

BioTrade & Access and Benefit Sharing: from Concept to Practice

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BIOTRADE AND ACCESS AND BENEFIT SHARING (ABS)

"Access and benefit-sharing (ABS) refers to the **way in which genetic resources may be accessed**, and **how the benefits that result from their use are shared** between the people or countries using the resources (**users**) and the people or countries that provide them (**providers**)." (CBD Secretariat)

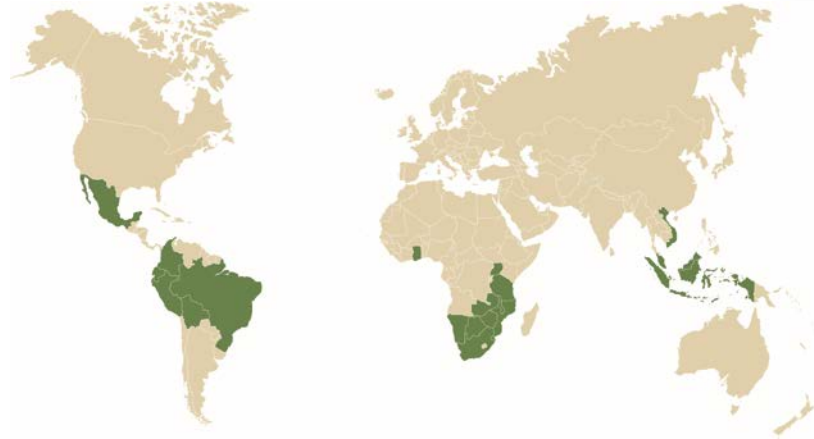
Basic conditions under the Convention on Biological Diversity are:

- 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 between users and providers

Governments need to put in place systems that facilitate access to genetic resources for environmentally sound purposes

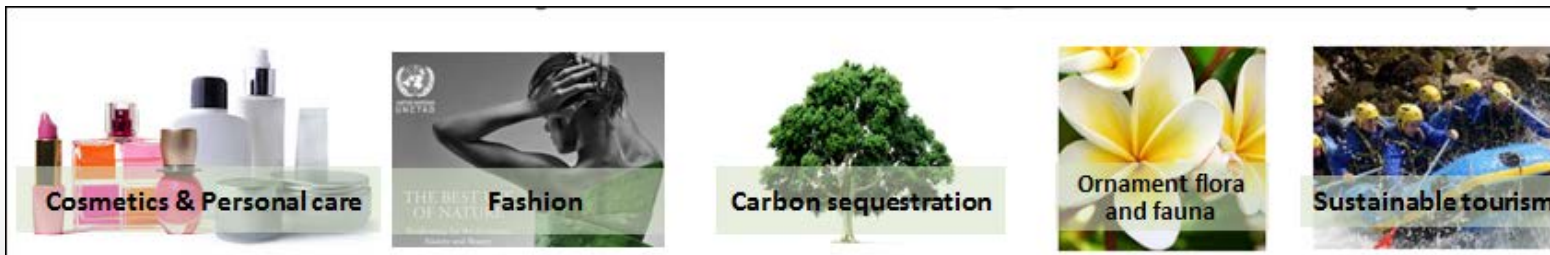
BIOTRADE: AN OVERVIEW

BioTrade refers to those activities of collection, production, transformation, and commercialization of goods and services derived from native biodiversity (species & ecosystems) under the criteria of environmental, social and economic sustainability



Provides economic, social and environmental benefits:

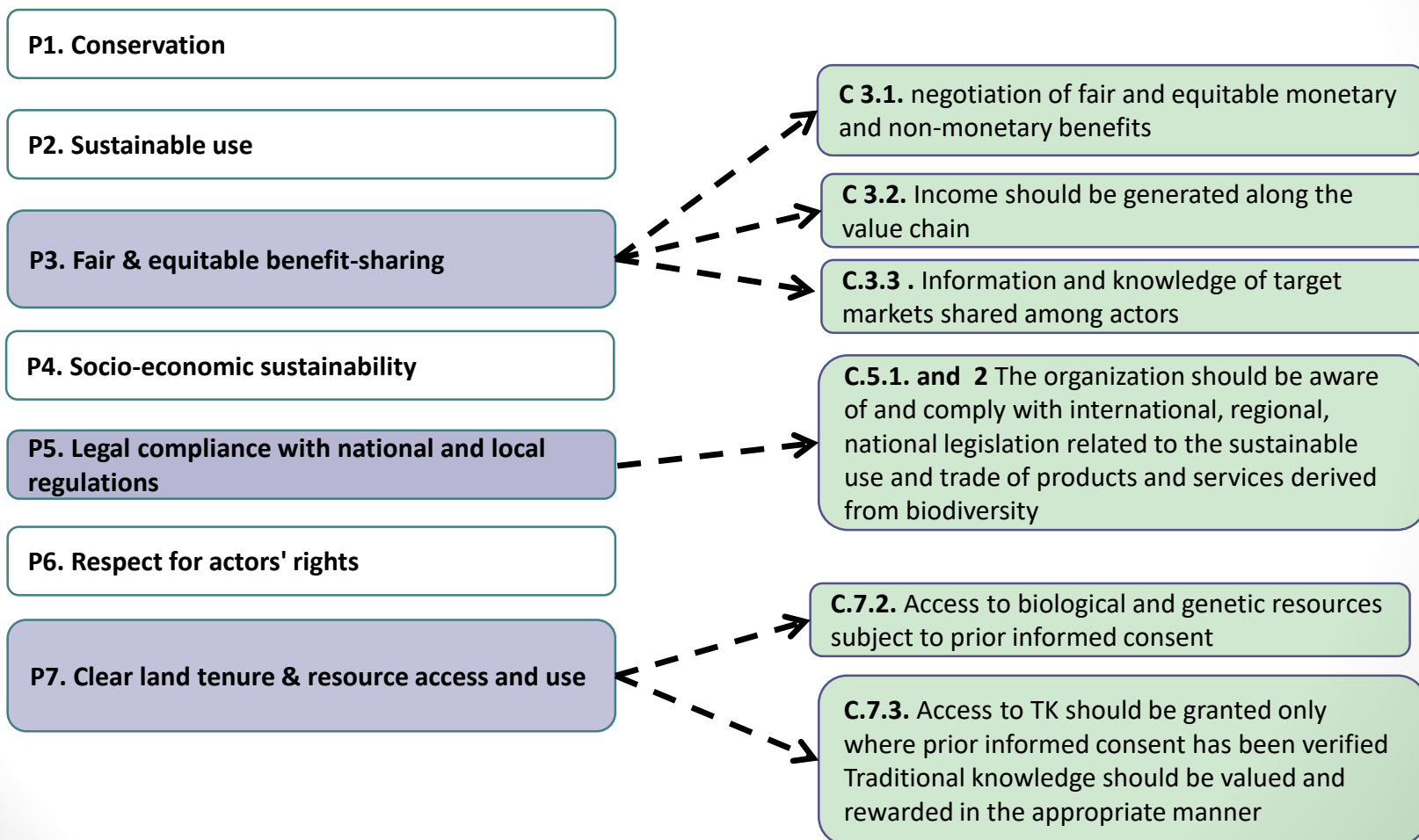
- **USD\$. 4.5 bn turnover of BT companies/associations**
- **Around 30,000 (producers/farmers, collectors/hunters)**
- **Sustainable management of 19+ million hectares**





BIOTRADE PRINCIPLES & LINKAGES with ABS

Non binding nature but certifiable



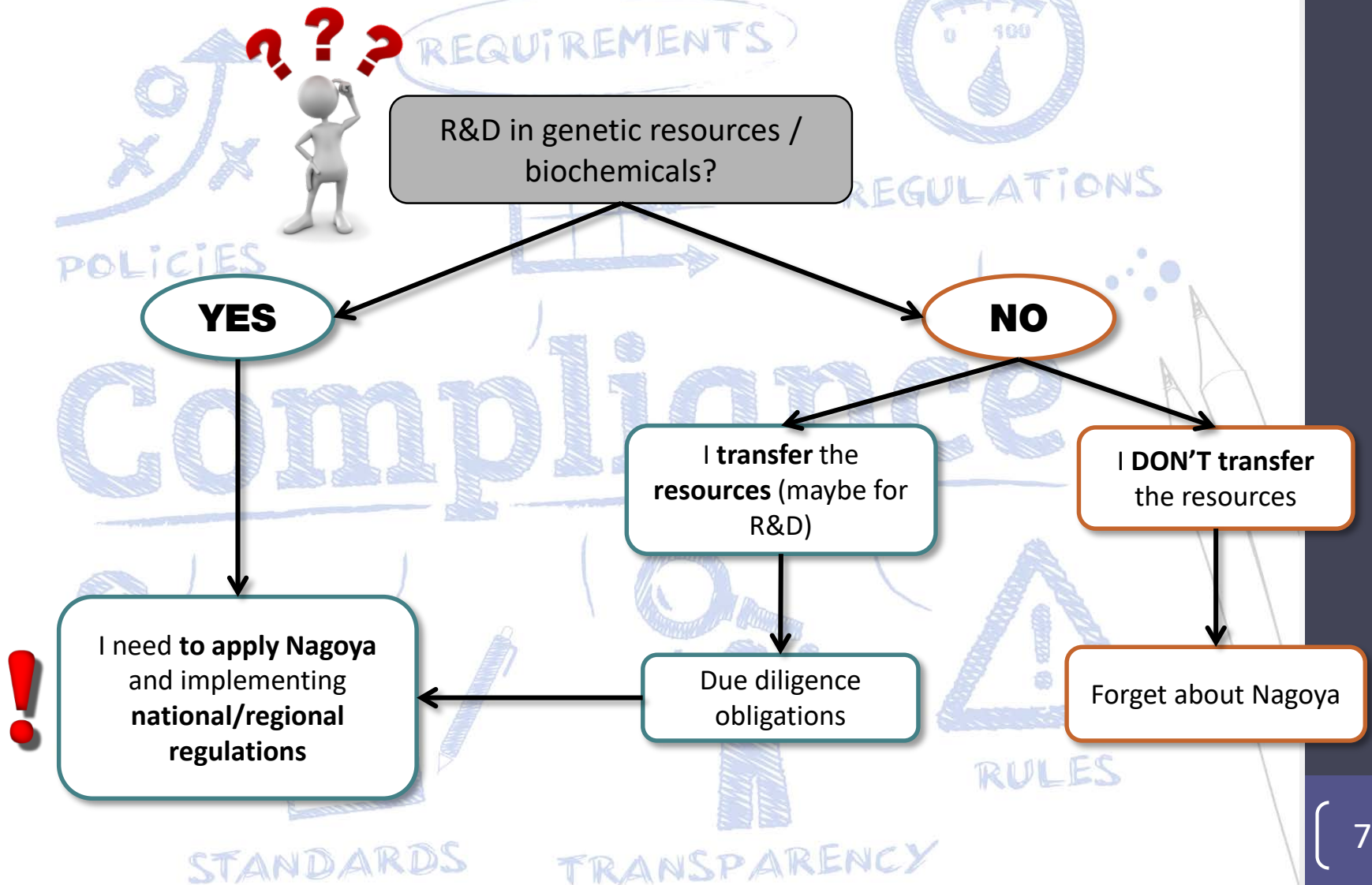


PRELIMINARY ISSUES FOR CONSIDERATION BY POLICYMAKERS AND REGULATORS

- **Assessing the project, business or activity**
- **BioTrade vs biotrade**
- **R&D as a trigger**
- **Sectoral considerations in benefit sharing**

BioTrade	Nagoya Protocol (ABS)
Voluntary system	Mandatory regulation
Use of biodiversity along the value chains	Access and utilization of genetic resources, biochemicals and/or derivatives (depending on national law).
Benefits can be monetary and non monetary (with all actors along the value chain)	Benefits can be monetary and non monetary (with State and/or TK holders)
Requires prior informed consent to access and use (not necessarily related to R&D) biodiversity and related TK	Requires prior informed consent (PIC) to access and use (when R&D is involved) genetic resources, biochemicals, derivatives &TK.
Implementation is guided by the BioTrade principles and criteria + private standards	MAT: defines the condition for access and use of genetic resources, biochemicals and derivatives
There are no specific laws to BioTrade However, it is affected by various sectorial laws and regulations	There are several ABS national, regional and international laws and regulations.

AM I COVERED BY THE NAGOYA PROTOCOL & IMPLEMENTING REGULATIONS?



LAW OR REGULATION	SPECIFIC PROVISIONS ON NATIONAL LAW
<p>Order No. 18, biodiversity law in Viet Nam (2008)</p> <p>Decree on Management of Genetic Resources (2015)</p>	<p><u>Article 3.29 (Definitions)</u></p> <p>Genetic resource includes all species and genetic specimens in nature, conservation zones, biodiversity conservation facilities and scientific research and technological development institutions and in nature,</p> <p>Access to genetic resources: means activities of investigating and collecting genetic resources for research and development and production of commercial products.</p> <p>Lately, derivatives have been also included in new ABS Decree</p>
<p>Biodiversity Act (2002) and Rules (2004) in India</p>	<p><u>2. Definitions. (f) "commercial utilization"</u> means end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in any agriculture (...)</p> <p>Chapter II. 3.1. No person shall, without previous approval of the NBA, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization.</p>
<p>Supreme Decree 002-2009-MINAM, ABS regulation on Peru (2009)</p>	<p><u>Article 4 (Scope).</u> The regulation applies to genetic resources of which Peru is a country of origin, its derived products, intangible components and genetic resources of migratory species ...</p> <p><u>Article 5 (Exclusions).</u> Excluded from this regulation are: e) Activities which imply the exploitation of non-timber natural resources used to produce natural products (nutraceuticals and functional foods).</p>

LAW OR REGULATION	SPECIFIC PROVISIONS ON NATIONAL LAW
<p>Andean Community Decision 391 (1996)</p>	<p><u>Article 1 (Definitions)</u>. Derived product: a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin derived from the metabolism of living beings.</p> <p><u>Article 3 (Scope)</u>. This Decision is applicable to genetic resources for which is the Member Countries are the countries of origin, to their derived products ...</p>
<p>Amendments to the Biodiversity Act No. 10, on bioprospecting and ABS in South Africa (2015)</p>	<p><u>Chapter 1. (Definitions)</u>. 1. Biotrade: Means the buying and selling of milled, powdered, dried, sliced or extract of indigenous genetic or biological resources for further commercial exploitation.</p> <p><u>(Application of these regulations)</u>. 3.1. These regulations apply to (a) commercial or industrial sectors that utilize any indigenous genetic and biological resources for biotrade or for research, application or development of drugs, complementary medicines nutraceuticals, industry enzymes, food flavors, fragrances, cosmetics, emulsifiers, oleoresins, colors, extracts and essential oils.</p>
<p>Law 13.123 on ABS in Brazil (2015)</p>	<p><u>Article 1. (General provisions)</u>. This law applies to rights and obligations related to:</p> <p>IV. the economic exploitation of the final product or reproductive material derived from the genetic patrimony.</p> <p>V. fair and equitable benefit sharing related to the economic exploitation of the final product or reproductive material derived from the genetic patrimony</p> <p><u>Article 2.I. (Definitions)</u>. Genetic patrimony: information of genetic origin of plant, animal, microbial or other species, including substances originated from the metabolism of living beings.</p>



YOU NEED TO KNOW YOUR VALUE CHAIN:



- Inputs-intermediates-outputs
- Processes
- Levels of value addition
- Legal arrangements

- Traceability requirements
- Participants
- Benefits to be shared
- Applicable regulations



WHAT CAN BE CONSIDER R&D?

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:

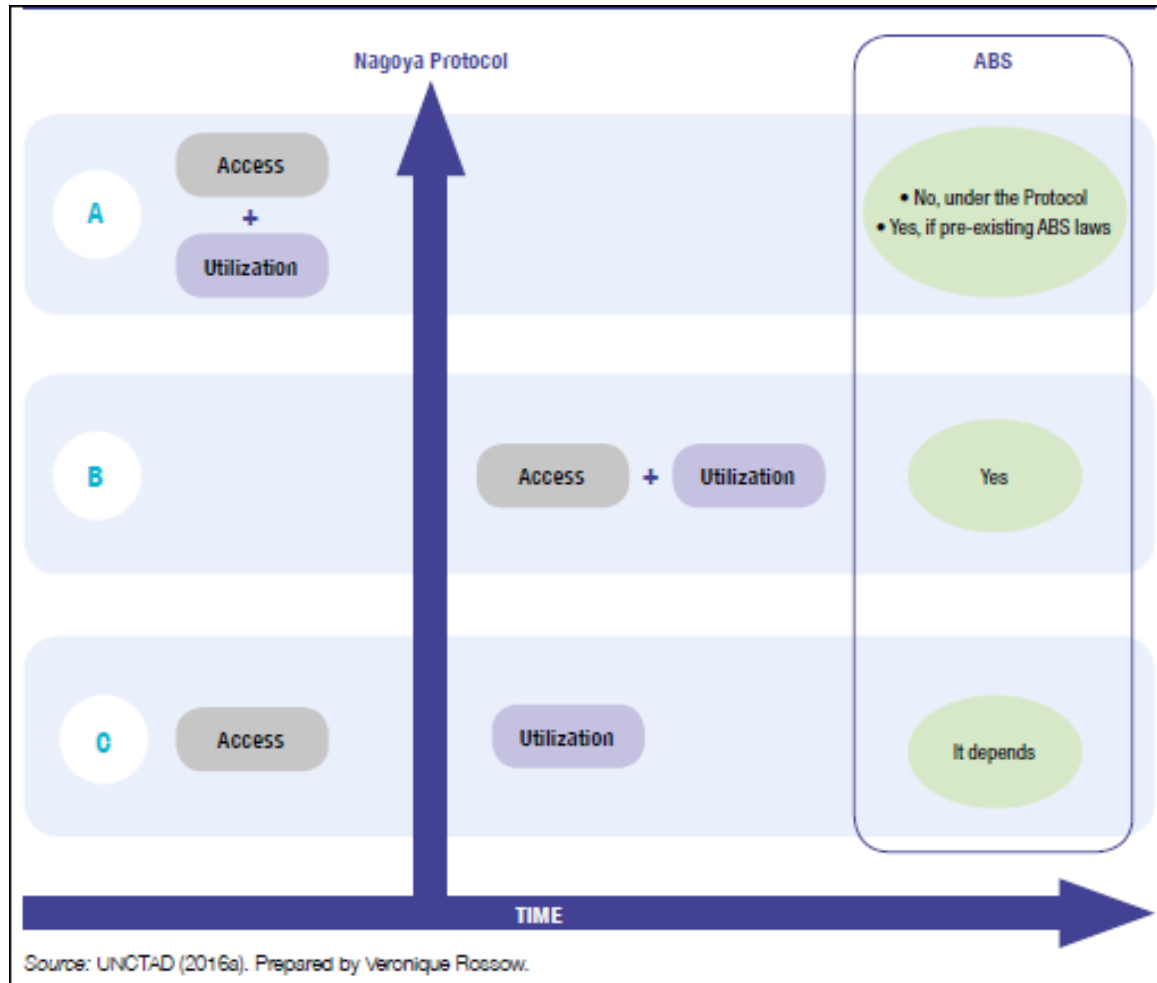
Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view.

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.

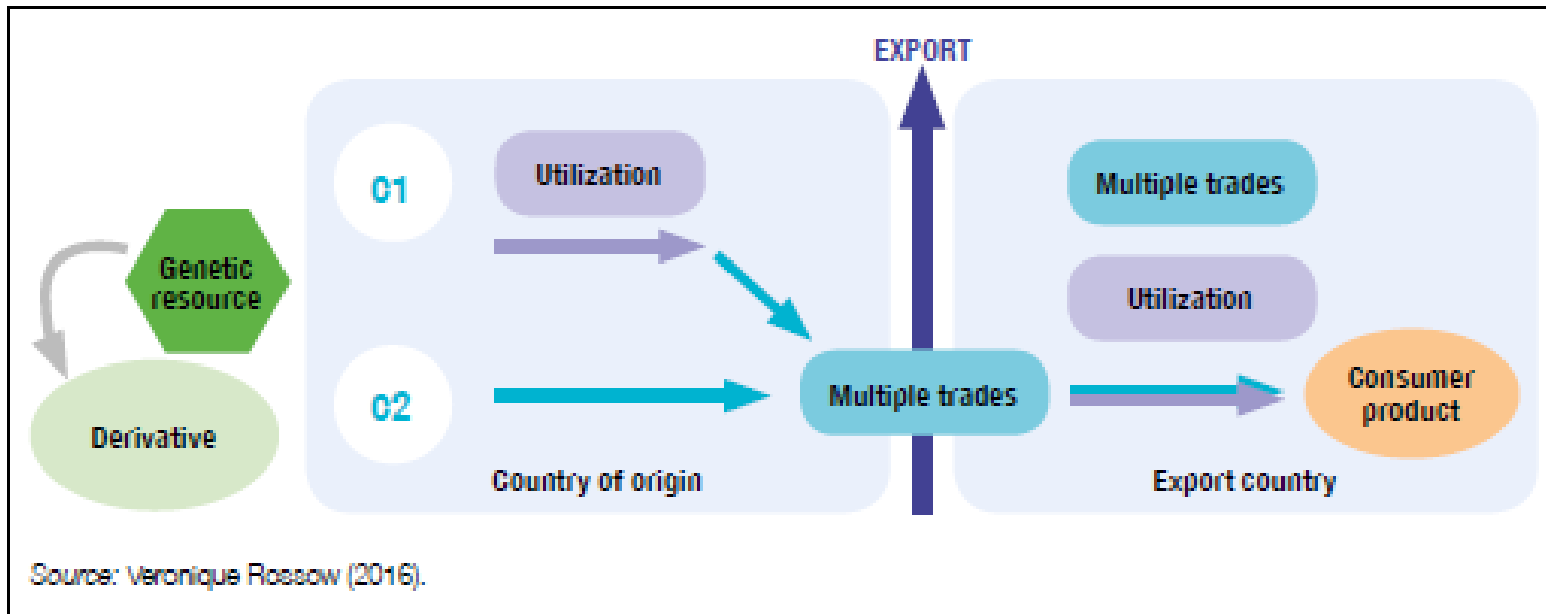


POTENTIAL TEMPORARY LINE IN R&D AND NAGOYA PROTOCOL IMPLEMENTATION





UTILIZATION MAY OCCUR AT DIFFERENT PHASES OF THE VALUE CHAIN



CONTRACTUAL ISSUES

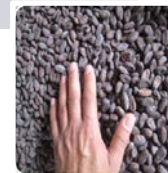
ABS contract / MAT

- **Object:** access, utilization and transfer of materials
- **Subjects:** State vs Private (research center or company)
- **Cause:** R&D and commercialization (potentially transfer)
- **Date**
- **Applicable law:** usually public law + contract law



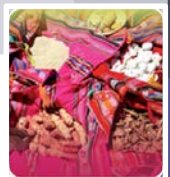
BioTrade Agreements

- **Object:** sales of goods and services (e.g. natural ingredients)
- **Subjects:** business to business
- **Cause:** sourcing, processing & commercialization (potentially R&D)
- **Date**
- **Applicable law:** commercial contractual law



TK Licenses / Agreements

- **Object:** access to knowledge (intangible)
- **Subject:** indigenous and local communities and Private (research center or company)
- **Cause:** R&D, fixation, production, commercialization
- **Date**
- **Applicable law:** TK regulations + private law + customary law





BENEFITS SHARING ISSUES



ABS

- Monetary
 - Access fees
 - Milestone payments
 - Royalties
 - R&D funding
 - Joint ventures
 - Joint IP ownership
- Non-Monetary
 - Sharing of R&D results
 - Scientific collaboration
 - Education & training
 - Technology transfer
 - Capacity building
 - Local development



BioTrade

- Monetary
 - Linked to the market value
 - Fair Price (products, volume, quality & ethics)
 - Exclusive sourcing
 - Value evolves as we move upward in the value chain
- Non-monetary
 - Local Employment
 - Value addition
 - Sustainable practices
 - Education & training
 - Technology transfer
 - Local development



TK

- Monetary
 - Access fees
 - Licenses fees
 - Joint IP ownership
- Non-Monetary
 - Moral rights & recognition
 - Local development
 - Food, seeds and inputs
 - Support to health & livelihoods
 - Preservation of TK context
 - Infrastructure
 - Employment

HOWEVER IN PRACTICE THEY ARE NOT CLEAR CUT AS ACTIVITIES MAY OVERLAP AND NOT ALL BENEFITS HAPPEN SIMULTANEOUSLY



Incentives for compliance and investment in ABS and BioTrade (1)



Regulatory measures (for policymakers):

- Clarify responsibilities of competent authorities
- **Facilitate legal access through simplified processes of PIC and MAT.**
- **Expedite ABS procedures for BioTrade companies**
- Recognize the benefits already granted under BioTrade as part of the benefits under ABS
- Allow for regularization mechanism

Administrative practice (for regulators):

- Issue contracts and permits within a reasonable period
- Issue binding assessments prior to the request for access coverage upon request
- Manage expectations on monetary & non-monetary benefits
- **Make use of single window systems and electronic procedures**
- **Automatically issue IRCC once contract of permits have been granted**
- Include BioTrade focal points in the administrative ABS decision



Incentives for compliance and investment in ABS and BioTrade (2)



Economic incentives (for policymakers and regulators):

- Avoid unnecessary transaction costs and burdensome procedures;
- Allow for one single request to multiple resources and uses;
- Allow facilitated ABS if R&D is local or local manufacturing is undertaken;
- Introduce tax incentives to companies that meet BioTrade Principles & Criteria.

Capacity building (for policymakers and regulators):

- Promote understanding bio-business and its relationship with ABS;
- Promote understanding on R&D and business models (basic, applied and regulatory and per sector).



Intellectual property in ABS and BioTrade businesses

Positive protection through patents and breeders' rights

- Patentability criteria: new, involve an inventive step and be capable industrial application
- Breeders rights protection criteria: new, distinct, uniform and stable
- Very few cases of successful application of a patent or breeders' rights that have also complied with ABS regulations:
 - Case of Ecoflora



Case of BioProcol





Intellectual property in ABS and BioTrade businesses

Positive protection through geographical indications

The case of Cacao de Arriba



The case of the Geneva thorny cardoon



Positive protection through Collective marks

The case of "Chirimoya Cumbe"



Source: Images from the "100 Festival de la Chirimoya de Callahuano, 2016"

ABS illustrations in the field of BioTrade

Bioprocol, Bioprocesos de Colombia S.A.S. (Biodiverse Chemistry)

- BioProcol manufactures natural ingredients and 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**.
- BioProcol 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.



ABS illustrations in the field of BioTrade

Bioprocol, Bioprocesos de Colombia S.A.S. (Biodiverse Chemistry)

- BioProcol was the first company to sign such an **ABS contract** with the Colombian Ministry of Environment and Sustainable Development in 2014: *"Bioprospecting for bioactive applications from plants from the southern Antioquia region for human health and wellness purposes"*
- 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.



Traphaco SaPa - Improved business practices

- **Dzao, a Vietnamese ethnic minority, uses Che-day (ampelopsis cantoniensis) a native plant to treat digestion-related diseases and hold a TK for pre-processing and fermenting this plant before it using it as a tea or a medicine**
- Traphaco, leading Vietnamese traditional medicine company, partnered with the National Board on Science to study Che-day. In 2003, it developed Ampelop (Che-day soft capsules) to treat gastric and intestinal inflammations common in Vietnam
- **With the success of Ampelop, demand for Che-day increased by 177% between 2010 and 2012**
- To meet the demand in a sustainable way, Traphaco supported by NIMM and the BioTrade Project contributed to the **creation of a Dzao cooperative with 60 vulnerable households**



Traphaco SaPa - Improved business practices

- Traphaco signed a **supply agreement** with the cooperative and provided a training on sustainable cultivation and harvest practices + established standard procedures to ensure the quality of the supply + pre-processing ensured by the Dzao
- **ABS and ATK implications:** R&D on *ex situ* reproduction methods for native biodiversity and the use of TK for processing and fermentation may need the development ABS Agreements and licenses
- **Results:** Sustainable supply of Che-day + Dzao TK protected and valued + Doubled income for the beneficiary community (Che-day purchased with a 20% premium) + Increased awareness of Traphaco on ABS



Many thanks

For further information see:

<http://unctad.org/en/pages/PublicationWebflyer.aspx?publicationid=1887>

<http://unctad.org/en/Pages/DITC/Trade-and-Environment/BioTrade.aspx>