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## **Clarifying BioTrade and ABS: *Dealing with national ABS frameworks***

David Vivas Eugui, UNCTAD & Balakrishna Pisupati, UNEP



[david.vivaseugui@unctad.org](mailto:david.vivaseugui@unctad.org)  
[Balakrishna.pisupati@unep.org](mailto:Balakrishna.pisupati@unep.org)  
[balapisupati@yahoo.com](mailto:balapisupati@yahoo.com)



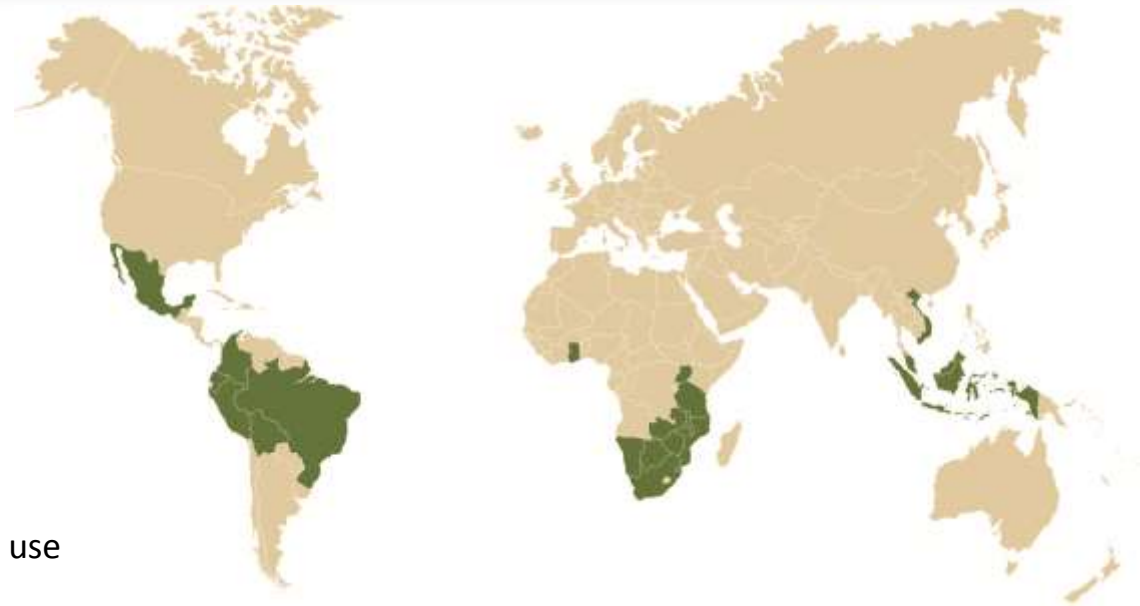
- The Nagoya Protocol entered into force on 12 October 2014.
- There are over 80 ratifications so far..
- The Protocol is the result of a "**compromise**" between the Parties. It does not represent the highest level of ambition expected by the richest countries in biodiversity.
- The protocol is **not self-executing** → It needs **national implementing regulations and administrative systems**
- The **ABCD** of the Nagoya Protocol:
  - **Access** (facilitated)
  - **Benefit Sharing** (subject to MATs)
  - **Compliance** (monitoring, verification, check points and enforcement)
  - **Definitions** (i.e. utilization & derivative)

# What is BioTrade?

BioTrade: activities of collection/production, transformation and commercialization of goods and services **derived from native biodiversity** under criteria of environmental, social and economic sustainability..

## BioTrade Principles

1. Conservation
2. Sustainable use
3. Fair & equitable benefit-sharing
4. Socio-economic sustainability
5. Legal compliance
6. Respect for actors' rights
7. Clear land tenure & resource access and use



Carbon sequestration



Pharma,  
healthcare,  
cosmetics and  
fashion



Sustainable tourism



Flora and fauna



Handicrafts



Textiles and  
natural fibres

# The economic value of BioTrade

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- Activities in BioTrade have benefited approximately **30,000 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.
- Sales revenues of BioTrade beneficiary organizations, working with small and medium-sized enterprises and multinational companies, amounted to **US\$5.2 billion in 2012 – compared with US\$2.3 billion in 2010.**



Principle	Criteria
<p><b>Principle 3:</b></p> <p>BioTrade activities which involve the commercialization of genetic resources are linked to the benefit sharing objective of the CBD. Equitable benefit sharing also arises in the context of sustainable use of biodiversity. Benefit-sharing is therefore also important in activities dealing with <b>biological resources</b>, which form the vast majority of BioTrade activities.</p>	<p><b>3.1</b> The organization should interact and involve actors along the whole value chain, where possible. This reduces asymmetries and ensures <b>negotiation of fair and equitable monetary and non-monetary benefits, especially by weakest links along the value chain.</b></p> <p><b>3.2</b> <b>Income should be generated along the value chain</b>, by contributing to the position of value-added products in the market, under transparent conditions, as a condition for benefit sharing.</p> <p><b>3.3</b> Information and knowledge of target markets should be made available and shared among actors, <b>to enable access to market opportunities.</b></p>

## Principle

### Principle 7:

Clarity about rights of access is very important. Only then can long-term investments be made or corresponding management measures be implemented to ensure sustainability. At the same time, clarity on this issue means that the responsibilities of each actor can be clearly established.

## Criteria

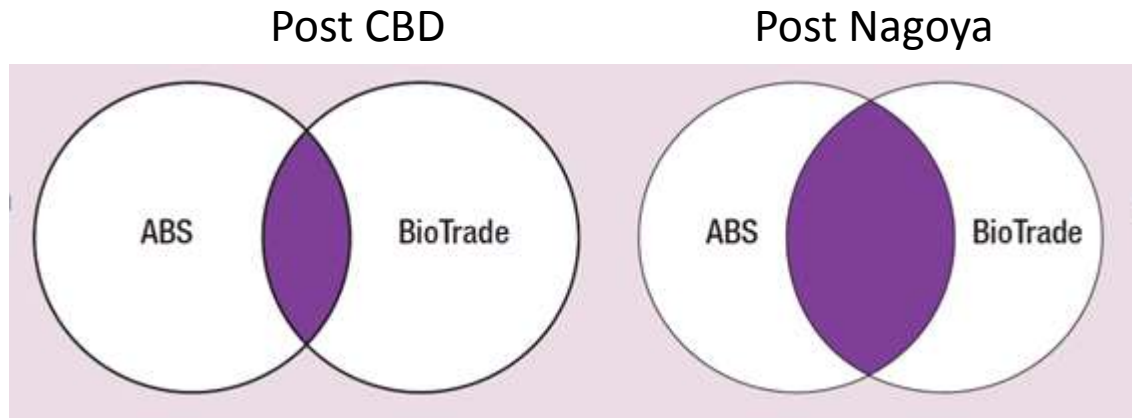
**7.2 Access to biological and genetic resources for sustainable use should be subject to prior informed consent.** The Convention on Biological Diversity requires access and distribution of benefits in relation to genetic resources. In such cases, the consent of all relevant national authorities in the provider country should be obtained. These cases are normally regulated by national legislation, in line with the Convention on Biological Diversity.

**7.3 Access to traditional knowledge should be granted only where prior informed consent has been verified.** Where traditional knowledge is used, the organization should follow all regulations and their established procedures to ensure that the rights of the actors providing this knowledge are recognized, including the right to prior informed consent of all relevant stakeholders, such as indigenous and local communities, as appropriate and subject to domestic law. **Traditional knowledge should be valued and rewarded in the appropriate manner.**

# Links between the Protocol and BioTrade

BioTrade	Nagoya Protocol (ABS)
Voluntary system	Mandatory regulation
Use of biodiversity along the value chains (BioTrade with capital "C & T")	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.

# Why are we discussing about ABS and BioTrade?



The definition of the scope depends of national legislation. There are two main triggers:

- **Object:** genetic resources, biological resources, biochemical of natural origin and derivatives
- **Activities:** R&D & commercialization but what type of R&D. The protocol does not specify.

In a post-Nagoya Protocol world, ABS rules and policies increasingly relevant to sourcing of natural ingredients, for actors along supply chains

It is almost impossible to bring new products and processes to the market in a value chain without some level of R&D

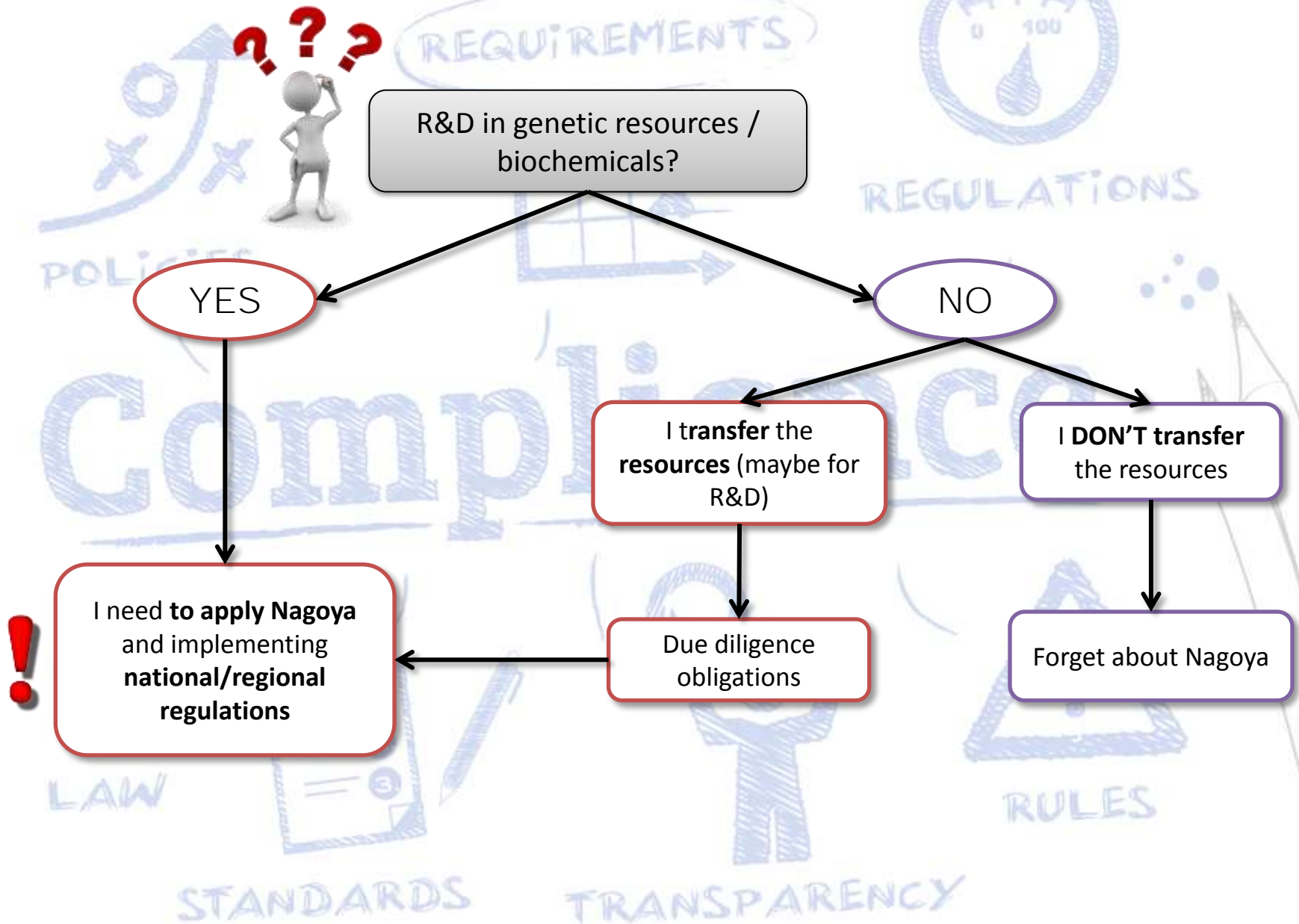


Law or regulation	Specific provisions on national law
Order No. 18, biodiversity law in Viet Nam (2008)	<p><u>Article 3.29 (Definitions)</u>  <b>Genetic resource</b> includes all species and genetic specimens in nature, conservation zones, biodiversity conservation facilities and scientific research and technological development institutions and in nature,  <b>Access to genetic resources:</b> means activities of investigating and collecting genetic resources for research and development and production of commercial products.</p>
Biodiversity Act (2002) and Rules (2004) in India	<p><u>2. Definitions. (f) "commercial utilization"</u> means end uses of <b>biological resources</b> for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture (...)  Chapter II. 3.1. No person shall, without previous approval of the NBA, obtain any biological resource occurring in India or knowledge associated thereto <b>for research or for commercial utilization</b> or for bio-survey and bio-utilization.</p>
Supreme Decree 002-2009-MINAM, ABS regulation on Peru (2009)	<p><u>Article 4 (Scope).</u> The regulation applies to <b>genetic resources</b> of which Peru is a country of origin, <b>its derived products, intangible components and genetic resources of migratory species ...</b>  <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>
Andean Community Decision 391 (1996)	<p><u>Article 1 (Definitions).</u> <b>Derived product:</b> 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.  <u>Article 3 (Scope).</u> This Decision is applicable to <b>genetic resources</b> for which is the Member Countries are the countries of origin, <b>to their derived products ...</b></p>
Amendments to the Biodiversity Act No. 10, on bioprospecting and ABS in South Africa (2015)	<p><u>Chapter 1. (Definitions).</u> 1. <b>Biotope:</b> Means the buying and selling of milled, powdered, dried, sliced or extract of indigenous <b>genetic or biological resources</b> for further commercial exploitation.  <u>(Application of these regulations).</u> 3.1. These regulations apply to (a) <b>commercial or industrial sectors that utilize any indigenous genetic and biological resources for biotope or for research</b>, application or development of drugs, complementary medicines nutraceuticals, industry enzymes, food flavors, fragrances, cosmetics, emulsifiers, oleoresins, colors, extracts and essential oils.</p>
Law 13.123 on ABS in Brazil (2015)	<p><u>Article 1. (General provisions).</u> This law applies to rights and obligations related to:  IV. the economic exploitation of the <b>final product</b> or reproductive material derived from the genetic patrimony  V. fair and equitable benefit sharing related to the economic exploitation of the final product or reproductive material derived from the genetic patrimony  <u>Article 2.I. (Definitions).</u> Genetic patrimony: <b>information of genetic origin</b> of plant, animal, microbial or other species, including substances originated from the metabolism of living beings.</p>

## Examples of BioTrade-type activities potentially related to the Protocol provisions or National ABS/TK regulations depending on the law

- 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 potential compositional variations. Example the utilization of *Centella asiatica* extracts whose compositions vary depending on the source, extraction process and harvesting practices
- Any biotechnology process which is using enzymes to lyse the plant cells and allow separating 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 TK from an indigenous community and using it to orient and guide initial phases of R&D processes (e.g. regarding use, characteristics, and dosages of medicinal plants)

# Am I covered by the Nagoya Protocol?



# User measures, international certificates and impact on flows



All countries are both providers and users (exporters and importers)

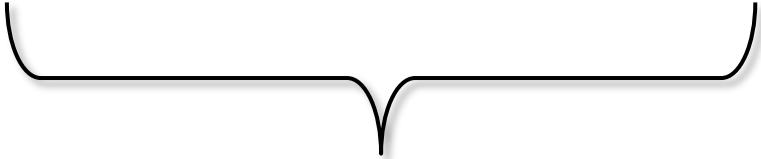
Demand for legal access → from regulations in user countries



First mover advantage for first business requesting access for commercial activities

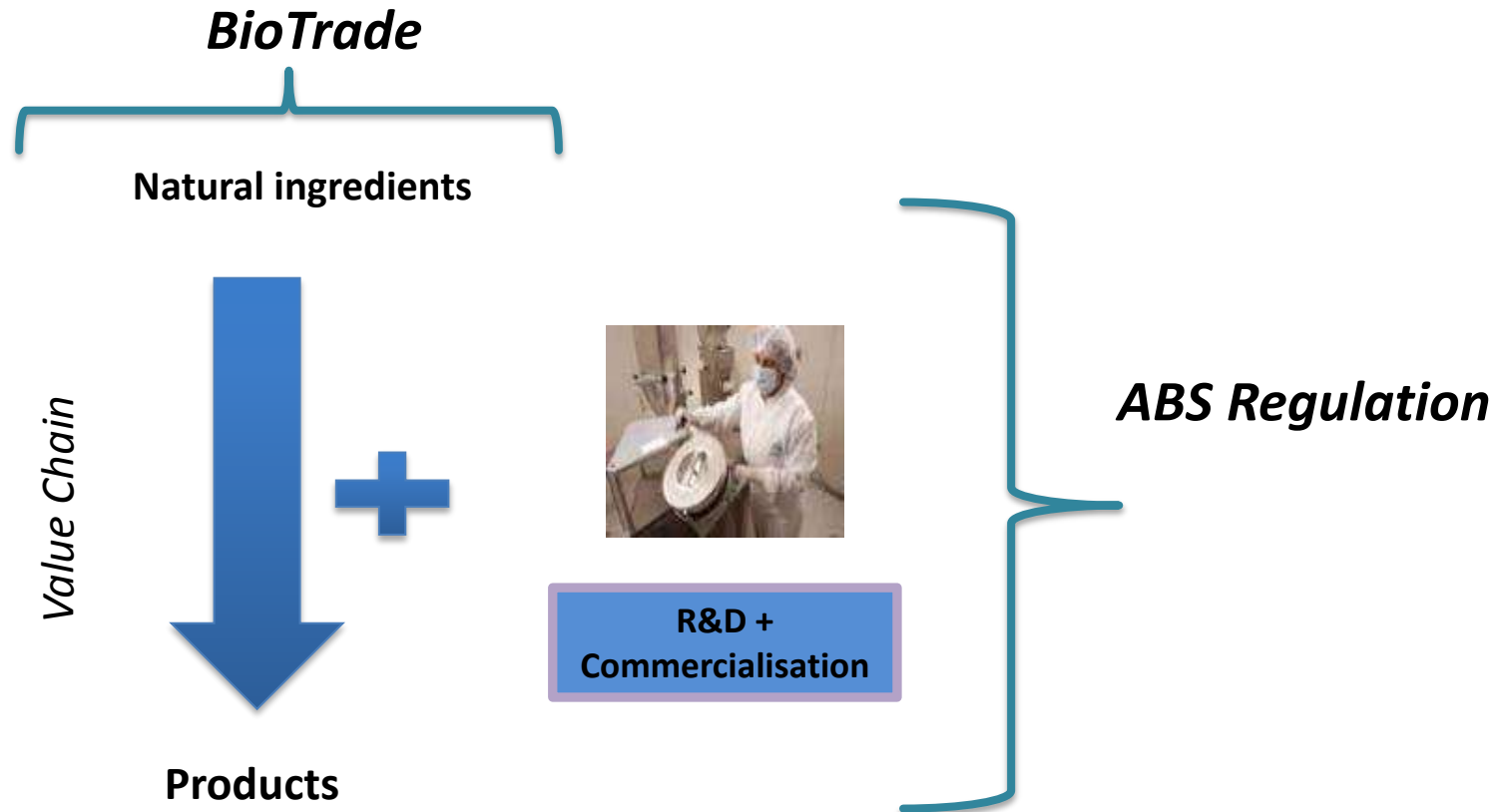


International certificates of compliance are starting to be issued

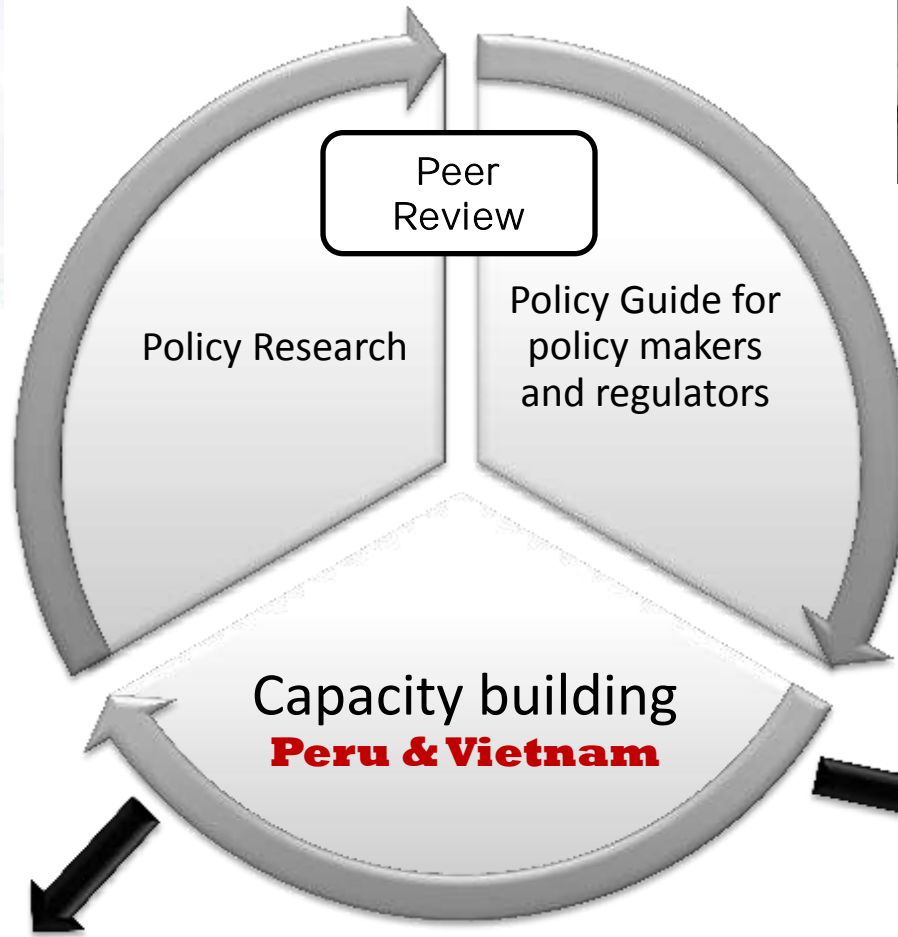


Comparative advantage from playing legal

# A simplified view of the relationship



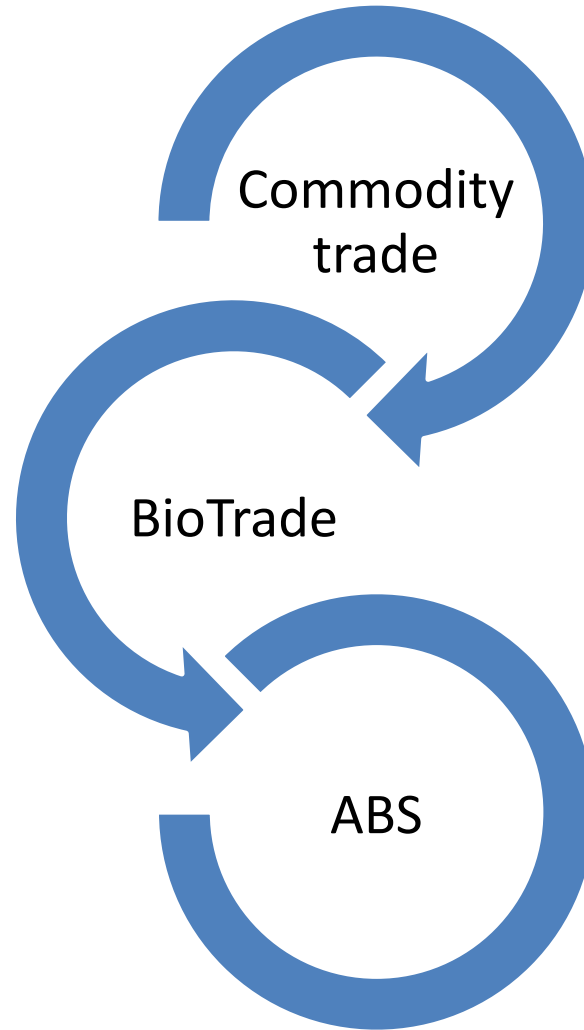
# UNCTAD's contribution



Training and consultations on Nagoya, ABS & BioTrade

Ad Hoc support on National implementation

# Wrap up comparison



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**Balakrishna Pisupati, UNEP**

[Balakrishna.pisupati@unep.org](mailto:Balakrishna.pisupati@unep.org)  
[balapisupati@yahoo.com](mailto:balapisupati@yahoo.com)



# Links between BioTrade and ABS – *Key Issues*

- Limited guidance from the Nagoya Protocol
- Interpretation and clarifying relationship left to individual countries;
- Significant activities on trade in biological resources at national level;
- Limited understanding of BioTrade principles;
- Misinterpretation of words such as ‘commercial utilization’, ‘extracts and derivatives’, ‘value addition’ and others

# Differentiating BioTrade and ABS

- In legal terms, access related to BioTrade and ABS are two different concepts although they might be mistakenly understood to mean the same.
- While one looks at trade in biological resources the other looks at research, development and prospecting on resources.
  - This misunderstanding may be due to the fact that both of them involve a variety of value chain actors, and
  - Activities involved in the utilization of genetic resources and the products derived there from

# BioTrade and ABS

Products from biological resources	BioTrade	ABS
Extracts, natural dyes, production of soaps, cream and butters, moisturizers, infusions from medicinal plants.	Supply of raw materials and natural ingredients to prepare such products employing fair trade practices	In case when access is sought to undertake R&D to eventually extract and commercialize natural ingredients or products containing them
Essential oils and natural medicines	Production under existing or known methods employing fair trade practices	R&D based on essential oils and natural ingredients  Depends on the national legislation.

# The Key Problem !

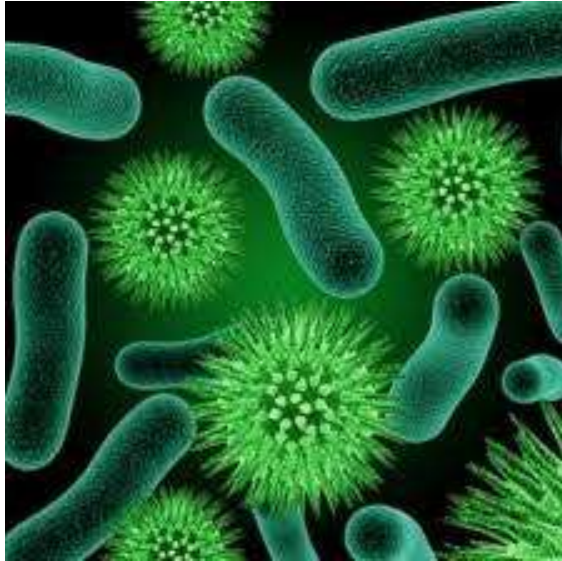
Attempting to cover any/all commercial uses of genetic resources under national ABS frameworks will not only create serious conflicts between the trade policies of countries and implementation of the Nagoya Protocol, but also will undermine the objective of ABS as elaborated under the CBD and the Nagoya Protocol.

# Commodity Trade



- ✓ Commodity trade always promoted and contributes to national and local economy
- ✓ Commodity trade in biological/genetic resources is largely out of preview of conservation, sustainable use and ABS
- ✓ Data on trade and monetary returns generally vague

# Utilization and Commercial Utilization



- Under Nagoya Protocol there is no definition for commercial utilization.
- Utilization of genetic resources defined as *“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”*

Lot of confusion exist at national level on differentiating commodity trade and commercialization

# How countries have defined ‘Utilization’ and ‘Commercial Utilization’

## A

"commercial utilization" means end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping;

## B

‘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

# Defining Utilization and Commercial Utilization

## 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.

**BioTrade:** means activities of collection, production, transformation, and commercialization of goods and services derived from native biodiversity under the criteria of environmental, social and economic sustainability

## D

“commercialisation” means the following activities in relation to genetic resources -

- (a) the filing of any complete intellectual property right application, whether in or outside the country;
- (b) obtaining or transferring any intellectual property rights or other rights;
- (c) *commencing clinical trials and product development, including the conducting of market research and seeking pre-market approval for the sale of resulting products;*
- (d) *the multiplication of genetic resources through cultivation, propagation, cloning or other means to develop and produce products, such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours and extracts; or*
- (e) any other legal, commercial or scientific process aimed at acquiring, protecting or realising any real or potential commercial value of any genetic resources or any component or any associated traditional knowledge; and
- (f) transfer of results of any research based on the accessed genetic resources and/or associated traditional knowledge



# Country Approaches

**Brazil:** Changing approaches to ABS On 20 May 2015, Brazil adopted Law 13.125, which establishes the procedures that companies and other organizations will need to follow to work with Brazilian biodiversity. The new law repeals a 2001 measure widely criticized as too complex and bureaucratic. Authorization to access biodiversity for research and development, until now granted by a national council, will no longer be required. Companies will have to register on an online database. Benefit sharing, previously negotiated for each individual case, will fall on the final product manufacturer, and take place primarily through payment of a percentage of profits to the national trust fund.

# Country Approaches

**S. Africa** : On 19 May 2015, the Department of Environmental Affairs of South Africa published amendments to its regulations on bioprospecting, access and benefit sharing. Among new requirements established is a permit for “biotrade,” defined as the buying and selling of dried, powdered, sliced or extracts of indigenous genetic and biological resources for commercial purposes. This would explicitly include the use of biological material in developing medicines, nutraceuticals, industrial enzymes, food flavors, fragrances, cosmetic ingredients and essential oils. An application for a biotrade permit must be accompanied by proof of prior consent, a material transfer agreement and a benefit-sharing agreement involving the local provider.

# Complimenting BioTrade and ABS

- ABS could be used to achieve BioTrade as a means of livelihood to local communities to ensure sustainability, conservation and socio-economic development.
- While applying the NP ABS obligations, businesses should also look into fulfilling the other principles of BioTrade and thus promote BioTrade implementation in the value chains.

# Complimenting BioTrade and ABS

- BioTrade programs could develop local communities' capacities to engage with market and commercial stakeholders in trade processes.
- This capacity development coupled with sensitization of rights under ABS could prove enabling for the communities' stakeholders to engage with accessors/users of genetic resources and associated knowledge through prior informed consent and mutually agreed terms.

# 6 things to do!

1. Ensure the ABS policy/framework considers the specificities of policies of trade and commerce
2. Clarify scope of the framework from the purview of utilization
3. Differentiate commodity trade and commercial use (from ABS perspective)

# Things to do...

4. Make ABS norms more predictable  
(exemptions and special conditions)
5. Ensure the focus is on promoting use  
and research and development
6. Provide for easy means to deal with  
non- commercial research and  
development

# ABS Clinic at COP MOP 2 ??

- ✓ Discuss specific issues and problems
- ✓ Exploring practical options to make ABS an innovative financing mechanism
- ✓ Identify options for implementation of the Nagoya Protocol, ITPGRFA and BioTrade actions



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**BioTrade**  
initiative

Thank you

[www.biotrade.org](http://www.biotrade.org)



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