



**“Working together for a better world”**

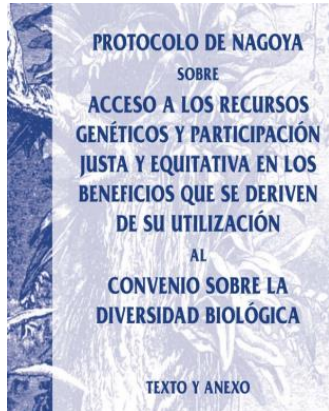
**- BioTrade Initiative -**



## ***Introduction to the links between the Nagoya Protocol, ABS & BioTrade***



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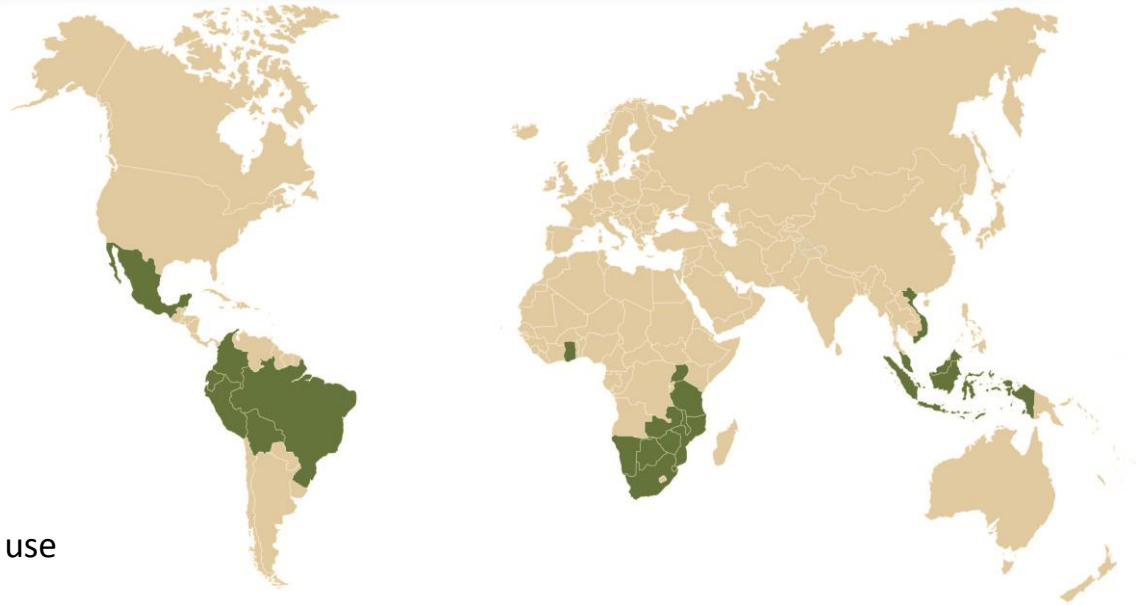
- The Nagoya Protocol entered into force on 12 October 2014.
- There are over 70 ratifications so far. Vietnam ratified in 2014.
- The Protocol is the result of a "**compromise**" between the Parties. It does not represent the highest level of ambition expected by the richest countries in biodiversity.
- 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

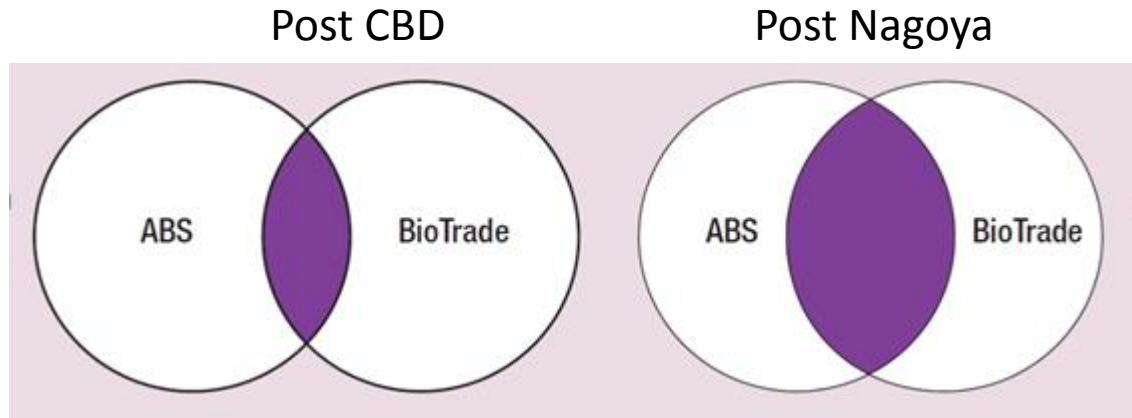
**7.2 Access to biological and genetic resources for sustainable use should be subject to prior informed consent.** The Convention on Biological Diversity requires access and distribution of benefits in relation to genetic resources. In such cases, the consent of all relevant national authorities in 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	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

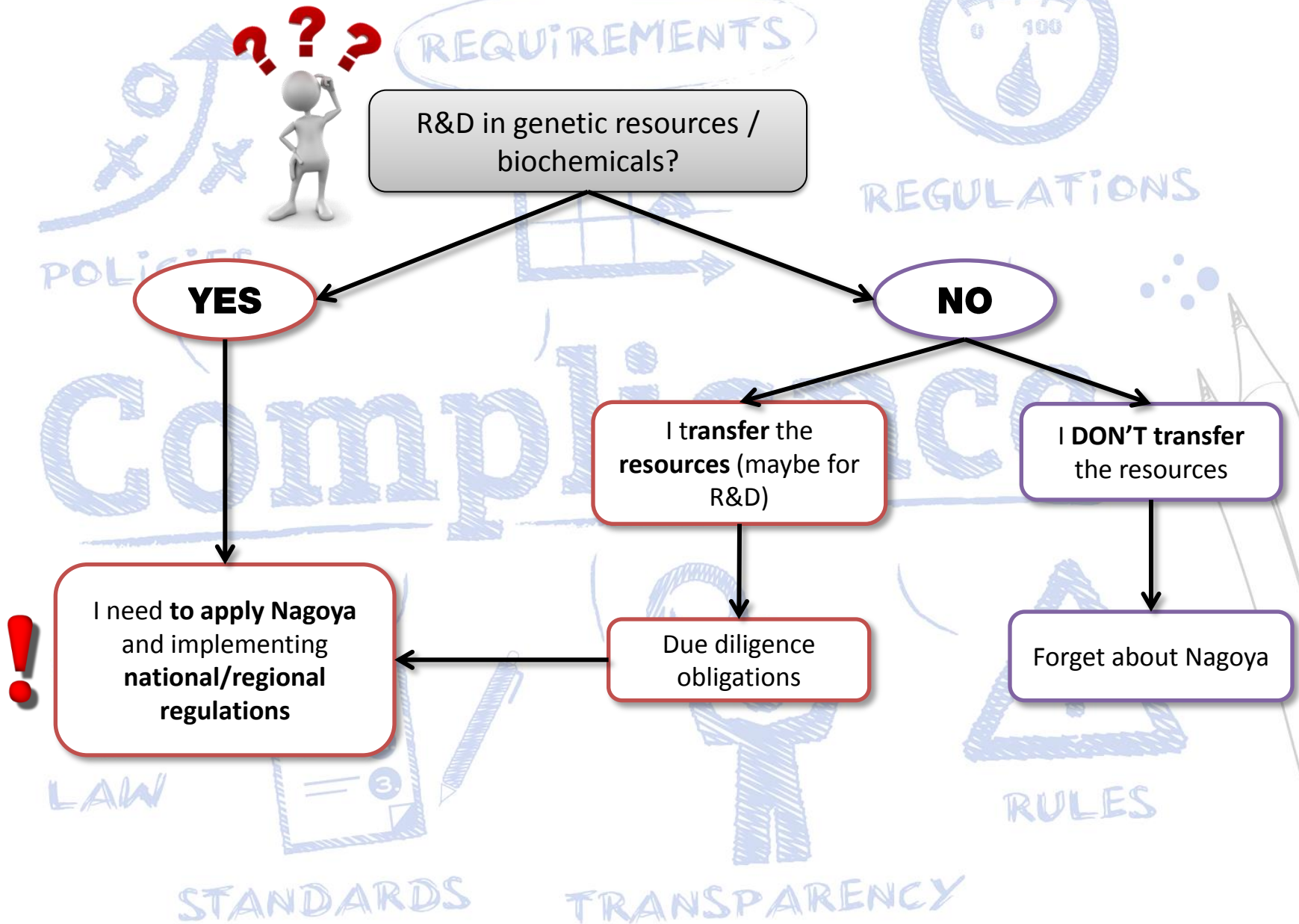


Law or regulation	Specific provisions on national law
Order No. 18, biodiversity law in Viet Nam (2008)	<p><u>Article 3.29 (Definitions)</u>  <b>Genetic resource</b> includes all species and genetic specimens in nature, conservation zones, biodiversity conservation facilities and scientific research 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?



# Example of ABS in a BioTrade value chain



# The case of Vietnam

Pre-Nagoya ABS regulations (2008 & 2010)



BioTrade sales = 100-200 Mil

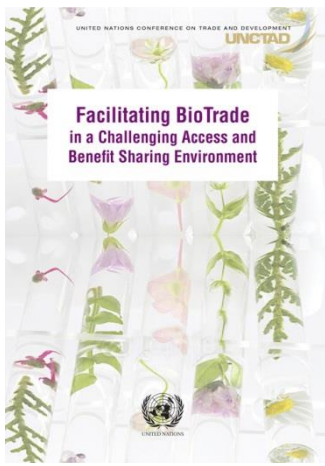
Only one ABS contract issued  
**BUT**  
4 access requests have been received since Nagoya

Vietnam is **revising its regulations and administrative practices** to effectively implement Nagoya

Simple

Not burdensome

BioTrade-friendly



## Some recommendations for decision makers and regulators

- ABS regimes should be transparent, clear, operational and applicable in practice to enhance legal certainty for all actors;
- Decision makers and regulators should ensure that their ABS frameworks truly facilitate ABS and do not overstress regulation and control;
- UNCTAD could develop a checklist that guides decision makers and/or regulators on how close or far is a particular BioTrade activity from the coverage by national ABS regulations and procedures;
- UNCTAD should develop a synthesis of case studies of how countries are determining the interlinkages between BioTrade projects and businesses and ABS frameworks;
- Competent authorities should communicate and coordinate in a regular manner to ensure coherent implementation of rules and procedures;



## Some recommendations for decision makers and regulators (cont.)

- Incentives to promote ABS and compliance with rules need to be put in place and into motion in order to promote legal, sustainable, equitable and ethical flows of trade in genetic resources and biochemicals;
- There is a need for further understanding on the changing and very diverse R&D landscape and the particularities of each sector;
- Decision makers and regulators should consider ways in which PIC and MAT within BioTrade projects or businesses can become regularized or validated through simple and practical administrative procedures;
- Clear and easy procedures to obtain permits or their equivalent may be evidence of the decision to grant PIC and of the establishment of MAT; and
- There is an urgent need for awareness raising and capacity building on ABS and BioTrade for national authorities and BioTrade actors.



Working together for a better world



Thank you

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

