



The Concept of BioTrade

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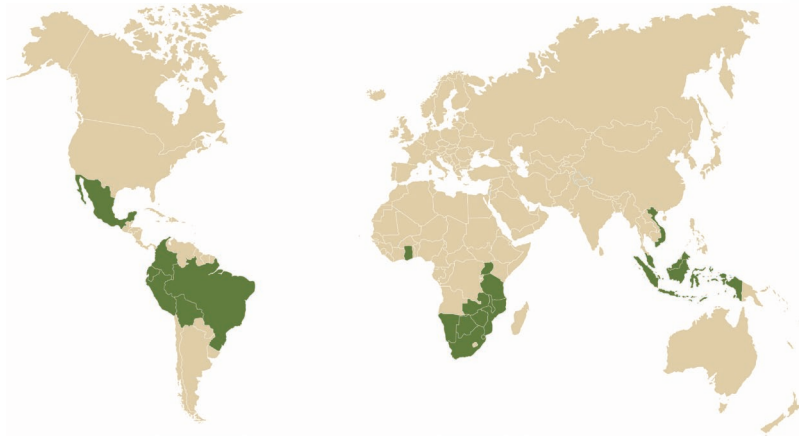


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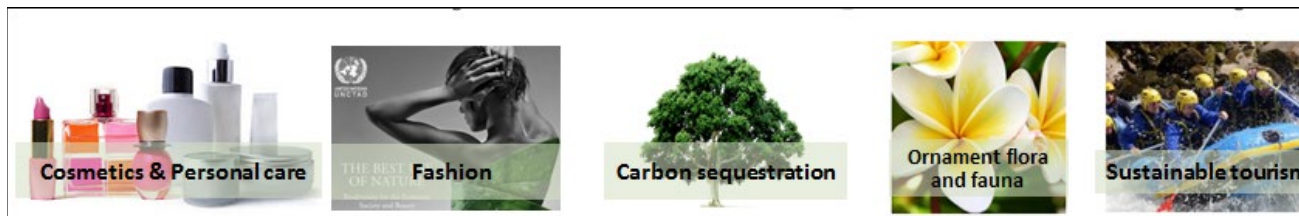
BIOTRADE: AN OVERVIEW

BioTrade refers to the 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 and associations;**
- **Around 30,000 producers, farmers, collectors and hunters involved;**
- **Sustainable management of 19+ million hectares.**



The Rationale

BioTrade Principles and Criteria (2007)

BioTrade Principles

P1. Conservation

P2. Sustainable use

P3. Equitable benefit-sharing

P4. Socio-economic sustainability

P5. Legal compliance

P6. Respect for actors rights

P7. Clear tenure & access to resources

International agreements and development processes have evolved and there is a need for alignment

- Nagoya Protocol
- Agenda 2030 and SDGs (14, 15 and 17)
- Paris Agreement

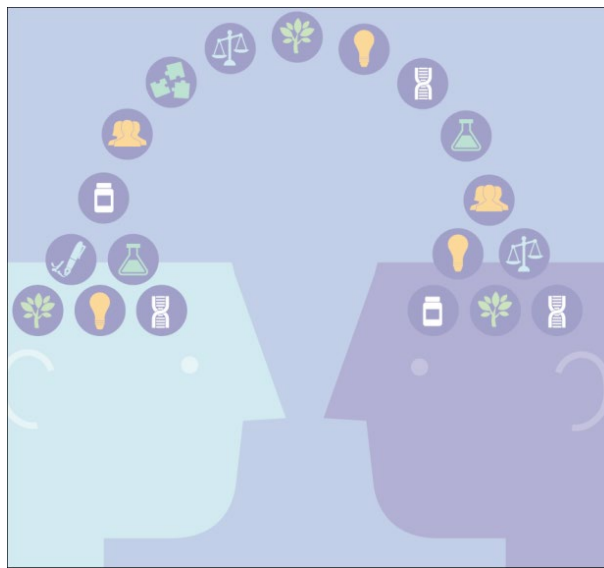
Lessons learned from BioTrade P&C implementation and further adaptation to national circumstances and value chains, including marine and coastal resources and ecosystems (Blue BioTrade)

Market trends: Growth in Consumer demand estimated at a 6 % annual increase (2018-2022)

Tools to raise awareness and understanding of BioTrade and its P&C

USE OF BIOTRADE P&C BY PARTNERS

BioTrade partner	Scope and level of adaptations (principle/criteria/indicator)
UEBT	Adapted criteria and indicators specific to: <ul style="list-style-type: none"> ▪ Natural ingredients
PERU	Adapted criteria and indicators specific to: <ul style="list-style-type: none"> ▪ Wildlife, timber, non-timber, animal breeding (zoocría) ▪ Agroforestry/cultivation ▪ Eco-tourism
MADS (Colombia)	Adapted principles, criteria and indicators considering green business classification based on G&S derived from: <ul style="list-style-type: none"> ▪ (a) natural resources which relates to BioTrade ▪ (b) industrial eco-products and (c) carbon-related
Bioemprende (Ecuador based on Andean BT Programme)	Adapted criteria and indicators specific to: <ul style="list-style-type: none"> ▪ Production from wild collection ▪ Production from cultivation Adapted criteria and indicators specific to: <ul style="list-style-type: none"> ▪ Sustainable tourism
PhytoTrade Africa	Adapted principles, criteria and indicators specific to: <ul style="list-style-type: none"> ▪ PTA focal and pipeline species (cosmetic, pharmaceutical and nutraceutical ingredients)



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:

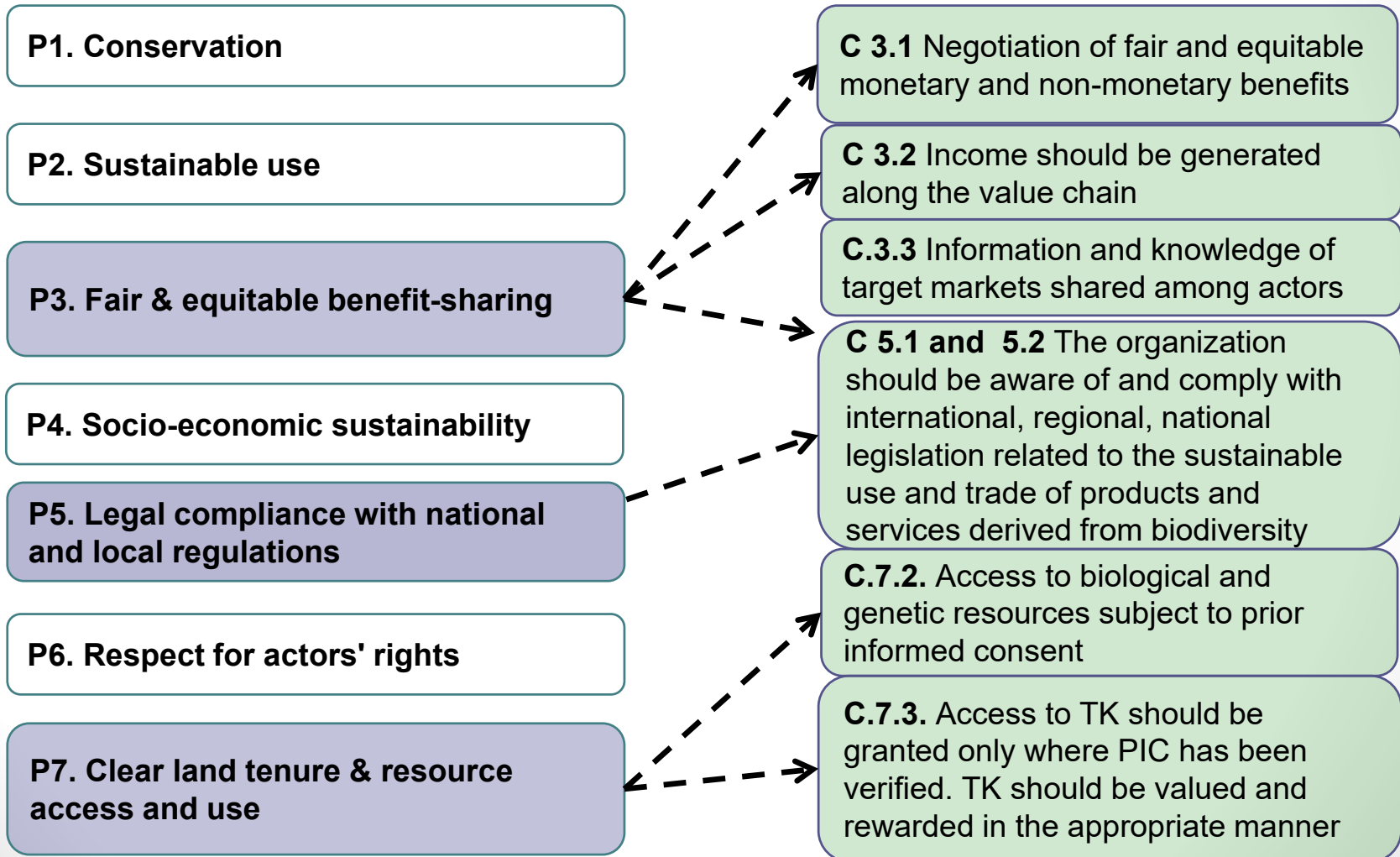
- Ensuring that **prior informed consent (PIC)** for access is provided by a national authority.
- **Mutually agreed terms (MAT)** are negotiated.
- **Benefits are shared equitably and fairly** between users and providers

Governments must put in place systems that facilitate access to genetic resources for environmentally sound purposes in alignment with the objectives of the CBD.



BIOTRADE PRINCIPLES & LINKAGES with ABS

Non binding nature but certifiable



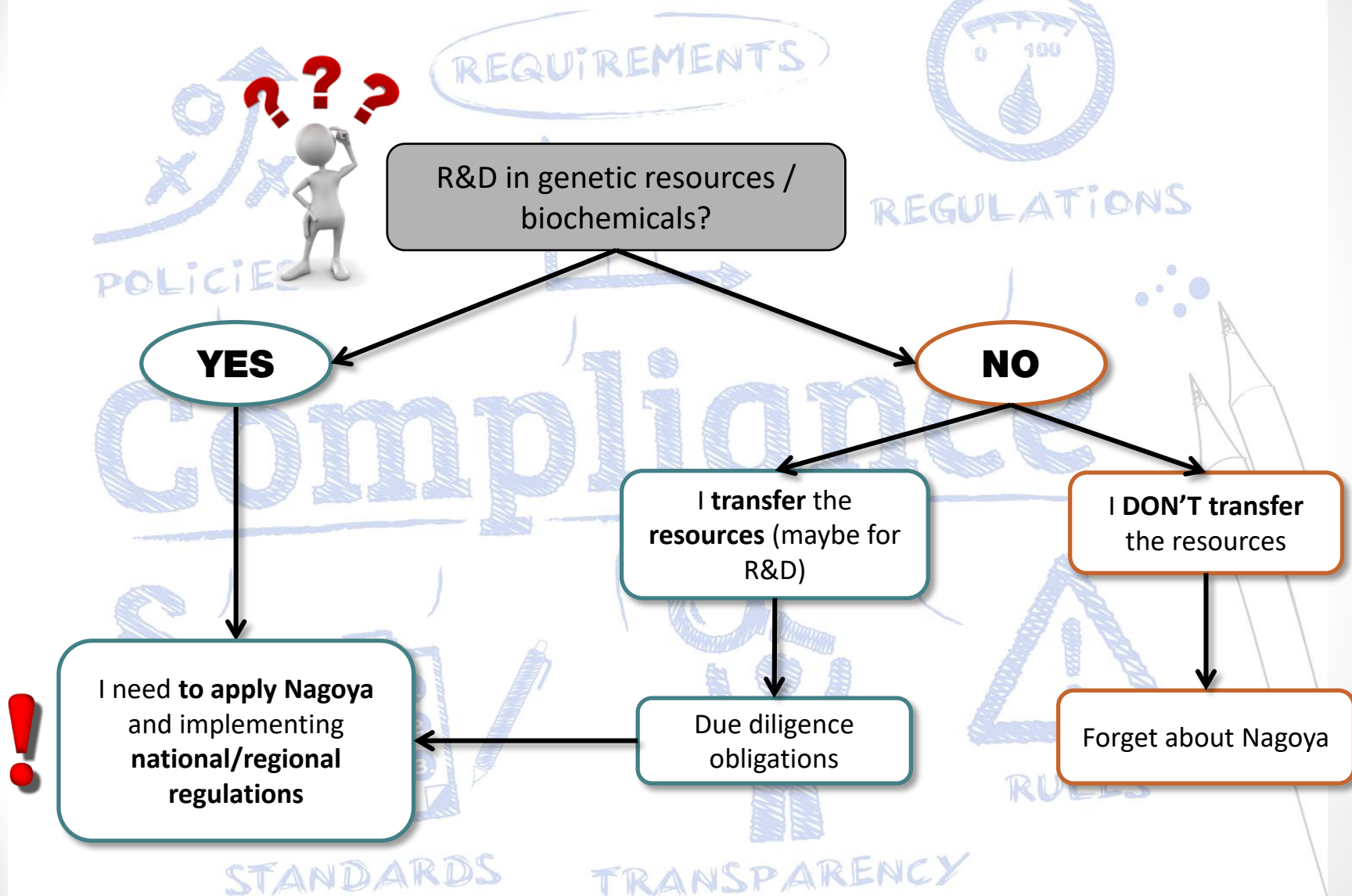


PRELIMINARY ISSUES FOR CONSIDERATION BY POLICYMAKERS AND REGULATORS

- **BioTrade vs biotrade**
- **Assessing the project, business or activity**
- **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?





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 IS 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.**

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 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.

BENEFITS UNDER ABS SYSTEMS



- Result of access to and utilization of GRs (R&D + commercialization)
- Transfer of low quantities of material: samples or extracts (few kg or even grs)
- Linked to bioprospecting, identification of new applications & product development
- Level of benefit linked to results of R&D + commercialization (mostly medium and long term)
- Mandatory
- To be shared with providers or States

BENEFITS FROM BIOTRADE



- Based on the sourcing of biological resources (natural ingredients)
- Transfer of significant quantities of unprocessed material, often in bulk
- It may imply at a certain stage also the utilization of GRs or TK
- Linked to payment for goods & services provided
- BioTrade P&C are voluntary but payment of price is business requirement
- Benefits emerge along the value chain (short & medium term)
- To be shared with local providers and processors (SMEs & local communities)

BENEFITS FROM TRADITIONAL KNOWLEDGE



- Consequence of access and use of TK (intangible).
- Multi use (from R&D to wide range of goods and services)
- Linked to licenses and biocultural protocols
- Only mandatory in countries with legislation
- Level of benefit depends on the value of the TK and use (short to long term)
- Shared with indigenous and local communities



BENEFIT 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



CONTRACTUAL ISSUES

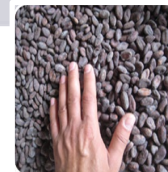
ABS contract / MAT

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



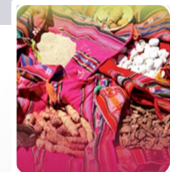
BioTrade Agreements

- **Object:** sales of goods and services (e.g. natural ingredients)
- **Subjects:** business to business
- **Cause:** sourcing, processing & commercialization (potentially R&D)
- **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
- **Applicable law:** TK regulations + private law + customary law





ABS compliance mechanisms



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

- Take appropriate, effective and proportionate legislative, administrative or policy **measures to provide that GR utilized within its jurisdiction have been accessed in accordance with PIC and MAT**, as required by domestic legislation.
- Take similar measures to **address situations of non-compliance**.
- **Cooperate in cases of alleged violations** of domestic legislation or regulatory requirements.

Example of user/provider country compliance measures:

- **Due diligence** (e.g. ensure legal access and that benefits are shared);
- **Register of trusted collections of GR**;
- **Disclosure** of origin/source and legal source in IP filings;
- **Check points** at research funding, commercialisation and borders;
- **Internationally Recognised Certificates of Compliance (IRCC)** can help in the verification process.



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.
- Introduce expedited ABS procedures for BioTrade companies
- Recognize the benefits already granted under BioTrade as part of the benefits under ABS
- Allow for regularization mechanism/legal

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 economic incentives to companies that meet BioTrade Principles & Criteria.

Capacity building (for policymakers and regulators):

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



Undertaking activities on TK and within IPLCs lands and territories (1)



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

- Check how biodiversity is sourced (e.g. harvesting of wild species or cultivation of native species);
- Check if uses of materials are linked to ATK (ATK is often associated with biological rather than genetic resources) and if ATK is used to orient R&D activities;
- Lack of care may lead to political conflict and unnecessary costs

BioTrade calls for respecting IPLCs rights and for the protection of ATK.

- See BT Principles 3 (Fair and equitable sharing of benefits derived from the use of biodiversity), 4 (Socio-economic sustainability), 6 (Respect for the rights of actors involved in BioTrade activities), and 7 (Clarity about land tenure, use and access to natural resources and knowledge).



Undertaking activities on TK and within IPLCs lands and territories (2)



The Nagoya Protocol includes specific provisions on ATK (Articles 7, 12 and 16). Main objectives are:

- Ensure that PIC and MAT are obtained when ATK is utilized,
- Ensure that benefits from utilization are shared with IPLCs,
- Ensure that national ATK-related legislation is respected and complied with in user countries, and
- that countries endeavour to support the development of community protocols, minimum requirements for MAT, and model contractual clauses

Understanding TK laws

- The use of ATK may not only be subject to special laws but to customary law
- Triggers for GR resource use may be different than for ATK
- Check for minimum conditions for PIC and MAT, as there may be different counterparts than for access to GR



Intellectual property in ABS and BioTrade businesses

Positive protection through patents and plant variety protection

- Patentability criteria: new, involves an inventive step, and is capable of industrial application;
- Plant variety protection: new, distinct, uniform and stable;
- Very few cases of successful application of patent or plant variety protection that have also complied with ABS regulations.

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 Colombia, developing natural ingredients with extraordinary dermo-cosmetic 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.





Working together for a better world



Thank you for your attention

BioTrade is supported by the Swiss State Secretariat for Economic Affairs SECO, Governments of Norway, Spain, The Netherlands, as well as the UN Foundation and UN development account

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