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BioTrade and Access and Benefit Sharing: From concept to practice

A handbook for policymakers and regulators

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Note

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For further information on UNCTAD's BioTrade Initiative please consult the following website:
http://www.unctad.org/biotrade or contact: biotrade@unctad.org

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- BioTrade and ABS: Medicinal plants in Viet Nam by Maria Julia Oliva (UEBT);
- BioTrade and ABS: *Echinops giganteus* in Cameroon by Maria Julia Oliva (UEBT);
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Contents

Purpose of the handbook

This handbook seeks to orient policymakers and regulators in the development and implementation of BioTrade and measures related to access and benefit sharing at the national level, consistent with the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, which entered into force in 2014.

Target audience

This handbook is mainly targeted towards policymakers and regulators in Parties to the Convention on Biodiversity and the Nagoya Protocol and where BioTrade and ABS-related activities and projects are taking place or may develop in the future. It may be especially relevant for countries that are in the process of defining or drafting their national ABS frameworks and at the same time working on BioTrade projects.

How to use this handbook

The handbook is intended to facilitate the process of development of sound legal, regulatory and administrative measures and assist daily practices of ABS regulators. It is a “how to do” tool, which is complemented with practical examples, case studies and checklists, which will facilitate its use and application mainly, albeit not only, by ABS and BioTrade policymakers and regulators. A distinction is made between policymakers and regulators. The former are responsible for designing, developing and approving policy, law and regulations whilst the latter are responsible for interpreting and applying these laws and regulations in practice, on a day-to-day basis. In some cases, policymakers and regulators may coincide. This depends considerably on how countries are organized administratively and institutionally.

Acronyms and abbreviations

ABS	access and benefit sharing
ABSCH	Access and Benefit Sharing Clearing-house (Secretariat of the CBD)
AoO	appellation of origin
ATK	associated traditional knowledge
BIG	BioTrade Interest Group (Viet Nam)
BTFP	BioTrade Facilitation Programme
CAF	Development Bank of Latin America
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CRISPR	clustered regularly interspaced short palindromic repeats
DDR	due diligence requirements
ERuDef	Environment and Rural Development Foundation (Cameroon)
FOEN	Federal Office for the Environment (Switzerland)
GACP	good agricultural and collection practices
GBIF	Global Biodiversity Information Facility
GEF	Global Environment Facility
GI	geographical indications
GMBSM	global multilateral benefit sharing mechanism
IEPI	Ecuadorian Institute of Intellectual Property
IFOAM	International Federation of Organic Agriculture Movements
INIA	National Institute of Agrarian Innovation (Peru)
IP	intellectual property
IPEN	International Plant Exchange Network
IPI	Swiss Federal Institute of Intellectual Property
IPLCs	indigenous peoples and local communities
IRCC	internationally recognized certificate of compliance
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture (FAO)
MADS	Ministry of Environmental and Sustainable Development (Colombia)
MAT	mutually agreed terms
MEAs	multilateral environmental agreements
MINEPDED	Ministry of Environment, Natural Protection and Sustainable Development (Cameroon)
MOSAICC	Micro-Organisms Sustainable use and Access regulation International Code of Conduct
MoU	memorandum of understanding
MTA	material transfer agreement
NBSAP	national biodiversity strategies and action plan
NCHA	Federal Act on the Protection of Natural and Cultural Heritage (Switzerland)
NGO	non-governmental organization
NTFP	non-timber forest product
OECD	Organisation for Economic Co-operation and Development
PGS	participatory guarantee system
PIC	prior informed consent
PoA	protected appellation of origin
PTA	PhytoTrade Africa
R&D	research and development
REDD+	Reducing Emissions from Deforestation and Forest Degradation
SCBD	Secretariat of the Convention on Biological Diversity
SECO	Swiss State Secretariat for Economic Affairs
SDG	Sustainable Development Goals
SME	small and medium-sized enterprise
SMTA	standard material transfer agreement
TRIPS	Trade-Related Aspects of Intellectual Property Rights (World Trade Organization)
UEBT	Union for Ethical BioTrade
UNCTAD	United Nations Conference on Trade and Development
USDA	United States Department of Agriculture
WIPO	World Intellectual Property Organization

EXECUTIVE SUMMARY

Since the Convention on Biological Diversity (CBD) was adopted in 1992, a new paradigm relating to the planet's natural capital has emerged. Contrary to the widely accepted legal precept that biodiversity is a "common heritage of humanity", individual States can now fully assert their exclusive entitlement to regulate and set up conditions for the access and use of their biodiversity, particularly their genetic resources through "access and benefit sharing" (ABS) regulations. The adoption of the CBD's Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol), detailing the ABS and compliance obligations relating to genetic resources, and associated traditional knowledge (ATK), has only fortified this new ethos. The challenge now is how the Parties develop and implement the provisions of the Nagoya Protocol so that legal, regulatory and administrative measures contribute to and fulfil the objectives of the CBD while facilitating the emergence and scale up of BioTrade.

This handbook addresses some of the practical opportunities and challenges regarding ABS in two ways. Firstly, by presenting the story of BioTrade and UNCTAD's role, and how, since the creation of the concept 20 years ago, it has emerged as a concrete practical model for identifying and bridging the gap between stakeholders (from the grassroots to the regulatory level) and the public and private sector, as well as enabling the implementation of the CBD's objectives, namely conservation of biodiversity, sustainable use and benefit sharing. Secondly, it offers a practical and easy way to understand some of the key issues policymakers and regulators may need to consider when developing and implementing ABS and BioTrade measures, and projects, in compliance with related international frameworks.

The handbook has been structured to highlight key issues and challenges with suggestions at the end of each section for both regulators and policymakers. A distinction is made between a regulator (i.e. a person who mainly applies a law or regulation) and a policymaker who basically develops the rules and frameworks – often these two roles coincide.

Comprising nine sections, the handbook provides a glossary, a series of annexes with relevant case studies and two sets of checklists to guide policymakers and regulators. Boxes and tables further illustrate practical examples and complementary information which will assist regulators in deciding and policymakers in developing policies and frameworks.

Although some analysis is provided throughout the handbook, the idea is that it may serve a more practical purpose and assist countries in their efforts to find positive synergies and complementarity between ABS and BioTrade.

Section 1 introduces key ABS and BioTrade Principles and outlines how they positively contribute to the advancement and implementation of recently adopted United Nations Sustainable Development Goals (SDGs) and other international and multilateral environmental agreements (MEAs). This section presents the basic content of and obligations under the Nagoya Protocol. Subject to national ABS frameworks, some BioTrade activities may be included in the Nagoya Protocol's scope, i.e. the benefit sharing rules being applicable to genetic resources, their genetic and/or biochemical compositions, and ATK. This will also depend on how national laws and regulations define the scope of their ABS frameworks.

In this respect, historically, BioTrade has encouraged the conservation of biodiversity, promoted sustainable use and secured the equitable sharing of benefits among the actors of its value chains owing to its fluid, non-mandatory and minimum standards compliance system. However, there are rarely laws or regulations relating to it, and, as such, policymakers are encouraged to design flexible, straightforward, transparent, practical and complementary ABS norms and regulations which allow for positive synergies.

Section 2 offers a brief discussion on the key issues that regulators and policymakers need to understand and consider in their bid to steer their national governments towards ABS and BioTrade compliance. These issues include:

- How to assess BioTrade projects, enterprises and activities;
- The main links between BioTrade and ABS principles;
- The need for clarity on requirements and conditions;
- How to differentiate BioTrade from biotrade;

- How to better understand the dynamic nature of research and development (R&D);
- How to incorporate private sector views; and
- The value databases and knowledge management tools for sustainable use.

The handbook also recommends parallel qualitative and quantitative analysis and assessment for the purpose of a more meaningful interpretation of the relevant laws and obligations. Pro forma checklists for policymakers and regulators have been provided in the Annexes.

Section 3 analyses and compares the scope and requirements under BioTrade and ABS regimes in light of the CBD and the Nagoya Protocol. Compliant ABS measures under the Nagoya Protocol should facilitate achievement of its benefit sharing objective and not impede it. Hence, regulators and policymakers must bear in mind the need to create conditions for facilitated access to genetic resources and avoid unnecessary procedural hurdles. It also explains how BioTrade works along value chains and when links and overlaps with ABS may emerge. Furthermore, it introduces ABS rules on the basis of what activities trigger benefit sharing, i.e. the R&D process, also better known as the *utilization* of genetic resources (including their genetic and/or biochemical composition). This section also explains how BioTrade and ABS implementation can be mutually supportive and provide actual examples on how this would work in practice.

Section 4 explores several factors that may influence how and when ABS obligations could be triggered. It considers the implications of "biological resources as inputs to R&D", *when* benefit sharing is triggered (i.e. at a given R&D phase), and the intricacies of its scope, change of intention and the ABS compliance requirements thereafter. In order to design optimal "valorization strategies", policymakers are encouraged to seek deeper understanding of the ongoing dynamics of value chains, how potential ABS R&D processes may occur depending upon their ABS scope and utilization definition, differentiate between commercial and non-commercial research and review typical business practices to establish effective, pragmatic and realistic legal frameworks and measures.

Section 5 provides examples of conceptual and benefit sharing scenarios as well as guidance to policymakers in regard to flexibilities required in drafting ABS laws and practical considerations for regulators when participating in the negotiations of ABS terms. Due to the composite nature of the R&D in genetic resources and their genetic and/or biochemical composition, as well as the ATK, if any, the handbook recommends employing suitable capacity-building tools, particularly in contract drafting and illustrating subtle differences between BioTrade and ABS contracts, benefit sharing requirements, mechanisms and further externalities that policymakers and regulators need to consider to steer clear of unnecessary duplication and over-regulation of their legal and administrative procedures relating to this stage of ABS.

Ensuring that legal access and the fair and equitable sharing objective of the Protocol are achieved entails the creation of transparency and compliance frameworks that are supportive of national ABS measures.

Section 6 examines existing mechanisms for information sharing, transparency and compliance. Article 13 of the Protocol obliges the Parties to appoint a national focal point to liaise with the Secretariat of the CBD (SCBD) and provide useful information on the national ABS procedures to potential users. In addition to the national focal point, a competent authority (which could be the focal point itself) is envisaged to provide guidance on access procedures and requirements. In BioTrade experience, such roles are fulfilled by either an environment/trade agency (e.g. National BioTrade Commission in Peru) or a non-governmental organization (NGO) (e.g. BioTrade Interest Group [BIG] Viet Nam).

The SCBD has launched the Access and Benefit Sharing Clearing-house (ABSCH), an online ABS information/knowledge sharing platform. As a vehicle for exchanging information and to promote transparency, ABSCH ensures that there is easy access to ABS-related information made available by countries under their country profile as national records, including: national focal points, competent national authorities, national procedures for access to genetic resources and ATK and the sharing of benefits arising from their use (e.g. policies, laws, regulations), internationally recognized certificates of compliance issued on the basis of national permits made available to the ABSCH. The ABSCH also contains reference records from relevant organizations or stakeholders, such as codes of conduct, guidelines, capacity-building projects and materials, publications and others.

The section also proposes a list of economic and regulatory incentives for ABS and BioTrade compliance and provides practical examples of monitoring, verification and compliance measures implemented by both user and provider countries, e.g. national legislation, voluntary/mandatory due diligence requirements (including when receiving research funding), patent law disclosure requirements and checkpoints, among other options.

Section 7 explores the complexities regarding the utilization of ATK in both ABS and BioTrade processes, underscoring the tailored measures that need to be considered particularly when dealing with indigenous peoples and local communities (IPLCs) as ATK holders. Despite the evident advantage of using ATK for R&D purposes, companies are becoming increasingly circumspect in dealing with ATK, particularly in regard to legal clarity of evolving definitions as to its nature, how it can be legally used in other countries (as an intangible part of a product), and rules relating to IPLCs, such as how ATK is accessed (e.g. prior informed consent [PIC] and codes of conduct and practice in entering the territories of IPLCs), national legal frameworks, unique circumstances and the needs of the relevant IPLCs. Crucially, significant points of contention regarding ATK, e.g. legitimate owners of shared ATK and ABS mechanisms associated with such TK have so far not been resolved yet. Also, the scope and protection of ATK may take very diverse approaches and modalities for protection in different laws depending on the nature of the knowledge in question, its holders, the traditional context, customary law and the national legal system. In effect, ATK regimes are still in the creation and experimental stages, characterized by different degrees of experience and practical application by countries that endeavour to legislate on ATK. Hence, the handbook recommends policymaking and regulation processes that are inclusive, flexible, enabling, supportive of IPLCs' needs and sensitized to the ATK's peculiarities.

The advancement of new technologies and the proliferation of the use of genetic resources and their genetic and/or biochemical composition by diverse users for different purposes in various sectors have had an impact on the implementation of ABS worldwide, yet very limited information is available about its practical application commercially.

Section 8 briefly considers private and governmental certification mechanisms that policymakers and regulators may use as a benchmark to consolidate the development of standards (e.g. sustainable harvesting practices and benefit sharing schemes). Private certification and verification schemes, such as those implemented by the Union for Ethical BioTrade (UEBT), can complement and provide evidence on the compliance of ABS requirements by private actors facilitating the assessment of ABS requests. In addition, UNCTAD BioTrade, through its projects, partnerships and collaborations, has developed an inventory of toolkits for bottom-up best practices and methodologies demonstrating equitable sharing of benefits along the value chain whilst promoting sustainable use of biodiversity. Where a user already complies with a certification scheme in its R&D/value chain, the handbook recommends incentivizing such practice by way of fast-track processing times or pooling applications – especially where the entity concerned is a small enterprise.

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Section 9 explores the value of intellectual property (IP) protection schemes for sustainable use and benefit sharing by providing case illustrations on how BioTrade companies and ABS frameworks deal in practice with value addition over genetic and biological resources and ATK, through the IP system. Intellectual property and its different categories, especially patents, breeders' rights, geographical indications (GIs) and trademarks, can offer opportunities to protect innovations along a value chain, to protect and promote brands and reputation, and improve market access and opportunities ("positive protection"). On the other hand, measures could be incorporated within the IP system to promote transparency on the origin, source, legal provenance and utilization of genetic resources, their genetic and/or biochemical compounds, and ATK. These measures could also alert any potential unlawful or unauthorized access or utilization in favour of provider countries and bona fide holders of the IP rights – in this case, the ATK holders ("defensive protection"). This type of measure is common in patent law.

Although patent law's defensive measures may seem an option for provider countries to enforce their sovereign rights over their genetic resources or for IPLCs to protect their TK or ATK from unauthorized use, policymakers need to take into consideration that not all utilization of genetic resources and ATK result in a patentable invention, and additional or complementary measures and checkpoints may be needed in order to ensure compliance.

Addressing IPLCs' expectations, includes acknowledging that IP (and plant breeders' rights) are insufficient to safeguard the broader cultural, economic and moral interests of IPLCs. In practice, *sui generis* systems and bespoke terms in contracts may be better suited for these purposes. In this direction, the handbook, provides several practical examples on how to use distinctive signs such as geographical indications, certification and collective marks (as applied in Ecuador, Peru, Switzerland and the European Union) to enhance product recognition, promote and protect the reputation of origin-based biodiversity goods as well as traditional production processes.

Finally, the handbook also includes unique, informative and inspiring **ABS-BioTrade case studies** from several Protocol Parties: Viet Nam's GACP-WHO certified medicinal plants (Annex 1), Cameroon's versatile *Echinops giganteus* (Annex 2), Colombia's sustainable luxury all-natural skincare line (Annex 3), a case study on the import of fresh plants from Namibia to the European Union (Annex 4) and the use of natural ingredients from Peru for the personal care industry (Annex 5).

SECTION 1.
AN INTRODUCTION TO BIOTRADE AND ACCESS AND BENEFIT SHARING

1.1 The key principles of ABS

Access to genetic resources and the fair and equitable distribution of benefits derived from their utilization, suggests a new way of understanding access to and research and development (R&D) in genetic resources, and their genetic and/or biochemical composition. Whilst the Nagoya Protocol offers some guidance, it is the Parties' national laws which will define more precisely the exact essence of these concepts. The notion of access and benefit sharing (ABS) is relatively new and was the result of long international discussions during the late 1980s and 1990s which modified certain legal precepts and changed the prevalent view that genetic resources and derivatives were, in some way, the "common heritage of humanity".

The Convention on Biological Diversity (CBD) was responsible for this shift in paradigm and thinking. The CBD recognized that countries have a sovereign right over their natural resources and are, therefore, entitled to regulate how and under what conditions their genetic resources can be accessed and used.

These basic conditions under the CBD are:

- Ensuring that prior informed consent (PIC) for access is provided by a national authority.
- Mutually agreed terms (MAT) are negotiated.
- Benefits are shared equitably and fairly as a result.

A provider country may be a country of origin or be legally entitled to grant access to genetic resources, for example through a seed bank or an *ex situ* facility. National policies and frameworks will specify a series of definitional and procedural aspects regarding PIC, MAT and benefit sharing.

Table 1.1 offers a summary of how the CBD and different international instruments address key ABS principles enshrined in the Convention.

Table 1.1 Summary of international institutional and legal frameworks for ABS and related principles

International instrument	Sovereignty	PIC	MAT	Benefit sharing
CBD (1992)	States have sovereign rights over their natural resources and therefore the authority to determine ABS conditions	Access to genetic resources shall be subject to PIC of the provider country (Contracting Party)	Access to genetic resources that were granted, shall be under MAT	Contracting Parties should adopt measures to ensure the fair and equitable sharing of benefits arising from R&D, commercial and other utilizations of genetic resources
ITPGRFA (2001)	Parties recognize that in the exercise of their sovereignty, they may mutually benefit from a multilateral system of ABS	Reflected in a standard material transfer agreement (SMTA)	Reflected in an SMTA	Realized through the multilateral system of ABS and includes: facilitated access to the ITPGRFA, information exchange, access to and transfer of technology, capacity building, monetary benefits arising from commercialization (via an international benefit sharing fund)
Nagoya Protocol (2010)	In exercise of their sovereign rights over natural resources and subject to national ABS legislation or regulatory mechanisms, access to genetic resources for the purpose of utilization shall be subject to PIC of the provider country	PIC or prior approval and involvement of indigenous peoples and local communities (IPLCs) is required for access to and the use of traditional knowledge associated with genetic resources (ATK) and for access to genetic resources over which IPLCs have established rights, in accordance with domestic law	Each Contracting Party, both users and providers, should ensure genetic resources and ATK are accessed and utilized in accordance with MAT	Benefits arising from utilization of genetic resources and subsequent applications and commercialization shall be shared equitably according to MAT. These may be monetary and non-monetary, and also apply to the utilization of ATK

Note: ITPGRFA – International Treaty on Plant Genetic Resources for Food and Agriculture.
Source: UNCTAD (2016e).

One key principle policymakers and regulators alike should take into account when developing or implementing policies and laws (including regulations), is that a balance needs to be struck between the need to *facilitate* access as: (i) an explicit CBD principle – Article 15(2); (ii) a means to enable the generation of benefits; and (iii) a mechanism to *regulate* access to and utilization of genetic resources to safeguard the economic, moral and legal interests of provider countries and national actors, including IPLCs – Article 15(1, 4, 5 and 7). Excessively restrictive ABS frameworks have proven to be of limited success to enable benefit generation and ensure that the provider countries' national interests in regard to genetic resources are safeguarded.[1]

1.2 What is new under the Nagoya Protocol on ABS?

The Nagoya Protocol builds on the ABS provisions of the CBD and further supports the implementation of its third objective: fair and equitable benefit sharing. Its mandatory nature and rapid ratification by many countries make it a strong and potent tool to support efforts to realize the benefit sharing objective of the CBD and ensure legal certainty for actors and Parties.[2]

The main thrust of the Protocol's conception was to ensure that the benefit sharing objective of the CBD was met through concerted international actions and specific obligations especially imposed on users of genetic resources, through so-called "monitoring and compliance measures." Table 1.2 provides a summary of the key dimensions of the Nagoya Protocol.

Table 1.2 Summary of key issues covered in the Nagoya Protocol

Coverage	In terms of its *material* coverage, the Protocol applies to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources (Article 3). Derivatives, whilst also defined in Article 2, are not cited in any other part of the Protocol. As for its *thematic* coverage, the Protocol focuses on the utilization of these resources through R&D on their genetic and/or biochemical composition and ATK, and the benefit sharing arising from their utilization (Articles 1, 2 and 3).
BioTrade	The scope of the Protocol and the fair amount of leeway and flexibility for national implementation, open the possibility for BioTrade stages along the value chain to be potentially covered under its provisions – depending on how countries define, legislate and regulate access to and utilization of genetic resources, their genetic and/or biochemical composition, naturally occurring biochemicals and ATK (Articles 2 and 3).
Benefit sharing	Benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared fairly and equitably with the country providing such resources as well as with IPLCs which have established rights over these resources in accordance with domestic legislation (Article 5).
Traditional knowledge	Benefits arising from the utilization of traditional knowledge associated to genetic resources shall be shared fairly and equitably with IPLCs holders of such ATK (Article 5). In implementing the Protocol about ATK, Parties should adopt measures to, among others, support participation of IPLCs, respect their customary rights, and consider the development of community protocols, etc. (Articles 5, 7 and 12).
Global multilateral benefit sharing mechanism and transboundary cooperation	Parties need to consider the need for and modalities of a global multilateral benefit sharing mechanism (GMBSM) in cases of transboundary genetic resources and ATK or for which it is not possible to obtain or grant PIC (Article 10). Where the same genetic resources are shared *in situ* by more than one Contracting Party, Parties will endeavour to cooperate with a view of implementing the Protocol. Likewise, if traditional knowledge, which is related to genetic resources, is shared by two or more IPLCs, Parties will also endeavour to cooperate with a view of implementing the Protocol (with the involvement of these communities) (Article 11).
Compliance with domestic ABS and ATK-related legislation (also known colloquially as "user measures")	All Parties shall take appropriate measures to provide that genetic resources utilized in their jurisdiction have been accessed per PIC of provider countries and MAT. This includes cooperation in cases of violation and non- compliance with national ABS legislation (Article 15). Similarly, Parties shall take appropriate measures to provide that ATK utilized in their jurisdiction has been accessed according to PIC from or with the prior approval and involvement of IPLCs in the provider countries (Article 16). User and providers should include in their MAT (contracts) provisions which cover dispute resolution, jurisdiction and applicable law (Article 18).
Monitoring utilization of genetic resources	Measures to support compliance through monitoring shall include: designated checkpoints; an internationally recognized certificate of compliance; reporting requirements in ABS contracts; among others (Article 17).

Sources: UNCTAD (2014; 2016e).

1.3 The emergence of BioTrade

The contours of BioTrade are defined by a set of Principles and Criteria (see Table 1.3), some of which are especially relevant to ABS dimensions, particularly Principles 1, 3, 5, 6 and 7.

Table 1.3 BioTrade Principles and Criteria

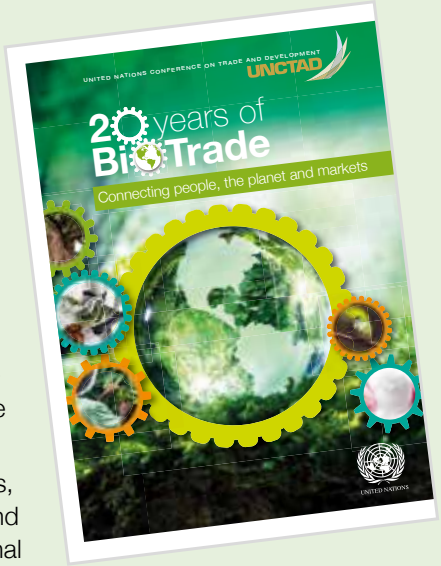
Principles	Criteria
P1 Conservation of biodiversity	Criterion 1.1 Characteristics of ecosystems and natural habitats of managed species should be maintained.
	Criterion 1.2 Genetic variability of flora, fauna and microorganisms should be maintained.
	Criterion 1.3 Ecological processes should be maintained.
	Criterion 1.4 Activities should be developed according to management plans for natural areas.
P2 Sustainable use of biodiversity	Criterion 2.1 The use of natural resources should be supported by management documents, monitoring systems and productivity indexes.
	Criterion 2.2 The management of agro-biodiversity should include agricultural practices that contribute to the conservation of biological diversity.
	Criterion 2.3 Technical standards for initiatives of environmental services should be met.
	Criterion 2.4 Information and records of experiences should be compiled that contribute to knowledge of biodiversity.
P3 Fair and equitable sharing of benefits derived from the use of biodiversity	**Criterion 3.1 The organization should interact and involve actors along the whole value chain, where possible.**
	Criterion 3.2 Income should be generated at all levels of the value chain, by contributing to the position of value-added products in the market, under transparent conditions.
	Criterion 3.3 Information and knowledge of target markets should be available and shared.
P4 Socioeconomic sustainability	Criterion 4.1 Potential markets should exist.
	Criterion 4.2 Financial profitability should be achievable.
	Criterion 4.3 Employment should be generated and the quality of life improved.
	Criterion 4.4 Negative impacts on, inter alia, productive and local cultural practices that affect diversification and food security should be prevented.
	Criterion 4.5 The organization should demonstrate organizational and management capacity to implement BioTrade Principles.
P5 Compliance with national and international regulations	Criterion 5.1 The organization should be aware of and comply with national and local legislation related to the sustainable use and trade of products and services derived from biodiversity.
	Criterion 5.2 The organization should be aware of and comply with international and regional legislation related to sustainable use and the trade of products and services derived from biodiversity.
P6 Respect for the rights of actors involved in BioTrade	Criterion 6.1 Human rights and gender issues should be respected.
	Criterion 6.2 Intellectual property rights should be respected as well as the value of traditional knowledge in obtaining the innovations and creations protected by these rights, should be duly respected.
	Criterion 6.3 Rights of local and indigenous communities (territory, culture, knowledge) should be respected.
	Criterion 6.4 Traditional knowledge should be maintained and revived.
	Criteria 6.5 The organization should offer labour security and proper work conditions.
P7 Clarity about land tenure, use and access to natural resources and knowledge	Criterion 7.1 The organization should demonstrate land tenure according to the relevant regulations.
	Criterion 7.2 Access to biological and genetic resources for sustainable use should be subject to prior informed consent.
	Criterion 7.3 Access to traditional knowledge should be granted only with prior informed consent.
Approaches	• Value chain approach.
	• Adaptive management approach.
	• Ecosystems approach.

Note: Bold letters are used to highlight those principles and criteria especially relevant to ABS and related issues.
Source: Adapted from UNCTAD BioTrade Initiative: BioTrade Principles and Criteria (2007).
Available from http://unctad.org/en/Docs/ditcted20074_en.pdf (accessed 12 June 2017).

The UNCTAD BioTrade Initiative (launched in 1996) generally works at national, regional and global levels with partners along three strategic lines: (i) enabling policy framework for BioTrade; (ii) value chain enhancement; and (iii) market creation and development for biodiversity products and services. National programmes on BioTrade, are developed and implemented jointly with national partners. Regional programmes are developed to share experience and knowledge, overcome common limitations and promote an enabling regional environment. At the international level, the BioTrade Facilitation Programme (BTFP) was launched under the BioTrade Initiative in 2003 to facilitate sustainable trade in biodiversity-based products and services. As a means to enhance the value chain, UNCTAD has developed the BioTrade value chain methodology to support the growth of biodiversity-based sectors. The aim is to enhance the production of value-added products and services derived from biodiversity, for both domestic and international markets. The Union for Ethical BioTrade (UEBT) is an enabling institution which further supports BioTrade activities and enterprises. UNCTAD itself, is a key promoter of BioTrade on different fronts. Box 1 presents the impact of BioTrade over the last 20 years.

Box 1. The impact of 20 years of BioTrade, 1996 to 2016

Since the launch of the BioTrade Initiative, considerable progress has been achieved by private actors and partners in embracing BioTrade concepts and principles. Over 20 developing countries in Africa, Asia and Latin America have been implementing the BioTrade Initiative since 1996. The products and services traded by beneficiary countries cover sectors such as personal care, food, pharmaceuticals, fashion, ornamental flora and fauna, handicrafts, textiles and natural fibres and sustainable tourism. For example, through the BioTrade Initiative and its partners:



- Sales revenues of BioTrade beneficiary organizations, working with small and medium-sized enterprises (SMEs) and multinational companies, amounted to $4.8 billion in 2015. Sales of BioTrade products in Peru have totalled $430 million; in Viet Nam the figure is $100 million.
- Activities in BioTrade have benefited more than 5 million farmers, collectors, breeders, hunters and producers; creating jobs and generating additional income opportunities for rural and marginal communities as well as other actors in the value chain.
- More than 19 million hectares of land are sustainably managed by beneficiary organizations working in BioTrade, promoting conservation and sustainable use of biodiversity.

Sources: UNCTAD (2016c; 2016g).

Notes

1 Prip C and Rosendal K (2015).

2 At the time of writing, there were more than 100 Parties to the Nagoya Protocol. It is expected that the number of ratifications will continue to increase to almost universal Membership over the following years. https://www.cbd.int/abs/nagoya-protocol/signatories/ (accessed, 4 June 2017).

SECTION 2.
PRELIMINARY ISSUES FOR CONSIDERATION BY POLICYMAKERS AND REGULATORS

2.1 Assessing the project, business and enterprise of an activity

No two BioTrade or ABS projects are exactly the same, as Annexes 1–5 show. They will often vary in terms of objectives, partners involved, the scientific or technological sector they pertain to, and the ways in which biodiversity and its components are accessed from *in situ* sources or an *ex situ* facility (e.g. a gene bank, a microorganism collection or a botanic garden) and thereafter utilized. These varying scenarios require that during policy, legal and regulatory drafting, flexibilities are allowed for, which can help regulators interpret and apply the laws and regulations. Regulators should be provided with clarity from the law, but at the same time, be able to manage and implement these frameworks with the necessary discretions to enable a facilitating environment for ABS and BioTrade to take place.

To highlight the importance of flexibility (particularly from the regulators) in these processes, case studies in this handbook, for instance the case of Bioprocol in Colombia (Annex 3) which focuses on bioactive compounds for pharmaceutical research, demonstrate that there are different issues to consider. Examples include the case of PhytoTrade in Namibia (Annex 4), which deals with herbal extracts from the importation of fresh exotic plants and fruits to the European Union, and V. Mane Fils (MANE) in Cameroon (Annex 2), which is about the extraction of natural oils from ethically sourced plants for the fragrance and flavour industries. Each business model is more or less sophisticated than others, and the phases and the type of R&D involved in each case vary. These diverse factors require particular attention from regulators when deciding which frameworks and specific rules to apply.

2.2 Understanding BioTrade and ABS regulations: Scope and coverage

BioTrade is well defined by a set of Principles and Criteria (see Table 1.3) which enable policymakers to consider and define the links with ABS regulations. Rarely are there specific BioTrade laws or regulations in place in countries, although sometimes references are made to Biotrade in these. On the other hand, national BioTrade strategies and programmes are more common (e.g. in Colombia, Ecuador, Peru, South Africa and Viet Nam).

Table 2.1 illustrates some of the most evident areas where links between BioTrade and ABS rules emerge. Whilst this interphase will depend on national regulations, activities can easily overlap in many situations whilst in others may just run in parallel.

In the case of ABS, the CBD, Nagoya Protocol and ITPGRFA establish principles and obligations which policymakers should implement at the national level through laws, regulations and administrative measures. Once enacted, regulators need to apply the rules and procedures set. Policymakers have a degree of flexibility to define the specific scope of both ABS and BioTrade through their national ABS frameworks. For example, the Andean Community, Brazil, Costa Rica, and the Philippines have historically covered genetic resources, their genetic and/or biochemical composition and naturally occurring biochemicals (derivatives) in their national frameworks.

To determine the specific scope and coverage of ABS requirements, policymakers and regulators may need to consider whether activities, such as isolation of compounds and natural extracts, analysis of compositions and extraction processes, identification

Table 2.1 Links between BioTrade and ABS regulations under the Nagoya Protocol

Bio Trade	ABS regulations
Use of biodiversity (including biological and genetic resources as well as ecosystem services) along value chains	Utilization of genetic resources (R&D on the genetic and/or biochemical composition of genetic resources)
Benefits can be monetary and non-monetary (to be shared among actors along the value chain)	Benefits can be monetary and non-monetary (to be shared with State and/or providers)
Requires PIC for access to and use of biodiversity (not necessarily related to R&D)	If so required by a Party, PIC to access genetic resources for their utilization, and ATK
Implementation is guided by BioTrade Principles and Criteria and private voluntary standards	Mutually defined terms define the conditions for the utilization of genetic resources
There are no specific laws on BioTrade, however, it is affected by various sectorial laws and regulations	There are several ABS national and regional laws and regulations

Source: Vivas Eugui D. and Cusi M. (2016).

of secondary metabolites, identification of and testing for specific enzymes, genetic engineering, identification of genes and gene sequences, biotechnology-based plant breeding, and extraction of oils or fractions of oils, fall under the scope of national ABS frameworks or not.

This can be done through detailed definitions or illustrative lists. The European Union, as a region that extensively utilizes genetic resources, is currently developing sector specific guidance documents that could illustrate which type of R&D might constitute "utilization" as defined by the European Union Regulation No. 511/2014 (European Union ABS regulation).[3]

Considering a sample list of specific activities covered by ABS (e.g. guidelines, directives, depending on national administrative practice) may be a useful way to subsequently draft laws and regulations and for regulators to better implement ABS frameworks.

BioTrade is relatively easier to understand in terms of scope and coverage as it applies to biodiversity broadly and is often associated with the utilization of biological resources as bulk, commodity-like or semi-processed products as well as ecosystem services. As a result, these activities and phases are often regulated through classic natural resource management tools such as collection permits, concessions, environmental assessments, and non-timber product authorizations, among others, which allow for access and use. However, some BioTrade activities might also fall under the scope of ABS and the Nagoya Protocol, if they result in utilization of genetic resources, including R&D on the genetic and/or biochemical composition of genetic resources, or otherwise fall within the scope of national laws or regulations on ABS. This may include cases such as: access to and use of natural plant extracts, PhytoTrade in Namibia (Annex 4); or essential oils, MANE in Cameroon (Annex 2); or the use of TK associated with genetic resources in traditional or herbal medicine, Traphaco SaPa in Viet Nam (Annex 1). Situations vary considerably and will depend on the type of activities that national legislation seeks to cover under an ABS framework.

2.3 Clear and transparent ABS requirements and conditions

Especially over the past few years, countries have acknowledged the need to develop and implement ABS regimes – which are clear, practical, transparent and straightforward – as a means to facilitate and promote bioprospecting, R&D and commercialization activities related to biodiversity-based products.

In Viet Nam for instance, the Biodiversity Law 2008 set out key requirements to legally access genetic resources,[4] which include application for a licence and registration of access to genetic resources as well as negotiating and forming a legally binding agreement for benefit sharing. Despite these seemingly straightforward requirements, the licence granting for access has proven to be more complex, onerous and difficult to put in practice.[5] Similar administrative hurdles occur in other Parties with ABS legal instruments in place. These administrative challenges are currently being addressed by Viet Nam's National Biodiversity Authority as well as other government agencies by developing a new implementing decree that would clarify scope, competencies and procedures in Viet Nam in line with the Nagoya Protocol.

Such experience clearly highlights the often overlooked objective of the CBD – the facilitation of access, which requires that policymakers and regulators alike, develop and implement ABS rules and regulations in ways which incentivize investment and interest from a wide range of potential users: from entrepreneurs to academic researchers. This will contribute significantly to legal certainty for users and providers as well as clarity on all fronts. The Nagoya Protocol establishes obligations for Parties to create conditions to promote and encourage research that contributes to conservation and sustainable development and R&D, particularly in developing countries, including through simplified measures for access to genetic resources for non-commercial research purposes – Article 8(a).[6]

BioTrade may offer useful examples to policymakers, as it has the advantage of a long tradition of implementing benefit sharing principles and practices and involving IPLCs in value chains. BioTrade also constitutes a minimum standard of principles, which apply to all actors involved in a value chain. Businesses may wish to go beyond these standards and expand their own sustainable performances or corporate social responsibility frameworks by, for example, including carbon emission reduction efforts along the value chain or developing stricter or specific codes of practice for engaging with IPLCs.

2.4 BioTrade vs biotrade

Specific BioTrade references in policies and legal frameworks are rare. Most of the time, biodiversity-related laws, National Biodiversity Strategies and

Action Plans (NBSAPs) and regulations, make general references to BioTrade and often "biotrade" as a means to enable and create a legal foundation and avenue for undertaking sustainable business activities in biodiversity. This is often sufficient to act as an initial trigger for interest and investments in BioTrade or biotrade. This generally flexible approach to incentivizing BioTrade has worked well, with national and regional programmes in place in a few countries such as Colombia, Ecuador, Peru and Viet Nam.[7] BioTrade (with capitals "B" and "T"), is governed by a set of Principles and Criteria, and 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". "Bio-businesses" and "biotrade" used more freely may refer to any activity which uses biodiversity in any form including trade in commodities. Box 2 explains the main differences between BioTrade and biotrade.

There are only a few cases where provisions related to BioTrade have been incorporated in ABS regulation. This is the case in South Africa and Peru. In Peru for example, development and production of nutraceuticals is excluded from the scope of ABS. In South Africa, on the other hand, biotrade in general, is covered by ABS. It may be expected that given the broader scope and coverage of the Nagoya Protocol, more and more specific phases along the value chain may become subject to ABS rules and procedures. To date, there has been no specific reference to BioTrade in ABS laws and regulations.

Whatever the option taken by policymakers, there is a need for coherence and complementarity between BioTrade and ABS frameworks so that regulators can then apply rules and procedures in an understandable and predictable manner, directly benefiting users and providers alike.

2.5 Understanding the dynamic nature of R&D processes and benefit sharing across different sectors

Especially at the time of designing ABS frameworks, policymakers should make sure that they understand the highly complex and dynamic nature of R&D in biodiversity, genetic resources, their genetic and/or biochemical composition and derivatives. Considerable differences also exist in regard to inputs, research technologies, results of research, timeframes, intellectual property (IP) usage and commercialization strategies.[8] Box 3 offers some examples of the types of research and activities, which may be covered by the Nagoya Protocol and ABS, depending on national legislation. Some other examples, such as synthetic biology and clustered regularly interspaced short palindromic repeats technologies (CRISPR),[9] are just

Box 2. BioTrade or biotrade?

"BioTrade" and "biotrade" appear to be interchangeable. However, the capitalization in BioTrade reflects a fundamental difference. Biodiversity provides inputs and ingredients for a range of industries, including agriculture, cosmetics, pharmaceuticals, pulp and paper, horticulture, construction and waste treatment. In particular, the term "biotrade" is sometimes used to describe the trade in biological resources, such as plant material for use as ingredients or inputs for food, cosmetic or industrial products. Unfortunately, these activities are often conducted without proper consideration of the conservation and sustainable use of biodiversity.

On the other hand, BioTrade activities are characterized by respect for environmental, economic and social criteria. For example, BioTrade activities must maintain the characteristics of ecosystems and natural habitats of the species being collected or cultivated. Income should be generated and distributed at all levels and to all actors of the value chain.

In conclusion, the terms are similar. The products involved may also be comparable, in cases such as non-timber forest products (NTFPs); plant-based extracts, oils and other ingredients or compounds; and natural textiles. However, there is a significant and meaningful difference in the approaches and impacts of "BioTrade" and "biotrade" activities. BioTrade is furthermore governed by a set of formal rules (non-binding), which make it an "institutionalized" activity or process.

Source: UNCTAD (2016e).

Box 3. Examples of types of research, research tools and activities which may be related to ABS

- Accessing and undertaking R&D on extracts of medicinal plants or identifying an active compound from a plant, animal or microorganism (e.g. medicinal plants sourced from Viet Nam).
- Undertaking R&D on different extraction processes regarding a plant extract, leading to compositional variations (e.g. the utilization of *Centella asiatica* extracts where compositions vary depending on the extraction process).
- Any biotechnology process which uses enzymes in lysing plant cells to allow separation of hydrophilic and lipophilic fractions from kernels, leaves, seeds, etc.
- R&D on 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.
- Plant or animal breeding using biotechnology.
- Obtaining ATK 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).

Source: Adapted from UNCTAD (2016e).

beginning to be looked at by the ABS community. There are innumerable other variants and examples to be considered.

Some of these examples may be part of broader BioTrade projects, such as Bioprocol in Colombia and Cosmo Ingredients in Peru (Annexes 3 and 5 respectively), which collect biological resources along classic BioTrade value chains but then pass them on to more sophisticated R&D using biotechnology and other tools to add value and commercialize in the pharmaceutical and cosmetics/fragrances sectors, respectively.

Actors involved in basic and applied research, may also vary considerably. Complex agreements and institutional arrangements among national researchers, universities, foreign research institutions and even companies, all with differing but converging interests at the same time, add an extra layer of complexity which needs to be considered and understood by policymakers and regulators when designing and implementing ABS frameworks.

Correspondingly, encouraging interest and potential investment in projects and R&D in biodiversity and genetic resources will require acknowledgement that benefit sharing schemes may in practice take place in very discrete ways and at different points along the value chain. For instance, price setting, participating in research activities, applying for an IP right or marketing of a final product, are a few examples in which benefits are taken account of and eventually shared. Especially among the academic sector, benefit sharing may involve the generation of non-monetary benefits which are then shared among different actors along the value chain (see Section 5 for further details).

These practices need to be taken into account to prevent stifling interest and potential investment in projects and R&D in biodiversity and genetic resources.

Often, as in the case of the Andean Community's ABS regime and ABS frameworks in many countries, policy and legal frameworks include objectives which refer to "promoting ABS" or "facilitating R&D". However, their actual text and implementation has not been sufficiently enabling of these types of projects and activities due to their complexity and the limited institutional capacities of the national authorities. On the contrary, there have been criticisms from the private sector and academic communities indicating that they are being subjected to rules and regulations which are too difficult to comply with. Nevertheless, further to the adoption and implementation of the Nagoya Protocol, many of these frameworks are being revised or beginning to be implemented in ways which facilitate investment in research in biodiversity and development at the national level. In essence, almost two decades of ABS practice has made it clear that policy and legal frameworks should promote R&D and facilitate involvement by researchers, users (e.g. companies, researchers, others), through streamlined administrative processes and clear institutional settings.[10]

2.6 The impact of the Nagoya Protocol on the private sector

Apart from economic and financial stability, the private sector and researchers in general are increasingly concerned about legal certainty and making sure their efforts and investments will be recognized and their reputation untainted by accusations of "biopiracy" or "misappropriation" in the course of implementing the Nagoya Protocol ABS rules. Goodwill and public relationships are key, especially in a world where consumers are more and more engaged in deciding their purchases (e.g. biodiversity-derived products products) based on better knowledge and information of where products come from and how they are produced. The case of PhytoTrade Africa (Box 4) underscores the "story from the other side", i.e. the themes and issues that the private sector encounters as it deals with the growing impact of the Nagoya Protocol on both domestic and international markets.

Box 4. PhytoTrade Africa: The story from the other side

PhytoTrade Africa (PTA) is a non-governmental organization (NGO) created in 2001 in southern Africa. Its main objective is to alleviate poverty through the support of BioTrade activities. To achieve its mandate, PTA acts as a trade association for local SMEs, and fulfils various needs of its members' endeavours to valorize southern African biodiversity.

Since its inception, PTA has contributed to the implementation of BioTrade Principles within its businesses networks, has actively participated in establishing several value chains, is developing new supply and value chains, and is extensively raising awareness on the potential of a biodiversity-based economy for provider countries, as defined by the Nagoya Protocol.[11] More recently, a restructuring process has been initiated within PTA to better adapt its support to a fast-changing BioTrade sector.

Most of the members of PTA's network are local entrepreneurs, who are in direct contact with the indigenous people collecting raw materials derived from the native biodiversity surrounding them. The main species that are used, e.g. baobab, devil's claw and marula, can be found in several African countries. PTA businesses target local, regional and international markets to sell their products, particularly in the food and cosmetic sectors. Hence, most PTA members can be regarded as local "users" in the Protocol's sense.

PhytoTrade Africa and its members came to the forefront of the ABS scene in southern Africa when the Protocol entered into force in 2014. Some of the main achievements in the last few years include: facilitation of access to derivatives of native genetic resources that potentially had ATK; conducting market research to boost sales; undertaking activities in African countries that have less advanced ABS legal framework; and exportation of products into regulated markets such as the European Union or Switzerland.

Despite the growing promise of PTA's BioTrade activities having stronger linkages with ABS, the increasing level of legal uncertainty in the region and internationally has also increased the risks of damage to or loss of business. A number of issues on ABS definitions and scope are currently requiring urgent clarification vis-à-vis strategic positioning from provider countries in southern Africa to prevent potential negative impacts on the industry, i.e. where investors become wary of investing in the BioTrade sector.

On a more positive note, and based on PTA's 15 years of practising "BioTrade from the inside", opportunities are certainly there to effectively support local development using pragmatic ABS measures. A growing number of formulators buying from the PTA network are positioning their brands with a clear claim about their contribution to the social, environmental and economic impacts of their procurement. In countries where there are no established ABS frameworks yet, achieving the right level of trust between and amongst business partners and potential users is key to encouraging both parties to participate in voluntary benefit sharing agreements given that such agreements would be held to be reasonable from a business perspective as they take into account risks and needs for a return on investment.

Source: Veronique Rossow, PhytoTrade Africa (2016).

2.7 National databases and knowledge management

The first step in understanding and valuing biodiversity and genetic resources potential is knowing what is available or, more simply, what exists. This means inventorying biodiversity and systematizing data and information from collections, literature and databases, among other sources. Official biodiversity or genetic resources databases or registers are not common. However, flora and fauna publications are often one step in centralizing information and data. Some countries such as Viet Nam and Peru are developing official inventories of genetic resources with specific potential in certain commercial and industrial sectors. For example, Peru has identified a set of 30 plants which are of special interest in the pharmaceutical and natural products sector. This information may serve to orient and guide interested users and authorities, both regarding industrial/commercial potential and interests in certain resources, and in terms of monitoring actions for which national authorities are responsible. This basic data and information gathering is the first step towards developing knowledge management systems which contribute to the overall valuation and practical use of biodiversity and genetic resources in R&D and value chains.

Marula (*Sclerocarya birrea* (A.Rich.) Hochst.), source fruit (genetic source) of marula products (See Box 4)

Source: http://powo.science.kew.org/taxon/urn:lsid:ipni.org:names:71162-1

IN FOCUS

FOR POLICYMAKERS

- BioTrade offers policymakers many examples of how the private sector, providers (including communities) and national institutions engage in value chains, as well as offer guidance on the types of benefits which are generated throughout the value chain as well as potential benefit sharing schemes (see Annex 6).
- The key dimensions and elements of R&D in genetic resources need to be understood – their complexities and challenges – to become streamlined into and be reflected soundly in the decision-making processes.
- Policies and laws need to reflect and make room for dynamic and rapidly evolving R&D paradigms.
- Policies, legal and regulatory frameworks should be clear, transparent and respond to reality, as a means to provide legal certainty to all actors and facilitate actions of national authorities and regulators.
- Policymakers can learn from and should review comparative experiences, particularly in regard to how ABS is being applied and its effectiveness in other countries.

FOR REGULATORS

- There is a need for legal, regulatory and administrative flexibilities to ensure appropriate assessment and approval of projects, businesses or activities.
- Instruments, such as guidelines and checklists, may allow for identifying and applying flexibilities in legal frameworks when assessing projects, businesses or activities (see Annex 7).
- When assessing national ABS and BioTrade applications, there is a need to carefully consider each project, business or activity to understand exactly and precisely elements regarding scope and potential linkages.
- There is the need to acknowledge that ABS may become relevant during certain phase(s) of BioTrade projects and activities.
- Comparative law and regulations, as well as institutional practices by ABS authorities, can serve to inform and orient national ABS agencies on how to apply and interpret certain situations regarding projects, businesses and other activities related to ABS and BioTrade.
- The CBD ABS Clearing-house (ABSCH) offers a rich source of information on comparative law, ABS national focal points, certificates of compliance, etc. which are available to help determine coverage and treatment of ABS projects and activities.

Notes

3 See European Union Regulation No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union Text with EEA relevance. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511 (accessed 4 June 2017).

4 Article 57 Biodiversity Law 2008 of Viet Nam.

5 See UNCTAD (2016e).

6 *"Each Party shall... (a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research…"*

7 The ABS Initiative has produced an excellent set of materials/booklets which clearly shows the specificities and differences across a wide range of sectors using and undertaking R&D with genetic resources and the relevance of ABS frameworks. Sectors covered include: botanical medicines, biotechnology, agriculture, pharmaceutical, food, beverages, and cosmetics. http://www.abs-initiative.info/knowledge-center/publications/ (accessed 4 June 2017).

8 The CBD ABS Clearing-house (ABSCH) is a rich source of information, on comparative law, measures, cases and best practices that are available to determine coverage and guide the treatment of BioTrade projects and activities. The ABSCH is called to facilitate access to information regarding institutional competences in ABS, laws and regulations that govern ABS procedures and, in general, offer transparency and certainty to potential users and interested parties. National databases and ABS authorities should be the very first entry point to ABS for users and Parties to understand how ABS procedures and institutions operate within countries. https://absch.cbd.int/ (accessed 4 June 2017).

9 This technology enables scientists to edit genes rather than insert genes as in modern biotechnology.

10 See, for example, the work of national and regional BioTrade programmes promoted by UNCTAD, the Capacity Building for BioTrade project coordinated by the United Nations Environment Programme, the International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (now merged with the FairWild standard), and the Ethical BioTrade Standard of the UEBT.

11 *"In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms."* (Article 5.1 Nagoya Protocol.)

SECTION 3.
INTERACTION AND SYNERGIES BETWEEN CONCEPTS AND REQUIREMENTS OF ABS AND BIOTRADE

3.1 ABS and BioTrade: Where pathways start crossing

Both BioTrade and ABS are concepts describing an activity or a process. BioTrade Principles are mostly based on non-binding frameworks whilst ABS provisions are derived from international and national binding instruments. There are evident, albeit often complex, linkages between ABS and BioTrade approaches. The rationale and aim of the BioTrade is to support the implementation of the objectives of the CBD, one of which is the fair and equitable sharing of benefits arising from the utilization of biodiversity. The CBD has also expressly recognized that BioTrade can be a positive incentive for the conservation and sustainable use of biodiversity, as well as a tool to enhance local livelihoods and capabilities under Aichi Target 3. The ABS approach on the other hand, is more focused on the benefit sharing dimension of the CBD and the Nagoya Protocol as it relates to genetic resources and ATK.

Identifying and, more importantly, enhancing the interaction between ABS and BioTrade concepts and frameworks (when required) is usually a complex task. Do ABS and BioTrade cover the same or different types of activities? How do requirements in ABS laws and regulations relate to the commitments involved in BioTrade projects? In which way could ABS and BioTrade become more mutually supportive? Table 3.1 addresses some of these questions.

It is always useful to revisit the basic concepts of ABS and BioTrade, already introduced in Section 1. This section looks at the distinction and overlap between activities governed by ABS and BioTrade Principles and how such principles may complement each other in advancing business, research and entrepreneurship in biodiversity and genetic resources.

3.1.1 BioTrade: Scope and characteristics

The term "BioTrade" is defined by UNCTAD to include activities related to the collection or production, transformation and commercialization of goods and services derived from native biodiversity that meet certain environmental, social and economic criteria – better known as the UNCTAD BioTrade Principles and Criteria. There are two important considerations that arise from this definition, which will be further explored. Firstly, BioTrade is characterized by practices that respect and advance sustainable development and, secondly, it includes the range of activities and sectors involved in biodiversity-based products and services along a value chain.

BioTrade activities are, by definition, conducted in line with BioTrade Principles and Criteria (see Table 1.3). These Principles and Criteria establish environmental, social and economic parameters that are based on and aim to advance CBD objectives and other internationally recognized SDGs. This is an important distinction because not all trade or use of biological resources necessarily consider or adhere expressly to sustainable practices. Indiscriminate trade in biological resources may involve unsustainable harvest or collection rates or negatively affect the ecosystem in which it takes place. On the other hand, biodiversity-based products – if sourced and elaborated with respect for equity, fairness and sustainability principles – can also provide a strong basis for local livelihoods, respect for traditional practices and values, and the conservation and sustainable use of biodiversity. That is why it is important to distinguish BioTrade from other trade in biodiversity-based products, sometimes called "biotrade" or "bio-businesses" (see Box 2) as the former clearly implies sustainable use.

A related point to consider is that BioTrade activities may take place within a range of frameworks and initiatives based on the BioTrade Principles and Criteria. Various programmes, initiatives and organizations have adjusted the approaches and requirements of the BioTrade Principles and Criteria according to their concrete needs and circumstances, as well as to provide more specific guidance for particular activities or sectors.[12] Yet, beyond the specificities required by the range of biodiversity-based products and services, as well as the components of biodiversity on which they depend, BioTrade activities should consistently adhere to intrinsic principles such as the conservation and sustainable use of biodiversity, equitable sharing of benefits derived from the use of biodiversity, compliance with international and national regulations, respect for the rights of actors, and clarity on land tenure and use of resources.

In terms of activities and sectors covered, BioTrade is an expansive concept. It refers to all activities involved in a value chain of biodiversity-based products and services, from collection and cultivation through to the different stages of transformation and production and, finally, the marketing and sale of intermediary and consumer products. BioTrade could, for example, include the production and trade in NTFPs or plant-based extracts and oils or natural textiles. It could also

cover ecotourism, trade in wildlife, carbon credits, agricultural commodities, handicrafts, construction material, natural fibres and natural ingredients used in pharmaceuticals, nutraceuticals and food and personal care products.

Figure 3.1 A typical BioTrade value chain – from sourcing to final product

Sources: UNCTAD (2016e); PhytoTrade Africa (2016).

Figure 3.1 illustrates a typical BioTrade value chain. Trade in handicrafts made with argan wood from Morocco could be biotrade. The use of argan oil[13] in food products could also be biotrade – so could the sourcing, elaboration and marketing of products that utilize the oil or other extracts or parts of the argan tree for their unique genetic or biochemical properties. Likewise, using the white carob tree (***Prosopis alba***) in northern Peru for construction timber and its leaves to produce ***algarrobina*** syrup for medicinal and culinary purposes may be considered biotrade. But these activities would ***only*** become "BioTrade" activities if they are conducted within a framework of equity and sustainability along the value chain from sourcing to commercialization. Such a commitment is voluntary, but may be independently monitored, assessed and verified, for example, in the context of the Peruvian BioTrade programme or the Ethical BioTrade verification system.

Table 3.1 provides a comparison between BioTrade and ABS in terms of activities, resources, requirements, compliance obligations and legal nature.

3.1.2 Scope of ABS requirements under the Nagoya Protocol

Both the CBD and the Nagoya Protocol recognize significant flexibility for the national implementation of their provisions. For example, countries may choose whether and how to regulate access to genetic resources – e.g. through prior informed consent from local authorities, an authorization from the competent

Table 3.1 Comparing ABS and BioTrade concepts and requirements

	Type of activities	Type of resources	Requirements	Compliance	Legal nature
BioTrade Principles and Criteria	Collection, production, transformation, and commercialization of goods and services	Biological resources and ATK	Conformity with environmental, social and economic sustainability criteria, including on fair and equitable sharing of benefits	Verification and certification systems, such as those based on UNCTAD's Principles and Criteria, national programmes (e.g. Peru) and the UEBT Standard, provide independent assessment of compliance	Voluntary
Nagoya Protocol on ABS	R&D on genetic and/or biochemical composition	Genetic resources and associated traditional knowledge	Obligations regarding requirements on PIC and MAT, including on fair and equitable sharing of benefits	Legislative, administrative or policy measures to ensure that genetic resources and ATK being utilized have been accessed in accordance with requirements	Mandatory and binding

Source: UNCTAD (2016e).

national authority or a material transfer agreement (MTA) from suppliers of genetic resources.

The scope of ABS requirements in particular, may differ from the international provisions, as well as vary from country to country, depending on their approaches and aims. Countries may refer to:

- "biological resources"
- "indigenous/native biological resources"
- "genetic resources"
- "genetic resources and their genetic and/or biochemical composition"
- "naturally occurring biochemical" (derivatives)
- "traditional knowledge"
- "indigenous knowledge" and/or "intangible component"
- and "bioprospecting", "research and development", "product development", "commercial exploitation", "export" and/or "discovery".

Table 3.2 provides some examples of the significant degree in variation of the scope of ABS requirements among national laws and regulations to date.

It is important to note that many laws and regulations on ABS in Table 3.2 pre-date the Nagoya Protocol. Some of these countries have or are in the process of revising their national ABS measures in order to be in line with the Nagoya Protocol. The Nagoya Protocol can be credited with providing significantly more certainty and amplitude in regard to the scope of ABS requirements, which is likely to be reflected in new or revised rules implementing its provisions. The Nagoya Protocol provides additional legal certainty through its definition on the "utilization of genetic resources". This definition

Table 3.2 Scope of ABS requirements in selected laws and jurisdictions

	Type of resources	Type of knowledge	Type of activities
Andean countries, including Colombia and Peru	Genetic resources and their by-products, defined as molecules and a combination or mixture of natural molecules, including substances that come from the metabolism of living beings	Intangible component defined as the know-how, innovation or individual or collective practices associated with genetic resources, their by-products or the biological resource that contains them	Obtaining and using genetic resources their by-products or their intangible components, for research, bioprospecting, industrial application and commercial use
Brazil	Genetic heritage defined as information of genetic origin from plant, animal, microbial and other species, including substances arising from the metabolism of these living beings	Associated traditional knowledge defined as information or practices of indigenous populations, traditional communities or traditional farmers about the proprieties or direct or indirect uses associated to the genetic heritage	Access to genetic heritage or associated traditional knowledge; the export of samples of genetic heritage; and the economic exploitation of a finished product or reproductive material arising from access
Indonesia	Biological resources	Traditional knowledge associated to biological resources	Research (and development) conducted by foreign nationals or institutions
South Africa	Indigenous biological resources	Traditional use or knowledge defined as the customary utilization or knowledge of indigenous genetic and biological resources by an indigenous community or specific individual, in accordance with written or unwritten rules, usages, customs or practices traditionally observed, accepted and recognized by them	Bioprospecting or export of material for the purpose of bioprospecting or any other kind of research. There are also requirements for biotrade; "biotrade" means the buying and selling of milled, powdered, dried, sliced or extract of indigenous genetic and biological resources for further commercial exploitation
Viet Nam	Genetic resources, which include plant, animal, microbial and other species and genetic material. A more recent regulation also included derivatives in the scope*	Traditional knowledge associated with genetic resources, which is defined as the knowledge, experience and initiatives of native people on the conservation and use of genetic resources	Access to genetic resources defined as activities to investigate and collect genetic resources for research and development and production of commercial products

Note: *See Viet Nam Decree 59/2017 on the management of genetic resources and their sharing of benefits arising from their utilization, 12 May 2017.
Source: UNCTAD (2016e).

establishes the parameters for when a particular activity falls under the scope of the Nagoya Protocol.

The concept of "utilization of genetic resources" becomes critical to interpret the main operational provisions to the Nagoya Protocol: requirements on access to genetic resources apply if the purpose is the utilization of genetic resources and it is the utilization of genetic resources that triggers benefit sharing obligations. With the decision to link ABS measures to how and for which purpose genetic resources are used, a decade-long controversy about the (perceived) differences between terms "biological resource" and "genetic resource" becomes obsolete. Experts and negotiators concluded that according to the definitions provided by the CBD, there is no difference in terms of material characteristics. Legal certainty can only be achieved by linking ABS to the *utilization* given to biological or genetic resources.

"Utilization of genetic resources" is defined as R&D into the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology (Article 2).[14] The definition provides several elements that resolve questions on the scope of ABS requirements raised prior to the Nagoya Protocol. For example, ABS requirements are now clearly linked to R&D, excluding any use of genetic resources classified as "commodities". That is, the Nagoya Protocol does not include activities such as the collection, harvest, processing and sale of plants or plant parts or substances, even if such material is used in value-added products, as long as the material is not subject to R&D. For instance, in the examples provided in Annexes 1–5, there are activities involving sourcing and collecting plants from Cameroon, Colombia, Namibia and Viet Nam, from which materials (mostly with biochemical composition and naturally occurring biochemicals) are subject to R&D as part of the value chain, thus potentially falling under the scope of the Nagaya Protocol.

It is also now clear that benefit sharing covers the "utilization of genetic resources" as well as subsequent applications and commercialization. Benefit sharing is negotiated on a case-by-case basis through MAT (often ABS contracts).[15] Another important clarification is that the utilization of genetic resources now clearly includes R&D on the biochemical composition of genetic resources. This is important because such compositions are the basis for a wide range of products, from drugs to food and cosmetic ingredients.

3.2 Distinctions and overlap between activities governed by BioTrade and ABS principles

The value of biodiversity is enormous. Nature's products support such diverse industries as agriculture, cosmetics, pharmaceuticals, pulp and paper, horticulture, construction and waste treatment.[16] The loss of biodiversity threatens food supplies, opportunities for recreation and tourism, and sources of wood, medicines and energy. It also interferes with essential ecological functions and the normal functioning of ecosystems. Not all of these activities, however, are regulated in the context of the Nagoya Protocol or covered by BioTrade Principles. So, where do these two approaches connect?

As mentioned, the BioTrade Principles and Criteria are applicable to all biodiversity-based products and services, no matter which actors, activities and sectors are involved. For example, the UNCTAD BioTrade Initiative, through its national and regional programmes, has supported work on natural ingredients for cosmetics (e.g. essential oils, seed oils and butters), foods (e.g. fruits, teas, cereals and fish products), leather and garments (e.g. crocodile skins), pets (e.g. butterflies, chameleons and snakes), flowers (e.g. helicons), handicrafts (e.g. furniture, decoration objects, and jewellery), and sustainable tourism (e.g. bird-watching).

Other instruments based on the BioTrade Principles and Criteria focus on specific resources, activities or sectors. The Ethical BioTrade Standard, an internationally recognized standard managed by the UEBT, further defines and develops the BioTrade Principles and Criteria for natural ingredients used in the food, cosmetics and pharmaceutical sectors. Companies joining UEBT commit to implementing the Ethical BioTrade requirements through their management systems, procedures and practices applicable to natural ingredients. This involves procurement, sourcing, research, sustainability, product development, legal compliance, sales and marketing activities.

The challenge for policymakers, and regulators thereafter, however, is defining the precise "trigger" in which biodiversity-based activities become or should become subject to ABS requirements. The Nagoya Protocol applies to the "utilization" of genetic resources, which becomes the trigger to benefit sharing; "utilization" is defined as R&D on the genetic

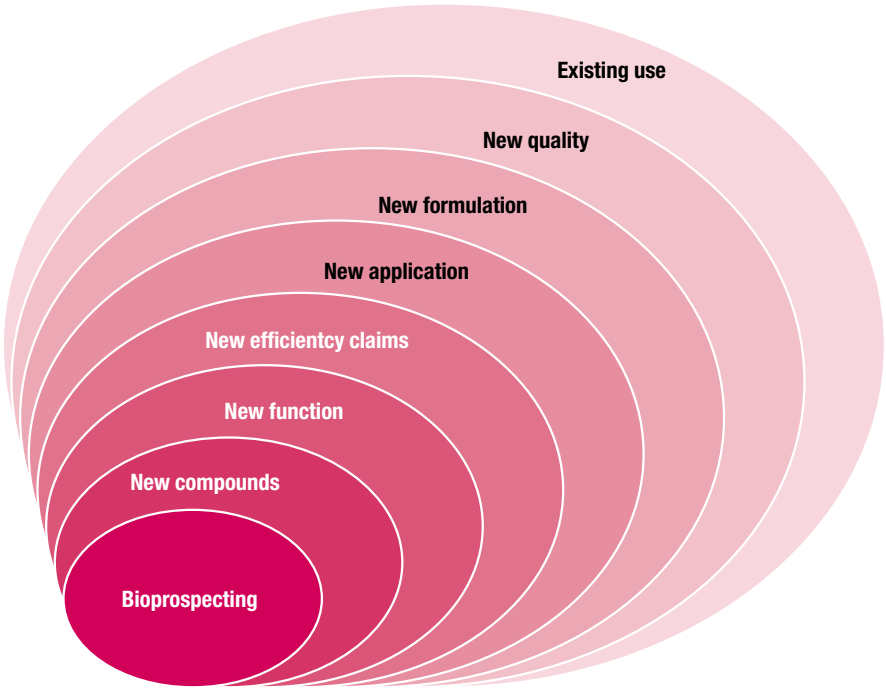
and/or biochemical composition of genetic resources, including through the application of biotechnology. The Nagoya Protocol does not contain a list of specific uses of genetic resources. It is a way to ensure that the "utilization of genetic resources" covers all possible R&D on genetic resources, allowing for rapidly evolving and sophisticated technologies and products.[17]

At the national level, countries will need to operationalize the "trigger" for ABS, in a way that the system is both practical and effective. In any sector, there are a range of R&D activities, which differ significantly in their nature, objectives and complexities. In many countries, pre-Nagoya Protocol ABS frameworks, benefit sharing is currently triggered by access per se, for conservation activities, industrial application and commercial use. This is the case, for example, in Andean Decision 391 of 1996.[18] The scope of ABS requirements, thus, will have significant implications on how many cases will be managed, what timelines are reasonable and what benefit sharing arrangement can be considered.

Figure 3.2 illustrates the spectrum of activities in relation to natural ingredients in cosmetics. ABS requirements may choose to cover a broad or narrow scope of these activities, depending on their policy objectives. A narrow scope for ABS requirements (covering, for instance, only activities in the central rings) will cover fewer, more in-depth R&D activities, such as the identification of new species or new properties or uses for genetic resources, their genetic and/or biochemical composition and derivatives. These are operations with more risk and potential from a business perspective. A broad scope for ABS requirements (covering, for instance, most of the activities mentioned) will include not only R&D but also sourcing activities – the routine collection of nuts, for example, to extract oil for use in cosmetic products. These are common operations that do not normally involve innovation. That is, the compounds, functions or claims involved are not necessarily "new." In some cases, they may be very well known and widely used.

The scope of ABS requirements – depending on the trigger for these requirements – will determine the extent of the distinction and overlap between activities covered by ABS and BioTrade Principles. The broader the scope of ABS requirements, the wider the number of activities it will cover, including activities conducted in the context of BioTrade projects. In this regard, it is important for policymakers to consider what the interaction between ABS and BioTrade Principles and requirements would entail and how they might be mutually supportive and be reflected in a law or regulation at national level.

Figure 3.2 Activities that use natural ingredients in cosmetics



Source: MJ Oliva (2015).
Note: Novelty and innovation are not present in all processes – this figure simply demonstrates the way research, development and commercialization may relate.

3.2.1 Interaction of BioTrade and ABS principles and requirements

BioTrade can support the implementation of ABS requirements, because over time projects and initiatives have raised awareness of benefit sharing, promoted engagement of governments, companies and other actors and provided practical examples for and guidance in its application to the range of activities along typically complex value chains. These may include the collection, production, transformation and commercialization of goods and services derived from native biodiversity.

BioTrade can also be the source of useful experiences and lessons, as policymakers strive to define rules that are workable and effective and companies look for practical approaches to comply with legal and ethical requirements. For example, BioTrade approaches to fair and equitable benefit sharing – even if they are not in the context of the utilization of genetic resources per se – provide interesting lessons for national authorities, communities and company representatives negotiating MAT. These experiences exemplify what monetary and non-monetary benefits may look like in practice.

For instance, Villa Andina, a small UEBT member enterprise in Peru sourcing fruits and grains for food products manufactured and exported internationally, supports producers beyond their commercial relationship. Producers are provided with seeds and seedlings of the varieties appropriate for the different altitudes, which then become the property of the producers and their communities. Under a joint project with civil society, producers also receive continuous training on enhancing their technical and production skills. Tailored agreements are negotiated to add local value. Another example is PhytoTrade Africa (Annex 4), a trade association which supports the export of plant extracts from communities in Namibia for use in the cosmetics industry in the European Union. Communities are provided with support in the negotiation of MAT, benefit sharing and in the paperwork to ensure exports have the appropriate documentation as required by the Namibian authorities. Bioprocol in Colombia (Annex 3), is another example of how engagement in BioTrade could provide lessons in achieving ABS compliance. Local communities and farmers are educated and trained on the subject of biodiversity so that they are able to undertake improved and informed participation in the value chain in which their plants are being sourced and used. The participants are also further empowered through BioTrade's support to communities and farmers' biodiversity management activities. Another example of a successful benefit sharing scheme[19] is that of a Swiss-based company and UEBT member, Weleda, which produces natural and organic cosmetics and anthroposophic medicines. Together with other activities on ethical sourcing of natural ingredients, it has a voluntary ABS arrangement with its local partner, TreeCrops, to pay levies to local communities. Likewise, many other BioTrade companies globally, such as Natura Cosmetics in Brazil and Ecoflora Cares in Colombia, provide examples of sourcing biodiversity and benefit sharing experiences through negotiation of MAT and securing permits from relevant local or national authorities.

BioTrade can also provide support and input into processes through which laws and regulations implementing the Protocol's ABS are being developed by acting as a tool to enhance capacities and improve compliance with ABS requirements. To date, it is the sectors in which BioTrade is particularly active, such as the cosmetics sector, that show more significant commitment to ethical practices linked to biodiversity. Specifically, in the area of monitoring and traceability including reporting requirements, as well as independent monitoring of compliance through third-party audits, experiences in BioTrade and the Ethical BioTrade Standard of the UEBT may offer best practice examples through the identification of each step, actors and dynamics in the supply chain and collection of information on the origin of genetic resources, their terms of utilization, and any ATK involved. In this regard, it is important to recall that Article 20.1[20] of the Nagoya Protocol calls on Parties to encourage the development and use of voluntary norms such as codes of conduct, guidelines, best practices and standards in relation to ABS. The BioTrade Principles and Criteria, as well as other instruments that further develop provisions, could be considered as examples of the aforementioned guidelines and standards.

IN FOCUS

FOR POLICYMAKERS

- When defining the scope of ABS requirements or the activities that trigger ABS requirements, consider implications for different types of entities, research and commercial activities and industrial sectors.
- Find a balance for ABS requirements so that they are practical and effective, provide legal certainty and are sufficiently flexible and result in meaningful processes.
- Promote fair and equitable benefit sharing through the application of the BioTrade Principles and Criteria and other tools for the ethical sourcing of biodiversity – whether activities are covered by ABS requirements or not.
- Consider how existing BioTrade guidelines, tools or best practices linked to biodiversity-based innovation and sourcing may provide useful approaches or experiences in developing ABS requirements.
- Ensure mutual supportiveness between ABS requirements and broader policies for BioTrade, sustainable use of biodiversity, enhancement of local livelihoods, traditional knowledge, innovation and value chain development.

FOR REGULATORS

- Use BioTrade platforms and initiatives as tools to raise awareness, promote engagement and receive feedback on ABS requirements from a range of stakeholders – from companies and producer associations to research institutions and sourcing communities.
- Identify ways in which collaboration with BioTrade initiatives may provide information, tools and expertise to facilitate monitoring and evaluation of the application of ABS requirements.
- Promote using the BioTrade Principles and Criteria as guidance for compliance with ABS requirements such as negotiations with IPLCs, PIC processes, development of MAT, and approaches for fair and equitable sharing of benefits.

Notes

12 See for example the work of national and regional BioTrade programmes promoted by UNCTAD, the Capacity Building for BioTrade project coordinated by the United Nations Environment Programme, the International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (now merged with the FairWild standard), and the Ethical BioTrade Standard of the UEBT.

13 Argan oil is registered as a GI, which may be one way to comply with BioTrade Principles and Criteria. http://www.wipo.int/ipadvantage/en/details.jsp?id=2656 (accessed 4 June 2017).

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

15 *"In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms."* (Article 5.1 Nagoya Protocol.)

16 See ten Kate K and Laird S (1999). More recently, see the booklets produced by Sarah Laird and Rachel Wynberg for the GIZ ABS Initiative, where there is an update on the figures and values related to genetic resources in a wide range of sectors and industries (biotechnology, cosmetics, pharmaceutical, etc.) as well as their features.

17 Per the OECD definition, *"Research and development is a term covering three activities: basic research, applied research, and experimental development."* See Section 4 of the handbook for further analysis and discussion of the significance of R&D.

18 WIPO (1996).

19 See Weleda institutional website: http://www.business-and-biodiversity.de/en/activities/archives/touring-exhibition/projects/weleda/ (accessed 4 June 2017).

20 *"Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit sharing…"* (Article 20.1 Nagoya Protocol.)

SECTION 4.
RESEARCH OBJECTIVES AND CHANGES IN INTENTION

In preparing to design or update an ABS legal framework, two preliminary questions to consider are: (i) the country's expectations in terms of outcome when valorizing[21] its biodiversity; and (ii) the extent to which ABS provisions support such a strategy? Indeed, as some definitions and provisions within the Nagoya Protocol remain subject to interpretation, provider countries could use such flexibility to support their own valorization strategy. This section provides some general insights into how to facilitate establishing a pragmatic connection between possible interpretations of utilization of genetic resources, their genetic and/or biochemical composition, as defined in Article 2 of the Nagoya Protocol,[22] and the objective of valorization of biodiversity. This section also reviews how BioTrade value chains work in practice particularly where there is potential change of intent, where value could be generated, and what could increase legal certainties across these value chains.

The Nagoya Protocol addresses access and utilization of genetic resources and/or ATK. This section, however, uses the broader term "biological resources", as defined by Article 2 of the CBD,[23] as a way to reflect upon the range of research activities occurring in BioTrade value chains (i.e. the processing of biological resources and by mainly generating derivatives as defined in Article 2 of the Nagoya Protocol).[24] In this regard, initial access to "biological resources" per se may not give rise to ABS requirements in many jurisdictions, but because they contain genetic materials on which R&D may be conducted further along the supply chain, most national or regional ABS laws envisage that ABS could then become applicable on the basis of such "biological resources" effectively being made of genetic resources.

When evaluating if a research activity conducted over a biological resource could ultimately trigger any ABS obligation, a list of several criteria to be used by regulators and practitioners is proposed to allow for self-assessment of the activity in question. One key legal element of such criteria is the subject matter (e.g. genetic resources and biochemical compositions) and scope of the ABS regulation (including definition of utilization and temporary scope) as illustrated in this section.

Also linked to such criteria are some examples provided within certain industrial sectors (food, pharmaceuticals and cosmetics) as well as suggestions for supportiveness between ABS measures and relevant value chains to enable and streamline implementation, traceability and avoid overregulation.

4.1 Factors influencing the definition of "R&D"

As previously mentioned in Section 3, different interpretations of "utilization" already occur amongst provider countries. Depending on the scope of ABS requirements in a country, (i.e. the range of activities these requirements cover), the utilization of derivatives may or may not trigger ABS obligations. In addition to specifying the nature of biological resources requiring access conditions, it becomes essential to further describe activities that can be defined under "utilization".

In most cases, activities in a given value chain are categorized according to systematic functions or roles, such as collectors, producers, intermediaries, traders, etc. Commonly, most value chain actors are not able to determine whether the R&D undertaken falls within the definition of "utilization" under the Nagoya Protocol or national legislation. This is mainly due to the fact that R&D is not categorically defined in the Protocol itself. To this end, it is imperative that policymakers and regulators provide definitions or guidance on what constitutes R&D vis-à-vis Protocol "utilization" at the national level to provide legal certainty and clarity, and crucially, to complement the implementation of their ABS laws.

For instance, if what is accessed is not considered as triggering any ABS obligation (which may be the case with derivatives that are not genetic resources[25] per se, as they do not contain any functional units of heredity), any R&D that may be then conducted on them may not be considered as "utilization" according to the Nagoya Protocol definition.

Besides the specification of the subject matter and the scope of the definition of utilization, there is another factor that could influence the definition of activities triggering ABS duties. When the Nagoya Protocol entered into force in 2014, a legal temporal line could be drawn as illustrated in Figure 4.1. Based on this temporal line, three distinct scenarios (A, B and C, each to be read from left to the right) could be inferred.

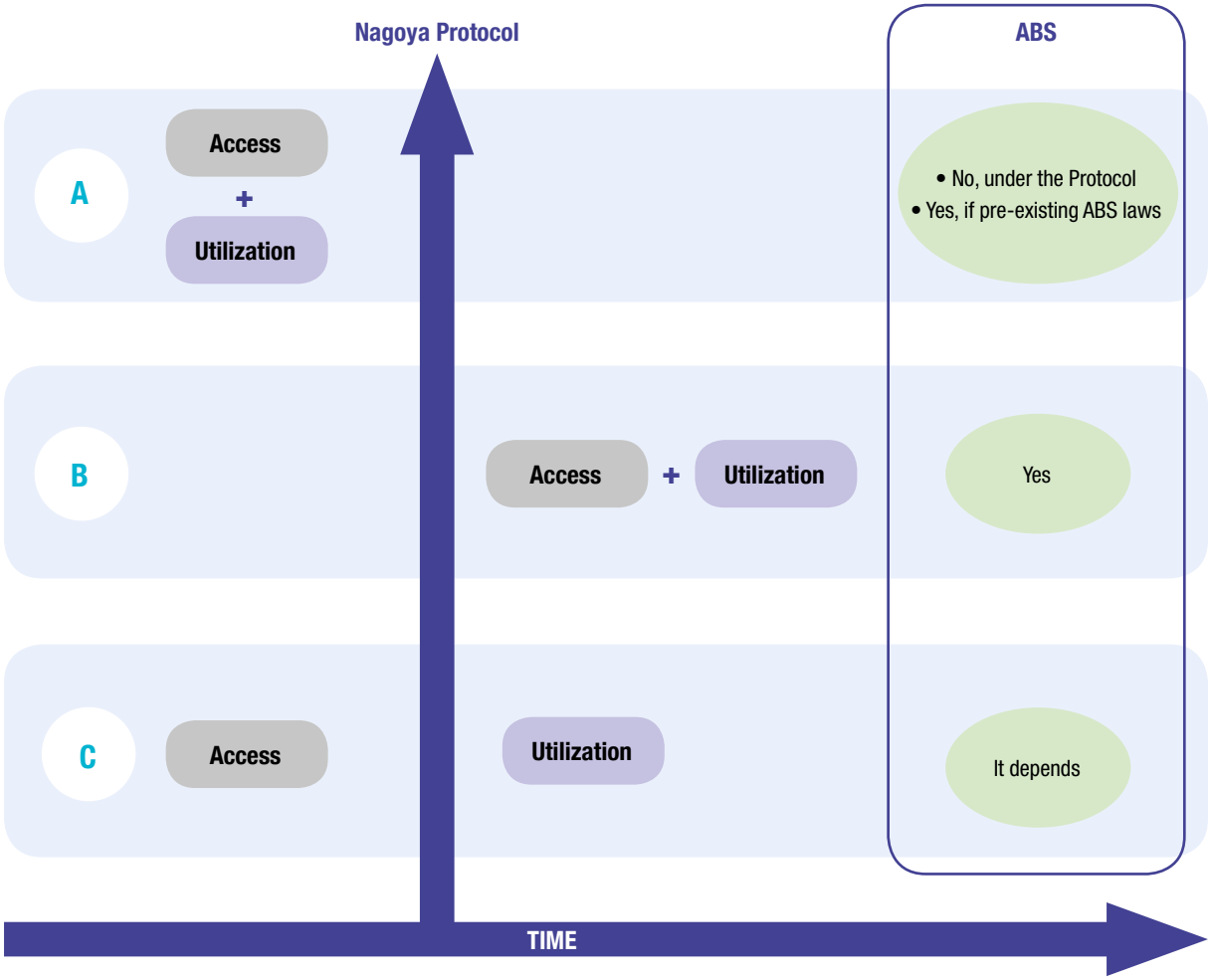
Case A covers all biological resources accessed and utilized before 12 of October 2014. This case is considered beyond the scope of the Protocol. However, access and utilization before the entry into force of the Protocol may be subject to obligations under pre-existing national or regional ABS regulations in the country of origin of the biological resource.

Case B is more straightforward and describes all biological resources accessed and utilized after 12 October 2014. Access of biological resources for utilization after this date may trigger ABS obligations, in countries that have national ABS regulations in place and are Parties to the Protocol. This scenario implies the requirement for having a clear definition of what "utilization" means for the provider country.

Case C addresses all other situations that do not fall under either A or B. In fact, the temporal scope of the Nagoya Protocol implies dealing with ongoing activities that do not follow these straightforward cases. Indeed, providers and users have to integrate unforeseeable situations whilst implementing their ABS and/or their compliance measures. Several references about "change in intent" scenarios are made in the Nagoya Protocol Article 6(g)(iv)[26] and Article 8(a).[27] Illustrated by Case C in Figure 4.1, the first scenario is when access for a declared utilization took place before 12 October 2014, and another new utilization that is not covered by the access agreement is conducted after this date. The second scenario in Case C could occur when access took place after 12 October 2014 without any intent to utilize the biological resource (for example BioTrade type of access) in terms of R&D, but one actor in this value chain "will later undertake utilization as defined by the country of origin of the biological resource".

Taking into account the legal uncertainties created by potential change of intent, particularly for users with ongoing activities on biological resources sourced from provider countries, there is an urgent need to clarify

Figure 4.1 Summary of temporal BioTrade cases with potential ABS implications



Source: UNCTAD (2016a). Prepared by Veronique Rossow.

what utilization stands for in the context of provider countries' ABS legal frameworks. In this regard, what qualifies as access for utilization" is the "intention", which is often linked to a research objective in a project document. Thus, "intention" must be explicit in access requests for regulators to be able to determine applicable law as well as conditions for access.

Most ABS laws usually require that the objective of the project or the intent for access is explicitly listed and described in application. But such detail is usually not required for normal commercial transactions of biological resources for the purposes of known transformation or manufacturing. This situation implies a practical challenge as most laws also provide that if resources are initially exported as commodities in trade and later used as genetic resources within the spectrum of the utilization definition under the NP, then ABS obligations will be triggered. This could indeed constitute change of intent or new utilization. In order to ensure traceability and compliance to the ABS law of the country of origin, the receiver of the biological resource should be informed of the associated conditions of use, even if such biological resources have been accessed as commodities. This could be done by inserting relevant information of authorized and not authorized uses in the export and sanitary documentations or within any other multi-use traceability scheme (e.g. origin and source documentation, biohazard notification forms, application for a permit for Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)-listed species and ABS compliance requirements). In the United Kingdom, user ABS compliance is through due diligence[28] requirements (DDRs) application to the National Measurement and Regulation Office that, (aside from the standard DDR thresholds), reflects the provider country's applicable ABS legislation or regulatory requirements.

4.2 What is R&D?

The key questions to answer refer to the type of activities that can be seen as utilization, and if they are the same for all industrial sectors along the value chains.

With a growing trend in "user markets" demanding renewable resources-based products, many actors are increasing their involvement in the natural products sector (e.g. food, phytomedicine, bioenergy, cosmetic, wellness and construction etc.). Whereas current uses of natural products would not trigger any ABS obligations, the following figures illustrate industrial sectors where new product developments could create great potential for research investments from the private sector. For example, in the area of cancer drug discovery, between the 1940s and 2014, of the 175 small molecules approved by sanitary authorities, around 85 molecules (49 per cent), are either natural products or directly derived therefrom.[29]

Additionally, the market for the global organic personal care market size was estimated at $10.16 billion in 2015 and it is expected to grow to about $16 billion by 2020, mostly driven by rising consumer awareness regarding personal health safety.[30] Moreover, when considering the recent developments within the fragrance and personal care industries, major brands are now referring to the sustainable and ethical sourcing of their ingredients.[31] From the provider countries' perspective, such sectorial facts and trends should imply a greater understanding of potential value and utilization activities in order to regulate access and benefit sharing in a pragmatic way.

To achieve formulations of products that meet the quality expectations of consumer standards, considerable investments in R&D have been and are being made in various industrial sectors to improve the organoleptical and functional properties of nature-based products. There is a great diversity of techniques and processes that could be included under "R&D" as defined in the Protocol. However, significant differences also exist when conducting R&D activities amongst industrial sectors. As a guidance to conclude whether an activity could be considered as R&D, and instead of providing positive lists of sectorial R&D activities, a checklist of compliance criteria could be used. This self-assessment approach could then further support the development of more detailed sectorial guidelines or best practices documents in provider or user countries, as already suggested for European Union users in the Regulation (No. 511/2014 on ABS).[31] Box 5 presents the checklist proposed by the Frascati Manual to better understand types of R&D activities.

The five interlinked qualifiers in (B) could be considered as good indicators for assessment if a specific activity falls within the definition of R&D. They would have to be linked to sectorial understanding of biotechnology and the type of subject matter (scope) covered by the Nagoya Protocol and national ABS regulations. The definitions of basic and applied research, then experimental development can be particularly useful

Box 5. The Frascati Manual checklist: Understanding R&D activities

According to the Frascati Manual, an activity falls under the definition of R&D if it satisfies the following criteria:

A. Definition: "Research and experimental development (R&D) comprise creative and systematic work undertaken in order to increase the stock of knowledge – including knowledge of humankind, culture and society – and to devise new applications of available knowledge".

B. Activity: Must in principle respond to the five following qualifiers: novel, creative, uncertain, systematic, transferable and/or reproducible.

C. Areas that qualify: Basic research, applied research and experimental development:

- Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view.
- Applied research is original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific, practical aim or objective.
- Experimental development is systematic work, drawing on knowledge gained from research and practical experience and producing additional knowledge, which is directed to producing new products or processes or to improving existing products or processes.

Source: OECD (2015).

in practice to define scope in national ABS regulations and for the purposes of creating different tracks for evaluation ABS applications. Parties to the Protocol can also develop their own definition that could be wide or narrow depending on their national biodiversity or BioTrade strategy.

4.3 Research objectives and processes in selected sectors

The definition of basic research in the Frascati Manual usually covers activities conducted without any commercial intent. Whereas within BioTrade value chains, most of the research activities fall either under the definitions of applied research or experimental development. Moreover, in value chains, the great majority of such research is usually undertaken on naturally occurring biochemical compounds and other derivatives.

Before establishing a value chain, industrial viability has to be determined. This can be done in two ways. First, through the screening of many biological resources to identify specific properties of commercial interest, or secondly, by identifying biological resources that are locally used and could further be valorized industrially. The corresponding value chains can be built either from a "top-down" ("from the user to the resource" to meet a specific demand) or with a "bottom-up" approach ("from the resource to the market" to generate a new offer), depending on who initiates and supports preliminary research steps.

Depending on the industrial sectors, some systemic R&D steps can be further identified and refined, considering the scope as a starting point.

In fact, the type of R&D activities may vary depending on the biochemical nature and state of the research substrate. When derivatives are not considered within the scope of ABS requirements, utilization activities on genetic resources and/or biochemical composition would be limited to R&D conducted on materials (or parts of materials) that were accessed with functional units of heredity – in other words the access was given to "living cells" that are still able to multiply or cells of genetic material which has not been denaturized.

The following tables (Tables 4.1 and 4.2) provide examples that illustrate research activities on various types of genetic resources (or part of genetic resources), and research activities on derivatives of the same genetic resources – all examples could potentially trigger ABS obligations depending on the national law. Some points to consider are also highlighted to bring attention to where and how industrial utilizations and related valorization steps can occur.

Table 4.1 Examples of R&D on genetic resources

Genetic resources	Silkworm	Microorganism (e.g. yeast)	Algae
R&D examples	Identification of factors that may influence the amino-acid content of the silk proteins secreted by silkworms	Evaluation of the fermentation properties to produce bio-surfactants	Nutritional composition and safety assessments for food and feed purposes
Points to consider	The R&D analyses may be on the derivatives but the subject matter remains the genetic resources	To select the optimal yeast strains, screening of various yeasts could be conducted and only one strain could be selected. Research results and subsequent outcome are difficult to anticipate before the results are obtained	Before some tests become routine (quality control), they first go through an R&D phase: this is the notion of "first use" and the need to build technical and regulatory dossiers for new substances to be used in the main consumer markets. This rule also applies to derivatives

Source: Veronique Rossow (2016).

As mentioned earlier in this chapter, in BioTrade or biotrade value chains it also happens that users access materials that do not contain functional units of heredity (i.e. derivatives). Such access either takes place in the country of origin or in an export country, when users commercialize the results of their utilization. In this latter scenario, it corresponds to transferring derivatives to a third party. What happens next to the derivatives may trigger ABS obligations or not, depending on the conditions of access as well as on the national law of the country of origin. A simple example could be honey. It is a derivative that would not need any access permit if the scope of the ABS law does not include derivatives. Any "innovative research" conducted on honey would not trigger any ABS obligations, even if the country of origin had a broad definition of utilization. Countries may consider one or the other way to include derivatives, depending upon their overall valorization strategy.

And in the process to define the scope of "utilization", provider countries should specify at which stage of value chains research activities would not be considered as utilization any more.

However, if derivatives are part of the scope of the national ABS regulations the examples provided in Table 4.2 may become relevant illustrations of what type of activities could be covered.

Table 4.2 Examples of R&D on genetic resources and their derivatives

Derivatives	Silk proteins	Bio-surfactants derived from yeasts	Salt alginates from dark algae
R&D example	Moisturizing properties of peptides derived from silk proteins for cosmetic use	Study on the functionalities of some molecules resulting from the fermentation of selected yeast strains in the presence of a defined substrate	Obtained through various chemical processes, resulting salt-alginates have various properties that can be studied, such as their viscosity behaviour in water solutions as a factor of concentration and temperature
Points to be considered	The same naturally occurring derivatives can be utilized in very eclectic industries such as fabrics, coating, cosmetic, etc. This utilization builds the stock of knowledge rather than changing the chemical nature of the derivative	These bio-surfactants may then be further used for the synthesis of more complex molecules that are not naturally occurring but could be part of any benefit sharing agreement This utilization implies having conducted some preliminary R&D to shape and select the right molecules to be studied	These molecules are not "naturally occurring" per se, but their functionalities are inherent to the naturally occurring fraction The names of the "salt-alginates" do not necessarily refer to the biological resource they are derived from

Source: Veronique Rossow (2016).

The pathways that a biological resource takes before it reaches its ultimate "destination" (e.g. final consumer products where no more utilization takes place) are very complex (see Figure 4.2 on the dynamics of biotrade value chains). Many actors may be involved, who are most probably located in different countries.

Ideally, each genetic resource, biochemical composition and/or biochemical compound should be accompanied by a document that provides all the information substantiating its legal access and the related modalities in case of utilization. In the case of genetic resources, this is the purpose of internationally recognized certificates of compliance (IRCC), which do not accompany the resource but are available in the ABSCH. But in the case of BioTrade value chains, there is no specific document that exists which would inform all actors across the corresponding value chain about basic Nagoya Protocol-linked details. Linkages could be made with existing traceability systems already in place for CITES, the International Plant Exchange Network (IPEN) or the Micro-Organisms Sustainable use and Access regulation International Code of Conduct (MOSAICC).[33] Private standards, checked through verification or certification systems, could also be used.

Such documentation would also allow recording all changes that may occur whilst the genetic resources or the biochemical compound "travel" along the value chain. This is particularly important in the "bottom-up" value chains, where users seeking access for a given utilization, may have no idea what the subsequent actors will do with the resource. For example, in the bio-surfactant case mentioned in Table 4.2, the first user who got access to the yeasts for producing some bio-surfactants could sell such derivatives to another actor, who could then further study the functionalities of these molecules to develop other products, the same actor could then sell such products to other actors who could also develop other products or simply trade what they have bought. For commercial reasons and in order to maintain the proper level of confidentiality and avoid being by-passed by others, each actor would not divulge the names of their suppliers. Nevertheless, each actor would have to be informed in a reliable way about ABS (if applicable), as well as the related obligations regarding any new utilization.

As a cornerstone of any valorization strategy, adaptive traceability and control measures to ensure proper compliance need to support and enable a benefit sharing strategy that fosters innovation.

4.4 Value chains in practice

Part of the process to implement a new regulation, necessitates an adaptive approach at looking at each stage of the value chain with a view that the ongoing business activities and practices are complementary and important to designing workable, pragmatic and realistic legal frameworks.

As mentioned and illustrated in Figure 4.2, BioTrade value chains can be very complex involving various actors, as well as the methods by which and venue where the R&D takes place. Some industrial sectors have a long history of multi-trader involvement, limiting traceability whilst the genetic resources or derivatives are being sold from one actor to another further down the value chain.

Often, the value-adding steps (including utilization) occur outside of the provider countries and by various actors. This is not necessarily anticipated or known by the provider at the time of export. In this respect, exporters need to be clear on "what" they sell and for "what purposes," they do so. In the case of ABS laws, intent is fundamental to determine how they apply. It does not imply the same level of responsibility in selling for commodities use or for R&D purposes. Moreover, prices and demand for different uses are and will be very different in the market place.

Despite efforts from some actors in the industry to start working in a more transparent way, there are still some commercial considerations preventing downstream actors from systematically ascertaining the origin of the genetic resources or derivatives they obtain. As mentioned earlier, it is unlikely for a provider to know the "route" taken by a biological resource before it reaches its final destination.

Where user obligations have become legal requirements, for example in the European Union or in Switzerland, the legal certainty requirements as brought by the Nagoya Protocol are expected to reflect traceability, clarity on providers' strategy towards their biodiversity, and efficient ABS measures. It is also expected in the case of acquiring material for R&D purposes that reliable providers can substantiate legal access to the resources, which implies exercising due diligence as specified in Article 4 of European Union Regulation No. 511/2014.[34] Box 6 provides a checklist that could help users to comply with due diligence requirements (for example, in the European Union or Switzerland), but that could also be used by providers

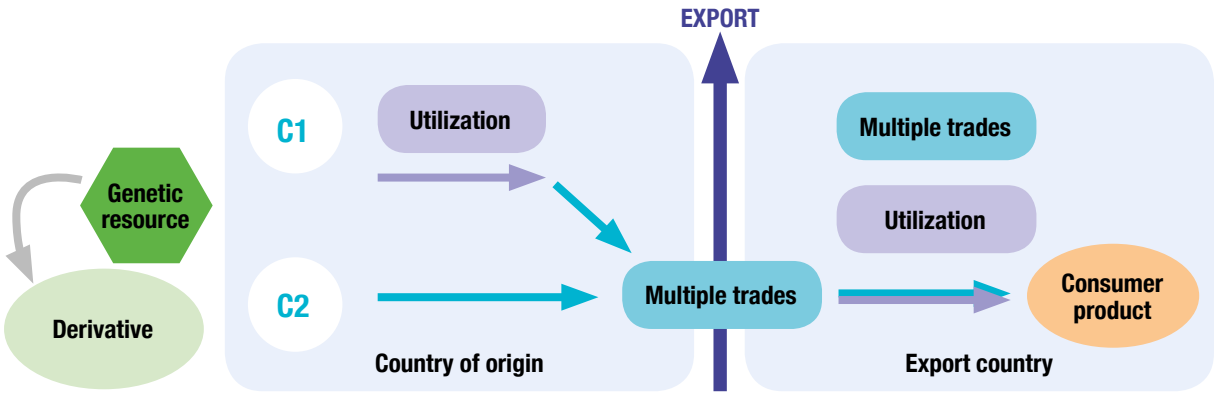
to establish corresponding supporting communication tools that would facilitate traceability. In this regard, it will be important for companies utilizing genetic resources but also for companies "transferring" those resources, to fully understand ABS implications, regardless of where they are located.

4.5 Additional points to consider

4.5.1 Traceability documents

More and more users or potential users are expressing concerns about possible ABS obligations and the many legal uncertainties that would ensue – suggesting that there is intent and willingness to comply. Barring any reliable source of information about the biological resources they obtain, users generally face situations of limited traceability tools shared by upstream value chains actors.

Figure 4.2 The dynamics of BioTrade value chains



Source: Veronique Rossow (2016).

Box 6. Due diligence checklist for value chain actors[35]

- ✓ Am I using genetic resources and/or biochemical compositions?
- ✓ In the case of a derivative: What is the genetic resource from which the derivative originates?
- ✓ What is the country of origin? (The answer could be "several".)
- ✓ What is the subject matter and the scope of activities covered by national ABS regulations in both provider and user countries?
- ✓ What was the date and purpose of access?
- ✓ What was the ABS status of the country of origin at the date of access and what is it now? (The effective origin of the resource in the case of multiple origins.)

  Then, depending on the answers:

  - ✓ What are the utilization conditions of the access?
  - ✓ Would my intended activity on the biological resource be considered as utilization by the country of origin?

    Then, depending on the answers:

    - ✓ Who shall I contact to apply for a permit to become compliant?
    - ✓ What and how do I communicate to my future customers (downstream users)?

As an interim, IRCCs, certificates, contracts or permits could remedy this dilemma and reassure (potential) users about the benefits of compliance. However, such documents may not be available for users at the time their activities trigger ABS obligations. As demonstrated in Box 6, provider Parties can facilitate clarity and legal certainty by providing basic but key information on the biological resource in question.

4.5.2 Origin of the resources including transboundary situations

The scope of the Nagoya Protocol covers "resources from a provider Party that is the country of origin" (Article 5.1 of the Nagoya Protocol).[36] Additionally, Article 2 of the CBD defines a country of origin as "the country which possesses the genetic resources in in-situ conditions". An interpretation of the notion of "country of origin" could be to consider native genetic resources or the resources that have been domesticated to the local environment and ecosystems as well as the origin of resources may also involve transboundary situations. The rights or share of rights associated to transboundary resources have to be anticipated, and would require clear identification of the geographical occurrence and related variation of laws that may be applicable.

In contrast, some countries may have acquired a resource "in accordance with the Convention" (Article 5.1 of the Nagoya Protocol), cultivated it for further commercial purposes, but are not the original country of origin of the resource. This situation is very similar to *ex situ* collections, as acquisition may not affect from which country ABS obligations have to be fulfilled.

From the user perspective, (who would, as may be expected, source from various countries), it would be rather difficult if not impracticable to find the country of origin and possible rights associated to the access and utilization of a genetic resource every time an entity conducts R&D on it. A potential solution could be to participate in an internationally recognized database such as that of the Global Biodiversity Information Facility,[37] in order to acknowledge the endemism of species and gather under one single database all its geographical occurrences.

4.5.3 First access, intellectual property rights, knowledge management

Another notion that was highlighted a few times in this section covers the possibility to have "existing utilization" and "new utilization," In fact, for a given biological resource, a specific utilization is linked to a specific access sought by one entity. Would another entity seeking access for the same resource for the same utilization be considered as new or existing utilization? Such consideration involves fair knowledge of management procedures in place within the competent authority providing access rights. This creates more complex considerations where IP rights are involved, where the first user would either be placed in a disadvantaged position to lose its IP rights or where a bona fide IP applicant loses against a competitor applicant who eventually gains exclusivity over IP rights through wrongful acquisition of IP rights.

Therefore, the temporal scope of the Nagoya Protocol and national ABS laws are important parameters to take into account, despite the accompanying requirement to challenge the way biological resources have been used and how the benefits derived from them are dealt with. The lack of coherence, clarity over important ABS concepts, as well as implementation of weak compliance measures, could only create unfair competition amongst industry actors.

To engage the private sector with long-term and sustainable BioTrade or ABS activities, a great level of legal certainty is required. Legal certainty will foster investment, innovation and capitalization of the benefits that can arise from the commercial exploitation of biodiversity. In this connection, provider countries should favour simplified, fast and efficient certification schemes that would complement IRCCs over over-regulation, and would clarify where legal obligations are triggered.

Lastly and most importantly, genetic resources and their derivatives constitute a "patrimony" that can be valued (and valorized) by provider countries in order to optimize the benefits that can be generated from them. The related valorization strategy should comprise clear objectives and messages towards practitioners, and should consider risks and needs for return on investments when investing in biodiversity-based activities. ABS and BioTrade provisions should be seen as tools to capture the value locally, and the valorization strategy should link the objectives of the National Development Plans and/or NBSAPs with the scope of their ABS law and subsequent benefit sharing principles.

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- Clearly define the scope of the national ABS law (i.e. if derivatives are included or if it only covers genetic resources). If derivatives are covered, to what extent when they are chemically modified.
- Understand that access to biological resources can lead to access to genetic resources depending on the intention of the user.
- Native species should be officially listed in a database such as GBIF so there is clarity over the identity and rights of the country(ies) of origin.
- Monitoring of access and subsequent utilization should allow traceability and sharing of responsibility throughout all actors along the value chains.
- Checkpoints could be created to conduct verification prior to export, and also to support user measures.
- In the case of BioTrade, use certificates for traceability purposes and include information on ABS requirements if utilization occurs. For this purpose, existing traceability schemes under CITES, safety and sanitary standards, as well as biosecurity could be used.
- When there is a change in intent or new utilization that clearly triggers ABS requirements, the notification process should be user-friendly. This could mean extending an existing ABS contract or creating a new one.

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- To prevent impacts on existing activities, outreach and consultation workshops should be initiated with actors involved in the natural product sector (including local users, scientists, and researchers, among others).
- Support the development of sectorial best practices, which could include sectorial decision-trees, based on utilization checklists (e.g. using the Frascati Manual and list of questions – see Boxes 5 and 6.

Notes

21 Valorization is usually considered a holistic approach that, through various utilization activities, national measures and IP tools, will enhance and provide additional values to biological resources.

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

23 *"Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity."*

24 Some industrial sectors mainly focus their research activities on derivatives, which are defined as "naturally occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources, even if they do not contain functional units of heredity" (Article 2(e) Nagoya Protocol). To ease the explanation of how and where research activities are conducted, the broader term "biological resources" is used rather than "genetic resources."

25 In Article 2 of the CBD (use of terms), *"Genetic resources means genetic material of actual or potential value,"* such a genetic material is *"…any material of plant, animal, microbial or other origin containing functional units of heredity."*

26 Article 6(g)(iv): terms on changes of intent, where applicable.

27 Article 8(a): create conditions to promote and encourage research (…) taking into account the need to address a change of intent for such research.

28 Article 4 (User Compliance) of the Regulation (European Union) No. 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

29 Newman DJ and Cragg GM (2016).

30 Grand View Research (2016).

31 For further reading, see McDougall (2015).

32 Recital 24 and Chapter II Article 8 of the Council Regulation (European Union) No. 511/2014 on ABS.

33 Vivas Eugui, D (2013).

34 *"Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements…"* (Article 4 of the Regulation (European Union) No. 511/2014).

35 This checklist is to be adapted based on the user country's specific legal requirements.

36 In accordance with Article 15, paragraphs 3 and 7 of the Convention, *"benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms…"* (Article 5.1 of the Nagoya Protocol).

37 See GBIF website: http://www.gbif.org (accessed 19 June 2017).

SECTION 5.
BENEFIT SHARING: DEVELOPMENT OF FRAMEWORKS AND NEGOTIATING CONTRACTS

5.1 What is benefit sharing?

There is no universally accepted definition for "benefit sharing". However, examples of what benefit sharing may look like are abundant. The Bonn Guidelines on Access to Genetic Resources and the Nagoya Protocol offer an extensive list of the types of benefits that may be shared in the context of ABS (see Table 5.1).

Benefit sharing demands negotiations between various actors, at different points along the value chain and R&D processes. This should lead to MAT which will be reflected in a contract or some form of legal agreement. Benefit sharing may mean ex ante negotiations or require reconsideration of original agreements to respond to new market or research opportunities. Flexibilities and legal openings (e.g. in a contract, cooperation agreement, partnership, etc.) are necessary to ensure this can occur.

Depending on national legislation, benefit sharing can take place between the State (through an ABS national competent authority) and an access applicant. But it may also occur between other actors. For instance, between a bioprospector and a local community on whose lands, collecting or sourcing activities may take place. Benefit sharing may also involve negotiations between private actors, when, for instance, a company seeks to access and utilize genetic resources maintained in a private *ex situ* gene bank or microbial collection. These collections may also be public. There may be situations where if ATK is sought, benefit sharing may require discussions between a bioprospector or researcher and a representative of IPLCs for the use of the ATK. Intermediaries and agents in the case of BioTrade sourcing activities may also play a role in the value chain as they become part of the "benefit sharing package" which includes multiple layers and different actors and beneficiaries – depending on the specific project or activity.

Policymakers need to consider flexibilities in ABS legislation to allow for these very different forms of benefits to materialize in very diverse and dynamic value chains and R&D contexts. At the same time, regulators, who may also have the responsibility to negotiate ABS terms in contracts (e.g. as is the case in the Andean Community), should consider the examples of benefit sharing modalities in the Bonn Guidelines and Nagoya Protocol, and include them in specific projects, businesses and entrepreneurships according to country needs. Negotiating fair and equitable benefit sharing in contracts will almost certainly require specific skills and expertise which may not necessarily be found "in-house"; external advisors and technical assistance could support national authorities and actors to negotiate benefit sharing along value chains and in specific ABS contexts. Benefit manifests itself between a user and provider, but these may vary considerably and give way to relations between companies and universities; companies and national authorities; providers and companies or research institutions; and so on.

5.2 Benefit sharing under the Nagoya Protocol

Although the Nagoya Protocol offers guidance as to what benefits may look like (see Table 5.1), benefits are really what negotiating Parties decide they are. This could be either an enabling or disabling factor depending on the case. In Viet Nam's experience, for instance, the quantification of the percentage of total monetary benefits at a minimum of 30 per cent[38] has proven to be a disabling factor for access. Particularly, as (i) there are no mechanisms to determine the total benefits in the first place; (ii) there is lack of guidance as to when (i.e. at which stage in the value chain) such benefits are triggered; and (iii) when benefit sharing ends; as well as (iv) whether benefits arising from use from third parties also need to be shared. These factors coupled with institutional and administrative hurdles in most provider countries may potentially undermine the process and outcome of benefit sharing both under the Nagoya Protocol and BioTrade projects and businesses,

To foster fair and equitable sharing of benefits which yield something additional to regular market, demand-driven transactions[39] there is a challenge for policymakers to exercise legal and regulatory flexibility to facilitate negotiations, and for regulators and actors to effectively negotiate that "extra" value which will define the fairness and equity in benefits in a R&D phase, a project or business. This is a particularly complex challenge, given the highly dynamic nature of R&D in genetic resources, their genetic and/or biochemical composition and derivatives, complex market structures and differences in available information between actors.

Market mechanisms in themselves will not necessarily result in fair and equitable benefit sharing terms. A price for sourcing a biodiversity specimen or a

collection or concession fees are not always fair and equitable nor satisfy providers' expectations and interests, especially when it is small communities from which biodiversity is sourced.

Additionally, the fact that genetic resources and ATK may be disseminated and diffused and shared by more than one community or country, may make it difficult to negotiate fair and equitable benefit sharing terms. For genetic resources, in particular, and R&D, new technologies (e.g. genomics, synthetic biology, bioinformatics) are making it more and more easy to "extract" useful genetic information, without relying on physical samples. This is already posing a practical challenge to policymakers and regulators in terms of legal coverage of the Nagoya Protocol and ABS frameworks in general.[40]

Table 5.1 Examples of monetary and non-monetary benefits from BioTrade and ABS

BioTrade	ABS – Nagoya Protocol
Monetary benefits • Fees paid to national authorities for sample/specimen collection • Fees paid to national authorities for authorization, concession or other administrative procedures • Payments made to communities for the cost of materials, specimens or biodiversity collected or sourced (these can be subject to fair price criteria) • Payments agreed with communities for successful commercialization of products developed from biodiversity • Monies for local or national conservation funds • Exclusive sourcing agreements with a community	**Monetary benefits** • Access fees/fee per sample collected or otherwise acquired • Up-front payments • Milestone payments • Payment of royalties • Licence fees in case of commercialization • Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity • Salaries and preferential terms where mutually agreed • Direct payments to local communities and authorities for support to projects • Research funding
Non- monetary benefits • Credit opportunities for local actors and producers • Opportunities to participate in value chains and identify and participate in market opportunities • Training and capacity building to improve production, storage, conservation methods, quality control, etc. • Use of certification and fair price schemes • Social recognition • Definition of land tenure and territorial rights • Economies of scale or more "niche" market-oriented production • Associativity and formation of legal persons to participate in a more balanced way in commercial activities and marketing • Access to relevant commercial information • Employment generation and improvements in labour conditions • Soft IP tools such as collective marks or geographical indications	**Non-monetary benefits** • Sharing of research results • Joint ventures and potential collaboration opportunities for further research and development • Joint ownership of relevant intellectual property rights • Participation of national researchers in research projects and development processes • Revalorization of ATK • Access to specialized information and data sources (databases, platforms) • Transfer of technology to countries of origin and providers • Institutional capacity building through specialized training • Support for postgraduate studies for national researchers • Research in national facilities (universities, laboratories, etc.) • Broader and general benefits associated to potential improvements in health, food security, etc. through commercialization of products and data and information

Source: Adapted from Nagoya Protocol, Annex.

5.3 Enabling conditions for benefit sharing under BioTrade projects and businesses

Well-informed policymakers and regulators, users and providers, is the best recipe to facilitate an enabling negotiating environment where benefits can be agreed upon. This requires long-term and continued capacity-building processes which ensure that these actors are provided with appropriate tools to understand and negotiate fair and equitable benefit sharing terms. Annexes 1–5 offer some examples of how benefits materialize and are shared in projects in Cameroon, Colombia, Namibia, Peru and Viet Nam.

Negotiating benefit sharing terms in BioTrade and ABS projects may require external advice and expertise from contract law experts. BioTrade and ABS contracts have different goals, subjects, cause (motivation and intentions), and are governed by different sets of national laws. These differences on the types of contracts need to be taken into consideration by all actors involved as contracts do not have effects on third parties.

Benefits in BioTrade and ABS projects may be similar, but there are some differences. In the case of BioTrade, except for an initial phase where fees will probably need to be paid to a national entity for the right to access and use biodiversity *in situ* (e.g. the forest authority or agricultural entity), benefits are mostly directed to immediate partners (e.g. communities or providers) or shared between private entities and institutions involved in the BioTrade project or value chain. When PhytoTrade in Namibia or Traphaco SaPa in Viet Nam source *in situ*, they are likely paying a sourcing price to communities or providers of biological materials – basically private transactions.

In the case of ABS on the other hand, and depending on national legislation, a state or government institution will probably be directly involved in not only authorizing access but in negotiating benefit sharing terms under an access contract – which reflect MAT. The case of Bioprocol and Ecoflora Cares in Colombia or Cosmo Ingredientes in Peru are exemplary: they are subject to an administrative ABS procedure under which the environmental or sectoral ABS agencies grant an access permit and negotiate an ABS contract (see Annexes 3 and 5).

This should be noted by policymakers: BioTrade will probably exhibit less public/state participation in benefit sharing than would be the case in an ABS project or initiative. State presence in the former may well concentrate on monitoring sourcing activities or conservation status of biodiversity in areas where sourcing is taking place. Health and phytosanitary authorities could also have a role at certain points along the value adding chain.

There may be cases where BioTrade phases come under the scope of national ABS rules. In these circumstances, it is important for policymakers and regulators to consider situations where, for instance, if along a BioTrade value chain benefits are negotiated between a company and a provider, these could also be considered or validated by the national ABS competent authority as part of the benefit sharing obligations under the ABS framework, as a way to prevent duplication in benefit sharing under a BioTrade scheme and ABS legislation. Likewise, duplications in PIC requirements and procedures need to be avoided when designing and implementing BioTrade processes which may include an ABS dimension.

Fair and equitable monetary benefit sharing terms continue to be what markets determine – plus "an

Table 5.2 Main contractual features of BioTrade and ABS

BioTrade	ABS – Nagoya Protocol
Object: Sales of goods and services (e.g. sales and transfer of natural ingredients or biological resources) ***Subjects:*** Business to business or business to community ***Cause:*** Sourcing, processing and commercialization (potentially R&D) ***Applicable law:*** Commercial – contractual law	***Object:*** Access to genetic resources and ATK for utilization ***Subjects:*** Often state to private (research centre or business), but depends on national legislation ***Cause:*** R&D ***Applicable law:*** Usually public law (ABS-related law or administrative law) and contract law

Source: Vivas Eugui, D and Adachi, K (2016).

extra" which is often part of fair price, public relations considerations and/or how much a user (company) is committed to truly engaging in conservation and sustainable practices throughout a project or business in the long term.

Depending on the nature of each project and business, particularly in the case of BioTrade, users may pay between 5–10 per cent of benefits derived from their total earnings. In ABS initiatives, the benefit sharing ranges between 0.5–2.5 per cent, subject to the viability of the commercial product entering the market successfully.[41] Benefits may also be non-monetary and include a wide range and types of benefits, as mentioned in Table 5.1. It is very important for policymakers and regulators to understand the specific markets and nature of R&D process to ensure appropriate legal and administrative flexibilities for benefit sharing to materialize. Issues such as taxing schemes, fees and other costs or investments, which may be associated with a particular business and project, should be considered and assessed within the context of a benefit sharing goal.

Both from the perspective of a policy and legal development process and a regulatory process, policymakers and regulators may consider asking certain questions which will provide them with a solid conceptual and practical foundation for decision-making. Some of the key questions to reflect upon involving users and providers may include:

- How much is a project or business costing and what are the type of benefits which may be realized along a value chain or R&D process?
- What is a fair price for raw biodiversity and its components?
- What determines this price and is this fair and equitable?
- What may be covered and should be accepted as "confidential" in agreements?
- What is the potential value of genetic resources used in a specific R&D project or activity?
- How can monetary payments be negotiated in terms of up-front payments, milestones along the R&D process, input provided by indigenous peoples' ATK, and future royalties in terms of commercially or industrially viable products derived from a genetic resource, their genetic and/or biochemical composition or derivatives, particularly when final results may be uncertain?
- What type of non-monetary benefit(s) may be feasible along a value chain?
- How do specific markets operate and determine prices for biodiversity "in bulk" and for genetic resources utilized in more sophisticated and complex R&D processes?

There are no simple answers to any of these questions given that responses will depend on specific situations and the nature of projects and businesses (some fairly simple in their structure and other more complex and dynamic) and institutional cultures in countries.

5.4 Other factors and conditions to promote BioTrade and enable benefit sharing

BioTrade and benefit sharing cannot rely only on an "understanding" of markets and commercial interests. Certain additional conditions will also act as promoters and enablers to facilitate involvement and engagement of the private sector and IPLCs in particular along the value chain.

Good governance and institutional structures: As mentioned, clear laws and regulations, coupled with well trained and informed officials and appropriately aligned incentives to support sustainable biodiversity based businesses, are the prerequisites to ensure most BioTrade Principles and Criteria can be met in specific projects and enterprises.

Good infrastructure: From roads to storage facilities to access to recognized and competent laboratories, infrastructure availability can define the viability of a BioTrade project or business. Even a very small-scale entrepreneurship or business, requires minimum facilities to ensure success. Non-related investments by the national, regional or local governments may be needed to ensure that these conditions are made available.

Early participation and involvement: As many reports have shown, early involvement by communities in planning BioTrade businesses or any ABS project will almost unequivocally ensure success.[42] Their informed and active involvement will facilitate a wide range of processes: from the negotiation of benefit sharing to rapid reaction from government institutions. Also in cases where local research centres or IPLCs are involved, the probability of obtaining non-monetary benefits increases significantly. Demands for technical

assistance, extension, human capacity building, etc. could generate a local dynamic which will strengthen capacities to collect, produce, test, sell and conserve, among others.

Secure land tenure and territorial rights: IPLCs may find that through BioTrade or ABS projects and activities, there may be possibilities to consolidate or strengthen their rights over lands and territories. Situations vary very widely across the world. However, communities often face tenure problems or pressures over their lands and territories from extractive, infrastructure or other large-scale activities. Recognition of rights over their lands and territories may provide further legal certainty, especially for investors and potential users of biodiversity and genetic resources. In the case of the Nagoya Protocol, defining the rights of IPLCs over genetic resources and ATK is key, and is often very much related to land tenure and territorial lands.

5.5 BioTrade benefit sharing in practice

Box 7 illustrates some actual examples of benefit sharing along the value chain in BioTrade. Some examples are linked to actual utilization of genetic resources as well as existing ABS contracts and permits or pending requests. They also reflect the many and varied forms in which countries and actors define how benefit sharing materializes in terms of monetary and non-monetary benefits. Some of these benefits are also the result of appropriate enabling conditions in each country which have facilitated and streamlined project development, investments, MAT, conservation and overall sustainable value chains. In some cases, such as in Peru and Colombia, these BioTrade projects are also subject to national ABS legislation and are therefore required to satisfy an additional layer of requirements, which companies have been committed to comply with from the outset.

Box 7. Brief examples of benefit sharing in a BioTrade value chain[43]

In Colombia, Bioprocol sources exotic plants from the Amazon to generate extracts, which it transforms into final products or provides to pharmaceutical, cosmetics and the natural products sectors. Bioprocol ensures that local and farming communities in the Antioquia region, where its activities take place, are trained regarding the features and potential of the biodiversity in the areas of collection, and to ensure they are informed and have active involvement in the value chain. Bioprocol has also established three agro-bio experimental centres in the region, to develop technological packages to cultivate and harvest certain crops, which are then shared with communities for use as feedstock. A percentage of the monetary benefits Bioprocol generates from its R&D results are shared with the Colombian Government. In this example, the linkage between BioTrade and ABS is clear and benefits are shared directly with communities and the government as the right holder of the genetic resources used at a certain stage in the R&D process.

In Cameroon, the French aromatics company V. Mane Fils (MANE), works with extracts of native plants to serve the fragrance and flavour industry. Through a MAT contract between MANE, the Ministry of Environment, Nature Protection and Sustainable Development (MINEPDED) and local communities (through the Kingdom of Magha Bamumbu), MANE has agreed to purchase a fixed quantity of dried roots between 2015–2017 at a fixed price; share 25 per cent of benefits generated from commercialization of products derived from these roots with the local communities; and develop a local fund to facilitate the transfer of the monetary benefits. Additionally, MANE has agreed to develop a manual on good practices and cultivation and financing local projects and scholarships for young students, especially women.

In Malawi, Weleda, a Swiss-based company producing natural and organic cosmetics and anthroposophic medicines, has a voluntary ABS arrangement with its local partner, TreeCrops, which involves paying levies to local communities from which biodiversity is sourced for R&D.[44]

In Peru, Cosmo Ingredients (a French company) undertakes research and development with biodiversity from different countries in Latin America, including Colombia, Ecuador and Peru. It focuses on uses and applications in the cosmetics and fragrances industry. In northern Peru, Cosmo is working with a group of farming communities, sourcing a rare native cacao variety from which natural oils are extracted. As part of its agreement with these communities, Cosmo pays a fair price for sourcing raw materials. Cosmo undertakes its activities under the framework of Peruvian ABS regulations.

Source: UNCTAD (2016f). Further information in Annexes 2, 3 and 5.

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- Allow flexibilities in legal and regulatory frameworks to facilitate negotiation of fair and equitable benefit sharing conditions in contracts.
- Clearly determine in what cases public authorities intervene in BioTrade and ABS value chains and phases.
- Create and/or promote development of enabling conditions at different levels (institutional, participation, governance, good information sharing and understanding of markets, etc.) which facilitate and stimulate investments in projects, businesses and particularly BioTrade and ABS activities in general.

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- In the case of ABS in particular, understand the "broad picture" of benefits involved in a particular project or business to ensure balance.
- Understand and be aware of the differences in contractual frameworks between ABS and BioTrade.
- In the case of BioTrade businesses and value chains, support and encourage investments and facilitate permits, concessions and other enabling legal tools for value chains to be undertaken.
- In the case of ABS, consider the very broad range of possible benefits (often not referred to as "benefits") and how these relate to specific projects in bioprospecting, and R&D in genetic resources and derivatives in general.
- Consider the recognition of benefits under a BioTrade value chain during negotiations and calculations of benefit sharing provisions under an ABS project or activity.

Notes

38 Decree No. 65/2010/ND-CP of Viet Nam. UNCTAD (2016f). The interface between access and benefit sharing rules and BioTrade in Viet Nam, 12. http://unctad.org/en/PublicationsLibrary/webditcted2016d9_en.pdf (accessed 5 June 2017).

39 UNCTAD (2016e).

40 Ruiz M (2015).

41 The BioTrade figures come from interviews and talks with a wide range of businesses over time. The UNCTAD-SECO-Andean Community-MINAM-GIZ regional workshop "Exploring the synergies in the implementation of the Nagoya Protocol, access and benefit sharing and BioTrade", held in Lima, Peru, (September 2016) was attended by companies such as Bioprocol (Colombia), Natura (Brazil) and Cosmo Ingredients (Peru) which provided concrete numbers and percentages they negotiate as part of their BioTrade projects. For more examples of ABS in particular see Ruiz (2015, 48–51).

42 UNCTAD (2009a).

43 To further understand the nature and features of BioTrade value chains see UNCTAD (2009a).

44 http://www.business-and-biodiversity.de/en/activities/archives/touring-exhibition/projects/weleda/ (accessed 5 June 2017).

SECTION 6.
ADAPTING THE NAGOYA PROTOCOL: KEY CONSIDERATIONS FOR NATIONAL LEGAL DEVELOPMENTS AND IMPLEMENTATION

The Nagoya Protocol significantly advances the benefit sharing objective of the CBD by providing a strong basis for greater legal certainty and transparency for both providers and users of genetic resources. The Protocol offers various novelties including obligations to designate national focal points, competent national authorities and checkpoints, as well as provisions on monitoring, compliance and enforcement. It also calls for the establishment of an ABS clearing-house as a platform for exchanging information on access and benefit sharing in light of Article 14 of the Nagoya Protocol.

Three important aspects for national legal developments that consider the function of BioTrade as a tool for achievement of CBD objectives and Aichi Targets are:

- Information sharing and transparency;
- Compliance; and
- Incentives for compliance.

6.1 Information sharing and transparency

Information sharing and transparency are enhanced through the obligation to designate and notify an ABS national focal point and competent national authorities under Article 13 of the Nagoya Protocol. The national focal points liaise with the SCBD and provide basic information regarding the competent national authorities and IPLC stakeholders. They make information available on access procedures, PIC and MAT requirements for both genetic resources and ATK.

Competent national authorities, as determined by national legislation, receive applications; grant access; provide information and advice on ABS and ATK; and are usually responsible for issuing information on compliance with access requirements. It is not unusual that there is more than one competent authority. For example, in both Peru[45] and Viet Nam,[46] there are several competent authorities, which are defined by the type of genetic resources (i.e. wild, cultivated and aquatic), and/or the level of governmental jurisdiction (i.e. national, regional or local).

In countries where BioTrade has a long-standing tradition, such as Colombia, Ecuador, Peru and South Africa, there are also BioTrade focal points (usually the environmental or trade agency) which are often responsible for the development of national strategies and the inclusion of legal references to BioTrade (e.g. Ministry of Environment in Ecuador). However, this is not a definitive rule. In Viet Nam, the BioTrade technical focal point is a civil society organization called BioTrade Interest Group (BIG),[47] which is in charge of advising and supporting enterprises and communities to develop value chain models in compliance with BioTrade Principles.

Additionally, Protocol obligations on monitoring and enhanced transparency on the *utilization of* genetic resources[48] stipulate the designation of checkpoints (which may differ from competent national authorities and national focal points) to collect or receive relevant information related to PIC, the source of the genetic resource, the establishment of MAT, and/or the utilization of genetic resources.[49] Checkpoints can be diverse and located in different national authorities depending on the type of genetic resources flow and activity they are seeking to monitor. They can be found in ministries of environment, IP offices, customs and/or sanitary or commercialization authorities and even in R&D promoting bodies. For regulators and policymakers, monitoring flows may become tricky when looking at biotrade (with small caps) or trade in commodities. In certain cases, the differentiation between genetic and biological resources may not be useful in practice at the time of checking. Instead, the actual *intent of the user* may be highly relevant. In this regard, it may be envisaged to have explicit rules on the "intent and utilization objective" in order to verify GRs flows, whilst not disturbing trade.

The CBD ABSCH (which is now fully functional) serves as a platform for sharing and exchanging ABS-related information. In particular, it provides access to information made available by countries relevant to the implementation of the Protocol, its Parties, ABS legislative, administrative and policy measures; information on national focal points and competent national authorities; information on ABS permits granted in order to constitute IRCCs; and designated checkpoints. The ABSCH is now fully functional. In addition to national records made available by countries, it also contains other ABS-related information, including guidelines, best practices, model clauses, capacity-building initiatives and material, as well as ABS-related literature that may be useful to both Parties and relevant stakeholders. Submitting information by BioTrade focal points in coordination with national competent authorities would enrich the ABSCH, enhance transparency and aid mutual supportiveness.

The information provided by the ABSCH is particularly useful to understand ABS regulatory and administrative procedures established by countries as well as permits granted by a country for access to its resources. This information is key for BioTrade companies interested in or are already engaged in R&D activities and/or in the process of assessing their investment interest in a BioTrade business.

UNCTAD has already started logging information on relevant guidelines, model clauses, materials and technical cooperation activities, but it could also be important to ask national BioTrade focal points to do so. Furthermore, UNCTAD could set up a webpage that contains a list of all BioTrade focal points in countries where national programmes exist to enable further cooperation with ABS national focal points and competent national authorities under the Nagoya Protocol.

BioTrade companies that have obtained legal access (in the form of contracts or permits), should notify ABS national focal points so that they in turn validate information for the ABSCH. When notified to the ABSCH, permits and authorizations will become IRCCs[50] that could have effects not only in the country of the granting authority but also in user countries. The IRCC is a useful tool at checkpoints in order to provide evidence that PIC was granted and that MAT were established. An IRCC facilitates monitoring of the utilization of genetic resources across borders. Obtaining an IRCC also grants title holders a first-mover advantage in the market. Figure 6.1 is a screen shot of key information available on the ABSCH.

One question commonly raised by BioTrade companies is whether a non-Party to the Protocol can make national records available to the ABSCH, including national focal points, competent national authorities, legislative, administrative and policy measures, as well information on national permits granted in order to constitute an IRCC. Article 24 of the Protocol is clear on this matter and directly encourages non-Parties to contribute with appropriate information to the ABSCH. Thus, a non-Party to the Protocol may submit

Figure 6.1 Logging on and checking in: The CBD ABS Clearing-house

Source: Secretariat of the CBD (August, 2017).

information on the ABSCH. This can be particularly useful, for the notification of permits by CBD Parties that have not yet acceded to the Protocol.

6.2 The importance of compliance measures

Although all countries are providers and users of genetic resources and biodiversity at the same time, some have historically been more providers or users than others. Since the CBD entered into force, ABS policies and legal frameworks have been largely developed by provider countries. It is only during the negotiations of the Bonn Guidelines in the early 2000s that the notion of "users" or "user countries" entered into discussions. In simple terms, it was soon acknowledged that national ABS measures in provider countries were insufficient to guarantee the realization of the benefit sharing objective of the CBD. Action and support were also required from user countries in order to ensure compliance. This idea, which now seems mainstream, was not generally recognized. The Nagoya Protocol builds on some of the provisions of the Bonn Guidelines (2002),[51] in particular those related to the obligations of countries with respect to users of genetic resources within their jurisdiction through compliance measures.

In general terms, for the purpose of compliance, the Nagoya Protocol requires[52] Parties to:

- 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 PIC and that MAT, as required by domestic legislation;
- Take similar measures to address situations of non-compliance;
- Cooperate in cases of alleged violation of domestic legislation or regulatory requirements.

These obligations may also apply to ATK in accordance with domestic legislation.[53] In this case, as explained below, it must be considered that traditional knowledge may be delinked from genetic resources and subject to more general traditional knowledge legislation and protection measures.

All these compliance obligations are a novelty as they imply some level of extraterritoriality in their effect. This implies responding to actions that may have occurred in the jurisdiction of other Parties of the Protocol but that can have an effect in jurisdiction of the Party where the claim has been brought. These obligations would only affect BioTrade businesses if their activity or some of their activities fall within the scope of the domestic ABS legislation of the country where the genetic resource or even the biological resource was found in *in situ* conditions (i.e. R&D based on genetic or biological material). Policymakers, regulators and BioTrade companies need to be aware, as mentioned in Section 4, that whilst acquisition of genetic or biological material may have occurred for simple processing or manufacturing, R&D activities may occur later in the value chain, generating changes in the intention and conditions for access. If such changes occur and are not foreseen, compliance with the domestic legislation will be required in order to avoid litigation and risk to goodwill.

To complement the Nagoya Protocol entering into force in 2014, policymakers in the European Union have developed a regulatory framework implementing the Protocol within the region – the 2014 European Union ABS regulation on compliance measures for users.[54] Box 8 features an introduction to how user compliance within the European Union and other European Economic Area countries is proposed to be achieved. At present, the European Union is one of the world's key players in the biotechnology and non-commercial biodiversity research sector. Successful implementation of compliance measures on this scale would certainly provide a guide for other user countries to follow a similar route.

ABS compliance mechanisms can be diverse. Countries such as Switzerland have implemented compliance measures associated with their commercialization permit system. In some instances, such as in Peru, national authorities are evaluating potential checkpoints to ensure compliance between ABS regulations and the national science and research council (CONCYTEC) grant policies. The customs mechanisms not only seek to ensure compliance with national legislation but also to enhance transparency and provide a legal title that can be used across borders.

Some countries and regional blocs, have additionally chosen to establish checkpoints within IP or patent systems. These include Brazil, Colombia, Costa Rica, India, Nepal, Panama, Peru and the Andean Community, and the African Union. Some user

Box 8. Compliance measures under European Union Regulation No. 511/2014, Switzerland and Norway

European Union Regulation No. 511/2014, 16 April 2014: Under the European Union ABS, Member Countries are required to adopt a series of measures supportive of compliance with national ABS and BioTrade laws including through:

Due diligence: All users of genetic resources and ATK in the European Union, should exercise due diligence to ensure that these resources and ATK have been legally accessed from a provider country, and that benefit sharing is equitably realized. To contribute to due diligence efforts, competent national authorities should implement a system of IRCCs as proposed by the Nagoya Protocol. Such certificates would prove that genetic resources were accessed legally and that MAT were established. Users should transfer the certificates to subsequent users to enable monitoring and ensuring legitimate transfers along a research chain.

Register of collections: *Ex situ* collections of genetic resources in the European Union will have the opportunity to sign up to a special register created and managed by the European Commission, provided they demonstrate capacity to transfer genetic resources using standardized procedures and in accordance with the Protocol's principles and obligations, and demonstrate that these resources and related information were accessed in accordance with national ABS legislation and complying with MAT.

Recently, the European Union has published a guidance document to support European Union institutions, bodies, offices and agencies in the practical application of the European Union Regulation No. 511/2014 (See, Commission notice 2016/C 313 /01).

Research funding: All recipients of funding for research in genetic resources within the European Union will be requested to declare that they exercised due diligence in regard to access and the utilization of these resources.

Some countries, such as Switzerland and Norway, which are not members of the European Union, have also implemented measures which to a considerable degree follow the mandates and orientation of the European Union regulation and the Nagoya Protocol.

The Federal Act for the Protection of Nature of Switzerland (2014) establishes that any person who utilizes genetic resources and benefits directly from their utilization, must act with due diligence to ensure that these resources were accessed legally and that MAT conditions have been determined (Article 23n). Notification of compliance of due diligence must be forwarded to the Federal Office for the Environment and Nature (FOEN) before market authorization has been obtained or before the commercialization of products developed on the basis of utilized genetic resources (Article 23o). These measures also apply to ATK of IPLCs, unless they are already freely available (Article 23p).

In the case of **Norway, the Nature Diversity Act (2009),** Section 60 on genetic material from foreign countries, establishes that the import into Norway of a genetic material requires consent for collection or export. The user in Norway is furthermore obliged to use the material in accordance with the conditions agreed upon with the provider.

Source: Compiled by the authors and contributors (2017).

countries such as Norway, Switzerland, Germany, France and Spain, also have in place different variants of compliance measures, some linked to their patent regimes. In some countries, disclosure of key information is mandatory (mostly developing nations) and in others voluntary (mostly in developed ones). There are exceptions, such as in Andean countries and Switzerland, where disclosure in patent applications is mandatory. Still a key gap in many developing, provider countries is making sure there are compliance measures in place as well, which ensure the interests of other countries with ABS legislation are taken into account and respected. Indeed, all Parties to the Nagoya Protocol have the same obligations as potential providers and users of genetic resources and ATK.

Regulators face the challenge of implementing compliance measures that can have differences in

scope and nature, which are not always straightforward due to the great diversity of the subject matter (genetic resources and biochemicals from species that include microorganisms, plants and animals). By way of illustration, Viet Nam's Biodiversity Law 2008 defines genetic resources as: "all species and genetic specimens in nature, conservation areas, biodiversity conservation facilities and scientific research and technological development institutions and in nature" which, by the Protocol standards would be broad in definition. An added layer of complexity for Viet Nam is the fact that it is not a signatory to the ITPGRFA, one of the "specialized international instruments" that the Protocol expressly excludes in its scope. In essence, and barring any other specific rules on materials, regulators need to either know (because the patent application says so or is accompanied by the documentation) or conclude that an innovation contains or is based on genetic resources obtained from a country with an ABS system in place – and decide accordingly. The latter situation is particularly complex, as proven by cases in Peru where half a dozen biotechnology patents are on stand-by because the IP authority (INDECOPI) is not sure whether these innovations have complied or not with national ABS legislation. Further details on how IP is used for positive and defensive purposes are further developed in Section 9.

With respect to all types of compliance measures, it should be noted that decision makers and regulators dealing with ABS in *provider* countries may also need to consider the development of user measures as a means to respond to Nagoya Protocol obligations and to provide reciprocity to other Nagoya Protocol Parties. This will be something that many policymakers and regulators will have to seriously consider as most ABS regulation prior to the Nagoya Protocol only claim jurisdiction over their own resources and in some cases, agree to cooperate in cases of shared resources with neighbouring countries.

Box 9. Defensive protection in IP as classic "user or compliance measures"

Around the world, "defensive protection" through IP procedures (particularly patents and breeder rights), have become a practical, albeit limited, checkpoint and compliance measure, where legitimate uses of genetic resources and ATK may be verified before granting of rights. In contrast with "positive protection", defensive protection does not grant rights but prevents others from seeking them due to, for example, unauthorised access to or illegitimate uses of genetic resources and ATK, as well as wrongly granted IP rights.

The IP system is used according to its own rationale and logic. Patent applications are processed upon condition that – in cases where innovations may involve genetic resources or ATK – ABS legislation has been complied with. In most cases, these are formal requirements, part of the administrative procedure. In others, such as in the Andean Community, these become in practice substantial conditions given the possibility that patents may not be granted or furthermore annulled.

Defensive protection is also often linked to registers and databases. For instance, the Traditional Knowledge Digital Library in India or the database managed by the National Commission against Biopiracy in Peru, operate by providing patent authorities worldwide with reliable information and data which may assist examiners in improving patent analysis and ensuring that wrongful patent rights are not granted. Both India and Peru have prevented many patents over biodiversity or TK-based innovations from being granted as a result of these efforts.

Examples of defensive protection legislation linked to IP and patent regimes in particular are plentiful, especially but not exclusively in developing countries, and include: Decision 391 of the Andean Community on a Common Regime on ABS (1996); Decision 486 of the Andean Community on a Common Regime on Industrial Property (2000); the Patent Act of Norway, Act No. 9 of 1967 on Patents, as amended in 2015; and the Patent Act of Switzerland, as amended in 2012. In some cases, defensive protection is included in biodiversity, genetic resources and ATK legislation, as in the case of Law 7788, the Biodiversity Law of Costa Rica (1998); Law 13.123 on ABS in Brazil (2015); and Law 27811 on the protection of TK in Peru (2001).

Source: Manuel Ruiz (2016).

6.3 Adapting national legislation, incentives for compliance and investment in ABS in BioTrade projects and businesses

The entry into force of the Nagoya Protocol and the enactment of compliance measures in user countries, such as the European Union and Switzerland, place an immediate challenge for policymakers in provider countries, who need to make sure that their ABS frameworks are operationally efficient and effective. The lack of any operational system in place to facilitate the requirements of user compliance regulations may result in considerable economic effects in trade also affecting the outflow of genetic resources or biodiversity-related goods into user countries.

Accordingly, various incentives can be introduced within the ABS regulation systems of the provider countries in order to facilitate compliance of BioTrade businesses or projects. Recommendations suggested by this handbook include:

A. Regulatory measures (for policymakers):

- Clarify responsibilities of competent authorities.
- Facilitate legal access through simplified processes of PIC and MAT.
- Introduce expedited ABS procedures for BioTrade companies that have already been verified due to their compliance with the CBD objectives as well as BioTrade Principles and Criteria.
- Recognize the benefits already granted under BioTrade as part of the benefits under ABS system (see Section 5 on Benefit sharing: Development of frameworks and negotiating contracts).
- Allow for regularization mechanism/legal amnesty for access that occurred before the entry into force of the Protocol.

B. Administrative practice (for regulators):

- Issue contracts and permits within a reasonable period (a process lasting longer than six months is considered burdensome by some BioTrade companies).[55]
- Issue binding assessments prior to the request for access coverage upon request (this type of mechanism is usually known as "prior ruling" in customs procedures).
- Manage expectations on monetary benefits and value non-monetary ones.
- Make use of single window systems and electronic procedures as far as possible (for example Peru is in the process of establishing such a system).[56]
- Automatically issue IRCC once contract of permits have been agreed or granted.
- Include BioTrade focal points in the administrative ABS decision when there are applications by BioTrade companies.

C. Economic incentives (for policymakers and regulators):

- Avoid unnecessary transaction costs.
- Allow facilitated access to genetic resources if R&D is local or local manufacturing is undertaken by the applicant.
- Introduce tax incentives to companies that meet BioTrade Principles and Criteria.

D. Capacity building (for policymakers and regulators):

- Promote understanding of the particularities of the BioTrade and the bio-business and its relationship with ABS.
- Promote understanding of the various types of R&D (basic, applied and regulatory).
- Train regulators on the different business models and type of companies usually engaged in ABS procedures.

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- Transparency measures adopted under the Nagoya Protocol should facilitate ABS compliance by BioTrade companies as well as other actors.
- Clarity on roles of focal points as well as competent authorities (especially if multiple ones exist) is essential not to confuse applicants on where and how to make access requests.
- Decision makers in provider countries may also want to consider reciprocity and how their frameworks offer reciprocal treatment to users from third countries which also implement compliance measures and take into account provider legal frameworks.
- Checkpoints can be quite diverse (the provider countries' commercialization or sanitary authorities, research grants or IP offices). Some countries may choose to have more than one in order to cover different activities or subject matter. For BioTrade companies checkpoints for commercialization or IP applications will be the most relevant ones as they probably will apply to the type of products and innovations generated under BioTrade projects and activities.

FOR REGULATORS

- The ABSCH contains valuable information on national focal points, comparative regulations, IRCCs, models, guidelines and best practices that can make it easier for BioTrade companies to select countries where they can obtain access, undertake R&D activities or invest.
- The notification to the ABSCH by the national focal point of the country of origin of contracts or permits obtained by a BioTrade company will be a clear advantage, as such notification will become an IRCC that could have effects not only in the country where the contract or permits were agreed but also in user countries.
- Coherence at the national level could be enhanced by also notifying national BioTrade focal points to the ABSCH when relevant.
- A great variety of regulatory, administrative, economic and capacity-building incentives can be introduced within ABS in provider countries in order to facilitate compliance of ABS regulations by BioTrade companies or projects. An illustrative list of incentives is included in this section for guidance.

Notes

45 UEBT (2016).

46 See UNCTAD (2016e).

47 For more information on BIG Viet Nam see: http://biotradevietnam.org/en/ve-big-viet-nam.html (last accessed, June 2017).

48 See Article 17.1 of the Nagoya Protocol.

49 See Article 17.1 (a) (i–iv) of the Protocol which provides standard (basic) guidelines on functions relevant to the implementation of a checkpoint (or checkpoints) as a measure to monitor the utilization of the genetic resources, highlighting the need that *"each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance."*

50 See Article 17.2 of the Nagoya Protocol.

51 See UNCTAD (2016e).

52 See Article 15 of the Nagoya Protocol.

53 See Article 16 of the Nagoya Protocol.

54 See http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm (accessed 10 June 2017).

55 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, see Secretariat of the CBD (2011).

56 See UNCTAD (2016a).

SECTION 7.
UNDERTAKING ACTIVITIES CONCERNING TRADITIONAL KNOWLEDGE AND IPLCS' LANDS OR TERRITORIES

7.1 What to look out for in projects, businesses and activities involving IPLCs

Frequently, both BioTrade and ABS projects either take place at some point on IPLCs' lands or territories or use their ATK, or both. Almost invariably, BioTrade projects engage with communities from which biodiversity is sourced, especially if harvesting of wild species or cultivation of native species takes place. Furthermore, during initial phases of R&D or a value chain, there may be instances when ATK is used to orient research activities. This happens both in BioTrade (where *biological* resources use is prevalent) and in more targeted bioprospecting of genetic resources or derivatives. It is widely accepted that ATK can contribute significantly to these initial phases of R&D. For example, the World Health Organization estimates that 25 per cent of modern medicines are made from plants first used traditionally, showing its value today.[57] Furthermore, compared with the conventional process of screening millions of synthesized chemicals, traditional knowledge-based bioprospecting may significantly cut costs of pharmaceutical R&D. In 2010 alone, 48 per cent of drugs in the clinical phase were derived from plants.[58]

But examples of the correlation between ATK and successful uses of products from biodiversity by the wider society are plentiful and go back in history. The use of quinine to treat malaria in Europe in the 17th and 18th century is attributed to indigenous peoples use in the Andean- Amazon of Peru; the many modern applications of "neem tree" and "turmeric" extracts and compounds have been part of traditional uses by communities in India for centuries; the Yuan peoples in northern Thailand have been using "aloe vera" for centuries for cosmetic purposes; local communities in southern Morocco have been for years cultivating and extracting through traditional techniques natural oils from the "argan tree"; and so on.

Traditional knowledge has historically served researchers and businesses to identify research and investment opportunities in the natural products, pharmaceutical, cosmetics, food and other sectors. BioTrade and ABS are directly related to these activities. This is mainly due to the fact that ATK has already identified by trial and error and accumulative intergenerational improvement and innovation via practical use, specific animal, plant, insect, mineral etc. materials. Whilst most businesses recognize the value of ATK for R&D purposes, many avoid its use due to the political complications and risks that could be involved in dealing with indigenous peoples, especially for less experienced companies.

Policymakers should also bear in mind that ATK can be closely linked to native species but it can also be developed separately as it is an intangible component in the application of nature.

BioTrade and ABS frameworks explicitly refer to IPLCs and their ATK. BioTrade also refers to land and territorial rights which always involve IPLCs. More specifically, BioTrade Principles and Criteria, as well as the BioTrade Ethical Standard and ABS laws and regulations worldwide include provisions which, in general terms, call for respecting indigenous rights and for the protection of ATK. This is particularly true for Principles 4, 6 and 7 (Criteria 4.4, 6.2, 6.4, 7.1 and 7.3).

The Nagoya Protocol on the other hand is also concerned with ATK and includes specific provisions in this regard. Its main objectives are to ensure that PIC and MAT are also obtained when ATK is utilized, that benefits from this utilization are shared with IPLCs, that national ATK-related legislation is respected and complied with in user countries, and that countries endeavour to support the development of IPLCs, community protocols, minimum requirements for MAT and model contractual clauses (Articles 7, 12 and 16).[59]

Regulators and BioTrade companies need to be aware that traditional knowledge is often not associated with genetic resources per se, but is linked to the use of biological resources in the form of specimens (e.g. plants, animals and insects), their parts (e.g. skins, leaves, saps and wools) or raw materials (e.g. timber, pulp and fruits). Lack of awareness about this point may generate unforeseen liabilities and problems along the value chain that could affect production and trade if not addressed from the beginning.

National policymakers should recognize IPLCs' rights to require PIC or prior approval or involvement before accessing, and ensure benefits are shared when resources over which IPLCs have established rights, and ATK, are utilized. The benefit sharing in this case is not linked to the utilization of genetic material but to the use of the associated intangible component. This later may become even more relevant if indigenous peoples have protected their knowledge through IP tools or *sui generis* systems (see Section 9 for further explanation).

Policymakers have the responsibility to make clear, jointly with IPLCs, how PIC and MAT should be obtained and be reasonable for ATK so there is legal certainty for all parties involved. Regulators should make sure that there is written evidence that projects and businesses which involve IPLCs have the appropriate permissions and consents to ensure that there is legal certainty along production and R&D value chains.

This may prove particularly important in cases where products or goods are exported to countries where PIC or other national requirements involving IPLCs' ATK are already included in the regional or national ABS legislation as in the case of the European Union and Switzerland. Though they may not have been designated specifically as checkpoints under the Nagoya Protocol, in Brazil, Andean Community countries and India for instance, IP offices have already assumed roles as national checkpoints. As such, their IP granting procedures, require that national ABS- and ATK-related frameworks are complied with as a condition to process biodiversity-related patents.

7.2 The role of PIC and MAT when engaging with IPLCs

Prior consultation principles and similar, such as in Guatemala, Peru, and the Plurinational State of Bolivia,[60] govern how researchers or businesses may enter IPLCs' lands and territories and how to consult in cases where measures and legislation are planned and may affect indigenous peoples' interests. Often, universities and research institutions have detailed codes of practice and conduct for entering indigenous peoples' lands. Prior informed consent and MAT rules and principles on the other hand, govern how and under what conditions ATK may be accessed and utilized: they legitimize activities of researchers and businesses regarding ATK in R&D in bioprospecting and BioTrade value chains. Prior informed consent and MAT are sometimes regulated (in detail or more generally) in ABS or ATK-related legislation such as in the case of African Union members, Brazil, Peru, Costa Rica, India and Panama.

For countries in the process of considering or developing policies and legislation regarding ATK, policymakers may need to consider including certain minimum conditions such as formal procedural aspects: (i) the type of information which needs to be provided; (ii) the format (e.g. standardized forms, minimum signatures, online or paper filing); (iii) language and methodology with which information is delivered (e.g. through workshops, assemblies, specific meetings with heads, elders or key individuals in a community); (iv) respect for customary practices with which decisions are made by IPLCs (i.e. administration of legal timeframes versus traditional and customary timeframes); (v) representation of IPLCs (i.e. authorized grantor of PIC, e.g. a community or representative body of a community).

As for MAT, asymmetries between users and IPLCs may require that measures are considered by policymakers to support these actors in their negotiation, including options for free technical and legal assistance during negotiations of MAT, provided either by a state specialized agency (e.g. the ombudsman or an indigenous peoples' ministry or agency) or civil society institutions (e.g. NGOs or pro bono lawyers).

Furthermore, the Nagoya Protocol requires that Parties support the development by IPLCs of:

- Community protocols in relation to access to ATK with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge.
- Minimum requirements for MAT to secure the fair and equitable sharing of benefits arising from the utilization of ATK with genetic resources.
- Model contractual clauses for benefit sharing arising from the utilization of ATK with genetic resources.[61]

Therefore, regulators may need to find ways to participate in PIC and MAT procedures as a verification effort or demand certain guarantees (e.g. written evidence or images or even a certification scheme), which ensure that IPLCs' rights to fair, balanced and transparent consultation and negotiation have not been affected.

Prior informed consent may not only be required for access and use of ATK, international conventions such as ILO 169, require consultations and participation of indigenous peoples in the use management and conservation of natural resources.[62]

7.3 Understanding traditional knowledge laws

Almost all countries have some form of legislation dealing with their IPLCs and recognizing certain rights in their favour. Consultation laws and regulations for example, are common place. However, specific laws and regulations addressing the protection of ATK are less common, although over the past decade or so this has begun to change. As indicated in Table 7.1, a considerable number of countries and regional organizations have adopted ATK protection- related frameworks. Invariably, these frameworks and laws recognize rights and principles regarding PIC, MAT, benefit sharing, customary practices and collective organization of IPLCs.

There is, therefore, considerable comparative legislation available for policymakers to use as an inspiration and to inform their own national processes (see Table 7.1). This should also be complemented with a search for and review of assessments and analyses of the impacts and effects these laws have had, particularly on the livelihoods of IPLCs themselves. The number of ATK-related frameworks and laws is a first step in the process of acknowledging and recognizing IPLCs' rights and interests, but should not necessarily be considered a good or the main indicator of success and progress.

A common factor among these existing legal frameworks is their complexity. Policymaking will require careful consideration of issues which until today, remain unresolved. For example, ATK, which is shared among IPLCs, typically brings forth associated pitfalls for users and ATK holders alike. Issues such as: (i) legitimate ownership – who is the right holder of this particular ATK: a single indigenous people, a group or a community? or the groups which happen to become involved in a project or business endeavour; (ii) beneficiaries of the utilization of the relevant ATK – are they owned jointly or severally?; and, if (i) and (ii) are resolved, (iii) with what practical mechanism could this be enforced?

The Traphaco SaPa case in Viet Nam (Annex 1),[63] which relates to the discovery of a medicine (from a new natural ingredient) for stomach ailments provides a classic insight to this seemingly persistent dilemma regarding the use of ATK. Here the good prospect of ATK holders enjoying the benefits of their traditional knowledge associated with a medicinal herb *(Ampelopsis cantoniensis)* through the patent system was lost as the ATK in question was deemed to have already existed in public domain[64] and identification of the specific rights holders was onerous if not impossible. The lack of a management database for genetic resources and ATK and the absence of any legal and administrative instruments to somehow safeguard the interests of the IPLCs' ATK proved to be a costly omission.

7.4 Benefit sharing options when using ATK

Benefit sharing alternatives when accessing and using ATK may not vary that much from options applicable to access to and utilization of genetic resources in terms of the type of benefits potentially involved. In some cases of BioTrade there may be a more constant flow of monetary benefits back to IPLCs as biodiversity is utilized in most cases in bulk whilst subject to sustainability criteria. Under more classic bioprospecting, monetary benefits may occur at later development and commercialization stages of innovations and products derived from genetic resources and activities. The actual use or "level" of use of ATK in these particular processes may require careful and case-by-case analysis in order to determine whether and when benefits (including monetary benefits) could be shared.

Circumstances and the needs of IPLCs are also very diverse according to national, regional and local contexts. For example, in Africa and Asia most of the population is indigenous whilst in the Americas, the term "indigenous peoples" refers to the nations living in the continent before Europeans and Africans arrived. Therefore, depending on the specific BioTrade or ABS project or business being planned, a menu of possibilities should be considered. Policymakers should maintain sufficient flexibilities within legal frameworks to enable negotiations on a case-by-case basis, according to MAT between users and IPLCs, possibly through their representative organizations. Regulators on the other hand, will need to take into consideration these particular needs if called upon to supervise or oversee benefit sharing negotiations and conditions agreed upon between IPLCs and users of ATK.

Table 7.1 Scope of selected traditional knowledge in selected laws and regulations

Country or organization	PIC	MAT	Benefit sharing	Customary law/ practices	Collective organization	Links with BioTrade
Law 7788, Costa Rica	Yes	Yes	Yes	Yes	No	Traditional knowledge related to biological resources
Law 27811, Peru	Yes	Yes	Yes	Yes	Yes	Traditional knowledge related to biological resources
Law 20, Panama	No	No	Yes	Yes	Yes	Traditional knowledge in general
African Union ABS guidelines	Yes	Yes	Yes	Yes	No	Traditional knowledge related to biological resources
African Regional Intellectual Property Organization (ARIPO) Swakopmund Protocol	Yes	Yes	Yes	Yes	Yes	Traditional knowledge related to biological resources

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- There are numerous examples of comparative ATK policy and legal frameworks which could be reviewed in order to undertake a national process to develop sound and operational ATK frameworks.
- The Nagoya Protocol, ABS legal frameworks and BioTrade make explicit reference to PIC and MAT with IPLCs when making use of or working on their lands, and offer some guidance as to how these could materialize in practice.
- Informed and active participation of indigenous peoples in policy and legislative ATK processes and ensuring that their views and opinions are adequately incorporated into debates and discussions is essential to legitimize these processes.
- To facilitate and enable benefit sharing from access to and use of ATK, clear legal and regulatory frameworks are indispensable. These need to ensure that potential users understand at what point in a value chain there may be the need to discuss benefit sharing conditions with indigenous peoples.
- Traditional knowledge can be closely linked to native species or biodiversity in general, but it can also be addressed separately as it is an intangible component (pure knowledge).
- There is need for clarity in regard to how PIC and MAT should be obtained in an ATK context, to ensure legal certainty for all parties involved.
- PIC may not only be required for access and use of ATK. International conventions, such as the ILO 169, require consultations and participation of indigenous peoples in the use, management and conservation of natural resources in general.

FOR REGULATORS

- In many cases, national regulatory bodies will act as an oversight to the implementation of ATK frameworks, specifically to ensure that contracts or agreements regarding access to and use of ATK are appropriately negotiated.
- There is an obligation to be aware that traditional knowledge may not only be associated with frameworks addressing genetic resources and naturally occurring biochemicals. There may be biological resources and derived products legislation which is also applicable to ATK.
- Benefit sharing is not always triggered by a link with the utilization of genetic material and biological resources. ATK-related benefit sharing can be then also triggered as a consequence of the use of an intangible component (knowledge and practices) under a bespoke traditional knowledge law.
- Depending on national legislation, regulatory bodies will be assigned a series of roles and functions including registration of ATK, acting as a checkpoint as part of Nagoya Protocol obligations, exercising defensive protection, etc.

Notes

57 WHO (2003).

58 Singh RD, Mody SK, Patel HB, Devi S, Modi, Kamani DR (2014).

59 See MINAM (2016). Traditional knowledge has become a commonly used concept, present in almost all existing international instruments, including the CBD (1992), the Bonn Guidelines (2004), the UNESCO Convention for the Safeguard of the Intangible Cultural Heritage (2003), the FAO ITPGRFA (2001) and in the WIPO IGC process.

60 Law 29875 on the Right to Prior Consultation to Indigenous Peoples (2011) and its regulation. La Republica Pe (2011).

61 See Article 12 of the Nagoya Protocol.

62 See ILO Convention 169 on Indigenous and Tribal Peoples of 1989 (ILO, 1989).

63 UNCTAD (2016e).

64 For an in-depth discourse on patents and the public domain see WIPO (2011).

SECTION 8.
MOVING FORWARD: ABS AND BIOTRADE CERTIFICATION SCHEMES, STANDARDS, METHODOLOGIES AND BEST PRACTICES

8.1 Certification schemes

Certification schemes assist in harmonizing products and processes, improve market access and commercialization at different stages of the value adding chain and R&D processes, especially in the case of BioTrade projects and related businesses.

Certification and verification schemes are mostly private and based on the application of private standards (e.g. through Ethical BioTrade, Fair Trade, Fair Wild or the Forest Stewardship Council). However, some certification schemes can also be set and managed by governmental entities. An example is the United States Department of Agriculture (USDA) organic labelling scheme in which the standard set by USDA and the certification is undertaken by a private accredited agent.[65]

Owing to certification trademarks, product certification schemes have become a way to share information about certain features of goods and services, such as their environmentally sound production process, the sustainability of harvesting activities, safety or whether socially responsible approaches to price setting are implemented, to name a few. Policymakers should understand and, if possible, encourage these mechanisms within BioTrade frameworks as a means to support overall *in situ* conservation of native species and sustainability in projects and businesses. Such a link with *in situ* conservation would promote local production, sustainable harvesting and avoid delocalization of the activity.

Figure 8.1 Certification scheme examples

Sources: https://www.usda.gov/topics/organic (accessed August 2017) http://www.fairwild.org/labelling/ (accessed August 2017) https://utz.org (accessed August 2017) https://ec.europa.eu/agriculture/organic/index_en/ (accessed August 2017) http://www.pgsorganic.in (accessed August 2017)

Participatory guarantee systems (PGS) operate in the same way but the certification process is undertaken directly by local communities, often small farming associations, following certain standardized practices in cultivation, production, seed preservation, storage and commercialization. This system caters mainly to local and regional markets, and is encouraged through the former International Federation of Organic Agriculture Movements (IFOAM), now Organics International.[66] This later certification scheme is present in 72 countries and involves almost 110 000 farmers worldwide.

Many of these certification schemes have a long-standing tradition of operations in many countries and can serve to orient policy or legal developments at the national level, as well as regulators in the implementation of permitting and other administrative requirements, which may be in place. To incentivize these schemes, fast track procedures and pooling applications by small producers may be considered if, for instance, certification schemes are used in a value chain or R&D.

8.2 The Ethical BioTrade Standard

Developed in 2007 and revised in 2012, the Ethical BioTrade Standard[67] builds on the BioTrade Principles and Criteria developed by UNCTAD as the foundation for addressing environmental, social and economic considerations in biodiversity-based products and services. The Ethical BioTrade Standard is designed to advance the objectives of the CBD and the recently agreed SDGs. For example, the Ethical BioTrade Standard requires sustainably managing plant species sourced; maintaining or restoring the ecosystems in which sourcing activities take place; paying equitable prices for natural ingredients; and complying with legal and ethical requirements on access to genetic resources and ATK, and fair and equitable sharing of benefits resulting from their utilization. The Ethical BioTrade Standard applies to the framework of policies, processes and procedures that companies apply to the sourcing of natural ingredients in the food, cosmetics and natural pharmaceutical sectors. It covers different stages of the supply chain of natural ingredients, from their collection or cultivation to applied research, product development, manufacturing and commercialization.

Box 10. The UEBT Standard operating procedure in practice

Assurance system

The Union for Ethical BioTrade (UEBT) uses a combination of self-assessments and second- and third-party audits to assess compliance with the Ethical BioTrade Standard. Companies wishing to join UEBT undergo an external audit that verifies compliance with entry indicators. The audit also assesses whether and how the company's management systems address issues in the Ethical BioTrade Standard. This initial audit thus sets the basis for the implementation of the standard.

Companies are then asked to develop short- to medium-term goals and concrete work plans for implementing the Ethical BioTrade Standard. For example, work plans may address gaps in the biodiversity management system, which should ensure that the Ethical BioTrade Standard is gradually implemented for the natural ingredient portfolio. The work plan may also focus on priority supply chains, for which – in light of strategic priorities or biodiversity-related risks – the Ethical BioTrade Standard, is implemented. The work plan must be approved by UEBT. Companies report annually on their progress, and undergo external audits every three years. Audits focus on whether a biodiversity management system exists, is applied and entails practices in line with the Ethical BioTrade Standard at the field level. UEBT member companies also have the opportunity to certify compliance of selected supply chains against the Ethical BioTrade Standard. This is a way to assess and provide market recognition for efforts focused on specific supply chains.

The assurance scheme for the UEBT supply chain certification programme involves an internal monitoring system, as well as external controls. The internal monitoring system is implemented at the level of the organization holding the UEBT certification, as a tool to ensure that local suppliers of certified natural ingredients comply with the Ethical BioTrade Standard. This internal monitoring system is subject to annual audits, conducted by independent and qualified certification bodies.

The UEBT membership logo is used in corporate communication and cannot be included on final product packaging. However, the UEBT certification programme allows UEBT members to make claims for natural ingredients that originate from certified supply chains that are in compliance with the Ethical BioTrade Standard. These claims can be made on final consumer products. Moreover, for the certification of herbal teas, UEBT and UTZ (label and programme for sustainable farming certification) have entered into a collaboration in which UTZ recognizes the UEBT certification (with some supplementary UTZ requirements) and allows for on-product use of the UTZ label. UTZ remains responsible for surveillance on the use of the label and for the chain of custody.

Source: UEBT (2017).

8.3 UNCTAD methodologies, guidelines and best practices

UNCTAD has developed a series of methodologies and best practices compilations to apply and enable better implementation of BioTrade Principles and Criteria. These are not private standards per se but compilations of bottom-up best practices and experiences applicable to certain key issues and aspects of the development of BioTrade value chains including ABS, Reducing Emissions from Deforestation and Forest Degradation (REDD+) in specific projects, resource assessment, etc. These methodologies and best practices can be applied by both public and private sectors. Many of these have been developed based on experiences in implementing BioTrade in national and regional programmes, for example Global Environment Facility (GEF) projects, Development Bank of Latin America (CAF) programmes, and country strategies such as in Peru, Ecuador and Colombia. They could then inspire further development of certification schemes and private standards on BioTrade. UNCTAD BioTrade has created and developed methodologies and guidelines including:

- Facilitating BioTrade in a challenging benefit sharing environment (2016)[68]
- Training manual on developing joint Biotrade and REDD+ projects (2015)[69]
- Guidelines for the sustainable management of BioTrade products: Resource assessment (2012)[70]
- Guidelines for the development and implementation of management plans for wild collected plant species used by organizations working with Biotrade (2009)
- Guidelines for a methodology to support value chains for BioTrade products (2009)[71]
- Applicability of traceability systems for CITES-listed medicinal plants (Appendices II and III) – Andean and other Latin American countries: Preliminary assessment (web-based) (UNCTAD/WEB/DITC/TED/2016/8)
- Applicability of traceability systems for CITES-listed medicinal plants (Appendices II and III) – Greater Mekong: Preliminary assessment (UNCTAD/WEB/DITC/TED/2016/7)
- Applicability of traceability systems for CITES-listed medicinal plants (Appendices II and III) – Greater Mekong: Preliminary assessment key findings (UNCTAD/WEB/DITC/TED/2016/5).
- Additionally, BioTrade partners in Africa, Asia and Latin America have also developed a variety of guidelines and best practices studies for implementing BioTrade in a variety of sectors such as food, personal care, phyto-pharma and sustainable tourism, among others.

IN FOCUS

FOR POLICYMAKERS

- Certification schemes and standards, whether public or private, convey important information to consumers on key features of products and production processes.
- Depending on the case, certification schemes and standards can support the application and verification of UNCTAD's BioTrade Principles and Criteria.
- There is a specific standard that developed from BioTrade Principles and Criteria: the UEBT Standard.
- The use of UNCTAD methodologies and best practices compilations can support the further development of standards, national strategies and regulations when seeking conservation and sustainable use and applying ABS.
- UNCTAD and other national and regional partners have developed a series of tools and materials which may serve policymakers to understand and develop national measures in the realm of certification and standards as they apply to genetic resources and biodiversity-related products and innovations.
- If there is an interest in the development of national BioTrade strategies or to introduce incentives to BioTrade activities or companies, the application and verification of BioTrade-related standards could be a secure way to identify such activities and companies.

FOR REGULATORS

- The use of specific organic and biodiversity-related standards can evidence compliance with mandatory regulatory requirements, including on ABS.
- Regulators should consider the value of evidence provided by these schemes when granting bioprospecting permits, negotiating ABS contracts, verifying qualities or special features of products, and issuing sanitary and commercialization permits.
- Whilst these standards may be private in most cases, procedures and companies seeking voluntary compliance and verification may be in a better position to comply with regulatory requirements.

Notes

65 USDA (2016).
66 IFOAM (2017).
67 For further details see UEBT (2017).
68 UNCTAD(2016e).
69 UNCTAD (2015).
70 UNCTAD (2012a).
71 UNCTAD (2009a).

SECTION 9.
THE EMERGING IMPORTANCE OF INTELLECTUAL PROPERTY IN ABS AND BIOTRADE PROJECTS AND BUSINESSES

Intellectual property[72] and its different tools,[73] especially patents, breeders' rights, trademarks and GIs can offer opportunities to protect innovations along a value chain, protect and promote brands and reputation and improve market access and opportunities.[74]

BioTrade companies tend to rely on the use of IP tools, especially at the higher end of the value chain. Whilst most companies that make use of IP are today located in developed nations this is slowly changing as BioTrade companies in Latin America, Asia and Africa have started to develop their own branding, innovation and R&D strategies and are actively seeking to protect their intangible assets through patent, breeders' rights certificates and trade secrets.

Whilst classic innovation and creative works can be protected through positive means (i.e. an IP regime that asserts specific rights such as a patent or breeder's right), in the case of genetic resources and ATK, these (or protectable innovations thereof) can be protected both *positively*[75]and *defensively* (see Box 9). Requirements in IP or biodiversity laws to disclose origin or sources of genetic resources or ATK used or "embedded" in a protectable innovation would be an example of defensive protection. The system and rules are used "defensively" rather than to assert a specific right.[76]

9.1 Positive protection through patents and breeders' rights

Patents and breeders' rights are often used to protect technological inventions and plant varieties based on genetic and biological resources (e.g. a new active ingredient or molecule, a new biotechnological process, or a new seed variety with higher productive yields). Patents and breeders' rights usually become more relevant downstream along the R&D chain as interesting results are obtained. To protect an innovation through a patent or a new plant variety through breeders' rights certain criteria and requirements need to be met and verified by a national IP authority. Patent and breeders' rights are not granted automatically though; they have to be requested by filing an application to the relevant authority. As an example, for an invention to be patentable, it must be new, involve an inventive step and be capable of industrial application. For a plant variety to be protectable through a breeders' right, it has to be new, distinct, uniform and stable. For both rights, further administrative requirements may apply which vary depending on the relevant national laws. Upon examination and successful application, titles (protection) are granted by an IP or industrial property authority and seed authority respectively.

The case of Bioprocol, Bioprocesos de Colombia S.A.S. - Biodiverse Chemistry - (Annex 3) and Ecoflora on natural dyes from *Genipa americana*[77] are examples of how innovation strategies can be developed and patents can be applied whilst also fulfilling ABS requirements of national and regional legislation. In both cases the companies involved secured ABS contracts and permits with national authorities and with IPLCs. They also applied R&D to transform promising active ingredients and natural dyes as tools for obtain a first mover advantage in the market.

In the case of IPLCs, policymakers should acknowledge the general view that patents and plant breeders' rights may not be the ideal alternative to safeguard their larger economic and moral interests in respect of their own and collective biodiversity-related innovations and creations.[78] IPLCs tend to be more keen on developing *sui generis* ("of their own") systems and contractual alternatives based on customary law principles that better suit their priorities and the specificities of traditional knowledge and their type of creations. More than 20 countries have specific *sui generis* and traditional knowledge regulations are not uncommon, for example Andean countries (1996), Guyana (2006), Peru (2002), Panama (2000), Portugal (2002), South Africa (2004) and Thailand (1999).[79] When they exist and when ATK is used in the value chain, BioTrade companies will also need to comply with those laws besides those on ABS (see Section 7).

9.2 Positive protection through geographical indications and collective marks

Geographical indications (GIs) are commonly used to promote biodiversity-related products (goods) with unique features expressed in their origin, method of production or ecological characteristics of the area where they are produced (e.g. a type of fruit, a honey or a derived natural product such as a beverage or a dairy product). According to the definition set out in Article 22 (Protection of Geographical Indications) of the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, a geographical indication "identifies a good as originating in a specific place, when a given

quality, reputation or other characteristic of the good is essentially attributable to its geographical origin". As this linkage is generally based on local resources and know-how, the recognition and protection of GI may also be an effective tool to conserve these resources and know-how by allowing the preservation of practices and sustain some income-generating livelihoods for the IPLCs.

The state (depending on national legislation), often becomes the titleholder of the GI whilst application and verification of the conditions and standards is done by an association of producers (usually called "regulatory council"), a national authority or private entities, resulting in a diversification of institutional arrangements among countries.

In the case of collective marks, the product is also distinguished by its origin and site specific ecological and cultural and historic features, but it is the group of producers or members of the association who owns the collective mark and allows its use according to a set of self-imposed mandatory bylaws and standards. Collective marks enable producers to identify the manufacturing origin (producers), methods or production and material, undertake collective marketing of products, and to appear as the holders of the respective right.

There are cases where IPLCs may choose to use a collective mark over a GI to protect their biodiversity-based products. This is the case of the *chirimoya* of Cumbe.[80] The *chirimoya* is a fruit native to the Andes *(Annoma cherimola)* with particular organoleptic properties and nutritional values.

Whilst in the beginning, some producers in Cumbe village wanted to have a GI to protect fruits originated in the village and surroundings, later they preferred the option of collective trademarks in order to keep full ownership and control over the mark. In this case, the producers applied for a collective mark, developed their own logo and their own production and handling requirements thereafter.[81]

Both GI and collective marks are tools that imply a relatively close connection between producers, national and even international markets, which means a degree of sophistication in the value adding chain and commercialization stage which may not necessarily be such a common feature in most IPLCs. How IPLCs interact with markets is very diverse from country to country and even within countries, especially in regard to international markets where these tools are most valuable.

Geographical indications, certification and collective marks, whilst different in their nature, could also provide IPLCs with a type of protection which improves their relation and interaction with the market. They can be used to identify the particularities of products and their geographical and manufacturing origin. For example, Ecuador, Peru and Cameroon have been actively using GI to protect food-related BioTrade products such as the "cacao Arriba", "mais Guigante del Cusco"[82] and "Oku white honey".[83] The same has occurred in countries like Switzerland with the case of the Geneva thorny cardoon. Two of these examples are presented in detail in Box 11.

Figure 9.1 Chirimoya Cumbe collective mark

Source: Images from the "XXI Festival de la Chirimoya de Callahuanca, 2016"

Box 11. Geographical indications: The Ecuador and Switzerland experiences

Building capacity for the creation of an appellation of origin: The case of cacao de Arriba

UNCTAD's BioTrade Initiative, WIPO and the Secretariat of the Andean Community joined forces to support countries in the Andean region to discuss and assess the feasibility of utilizing GI to protect, promote and market native biodiversity products such as cocoa "Arriba" during the period 2005–2008. The support consisted of feasibility, environmental and organoleptic studies, exchange of information among producers and discussions on lessons learned on similar cases. Guidance on next steps needed to obtain the appellation of origin (AoO) was also provided. The term "Arriba" refers to the cocoa produced on the upper basin of the Guayas River where some of the finest and most aromatic cocoa of Ecuador is produced.

After two years of work by the BioTrade programme in Ecuador, jointly with the support of producers' associations (UNOCACE, FEDECADE), sector associations (ANECACAO), the Ecuadorian Intellectual Property Office (IEPI), and Ecuadorian research organizations and individual producers, the AoO for cocoa "Arriba" was obtained in 2008. Many cacao Arriba producers applied BioTrade Principles and Criteria and several of those principles made it into the production and quality standards of the AoO.

"Cacao Arriba" became the first of its kind issued in Ecuador. This appellation was built on the worldwide reputation of the product that is based on its unique combination of geographical, historic and human factors. Cocoa "Arriba" is an important product for the country's economy as it generates significant export revenues, it is a sustainable source of local employment, and contributes to the conservation of biodiversity via agroforestry. The first authorized use of the AoO cocoa Arriba was issued by IEPI in 2014.

Source: Ecuadorian Institute of Intellectual Property (IEPI), 2017

Using geographical indications to protect local plant varieties: The Geneva thorny cardoon

Registered as a protected appellation of origin (PAO) in 2003, this vegetable is similar to the artichoke, but cultivated in a different way in order to get fleshy stems (not the flowers). The local plant variety is closely linked to the history of Geneva, as it was introduced by French Huguenot refugees and then selected through centuries to maintain the thorny character that corresponds to the local traditional preference and distinguishes this cardoon from the cardoons originating in other regions. As most Geneva cardoons are now commercialized in prepared form, the thorns cannot be seen by the consumers who must rely on a label guaranteeing the authenticity of the thorny local variety. Geneva's 100- to 130-ton production per year of thorny cardoon is presently produced by 10 producers. The recognition as a PAO supported the efforts to maintain this very labour-intensive production based on specific local know-how to select, grow and bleach the cardoon. Being the traditional dish served for and around Christmas in Geneva, this vegetable is strongly linked to the local Swiss identity. By developing ready-to-cook and preserved PAO Geneva thorny cardoons, the producers aim at not only making authentic cardoons available to local consumers but are also expanding the market in order to support the sustainability of this heritage. From an endangered local tradition, the collective dynamics and visibility based on the AoO are allowing consumers further afield to enjoy this delicacy.

Sources: Prepared by UNCTAD and the Swiss Federal Institute of Intellectual Property (2016). See UNCTAD (2012b); IEPI (2014), Las denominaciones de origen a través de la historia; IEPI (2014), IEPI entrega primera autorización de uso de DO Cacao Arriba. Image: http://www.aop-igp.ch (accessed August 2017)

Geographical indications, certification and collective marks can serve to support sustainable use of biodiversity and its components at a local scale, as it is precisely biodiversity (at the ecosystem or species level) which makes the goods or service valuable and different in the first place. This effect can be observed either at the scale of one or several species, plant varieties or animal breeds, when they are the essential basis of the goods, or at the scale of a whole ecosystem, and, in most cases, at both scales. They may also have a positive effect on ATK for the same reason: there may be a positive incentive to continue using traditional techniques or know-how to fabricate, produce or harvest particular goods. A comparison on the nature, content and legal nature of GI, collective and certification marks is presented in Table 9.1.

Policymakers should ensure that BioTrade and ABS frameworks allow for the necessary flexibilities to accommodate both GI, certification and collective marks, not only as a potential option to improve market access and commercialization of certain biodiversity goods and products, but also as evidence of genuine origin-related products and good practices along value chains.

9.3 Defensive protection within the IP system

Defensive protection means using the rules and principles of the IP system particularly in the case of patents and breeders' rights, to ensure that the interests and rights of countries of origin and IPLCs over their biodiversity and ATK are safeguarded through the granting of legitimate and "good" patents or breeders' rights.[84] Defensive protection may contribute to the mutually supportive implementation of IP and ABS regimes, and further secure legal certainty for both providers of biodiversity components and traditional knowledge, and creators and innovators (users). Defensive protection will only operate in cases where R&D and breeding processes derive a patentable product or new plant variety.[85]

Policymakers may want to consider the value and use of mechanisms for disclosing the origin, source and/or legal provenance of genetic/biological resources and relevant ATK within the IP system (specially on patents and breeders' rights) as a means to enhance transparency, ABS compliance, and/or as one potential checkpoint as provided for by the Nagoya Protocol.[86]

Table 9.1 A comparative analysis of key features of geographical indications, certification and collective marks

	Geographical indications	Certification marks	Collective marks
Subject matter	Only applicable to goods	Applicable to goods and services	Applicable to goods and services
Rights	Mixed rights (public/private). The identification belongs to the State and the administration corresponds to the regulating council (producers) Any producer in the area whose production fulfils technical standards can use the geographical indication Homonymous GI has a regulation	Private right. The property and the administration belong to a certification association/certifier Access to owners or certified users (those who comply with the standard) Homonymous issue does not exist. There must be just one right holder	Private right. The property and the administration belongs to an association of manufacturers or producers Access might be limited by "owners or members of the association" Homonymous issue does not exist. There must be just one rights holder
Protection	Protects real identification of the origin and its link with quality and reputation Based on ex officio and private actions There is no automatic collateral protection	Certify quality, characteristics, origin, materials, methods, etc. Protection is based on private actions There is usually collateral protection. Protection against use in other products (e.g. T-shirts and mugs)	Certify the individual industrial and manufacturer source of the goods or the services Based on private actions There is collateral protection
Term of protection	From date of registration up until the conditions that create them persist	Must be renewed after a certain period. Fees have to be paid for each renewal	Must be renewed after a certain period of time. Fees have to be paid for each renewal

Source: Vivas Eugui D (2017).

There is already some experience on the introduction and use of this type of mechanism with different scope, features and levels of enforcement and its utilization in several countries including the Andean countries, Brazil, Costa Rica, European Union, India, Norway, Panama, South Africa, Switzerland and Viet Nam.[87]

In some cases, e.g. Domenican Republic, Germany Kenya, Peru and Switzerland, IP offices are listed among the checkpoints notified under the ABSCH.[88] Examples on how Peru and Switzerland apply this mechanism are presented in Box 12.

Box 12. Countries with checkpoints at patent offices

The Andean Community and Peru: Decision 391 of the Andean Community on a Common Regime on Access to Genetic Resources (1996) was the first legal framework to include an IP checkpoint to verify compliance of national legislation with ABS and ATK laws and regulations. Decision 391 essentially indicates that Member States will not recognize IP rights in cases where genetic resources, derivatives and ATK were accessed or obtained without complying with the requirements set by the decision (Second Complementary Provision). Furthermore, national IP offices will request from the patent applicant that evidence (i.e. the ABS contract or the certification of legal access) is provided accordingly (Third Complementary Provision).

In 2001, the Andean Community enacted Decision 486 on a Common Regime on Industrial Property, which became the first IP norm to expressly include references to ABS and ATK legislation and to create a condition in the granting of IP rights (in general) to comply with national ABS and ATK rules (Article 3). Decision 486 also specified that in cases where these requirements were not met, patents could be revoked (Article 75).

For the official receiving the patent application it is not immediately evident that there may be a need for consideration of ABS and ATK dimensions. This may require an initial analysis of the content of the patent to identify the sector or industry or innovation to determine if there may be need to demand an ABS contract. Secondly, a key condition for the checkpoint to operate is that the ABS and ATK regimes (Decision 391, the national regulation of 2009 and the law for the protection of ATK of 2001) are being effectively implemented and administrative procedures in these realms are streamlined.

In the particular case of Peru, about 40 patents have been checked by the national authority (INDECOPI) for potential utilization of genetic resources and derivatives. Among these applications, three patents have been granted. One was the result of presentation of required evidence (i.e. dossier 654-2011/DIN for a new natural blue dye derived from *Genipa americana)* and other two did not need to have an access contract as the activity in question did not imply "utilization" of a genetic resource or a derivative. In the case of the blue dye from *Genipa americana*, it is important to note that this patent was filed by Ecoflora, a BioTrade company that has legally obtained their access contract and ATK licences in Colombia. Ecoflora have applied for the patents for the same invention in several jurisdictions including in the Andean countries and the United States of America.

Switzerland: Switzerland introduced a declaration of source requirement in the Federal Act on Patents for Inventions (PatA) in July 2008. Article 49a states that the patent application must contain information on the source of a genetic resource, to which the inventor or the patent applicant had access, provided the invention is directly based on this resource. Similarly, the patent application must contain information on the source of traditional knowledge of IPLCs associated with genetic resources, to which the inventor or the applicant had access, provided the invention is directly based on this knowledge. Article 59 para. 2 states that if the patent application does not meet the disclosure requirement, the Swiss Federal Institute of Intellectual Property (IPI) shall set a time limit for the patent applicant by which this deficiency must be remedied. The IPI shall reject the patent application, if this deficiency is not corrected in a timely manner (Article 59a para. 3). Moreover, if the patent applicant intentionally makes a wrongful declaration according to Article 49a, they shall be liable to a fine of up to 100 000 Swiss Francs, and the judge may order the publication of the ruling (Article 81*a*).

This declaration of source requirement was introduced in order to increase transparency relating to the specific genetic resource and/or associated traditional knowledge in inventions which are directly based on such resources or on such knowledge. The measure is envisaged to support compliance with the ABS regulatory requirements of other countries. The IPI can therefore be regarded as a checkpoint per Article 17 of the Nagoya Protocol, which specifically states that checkpoints would collect or receive information related to, among others, the source of genetic resources. For that purpose, Switzerland included: (i) a due diligence requirement for those utilizing genetic resources and/or associated traditional knowledge; and (ii) a notification requirement before market authorization or commercialization of products developed on the basis of utilized genetic resources and/or associated traditional knowledge.

In the context of "BioTrade", it is worth noting that the above-mentioned measures do not apply to genetic resources that are classified as commodities or goods in trade not utilized as genetic resources as defined in the Nagoya Protocol (Article 23n para. 2 letter f, Federal Act on the Protection of Nature and Cultural Heritage [NCHA]). However, they would apply, if there was a change towards "utilization" as defined in the Nagoya Protocol, provided that access took place after 12 October 2014 in a Party to the Nagoya Protocol which had ABS regulatory requirements in place.

The declaration of the source according to the PatA and the due diligence and notification requirement in the NCHA are mutually supportive measures. The information which has to be recorded, kept and transferred to subsequent users according to the due diligence requirement allows for the relevant information relating to the source of genetic resources and/or related traditional knowledge to be more readily available to patent applicants without additional efforts or costs involved. Similarly, the enhanced transparency due to the declaration of the source requirement in the PatA will facilitate the implementation of the due diligence requirement in the NCHA. Moreover, the declaration of source also assists providers of genetic resources to verify whether specific users have obtained PIC, if so required, and whether they complied with the obligations agreed in an ABS contract.

In summary, the declaration of source in the PatA serves to increase transparency in patent applications, whilst the due diligence and notification requirements according to the NCHA serve to implement the "user compliance obligations" of the Nagoya Protocol. This allows a coherent and cost-efficient approach to implement the Nagoya Protocol across all sectors, no matter whether patent protection is involved or not. The Nagoya Protocol is an instrument developed under the CBD, and in many countries, the know-how, competence and resources to implement its provision remain within environment ministries. Therefore, it might be more appropriate to implement the provisions of the Nagoya Protocol outside of the patent system in other fields of law, and to ensure mutual supportiveness between these measures and the disclosure requirement in the patent system.

Sources: UNCTAD (2016e); INDECOPI (2016), La Experiencia del Perú en su rol como punto de verificación en las solicitudes de patentes nacionales; and IP Watch (2016), Access and benefit sharing mentioned in United States patent for natural dye, might be a first.

Case of Switzerland: Swiss Federal Institute of Intellectual Property (2016); Federal Act on Patents for Inventions (PatA, 2008); Federal Act on the Protection of Nature and Cultural Heritage (NCHA, 2014) (see, in particular, Articles 23n, 23o, 23p, 23q, 24a para. 2, 24h para. 3, and 25d NCHA); and Ordinance on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (2016).

In terms of regulators and depending on national legislation, patent officials may need to verify if applicants have provided information regarding the origin, source, and whether ABS or ATK permits or contracts and IRCCs support the patent application as evidence of compliance with national ABS frameworks, specifically in the case of innovations related to natural products or biotechnology. This activity by IP offices supports the implementation of the Nagoya Protocol. It should be noted that not all

R&D on genetic resources ends in IP (usually patent) application; many benefits (including non-monetary benefits) may arise throughout the R&D process. This is particularly relevant in the case of BioTrade as most of the activities undertaken so far are more related to the manufacture and processing of biological resources than R&D on genetic resources per se.

To ensure procedures are streamlined, there is a need expressly state in the law or through regulatory guidelines, under what particular circumstance the relevant information and/or evidence is required.

This may involve asking questions such as:

- Is the information provided sufficient to comply with disclosure or due diligence (these are two different requirements) and whether they are in place?
- What is the exact role of the IP office; is it (i) to verify compliance with ABS regulatory requirements? or (ii) to perform transparency functions in the context of genetic resources and ATK in patent applications?
- How does the IP office notify the ABS national focal point when information is relevant for ABS verification?
- Are there more specific considerations which may enable regulators to better focus on a certain type of innovation (e.g. biotechnology inventions)?

Countries may have different approaches and experiences when addressing these issues. The "checkpoint communiqué' under the ABSCH is a key tool in helping answer such questions.

BioTrade companies need to consider that if they apply for patents or other IP rights in countries with IP or other checkpoints (e.g. European Union), they will need to present evidence on the origin, sources and/or legal provenance. This is particularly the case in several other countries where BioTrade projects exist, including Andean countries, Brazil, Mexico, South Africa and Viet Nam – such jurisdictions also having different forms of ABS regimes in place.

***Genipa america*, source fruit (genetic resource) of the natural blue dye isolated by Ecoflora Cares (see Box 12)**

Sources: UNCTAD (2016a). Photograph www.flicker.com under creative common license https://creativecommons.org/licenses/by/4.0/

IN FOCUS

FOR POLICYMAKERS

- Understanding the real implication of different IP instruments as applied to innovations and creations as well as goods and services, as they relate to biodiversity and ATK, is critical to manage expectations of key actors, such as IPLCs.
- There is a general consensus that patents and plant breeders' rights may not be the ideal alternative to safeguard the larger economic and moral interests of IPLCs.
- The IPLCs tend to favour their own systems and contractual alternatives based on customary law principles that better suit their priorities and the specificities of ATK as it relates to them and their creations/products.
- Measures in IP and patent laws may be needed for a coherent implementation of the Nagoya Protocol as they complement verification action by ABS national focal points and other checkpoints.
- Implementation of ABS and ATK frameworks at the national level is a pre-condition for checkpoints to fulfil their roles.
- Offices granting patents and plant breeders' rights may be selected as checkpoints and therefore be asked to guarantee levels of transparency, supportiveness and complementarity between ABS and ATK regimes and patent and plant breeders' frameworks.
- Clarifying in the law as far as possible the precise circumstances and situations where IP authorities may need to request the source/origin, ABS contracts or the IRCC is critical to ensure effective and efficient operations when appointed as checkpoints and implementing defensive protection measures.
- Defensive measures within the patent system will by themselves not be sufficient to implement the provisions of the Nagoya Protocol. Many genetic resources as well as associated traditional knowledge are utilized without leading to patent protection, for instance in non-commercial research projects and in the sector of natural remedies or natural cosmetic products.

FOR REGULATORS

- Intellectual property tools such as patents and breeders' rights can be used to protect R&D outcomes. However, applicants need to not only comply with IP requirements but also with ABS and ATK laws and regulations in the countries where the filing is made.
- Geographical indications and collective marks can play a significant role in protecting origin-related names and their reputation and to collectively market BioTrade and biodiversity-derived products and services. Their wider use should be enabled and encouraged.
- Coordination between ABS, ATK and IP authorities is necessary to ensure appropriate flows of information and consultation possibilities between them, thereby contributing to coherence in implementation of rules and procedures.

Notes

72 For detailed analysis of the relations between IP, biodiversity and ATK, see UNCTAD (2014).

73 Intellectual property, broadly, confers a temporary, monopolistic right to a person (natural and legal) who generates an innovation and complies with a set of criteria, which allows this person to exclude unauthorized persons from, among other activities, using, commercializing, exporting the protected innovation.

74 BioTrade Criteria 6.1 specifically requires that IP and the value of traditional knowledge should be respected.

75 Positive protection usually refers to the use of IP instruments to protect intangible assets. Positive protection of biodiversity related goods and services may offer the potential to add value to biodiversity products and innovations and improve benefit sharing opportunities for different actors along value chains. IP tools help in keeping control over assets that could have a strategic purpose in the positioning and marketing strategy of companies and actors within a value chain.

76 Debates about disclosure of origin, source and/or legal provenance of genetic resources and traditional knowledge can be traced back to the early 1990s. At the time, a small group of academics deliberated on ways to link ABS with the IP system in a more positive manner. Debates at the time where dominated by arguments which highlighted the negative effects of patents over biodiversity in general, and the "biopiracy" phenomenon in particular. Although the Andean framework is often recognized as the pioneering legislation in regard to IP checkpoints, it was a Peruvian regulation (Supreme Decree 008-96-ITINCI, of 1996) on plant breeders' rights that first established a specific checkpoint to ensure national ABS and traditional knowledge related regulations were complied with before granting a right. In practice, the national IP authority (INDECOPI) has been facing considerable challenges in implementing its checkpoint role.

77 See Box 3, case study on BioTrade and ABS: A natural blue colorant derived from *Genipa americana*, in UNCTAD (2016e).

78 McManni C and Teran Y (2011).

79 For further examples, see Chapter 5, Protecting traditional knowledge, UNCTAD (2014).

80 A region in the northeast of Peru.

81 INDECOPI (1999).

82 https://www.indecopi.gob.pe/web/signos-distintivos/denominaciones-de-origen-nacionales (accessed 10 June 2017).

83 WIPO (2017).

84 For a good, detailed summary of the different implications of defensive protection and disclosure see, Chouchena-Rojas M, Ruiz M, Vivas D, Winkler S (2005).

85 There is an extensive and well researched literature regarding "defensive protection". See for example, WIPO (2003), Practical mechanisms for the defensive protection of traditional knowledge and genetic resources within the patent system. WIPO/GRATKTKFF/IC/5/6. http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_5/wipo_grtkf_ic_5_6.pdf (accessed 10 June 2017).

86 Article 17 of the Nagoya Protocol.

87 See UNCTAD (2014).

88 See list of notified checkpoints under the ABSCH at: https://absch.cbd.int/ (accessed 10 June 2017).

GLOSSARY

Note: This glossary is only provided for the purposes of this handbook. The definitions herein may evolve and vary significantly from one national/regional context to another.

Access and benefit sharing

Process through which, as a result of accessing biodiversity components (e.g. specimens, samples, biochemicals), genetic resources and related traditional knowledge, and using them in research and development or value chains, the different types of benefits generated thereby are shared fairly and equitably between the provider and user. The CBD has developed an information kit that can provide additional information on terms and glossary presented in a user-friendly manner.[89]

Adaptive management

Adaptive management allows for the implementation of corrective measures in systems on an ongoing basis, based on a process of continued monitoring. This type of management allows for the appropriate adjustment of the productive processes, including modification or suspension of activities that are affecting the populations and their habitat. Adaptive management should be practiced, based on:

- Science, and traditional and local knowledge.
- Iterative, timely and transparent feedback derived from monitoring the use, environmental, socioeconomic impacts, and the status of the resource being used.
- Adjusting management, based on timely feedback from the monitoring procedures.

Applied research

Original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific, practical aim or objective (Organisation for Economic Co-operation and Development [OECD]).

Basic research

Experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view (OECD).

Biochemical composition

Commonly perceived as the result of studies that provide details upon the chemical nature of biomolecules (or biochemical compounds) that are present in a substrate together with their biological functions in this substrate, which are determined by the types of interaction processes that occur between the identified biomolecules. An example of a biochemical processes would be all interactions between biochemical compounds that define the photosynthesis, and the one of a biochemical compound would be the chlorophyll or the glucose respectively participating or generated by such processes.

Biochemical compound

Any compound that contains carbon and is found in living things. Usually biochemicals are classified as under four classes: carbohydrates, proteins, lipids (fats) and nucleic acids.

Biological diversity

The variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems (CBD).

Biological resources

Include genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity (Article 2, CBD).

BioTrade initiatives/projects/companies

Business ventures in different stages of development headed by economic actors (communities and community-based associations, among others) that meet the BioTrade Principles and Criteria (UNCTAD).

BioTrade products and services

BioTrade activities are generally oriented towards the production, transformation and commercialization of products derived from the sustainable use of biological resources, or the provision of services derived from such resources. BioTrade products may include those coming from wild collection or from cultivation practices. The latter refers to products derived from cultivation of native species (domesticated and wild varieties) through activities such as agriculture or aquaculture. Products derived from wild collection include products such as fauna (e.g. ornamental fish), fauna derivatives (e.g. crocodile leather or meat) and flora (e.g. medicinal plants, flowers and foliage). Services include, for example, carbon sequestration and sustainable tourism (UNCTAD).

Community protocols
Tools which enable IPLCs to organize the management and conditions under which their natural resources, biodiversity, and ATK are used within communities and by third parties.

Country of origin of genetic resources
The country which possesses those genetic resources in *in situ* conditions (Article 2, CBD).

Biotechnology
Any technological application that uses biological *systems,* living organisms, or derivatives thereof, to make or modify products or processes for specific use (Article 2, CBD).

Decision makers
Persons or institutions responsible for designing and developing policy principles and frameworks in the subject matter of BioTrade and ABS.

Derivative
A naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity (Article 2, Nagoya Protocol).

Distinctive signs
Distinctive signs identify products or services in relation to their source, origin, quality, enterprise responsible for its commercialization, or other characteristics, and thus allow consumers to distinguish them from others in the same category. These signs protect against misappropriation or unauthorized use, aim to stimulate and ensure fair competition, and protect consumers by enabling them to make informed choices. Distinctive signs include trade names, trademarks and geographical indications (UNCTAD).

Ecosystem approach
A strategy for the integrated management of land, water and living resources that promotes conservation and sustainable use in an equitable way. Application of the ecosystem approach will help to reach a balance of the three objectives of the CBD. It is based on the application of appropriate scientific methodologies focused on levels of biological organization, which encompass the essential processes, functions and interactions among organisms and their environment. It recognizes that humans, with their cultural diversity, are an integral component of ecosystem (UNCTAD).

Experimental development
Systematic work, drawing on knowledge gained from research and practical experience and producing additional knowledge, which is directed to producing new products or processes or to improving existing products or processes (OECD).

Genetic material
Any material of plant, animal, microbial or other origin containing functional units of heredity (Article 2, CBD).

Genetic resources
Genetic material of actual or potential value (Article 2, CBD).

Indigenous peoples
Peoples in independent countries who are regarded as indigenous on account of their descent from the populations which inhabited the country, or a geographical region to which the country belongs, at the time of conquest or colonization or the establishment of present state boundaries and who, irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions (ILO Convention 169).

Local community
The human population in a distinct ecological area who depend directly on its biodiversity and ecosystem goods and services for all or part of their livelihood and who have developed or acquired traditional knowledge as a result of this dependence, including farmers, fisher folk, pastoralists, forest dwellers and others (United Nations Environment Programme-CBD).

Providers
Countries, persons, institutions or communities from where biodiversity components and genetic resources are accessed and obtained.

Regulators
Persons or institutions responsible for managing and implementing policy, legal and regulatory frameworks in the subject matter of BioTrade and ABS.

Research and development
An activity falls under the definition of R&D if it satisfies the following criteria:

A. Definition: "Research and experimental development (R&D) comprise creative and systematic work undertaken in order to increase the stock of knowledge – including knowledge of humankind,

culture and society – and to devise new applications of available knowledge".

B. Activity: Must in principle respond to the five (5) following qualifiers: "novel, creative, uncertain in its outcome, systematic, transferable and/or reproducible" (OECD).

Sustainable use

Sustainable use means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations (Article 2, CBD).

Traditional knowledge

Knowledge, know-how, skills and practices that are developed, sustained and passed from generation to generation within a community, often forming part of its cultural or spiritual identity (WIPO literature).

Users

Countries, persons or institutions that access and utilize biodiversity components, genetic resources and related traditional knowledge.

Utilization of genetic resources

To conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology (Article 2(c) Nagoya Protocol).

Valorization

Usually considered as a holistic approach that, through various utilization activities, national measures and IP tools, will enhance and provide additional values to biological resources.

Value chain

Relationships established between actors involved directly and indirectly in a productive activity with the aim of adding value in each stage of the value chain. A value chain involves alliances among producers, processors, distributors, traders, regulatory and support institutions, whose common starting point is the understanding that there is a market for their products and services. They then set out a joint vision to identify mutual needs and work cooperatively in the achievement of goals. They are willing to share the associated risks and benefits, and invest their time, energy, and resources into realizing these goals (UNCTAD).

Note:

89 For further information see the SCBD ABS Information Kit available at: https://www.cbd.int/abs/awareness-raising/default.shtml

ANNEX 1. BIOTRADE AND ABS: MEDICINAL PLANTS IN VIET NAM

The company

Traphaco SaPa is a Vietnamese company specializing in the sourcing and initial processing of natural ingredients for the Traphaco Group, the largest traditional medicine producer in Viet Nam. It also manages the cultivation of five medicinal plants (artichoke, *Polyscias fruticosa*, Convolvulaceae, Molluginaceae and *Ampelopsis cantoniensis*), which are the ingredients for Traphaco flagship products, representing 90 per cent of the volume of raw materials used, and are good agricultural and collection practices (GACP)-WHO certified.

The Traphaco Group has a range of commercial activities, including producing and trading pharmaceutical, cosmetics and food products. It also conducts R&D in these sectors. Indeed, over the past few years, the Traphaco Group has leveraged Viet Nam's biodiversity as well as the wealth of knowledge in Vietnamese traditional medicine to develop new herbal products. The Traphaco Group has hundreds of internal research projects, as well as collaborations with government institutions, including exploring and developing the gene pool of *Dioscorea persimilis* and *Coix lacryma-jobi,* two of the many valuable medicinal plants in Viet Nam.

Since 2013, the Traphaco Group has focused on its sustainable strategy called, "The Way of Green Health" which is based on the integration of economic efficiency, social responsibility, and environmental protection. 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 UEBT in 2014.

On BioTrade Principles and Criteria

As a UEBT member, Traphaco SaPa is committed to the BioTrade Principles and Criteria. It 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 R&D.

For example, with the support of the Helvetas Viet Nam BioTrade project, Traphaco SaPa focused on improving practices for the *Ampelopsis cantoniensis* supply chain, a medicinal herb described in many scientific books and journals in Viet Nam for treating gastric and intestinal inflammation. The project

Traphaco Group training farmers © BIG Viet Nam

assessed the socioeconomic aspects and the mapping of the actors in 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 group, supporting their organizational mechanisms, technical training and capacity development. Currently, Traphaco SaPa has agreements in place with both collector groups and local authorities which are linked to ethical practices.

Interface with ABS

As part of its work with UEBT, Traphaco SaPa received training on concepts and requirements linked to access to genetic resources and fair and equitable benefit sharing. Viet Nam's Biodiversity Law 2008 (BL 2008) establishes ABS requirements and procedures, which are further outlined in a 2011 decree. In 2014, Viet Nam became a Party to the Nagoya Protocol, providing the opportunity for the government to revise BL 2008 to reflect the provisions of the Protocol and streamline procedures which are seen as overly burdensome.

ABS approaches under discussion include naturally occurring biochemical molecules and compounds (e.g. vitamins or enzymes), as well as essential oils, extracts and other compounds obtained through processing biological or genetic material. Potentially, ABS requirements would thus apply to R&D in natural ingredients, which would be relevant for companies such as Traphaco SaPa and the Traphaco Group.

To date, companies engaged with BioTrade in Viet Nam have significant awareness of ABS issues, but limited experience. So far, only four requests for access to genetic resources have been received by the competent authorities in Viet Nam, and these requests cover only academic research. At least one of the companies involved in BioTrade projects, however, has expressed an interest in making a request for access to genetic resources in the near future.

Lessons learned

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 R&D of new natural ingredients. The project did not include direct relationships with traditional knowledge holders though. This may be due to the fact that traditional knowledge related to these plants is being widely used, known and shared throughout Viet Nam, making it difficult to define legitimate holders and potential benefit recipients for the relevant traditional knowledge.

Sources: UEBT, Helvetas Viet Nam BioTrade project, Traphaco Group 2015 annual report.

Polyscias fruticosa © Fotolia: photostockatinat

Ampelopsis cantoniensis © BIG Viet Nam

ANNEX 2. BIOTRADE AND ABS: *ECHINOPS GIGANTEUS* IN CAMEROON

The project

Thistle is a family of flowering plants easily recognized by its big spiny leaves and rounded head. In Cameroon, children use the tip of the *Echinops giganteus*, a species of thistle native to that part of Africa, as a football. Its roots are used as a spice in traditional dishes. Local people also use the flowers and leaves to treat a range of ailments.

In 2012, the French flavours and fragrances company V. Mane Fils (MANE) began exploring the aromatic properties of *Echinops giganteus*. In particular, the roots can be crushed and distilled to obtain the essential oil, or extracted with a supercritical fluid resulting in a woody, earthy extract. MANE considered the characteristic aroma of *Echinops giganteus* as potentially interesting to the perfumes sector. It also saw an opportunity to develop a supply chain based on ethical sourcing practices and to use the case as a pilot for ABS compliance.

Key actors

To advance the project, MANE collaborated with a local NGO, the Environment and Rural Development Foundation (ERuDef), which is already active in valorizing local plants as an alternative source of income for local communities. In particular, ERuDef was charged with identifying a local partner for the *Echinops giganteus* supply chain and ABS agreement. ERuDeF identified the Kingdom of Magha-Bamumbu, a region where the plant is widespread. In 2012, work to set up the *Echinops giganteus* supply chain, conducted in collaboration with ERuDef and the French NGO Man and Nature, began at the local level, conducting an inventory, developing sustainable production protocols and harvesting and drying of the roots.

Addressing the utilization of genetic resources required engaging the national government, particularly the Ministry for Environment, Nature Protection and Sustainable Development (MINEPDED). Cameroon has just very recently acceded to the Protocol and has not adopted legal or regulatory requirements on ABS.

As a result, the ABS Capacity Development Initiative, jointly with the project Regional Support for the Central African Forests Commission, were critical in bringing actors together and providing a platform for negotiations.

ABS agreements

Separate agreements were signed in relation to the research and commercialization phases. In May 2014, MANE and the MINEPDED signed a memorandum of understanding (MoU) highlighting initial research on *Echinops giganteus.* This MoU focused on information exchange and management, and reflected elements of both PIC and MAT.

In April 2015, the agreement for the commercialization of essential oils and extracts of *Echinops giganteus* was signed by MANE, the MINEPDED and the King of Magha-Bamumbu. In this agreement, considered as MAT, MANE guaranteed the annual purchase of 1000, 1500 and 2000 kilograms of dried roots from 2015 to 2017, with a fixed price of €4.10 per kg. MANE also pledged to share 25 per cent of profits directly attributed to *Echinops giganteus.* Such monetary benefits are to be deposited in a fund owned by the local community and managed by the King, who committed to disclosing the amount and use of funds for the benefit of the community. For example, with the initial funding provided by MANE, the Kingdom of Magha-Bamumbu created the Mount Bamboutos Echinops Co-operative Society and built drying stations for the plant material. Non-monetary benefits include recognition of the origin of the plant, a manual on good cultivation and sourcing practices, financing for local development projects, scholarship grants for local students (particularly women) and capacity-building activities.

Other BioTrade considerations

Part of ERuDef's involvement in the project was supported by the small grants programme of the GEF. The project included goals such as supporting local institutions and capacities for the sustainable management of the *Echinops giganteus* supply chain and the restoration of the forest landscape of Magha-Bamumbu. Project activities reflect many of the BioTrade Principles and Criteria. For example, over 200 people received training to enhance their organizational and management capacities, as well as on sustainable management of *Echinops giganteus*, agro-forestry and ABS. The project also involved activities to restore vegetative cover and create a community-managed forest.

Lessons learned

Collaboration on the *Echinops giganteus* case has proved positive and constructive for actors involved – indeed, other projects are now in the pipeline. The combination of ABS compliance and ethical sourcing practices seems to be particularly valuable; it creates additional business incentives on one side, and strong links with local development and sustainable use of biodiversity on the other.

The project had some lessons learned along the way. Negotiations were lengthy – more than initially envisaged. This meant, for example, that Parties agreed for certain R&D activities to begin prior to finalizing the MoU, as a way to avoid further delays. Additionally, there were other procedures that needed to be advanced in parallel, including requests for research permits and prior informed consent. Streamlining processes and paperwork may be useful to facilitate putting in practice ABS requirements as well as it increases transparency and cooperation among actors. Nevertheless, working in line with ABS requirements undoubtedly adds a layer of complexity, particularly in the initial stages of R&D projects.

Sources: V. Mane Fils,[1] ABS Capacity Development Initiative,[2] GEF small grants programme.[3]

Notes:

1 http://www.mane.com/news/mane-french-tv-show

2 For more details (in French) see: http://www.abs-initiative.info/countries-and-regions/africa/cameroon/mise-en-oeuvre-nationale-de-lapa-au-cameroun/

3 For more details (in French) see: https://sgp.undp.org/web/images/index.php?option=com_sgpprojects&view=projectdetail&id=22749&Itemid=272

***Echinops* genus** © Fotolia: renian

ANNEX 3. BRINGING COLOMBIAN BIODIVERSITY TO THE WORLD

The business

Bioprocol, Bioprocesos de Colombia S.A.S. (Biodiverse Chemistry) was founded in 2004 and manufactures natural materials from native plants. The pure plant extracts developed by Bioprocol can be converted into finished products or used as raw materials for the co-creation or development of innovations and brands with pharmaceutical, cosmetics and nutraceuticals laboratories.

Mr. German Schäfer, founder and creator of Bioprocol, successfully established his business and industrial solutions for the health, beauty and well-being market in Medellín, Colombia, and Indiana, United States of America. He was a pioneer in the research of exotic Solanum genus plants from Colombian mega diverse resources, validating natural ingredients with extraordinary dermo-cosmetics and cosmeceutical properties. Bioprocol has also created a success story by achieving the process of formulation, integrating these active ingredients into a final luxury skin care product under the brand IDONA, Ideas of Nature. IDONA skin care cream is starting to be marketed at the global level.

Interface with BioTrade and ABS

Access: Bioprocol's research is conducted in the Antioquia region, home to thousands of novel and exotic plants and where crops are being scaled up in several farms with different climates and soils. Organic horticulture processes are implemented to harvest the best raw plant materials. Bioprocol has its own methods to propagate, crop and process the feedstock, based on good agricultural practices.

Bioactive extracts are manufactured using a unique and patented extraction process applied to exotic plants cultivated in the Andean region under a multiyear access contract with the Colombian Government (Ministry of Environmental and Sustainable Development [MADS]) to research its biodiversity and genetic resources for commercialization. In the process, this required Bioprocol to comply with the Colombian legislation and the CBD.

Being the first company to sign such an access contract with the Colombian Government, Bioprocol had to undergo long and exhaustive procedures. Without any precedent to guide them and without clear understanding of the challenges this would entail, Bioprocol initially requested a permit for the access and right to investigate selected genetic resources without any commercial purpose. The request was submitted to the MADS in March 2014. In parallel, Bioprocol also submitted a "collecting permit" request to the regional authority Corantioquia.

Months later, Bioprocol was ready to bring some of the results of their investigation to the market. Again, following BioTrade Principles and wanting to comply with existing ABS regulations, it requested MADS for an access contract to the selected genetic resources, this time, with commercial purposes. On 3 December 2014, ten years after the foundation of the company, Bioprocol and MADS successfully signed contract No. 0110 on *"Bioprospección en el suroeste Antioqueño para identificar y caracterizar sustancias bioactivas con aplicaciones en productos orientados a la salud y el bienestar humano."* (Bioprospecting for bioactive applications from plants from the southern Antioquia region for human health and wellness purposes). The contract was then submitted to the MADS Directorate of Forestry, Biodiversity and Ecosystem Services.

Benefit sharing in the value chain: Following BioTrade Principles, Bioprocol ensures that the benefits from their bioprospecting activities are shared with the local community and farmers living where the genetic resources (through its investigation) originate. Bioprocol thus provides these communities and farmers with education and capacity building regarding the region's biodiversity with the aim of allowing them to participate fairly in the bio-commerce value chain.

Furthermore, Bioprocol established three agro-bio experimental centres in this rural area. There they have developed technology packages to cultivate and harvest the best "super" fruits which are then shared with the community so they can become providers of feedstock. This process continues with refining bioprocesses in the regional laboratory. There, the highly concentrated active ingredients are extracted under the optimal conditions to preserve the environment and to provide the final marketed products with the desired safety and efficacy.

In addition, Bioprocol (as part of its contractual obligations) shares a percentage of the monetary benefits derived from its research on the accessed genetic resources with the Colombian Government.

Results: Bioprocol has developed its own all natural luxury skin care brand (IDONA, Ideas of Nature). This brand hosts the company's first luxury cream (IDONA bio-revitalizing cream 4-in-1), developed through extensive research on Colombian's biodiversity and genetic resources whilst observing strict sustainability principles at all times.

The company's innovations have been recognized and presented at the most important cosmetic and industry-related shows, such as COSMOPROF (Bologna) 2015 and the In-Cosmetics fairs in Barcelona 2015 and Paris 2016 with the support of PROCOLOMBIA and the Dutch Import Promotion Agency from the Ministry of Foreign Affairs of the Netherlands.

Bioprocol continues to adhere to the BioTrade Principles and Criteria. It is recognized in the North American, European and Asian markets as a brand that cannot only boast of its sustainability and social responsibility achievements, but one that also holds an access contract to use (for commercial R&D purposes) the genetic resources accessed from Colombian biodiversity. This means that despite Colombia being a non-Party to the Protocol, Bioprocol is compliant with the ABS requirements under it by way of its BioTrade membership. Bioprocol continues to be a reliable supplier of natural ingredients and products and (subject to the limitations of its ABS contracts) could also supply natural ingredients to other producers in the value chain.

Lessons learned

It is possible to undertake sustainable processes from the production of exotic plants to the production of high value-added and sophisticated products whilst being compliant with sustainability and environmental regulations as well as observe BioTrade Principles and Criteria. Through its ethical standards, Bioprocol has emerged as a company that is a reliable and legitimate source of products, information and even advice.

Policymakers should be aware of the consequences and challenges that complex, unclear or ambiguous procedures on companies that wish to be compliant with national sustainability and environmental objectives. Accordingly, incentives should be available for companies and programmes that apply sustainability principles and criteria, comply with national and international regulations, and develop technology and products for people's health and well-being – the latter being the source of useful inventions that promote a successful and ABS-sensitive brand globally.

Sources: German Schäfer, Jessica Andrade and Jaime Gonzalez (Bioprocol); Mariona Cusi and David Vivas Eugui (UNCTAD). For more information about Bioprocol see: http://Bioprocol.com/

ANNEX 4. ABS AND BIOTRADE AT WORK: FACILITATING THE IMPORTATION OF FRESH PLANTS FROM NAMIBIA TO THE EUROPEAN UNION

Summary of the business

A farm in Namibia, already producing and selling plants for herbal supplements in the European Union and the United States of America, wanted to expand its activities and offer its products to the international market. A potential ingredient at hand was an endemic plant which was easy to reproduce and whose sap is known for its skin healing properties. In order to develop the plant extract, they needed local extraction methods and facilities which were not easily accessible to them. Eager to enter the cosmetic industry with an innovative and competitive ingredient, they contacted their trade association, PhytoTrade Africa, to assist in finding extraction methods they could possibly outsource. An SME in the European Union providing the required services was identified and was duly contracted for the extraction trials and related analytical work. Consequently, several kilograms of fresh plants were imported to the European Union for a series of tests.

BioTrade and ABS considerations

Namibia is a Party to the Protocol since 2014 and has had national ABS measures in place whilst the national law is still under discussion. Due to these policy developments at the time of the project and the risk of retroactivity on utilization of *ex situ* collection pre-Protocol becoming part of the national ABS law, the parties considered the possible ABS obligations arising from the development process, and the destination of the fresh plants being the European Union, an MTA for commercialization purposes was signed by PhytoTrade Africa on behalf of the farm.

The purpose of the transfer of material was explicitly described as "compositional and activity research on the material for potential product development." However, no further confidential details were provided in the processes. The farm was granted a research permit for the exact same purpose as that written in the MTA. A non-disclosure agreement and contract were signed with the European Union-based SME providing the services thereafter.

Pursuant to the European Union Council Directive 2000/29/EC (on Measures to Protect the Health of European Union Plants), PhytoTrade Africa contacted the competent authorities to enquire about the relevant due diligence requirements prior to the importation of fresh plants i.e. the phytosanitary certificate. This certificate contains key information about the shipment including: the plant name, imported plant parts, name of the importer, contact details of the final destination and the intended use. Crucially, the document also certified the phytosanitary conditions of the fresh plants that were to be exported to the European Union, and also that the shipment had been officially inspected, compliant with statutory requirements for entry into the European Union, and was free of quarantine pests and other harmful pathogens.

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

Lessons learned

This case illustrates the need to look at both provider and user ABS regulations (in Europe) underscoring the importance of fulfilling due diligence obligations for international trade and export to Europe, where customs or other institutions could become a checkpoint. The use of an MTA as a means of securing MAT, which anticipates the potential ABS duties arising in this BioTrade process and requires an export phytosanitary permit to ensure legal export of fresh material to Europe, highlights the pragmatic potential of developing a "one-stop shop" approach in provider countries.

Source: UNCTAD and PhytoTrade Africa (2015). See http://PhytoTrade.com/news/biotrade-for-biodiversity-project-approved-2/

ANNEX 5. THE CASE OF COSMO INTERNATIONAL INGREDIENTS IN PERU

Cosmo International Ingredients, since its creation, has been dedicated to designing unique natural ingredients for the cosmetic and fragrance industries. With its three research centres in France, Peru and Colombia, Cosmo International Ingredients offers a bespoke ingredient portfolio exclusively composed of natural and innovative ingredients derived from biodiversity.

Cosmo International Ingredients' objective is to promote the "sourcing with respect of biodiversity and people", by focusing its energies into four spheres of action:

- Recognition of the biodiversity's value through the granting of relevant national permits and requirements.
- Raising of awareness among local suppliers on biodiversity conservation through ethical sourcing practices and training.
- Transmission of the immeasurable biodiversity richness and potential to all stakeholders of the supply chains through the development of value-added products and the establishment of an effective system of traceability and transparency.
- Respect of biodiversity holders through commitment to long-term partnerships and the protection of traditional knowledge.

Apart from Cosmo International Ingredients' commitment to providing the most innovative, sustainable and fairly traded natural ingredients, it also aligns its own sustainability values and goals with the United Nations SDGs on the basis of close collaborations with their long-standing partners and local institutions. As part of its commitment to sustainability, Cosmo International Ingredients joined UEBT in 2016. Evidently, Cosmo's application of UNCTAD BioTrade's Principles and Criteria can be regarded as complying with the CBD obligations voluntarily.

Additionally, Cosmo Peru, part of Cosmo International Ingredients and founded in 2013, has development projects for cosmetic ingredients from Peruvian native plants. Cosmo has requested five authorizations to access to genetic resources,[4] in accordance with the national ABS legislation in Colombia and the Nagoya Protocol in Peru and it is exploring options to do so in Ecuador. All these requests are pending approval.

In the case of Peru, the company identified the competent authorities and approached them to understand the administrative ABS process which the company would have to undertake. The National Institute for Agrarian Innovation (INIA) and the Forest Service showed openness and willingness to guide

Uros island in Lake Titicaca, Peru © Fotolia: SB

Cosmo during the process and assist the company as best as they could. Following guidance from authorities, Cosmo submitted all the requirements and documents in 2015 in a simple format, as indicated by the authority, INIA, and in collaboration with suppliers, and a national support institution. It is a requirement under the Andean Decisions and national regulations in Peru to undertake the project with a national support institution.

Cosmo Peru has also submitted requests to the INIA (i.e. the competent authority) for access to genetic resources for native crop species. In line with this request a cooperation agreement framework was signed with the Museum of Natural History of the National University of San Marcos, agreeing to participate as a national support institution. The agreement was intended to benefit an institution that had better knowledge of the national flora taxonomic record which could fulfil the role of a monitoring system for Cosmo as required by the ABS application process.

Providers of biological resources[5] were informed about the research projects, the scope and prospective achievements as well as the procedures to procure commercial potential for the research outcomes. Currently, Cosmo Peru has extended discussions about the possible benefits that can be specified in the future, in accordance with the interests of the provider and their development strategy, e.g. supporting them in their own ventures, crop improvement or projects that are already under way. In some cases, the providers have solid experience on benefit sharing schemes.

The local authorities should also carefully consider not only monetary benefits but also non-monetary benefits that are important and have an immediate impact on communities which should be considered by local authorities. Where benefits are in the form of cash, the government's and the ATK holders' expectations should be reasonable and based on practical and realistic business perspectives.

Cosmo Peru is the first company to present such access applications and aims to achieve the IRCC issued by Ministry of Environment of Peru. At present Cosmo Peru and INIA are discussing initial elements of an access contract.

Timely response to access requests is also fundamental for companies as they undertake project implementation; lack of or late responses can severely affect the viability of those projects. There is a need to support companies in making access requests, as generally in practice their access application process experiences are limited. This will be particularly relevant for SMEs as they have much less capacity to comply with regulatory requirements than transnational companies. In sum, the need to respond to requests is essential in order to encourage future investments linked to conservation, sustainable use and livelihoods.

Lessons learned

It is important for regulators and policymakers to develop a user guide, which allows other companies to know the procedures and requirements in a quick and simple manner;

- The application form should include information about confidentiality and be readily available, to facilitate its use by companies in Peru.
- Develop model contracts to be used as a tool in negotiations between companies and public institutions (e.g. INIA, the Forestry Service, the Ministry of Produce).
- Timely response is essential for keeping interest in the legal access and viability of BioTrade projects.
- There is a need to consider facilitating processes for BioTrade companies and SMEs.

Sources: Jessica Garcia (Cosmo Ingredients S.A.C., Peru), Lea Mazzina (Cosmo, France) and Astrid Peláez (Cosmo, Colombia).

Notes:

4 The specific genetic resources list is confidential as these applications are currently subject to approval.

5 In this case, providers of biological materials refer to companies or cooperatives selling different materials, usually in raw form, for manufacturing processes (e.g. fruit peel).

ANNEX 6. SAMPLE ABS-BIOTRADE CHECKLIST FOR POLICYMAKERS

In the process of designing and developing policies which will cover ABS and may also address BioTrade, policymakers should:

- ❑ Consider how ABS and BioTrade measures can be designed to recognize and enhance the social, economic, ecological and cultural value of biological and genetic resources.
- ❑ Ensure integration of ABS and BioTrade measures in existing strategies for poverty alleviation, sustainable use and conservation of biodiversity, R&D, local development and technology transfer, among other policies and policy goals.
- ❑ Review and understand the substantive content and implications of the Nagoya Protocol, national ABS frameworks, the ITPGRFA, and BioTrade Principles and Criteria, particularly in respect of coverage, scope and intersections between these international instruments.
- ❑ Clarify the roles of different focal points (ABS, BioTrade or others), checkpoints as well as competent authorities, especially if multiple ones exist.
- ❑ Consider that the dimensions and elements of R&D models in genetic resources, their biochemical derivatives and biodiversity in general, need to be understood in their complexities and challenges, and streamlined into and reflected in ABS and ATK policymaking.
- ❑ Review comparative legislation pertaining to ABS and assessments made regarding impacts and effects on national research, conservation efforts, etc.
- ❑ Review comparative legislation pertaining to ATK and assessments made regarding impacts and implementation in practice.
- ❑ Assess national BioTrade frameworks or references in laws, strategies, regulations and other instruments.
- ❑ Evaluate how ABS frameworks may link to BioTrade and whether cross-references should be made explicit.
- ❑ Discuss with national authorities responsible for natural resources and biodiversity management how concessions, permits, authorizations, impact assessments, etc. for utilization of biological resources and specimens operate in practice.
- ❑ Develop nationally adapted indicators for benefit sharing both in regard to BioTrade and ABS.
- ❑ Create enabling frameworks and introduce incentives which support benefit sharing realization and value addition in BioTrade and ABS.

ANNEX 7. SAMPLE ABS-BIOTRADE CHECKLIST FOR REGULATORS

- ❑ Clearly define in what cases public authorities intervene in BioTrade value chains and the ABS process.
- ❑ Understand the nature of the project, activity or process for which an authorization, permit, ABS contract or other is being sought.
- ❑ Provide with timely information and documents which orient users to the procedure to be followed whether for a BioTrade or ABS activity.
- ❑ Explore the value of online tools for ABS requests in order to keep complete track of and give predictability on timely responses by the administration to users and applicants, or at least within legal timeframes.
- ❑ Understand and be aware of the differences in contractual frameworks between ABS and BioTrade.
- ❑ Understand the wide variations and forms in which benefit sharing may take place both for BioTrade and ABS initiatives and promote recognition of benefits already granted.
- ❑ Explore the use and the application of the BioTrade Principles and Criteria as guidance for compliance with ABS requirements.
- ❑ Create a group or network of technical advisors to support decision-making at different stages of projects and activities.
- ❑ Undertake yearly evaluations of BioTrade and ABS projects and activities, through surveys and direct assessments to ensure adjustments are made where need be.
- ❑ Continuously interact with users, especially the private and academic sectors, to understand specific needs and interests.

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