all over the world to ensure they meet the highest environmental and social standards.
International Federation of Organic Agriculture Movements (IFOAM) www.ifoam.bio	IFOAM is an international federation of organizations dedicated to the promotion of organic production. Through IOAS, it certifies that organic standards are met by certification bodies worldwide.
International Standards Organization (ISO) www.iso.org	ISO is an international organization which sets different process/product quality standards which are then applied by certification organizations. Especially relevant for BioTrade, are ISO 9000 environmental quality and management standards.
Country Mark or Trademark (e.g. Marca Peru, Beautiful Malaysia, All you Need is Ecuador, Magic Colombia).	A distinctive sign which is used to identify a country and its specific features, values, culture, tradition, excellence, etc.

Source: Produced by the authors.

10. ISSUES FOR CONSIDERATION AND NEXT STEPS

When the Nagoya Protocol entered into force, Mr. Mukisha Kituyi, Secretary-General of UNCTAD, hailed it as an "…historic achievement in the annals of multilateral environmental agreements. He further expressed that the protocol "…will have major … positive implications for genetic resource flows, trade in biodiversity-based products and related R&D activities. These strengthen the conservation of biodiversity, its sustainable use and ensure more equitable access to and sharing of benefits between communities and companies." The Nagoya Protocol is thus more than a pillar for realization of key principles of the CBD. It will also strengthen multilateralism through coordination and coherent national actions. It further responds to the wake-up call in the United Nations 2030 Agenda for Sustainable Development in placing biodiversity within a responsible, equitable and ethical approach to biodiversity conservation and sustainable use in support of improved livelihoods.

In order to improve understanding and advance practical options on how to implement ABS obligations under the CBD and the Nagoya Protocol and BioTrade principles in a coherent and mutually supportive manner, the following issues should be considered by decision makers, regulators, international governmental organizations such as UNCTAD, BioTrade businesses and other relevant stakeholders:

a) The CBD and Nagoya Protocol principles should be interpreted systematically. Parties are entitled and have the right to regulate access to their genetic resources and biochemicals and, at the same time, *facilitate* access as a means to generate and thereafter share benefits fairly and equitably. Now that clear compliance obligations have been introduced by the Nagoya Protocol on Parties as users of genetic resources, biochemicals and TK, provider country ABS requirements could become less restrictive. This would contribute to legal certainty for all parties and actors involved in the utilization of genetic resources. *Decision makers and regulators should ensure that their ABS frameworks adequately respond to both aspects and do not overstress regulation and control only which, for almost two decades has been limited in its effectiveness to generate benefits and facilitate sharing. Incentives to promote ABS and compliance with rules need to be put in place and into motion in order to promote legal, sustainable, equitable and ethical flows of and trade in genetic resources and biochemicals.*
b) *Access and benefit sharing regimes should be transparent, clear, operational and applicable in practice to enhance legal certainty for all actors.* These are also goals of the Nagoya Protocol. At the same time, *regulators need to implement these regimes in a logical and coherent manner*. Compliance measures called upon by the Nagoya Protocol, such as those being developed and implemented by some countries, also demand effectiveness and efficiency in ABS regimes and procedures from provider countries.
c) Support should be continuously provided to decision makers and regulators alike on BioTrade-friendly implementation of the Nagoya Protocol, especially in the initial stages of the enforcement of the Protocol. Firstly, *UNCTAD could develop a set of indicators or a checklist that guide decision makers and/or regulators on how close or far is a particular BioTrade activity from the coverage by national ABS regulations and procedures*. Secondly, *UNCTAD could also develop a synthesis of case studies and examples of how countries are determining the connections and interlinkages between BioTrade projects and businesses and ABS frameworks*. Finally, *useful lessons from existing experiences in benefit sharing in BioTrade case studies and examples can be disseminated among ABS policy makers and regulators to extract useful lessons from existing experiences,* since BioTrade offers a proven enabling environment to support the realization of benefit sharing. This would substantially improve synergies and complementarities between ABS and BioTrade.
d) Authorities with responsibility for *BioTrade-related activities and ABS rules and procedures should communicate and coordinate in a regular manner* to ensure coherent implementation of rules and procedures. *Duplication in procedures or unnecessary transaction costs that act as a disincentive to undertaking research, and developing productive and commercial activities need to be avoided*.
e) Understanding the changing and very diverse R&D landscape is important to better determine where and how connections between BioTrade and ABS

may occur. From changes in intention to moves into unplanned research areas and the use of state of the art technologies, relevant entities *should illustrate this particular landscape and assess its specific relevance to BioTrade*. Starting with the cosmetics, nutraceutical and other natural products industries may offer some insights into the intricacies of R&D and enable better understanding of its importance in the context of the BioTrade and ABS interface.

f) *UNCTAD could undertake an assessment to determine and analyze how TK relates to the interface between BioTrade-related activities and ABS*. This assessment could include analysis of how PIC, MAT and benefit sharing take place in the particular context of indigenous peoples and communities participating in BioTrade value chains and specific ABS projects as well.

g) *Decision makers and regulators should consider ways in which PIC and MAT within BioTrade projects or business arrangements can become regularized or validated through simple and practical administrative procedures*. In light of the rapid implementation of the Nagoya Protocol, this may prove a useful way to ensure the continuation of businesses, employment and value addition. It could also facilitate market accessibility, especially in Europe and Switzerland for products developed through BioTrade but also covered under ABS laws and regulations.

h) The value that non-monetary benefits could generate is often underappreciated and rarely linked to providers' national scientific, technology, development or biodiversity strategies, plans and programs. *Decision makers and regulators should develop and implement measures that strongly encourage specific and measurable non-monetary benefits as a means to support a sustainable biodiversity-based economy*.

i) *Clear and easy procedures to obtain permits or their equivalent as evidence of the decision to grant PIC and of the establishment of MAT , as well as well-selected checkpoints will be critical to ensure proper traceability frameworks*. Such measures *need to create incentives to comply* while bringing legal certainties required by users.

j) UNCTAD, the CBD and other relevant entities need to intensify their efforts and activities related to *awareness raising and capacity building for different BioTrade actors, including national authorities, on the Nagoya Protocol*. Although existing experiences demonstrate that BioTrade activities and business are often quick in adapting and responding to a series of national regulatory and legal requirements (e.g. obtaining concessions, formalizing organizations along the value chain, forming alliances and partnerships with communities, paying taxes, complying with phytosanitary norms, obtaining commercial authorizations, etc.), they often have difficulties when specifically seeking to comply with ABS frameworks. *BioTrade entrepreneurs, businesses, projects and related actors need to be fully aware that there might be connections between their activities and ABS dimensions and that this will demand additional efforts to comply with regulatory and procedural ABS requirements at the national level (both in user and provider countries)*.

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Notes

1 BioTrade refers to “activities of collection, production, transformation, and commercialization of goods and services derived from native biodiversity under the criteria of environmental, social and economic sustainability”. See Chapter 1 of this study for further information.

2 The CBD was signed in June 1992, as part of a series of international instruments adopted during the United Nations Conference on the Environment and Development (UNCED), held in Rio de Janeiro, Brazil, better known as “Rio 92”. The Nagoya Protocol was adopted during the Tenth Conference of the Parties of the CBD held in Nygoya, Japan, October 18-29, 2010. The Protocol entered into force on October 12, 2014.

3 Regional frameworks include Andean Decision 391 and the African Union Model Law of access to biological and genetic resources. National frameworks are now in place in Australia, the Plurinational State of Bolivia, Brazil, Colombia, Costa Rica, Ecuador, India, Panama, Peru, South Africa, the Philippines, the Bolivarian State of Venezuela, among others. In addition, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), adopted on November 3, 2001, is an ABS instrument targeted specifically at plant genetic resources for food and agriculture.

4 UNCTAD. BioTrade Initiative, Principles and Criteria. Geneva, New York, 2007. http://www.biotrade.org/ResourcesPublications/UNCTAD_BT_PC_en.pdf.

5 BioTrade activities usually go from the sourcing stage (phase 1) were materials are harvested, collected and stocked (prophase 1); to a processing phase (phase 2) were materials are transported, transformed and processed; to a research and product development phase (phase 3) were specific R&D takes place and, finally to the manufacturing and commercialization phase (phase 4) were sales and marketing occur. Within this process, there may be a particular instances (phase 3) when specific R&D takes place which triggers benefit sharing obligations.

6 "Native" can be understood to mean biodiversity which is truly unique and singular to a particular country (as in "the country of origin" in literal terms) or which over time has become adapted to an environment and has *become* native or naturalized. For instance, Peru is not the country of origin of cocoa nor is cocoa a native crop. Nevertheless, there are BioTrade projects focusing on Peruvian cocoa that has become adapted, has diversified in the country and is "almost" native after time. More than one country may also be the origin of a particular plant or crop, but this crop may still be "native" in terms of the BioTrade definition.

7 See UNCTAD. *BioTrade Initiative, Principles and Criteria*. Geneva, New York, 2007. http://www.biotrade.org/ResourcesPublications/UNCTAD_BT_PC_en.pdf.

8 See also Vivas Eugui, David and Cusi, Mariona. *The Nagoya Protocol and the potential of BioTrade as a vehicle to promote ABS compliant value chains,* CBD business .2020, Vol. 10 - Issue 1, Nov. 2015.

9 Article 1 of the CDB establishes that: *The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding*.

10 In its definition of "biological diversity", the CBD refers to three levels: diversity in *ecosystems*, *species* and at the *genetic* level. "Biological resources" are defined as including "*genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity*". Therefore any entrepreneurship undertaken with native biodiversity –at any of these levels – and in accordance with BioTrade Principles, would fall under its scope.

11 See http://www.biotrade.org/aboutINTRO.asp

12 These include for example the Andean BioTrade Program (2010-2014) CAF/GEF (Colombia, Ecuador, Peru) (http://www.biocomercioandino.pe/proyecto-biocomercio-andino/descripci%C3%B3n-del-proyecto.aspx), the national program in Peru (http://www.biocomercioandino.pe/biocomercio-en-per%C3%BA/programa-nacional-de-promoci%C3%B3n-del-biocomercio.aspx), and the BioTrade support program in Viet Nam (https://vietnam.helvetas.org/en/activities/projects_in_vietnam/biotrade/), among others. Depending on the BioTrade program, sometimes these exclude certain activities which may involve genetic resources such as the generation genetically-modified organisms.

13 The First BioTrade Congress was held in Rio de Janeiro, Brazil, in 2012 (http://r0.unctad.org/biotrade/congress/event3rdCongress.htm); the Second BioTrade Congress was held in Geneva, Switzerland, in 2013 (http://r0.unctad.org/biotrade/congress/event.htm). The third and most recent BioTrade Congress was held in Pyeongchang, South Korea, in 2014 (http://r0.unctad.org/biotrade/congress/event3rdCongress.htm)

14 UEBT has become a key promoter and implementer of BioTrade and its principles, with direct action with the business community and other social actors. Through a membership structure that includes large, medium and small businesses, especially in the natural ingredients and cosmetics sector in many countries, and a strict verification program, UEBT has been successful in supporting sustainable international trade in biodiversity. UEBT has developed a Verification Standard, to "measure" how well BioTrade Principles and Criteria are being implemented, as a means to shape and inform sustainable sourcing practices. See, http://ethicalbiotrade.org/verification/ethical-biotrade-standard/

15 For example, COP 10 Decision X/21 (2010) on Business Engagement makes an explicit reference to the BioTrade Initiative (and other initiatives and institutions) and its role in supporting incorporation of biodiversity dimensions into business practices. A more recent example includes COP 12 Decision XII/10 (2014), also on Business Engagement, which recognizes *"[…] the Biotrade Initiative of the United Nations Conference on Trade and Development, as well as existing initiatives that promote corporate social responsibility and the greening of supply chains…*". It also mentions BioTrade an "*its importance as an engine for sustainable use of biodiversity and conservation through involvement of the private sector*". Similarly, COP 12 Decision XII/6 (2014) encourages that business "*increase, as appropriate, participation in and cooperation with, the BioTrade Initiative (…) at the national, regional and global levels that are committed to the sustainable use of biodiversity, sustainable harvesting practices, and access and benefit sharing under the framework of the Nagoya Protocol (…)*".

16 The MDGs were adopted at the Millennium Summit in 2000, in New York.

17 These goals were approved by the United Nations General Assembly on September 25, 2015. Specifically relevant targets under SDGS 15 include: target 15.1 regarding halting loss of biodiversity; target 15.6 regarding the fair and equitable sharing of benefits; target 15.9 on integrating ecosystem and biodiversity values into national planning. Also relevant, albeit more indirectly, are SDG 12 (Responsible Consumption and Production), 14 (Marine resources conservation) and Goal 17 (Partnerships). For details of this process see https://sustainabledevelopment.un.org/topics. The specific goals and targets are available at https://sustainabledevelopment.un.org/?menu=1300

18 The identification of the synergies between REDD + and BioTrade activities have taken place in Brazil, Colombia and Ecuador, see http://www.biotrade.org/ResourcesPublications/webditcted2015d5_en.pdf The Second BioTrade Congress also addressed this issue, which is also reflected in its report, available at http://unctad.org/en/PublicationsLibrary/ditcted2014d6_en.pdf

19 Correa, Carlos (2011) *Implications for BioTrade of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization*. United Nations, New York and Geneva. Available at http://www.biotrade.org/ResourcesPublications/UNCTAD_DITC_TED_2011_9.pdf

20 Genetic resources may include specific genes or a strand of DNA or even a seed as is. Basically, any material of biological origin which contains functional units of heredity, as defined by the CBD.

21 A naturally occurring biochemical may include polyphenols, polysaccharides or fatty acids. A natural sap or extract from a plant, tree or biological specimen, may broadly be considered a derivative and thus covered under the Nagoya Protocol.

22 In some countries such as South Africa, BioTrade and ABS are governed under a single institutional setting and administrative procedure; in most countries, ABS and BioTrade are regulated under different legal frameworks. For example, collecting non-timber forest products (NTFP) in Peru (many BioTrade activities fall under this category) falls under the forestry regime of the agricultural sector, whilst ABS has specific legislation in place which involves also the Ministries of Agriculture, Environment and Production. Furthermore, promotion of NTFP falls under the competences of the Ministry of Commerce, Industry and Tourism, and a specific commission within.

23 This is expressly recognized by the BioTrade Initiative on page 5 of the Introduction to Principle 3 of the document UNCTAD. *BioTrade Initiative, Principles and Criteria*. Geneva, New York, 2007.

24 These examples included: Executive Order 247 and its regulation in The Philippines (1996), Andean Decision 391 on a common regimen on ABS (Plurinational State of Bolivia, Colombia, Ecuador, Peru and the Bolivarian Republic of Venezuela) (1996), Provisional Measure 2.186-16 on ABS in Brazil (2001), African Union Model Law on access to genetic and biological resources (2000), Executive Decree 257 on ABS in Panama, among others. Only Costa Rica and its biodiversity law 7788 (1998) and its regulations could be consider effective (at least in terms of number of ABS contracts signed), but mainly due to a very specific institutional and administrative structure focusing on activities undertaken by the National Biodiversity Institute (INBIO).

25 Although all countries are users and providers of genetic resources alike, some are more users than others and the Nagoya Protocol is based on the assumption that, historically, genetic resources have moved primarily from Southern, biodiversity rich countries, to Northern, industrialized nations.

26 The Group of Like-Minded Megadiverse Countries is formed by: the Plurinational State of Bolivia, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, South Africa and the Bolivarian Republic of Venezuela. See https://www.environment.gov.za/likeminded_megadiversecountries_lmmc

27 The Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, were approved by Decision VI/24 during COP 6 of the CBD, held in The Hague, The Netherlands, in 2002, and include specific provisions on user measures. Available at https://www.cbd.int/decision/cop/default.shtml?id=7198

28 However, if natural molecules are accessed from biological sources such as medicinal plants, algae, native crops or microorganisms for utilization in the cosmetic, pharmaceutical, bio-remediation or breeding industries, these would *not* be excluded from the national ABS framework in Peru.

29 See, Cabrera, Jorge (2013) *El Protocolo de Nagoya: Opciones para su Implementación Política en América Latina*. Proyecto GEF sobre Acceso a Recursos Genéticos y Distribución de Beneficios para América Latina y del Caribe - GEF ABS LAC. UICN, GEF. Quito, Ecuador. Available at http://www.portalces.org/sites/default/files/migrated/docs/Doc_Tec_PN_Retos_AL.pdf

30 The coverage of “derivatives” and how these relate to biochemicals, will depend entirely of the national/regional ABS regulations. Literally speaking, “derivatives” mean something which *comes from*, so it’s most likely a generic word. Whereas “biochemicals” bears a scientific connotation, implying that a value adding step has occurred and has allowed to scientifically define the matter (for example, beeswax is a derivative in a sense that it is secreted by bees from *Apis mellifera* species - but it is also a biochemical as it can be put in the category of oils & fats because R&D steps have allowed to defined its biochemical composition. There is a certain controversy regarding whether “biochemical compositions” include some derivatives, all derivatives, or on the contrary, they are two different “objects”. This can only be resolved at the national and regional level in ABS legislation. CBD COP Decisions may also provide technical guidance on the matter to Parties. What seems to be important is that the explicit incorporation of “derivatives” will generate a clear expansion of the type of activities covered by ABS regulation.

31 See definitions by the Food and Agriculture Administration in the United States, http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm#Definecosmetic

32 See REACH regulation EC 1907/2007 http://ec.europa.eu/growth/sectors/chemicals/

33 See European Union regulation on Cosmetics EC 1223/2009 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:EN:PDF

34 See Novel Food Regulation in the European Union http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1449760581954&uri=OJ:JOL_2015_327_R_0001

35 See GRAS in the USA http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/

36 See Article 15 of the Nagoya Protocol on compliance with national legislation and ABS regulatory requirements and Article 17 on monitoring the utilization of genetic resources.

37 The application for a patent or a breeder right is usually the consequence of successful R&D process. There is no way to obtain a new invention or a plant variety without some degree of R&D.

38 South Africa makes continued references to and addresses biotrade (not "BioTrade") throughout its ABS framework (Amendments to the regulation on bioprospecting and ABS, Government Gazette, May 2015).

39 To date, there are very limited studies which address the "fairness and equity" dimensions of benefit sharing. "Fairness" and "equity" seem to mean, in practice, whatever is negotiated or agreed within the BioTrade or ABS project. For some insights into fairness and equity in ABS see, De Jonge, Bram (2009) *Plants, Genes and Justice. An Inquiry into Fair and Equitable Benefit Sharing*. Thesis, Wageningen University, The Netherlands.

40 Many bioprospecting projects for example, include milestone payments that are *not* related to commercialization, but to different advances along the value adding chain on the genetic resource(s). The International Cooperative Biodiversity Group Program (ICBG) project in Peru, which in the 1990´s explored Amazon communities land for useful medicinal plants, offered a series of annual payments, directed to indigenous communities, according to progress in research. These payments were of approximately $ 30,000. Other similar arrangements were also set up in cases were later along the R&D process, successful commercial products or IP were generated.

41 It should be noted that this might not hold true when TK is involved. If a country has a regulation protecting TK and associated TK is involved, it is quite probable that such regulation will apply to activities in the value chain from phase 1 onwards.

42 There are many examples throughout the world of biodiversity-related projects that have not been successful because of these factors. One of the better known examples is the ProBenefit Project – Implementing the CBD in the Ecuadorean Amazon (Ecuador), carried out from 2003 to 2007. This project basically did not succeed because of the inability unable to define the exact scope, coverage and administrative procedures to secure legally certain access to Ecuadorean genetic resources. Similar situations have happened in Peru, the Plurinational State of Bolivia and the Bolivarian State of Venezuela and in other parts of the world.

43 See https://absch.cbd.int/

44 The first internationally recognized certificate of compliance, incorporated into the ABS- CH, was issued recently by India and its National Biodiversity Authority. This instrument offers information about resources, PIC and MAT. See https://www.cbd.int/doc/press/2015/pr-2015-10-07-abs-en.pdf

45 In the case of BioTrade, by principle, all actors along the value chain are full participants of the process and have responsibility in the success of the operation. Therefore, they are not simple receivers of money if and when useful applications and commercialization take place.

46 How prior informed consent (PIC) and mutually agreed terms (MAT) are expressed varies considerably depending on national frameworks. "Who provides PIC and how are MAT negotiated and also expressed" has many answers. Furthermore, in the case of BioTrade, there is another level or set of principles applicable that may or may not converge on similar authorities or actors. In some cases, the State is a key PIC provider and negotiates MAT; in other cases, communities, institutions and even individuals may also participate in PIC related procedures and MAT negotiations.

47 All countries are users and providers of biological and genetic resources to some extent. However, the idea of "user measures" responds to a historic trend in which Southern countries have contributed more substantially to international flows of these resources. See, Pistorious, Robin (1997) *Scientist, Plants and Politics: A History of the Plant Genetic Resources Movement*. IPGRI, Rome, Italy.

48 The "omics" revolution (genomics, proteomics, proto-boleomics), together with genetic engineering and, especially, bioinformatics, have radically altered the way in which R&D is undertaken on genetic resources and rendered monitoring their use along complex research chains even more problematic. See, Pastor, S., Ruiz, M. *The Development of an International Regime on Access to Genetic Resources and Fair and Equitable Benefit Sharing in a Context of New Technological Developments.* Initiative for the Prevention of Biopiracy.

SPDA. Year IV No. 10 April 2009. Available at: https://www.cbd.int/abs/doc/serie-iniciativa-2009-04-en.pdf

49 User measures were first proposed in the Andean Community, as part of the negotiations of Decision 391 on ABS. At first, they were associated to defensive protection and ensuring IP regimes take into account ABS frameworks as a pre-condition for granting rights, especially patents. See, Tobin, Brendan (1997) Certificates of Origin: A Role for IP Regimes in Securing Prior Informed Consent. In: Mugabe, J., Barber, C., Henne, G., Glowka, L., La Viña. A. (Eds.) *Access to Genetic Resources: Strategies for Benefit Sharing*. ACTS Press. Nairobi, Kenya. Available at, https://www.academia.edu/6636676/Certificates_of_Origin_A_role_for_IPR_Regimes_in_Securing_Prior_Informed_Consent

50 The Bonn Guidelines, section II (Roles and responsibilities in ABS), numeral 16, paragraph d) establishes that: *Contracting Parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted. These countries could consider, inter alia, the following measures:*

- Mechanisms to provide information to potential users on their obligations regarding access to genetic resources;
- *Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights;*
- *Measures aimed at preventing the use of genetic resources obtained without the prior informed consent of the Contracting Party providing such resources;*
- *Cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements;*
- *Voluntary certification schemes for institutions abiding by rules on access and benefit-sharing;*
- *Measures discouraging unfair trade practices;*
- *Other measures that encourage users to comply with provisions under subparagraph ?16 (b) above.*

51 The first specific user measure can be traced to Supreme Decree 008-1996-ITINCI, the national plant breeder´s regulation in Peru, from 1996. It established that the any application for a breeders right should contain or indicate the country of origin and provide with legal proof that genetic resources used in the new variety (as well as related knowledge, including TK), were obtained legally. This was a milestone and soon thereafter influenced the Andean Community´s Decision 391 and, most importantly, Andean Decision 486 from 2001, on the Common Regime for Industrial Property Regime, which became the first IP norm in the world to condition the granting of patents to legal access to genetic resources and TK in the case of biotechnological inventions. Examples like these have multiplied thereafter, whether within IP frameworks or under biodiversity related laws in many regions, including Europe.

52 Article 15 of the Protocol develops a series of provisions regarding compliance with domestic legislation or regulatory requirements on ABS; article 16 further develops provisions on compliance with domestic legislation or regulatory requirements on TK; article 17 focuses on monitoring genetic resources through national checkpoints; article 18 focuses on compliance with MAT.

53 Article 15. *Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing*

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.
2. *Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.*
3. *Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.*

54 Article 16. *Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing for Traditional Knowledge Associated with Genetic Resources*

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

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

55 Article 10 of the Nagoya Protocol, on the Global Multilateral Benefit Sharing Mechanisms suggests that "*Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally*." This should be read in conjunction with Article 11 which establishes that "

56 New technological and scientific paradigms where bioinformatics, proteomics, genetic engineering, among others, are creating powerful R&D platforms where *natural information* is becoming the key asset and interest for biotechnology and industry. See, Ruiz, Manuel (2015). *Genetic Resources as Natural Information. Implications for the Convention on Biological Diversity*. Earthscan from Routledge. Oxon, New York.

57 See http://unctad.org/en/pages/PublicationWebflyer.aspx?publicationid=1040