

# PEER REVIEW ON THE IMPLEMENTATION OF THE NAGOYA PROTOCOL AND ITS IMPACT OVER CERTAIN ASPECTS OF BIOTRADE

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## CHALLENGES ON THE IMPLEMENTATION OF BIOTRADE AND ACCESS AND BENEFIT SHARING

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### Challenges on the Implementation of BioTrade and Access and Benefit Sharing

Expert contribution to the UNCTAD Peer Review on the "Implementation of the Nagoya Protocol and its impacts over certain aspects of BioTrade"

#### Issues related to use of ABS regulations in BioTrade activities

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#### Scope of the contribution

Though the NP addresses ABS in both providers and user countries, the purpose of this note, as a contribution to the UNCTAD's Peer Review, is to provide a series of questions that need to be addressed in development of clear national ABS regulations that would facilitate the development of BioTrade projects/initiatives in countries providing biological resources.

#### Key ABS requirements and BioTrade

With the entry into force of the Nagoya Protocol on Access and Benefit Sharing (NP), both BioTrade companies to access international markets, and indigenous people and local communities (IPLCs) engaged in providing biological resources derived from biodiversity to fully and efficiently participate to the development of BioTrade value chains now face access and benefit sharing (ABS) regulatory compliancy.

They both require an ABS system that is transparent and provides the legal certainty they need to ensure the economic sustainability of their activities and the long-term commitment required for their investments. In that sense, efficient administrative procedures for evaluating requests to access genetic resources (PIC), negotiating stable contracts with providers (in particular with IPLCs) and enforceable MATs (community protocols) specifying benefit-sharing arrangements will be essential.

Moreover, it is widely acknowledge that the BioTrade concept represents a valuable guide for implementing NP-ABS compliant value chains since they already incorporate benefit sharing schemes and the direct involvement of IPLCs in harvesting and processing raw material. In addition, the BioTrade concept includes the respect of additional principles such as the conservation and sustainable use of biodiversity, respect and clarity about rights, and compliance with national and international regulations.

One of the key conditions for the success of BioTrade activities is, therefore, to be contingent to smooth ABS functioning national frameworks that will benefit all parties and stimulate the creation of knowledge and benefits from R&D on genetic resources while making value chains an effective tool to enable biodiversity conservation and promote the sustainable use of biodiversity, including natural ingredients and other bioactive compounds for the cosmetics, food and pharmacy sectors. Meeting this goal would require all stakeholders working in BioTrade value chains – government, traders, business, researchers, and ILCs – working together and building mutual trust.

However, for the NP to represent an adequate national framework that would support/facilitate the development of BioTrade initiatives – aimed at promoting biodiversity conservation and supporting the sustainable use of biological resources derived from biodiversity for the development of innovative business, while creating more benefits for all BioTrade value chains' stakeholders - additional work should be done to go beyond regulations and provide more guidance on how to comply with the new NP-ABS requirements.

#### The Challenge

For the time being, however, larger companies operating in the natural cosmetics, food and pharmaceutical sectors remain generally uninformed about the CBD and the NP and the issues they address, or generally cautious and, therefore, disinclined to invest in ABS agreements.

In 2012 and 2013, based on terms of reference developed by the IFC, a market mapping was conducted by the Union for Ethical BioTrade (UEBT) in Colombia, Peru, Bolivia and Brazil. The objective of this market mapping was to provide a thorough understanding of challenges faced by companies operating in the natural cosmetics, food and pharmaceutical sectors of these four Andean and Amazon countries, serve as foundation for the development of BioTrade market expansion strategies and yield to a short list of companies that could potentially be involved in Ethical BioTrade in the short term.

As part of this study an internet survey tool was developed by UEBT followed by in-depth interviews of several hundreds companies' representatives and national experts of these four countries in relation to three key areas, namely (i) sustainability, biodiversity and natural ingredients; (ii) access and benefit sharing; and (iii) ethical BioTrade practices.

The summary table below indicates that, aside of UEBT members and some other certified companies operating at international level, a large amount of producers and manufacturers operating in the three aforementioned sectors are too rarely familiar with the ABS concept, intellectual property and traditional knowledge or insecure (due to the lack of understanding of ABS rules and procedures), or even only concerned by administrative complications and, therefore, inconsistent with or uninterested by adherence to ABS requirements.

Companies' answers and positions regarding ABS	Colombia in %	Peru In %	Bolivia in %	Brazil in %
Do not know the meaning of ABS	18	NA	19	32
Do not consider developing an ABS policy	10	NA	11	14
Have consider having an ABS policy, but have not yet having any ABS policy in place	35	36	31	31
Have an ABS policy in place with only a few practical cases of ABS	20	28	25	9
Have an ABS policy in place with an increasing number of ABS practical cases	16	36	17	14

Therefore, promoting BioTrade initiatives based on biological resources derived from biodiversity must be enhanced by a strong information strategy for companies to consider the relevance of ABS for their activities, their policies and their supply practices.

#### Clarifying national ABS concepts to streamline BioTrade initiatives at national level

Implementing with success BioTrade initiatives would be challenging when legal ABS provisions would remain unclear. The draft document submitted to our review rightly states that the successful implementation of ABS regulations within BioTrade initiatives would clearly depend on the clarification of remaining uncertainties that should be made transparent into ABS national legislation.

Therefore, there is a series of questions that should be address when developing national ABS frameworks<sup>1</sup>:

• What should national ABS regimes cover to facilitate the development of BioTrade activities?

It is critically important for countries to clearly define what the scope of national ABS frameworks is and what biological resources are covered and what kind of biological resources are exempted. Some of key issues that should be addressed in this context are related to:

- What nature and types of biological resources are concerned with ABS and for what purpose(s) or utilization(s);
- How is access to biological resources or utilization of biological resources defined and what activities are covered by ABS requirements?
- What makes a transaction eligible to ABS e.g. what kinds of activities constitute "utilization of genetic resources"?
- o Who owns biological resources?
- o How is indigenous and local communities and traditional knowledge defined, e.g. who owns traditional knowledge associated with biological resources and what rights are associated with this ownership?
- Under what conditions can national users (research institutions, universities, public or private sector commercial companies, etc.) be authorized to access biological resources – e.g. are they subject to Prior Informed Consent (PIC) from traditional knowledge owners?
- Under what conditions can foreign users be authorized to access national biological resources – do they need specific authorizations, and if so what are they?
- Who grant PIC for use of biological resources and/or traditional knowledge?
- What are the PIC procedures for either scientific or commercial activities and what are the key conditions for obtaining PIC e.g. are there different PIC requirements for different types of biological resources and different types of utilization?
- What are the key elements of Mutually Agreed Terms (MATs community protocols) and what are the procedures for the negotiation of MATs?

<sup>&</sup>lt;sup>1</sup> Most of these questions were asked during the inception phase of the Vietnam BioTrade project implemented by Helvetas/Intercooperation during the period 2012-2014. They, however, for most of them remain unanswered at the project official completion time in December 2014).

- What are the specific elements in place for the sharing of monetary and non-monetary benefits e.g. national users vs. foreign users?
- How to implement Prior Informed Consent (PIC) and Benefit Sharing regulations

The NP obliges Parties to develop clear rules for access to genetic resources and TK associated with genetic resources/biological resources. It further asks Parties to take into consideration IPLCs customary laws and rules, community protocols and procedures when implementing ABS regulations.

In spite of the fact that the above elements are widely recognized by both the NP and BioTrade Principles, their operationalizing remains a challenge. In particular, processes for companies to obtain PIC and for negotiating MATs (i.e. community protocols) should be clearly identified and should take into account IPLCs own decision decision-making process as well as customary norms, values and laws. Furthermore, IPLCs are generally not aware of their rights to PIC and benefit sharing and do not have yet the capacity to assert these rights. Furthermore IPLCs' collectors and growers have little power to influence prices in the face of companies' middlemen or traders. As a result, in most cases, they accrue little direct benefits from participation in ordinary supply chains (e.g. BioTrade Vietnam; TRAFFIC Bac Can dealing with ethnic minority groups).

The context of MATs (NP Art. 12), which are supposed to act as an interface between IPLCs and companies, needs also to be clarified in national ABS legislation, notably with regard to which institution is mandated to give PIC for the access of genetic resources/biological resources and under which conditions. MATs (community protocols) are indispensable instruments to increase IPLCs awareness and improve their negotiating capacity through community-based capacity building and community level training on ABS.

In addition, rules and criteria regarding benefit sharing are also to be further clarified in ABS national legislations, in particular considering the two possible options: monetary and non-monetary forms (such as access to education, health and sanitary improvement, food security, development of SMEs, etc.).

In case of monetary benefit, it is apparent that benefit sharing will be applied to the final link of the value chain (final products). Therefore, additional questions need to be addressed:

- How to and who should decide between the two options?
- How would those benefits be shared between the government and IPLCs sourcing (or producing) biological resources?
- Where those benefits would be deposited? In the case of Brazil, the government establishes a Benefit Sharing Fund. What kind of other institutional options are available that would lead to biodiversity conservation and sustainable use through an effective combination of rights and incentives?
- Who is entitled to negotiate and sign a benefit sharing agreement?
- Which institution would be responsible for the management of those benefits, disbursement and monitoring?

• What Institutional mechanism would be needed for effective implementation of national ABS frameworks

ABS is not an independent issue that should/could be implemented just for better governance of genetic and biological resources. Appropriate links should be established between the institution that do have the mandate to implement ABS (i.e. in general Ministry of the Environment) with institutions dealing with rural development/forestry (right-based approach to access biological resources, implementation procedures for PIC and MATs on benefit sharing, establishment and management of local committees to implement ABS provisions); with agriculture (notably with regard to the ITPGRFA); sciences and technology (R&D, with reference in particular to IP protection, bioprospecting and investments in prospecting and related benefit sharing using genetic resources); finance and planning (resources needed to implement ABS – capacity building); trade and investment (for tracking and tracing movement of genetic resources outside national boundaries); and with chambers of commerce and professional associations (to popularize the concept of ABS among those members).

The formulation of comprehensive national ABS institutional arrangements would, therefore, be crucial for the development of BioTrade initiatives. In many countries, this would require primarily the harmonization of existing sector policies, notably those related to forestry, biodiversity conservation, agriculture and trade. However, in many instances, many of those institutions are weak or with unclear mandates, notably with regard to authority to deal with biological resources conservation and management. In addition, they may lack suitable capacities and funding to deal with capacity building, awareness raising and training competencies to implement the ABS regulatory and legal components.

In response to the above weaknesses, it is important for countries to clarify mandate over ABS issues, strengthen their ability to function independently in an inter and cross sectoral manner considering ABS implications on forestry, agriculture, rural development, research, trade, finance and women's development policies and ascertain that they are endowed with sufficient financial means, capacities and authority to deliver the mandate.

• How to increase ABS awareness and expand ABS knowledge at local and national levels?

From a BioTrade value chain stakeholders' perspective, the potential challenges of national ABS legislators are to make aware of ABS regulations and benefits both:

- o Providers of genetic resources (IPLCs, SMEs, traders) of the challenges relating to negotiating PIC, MATs and benefit sharing arrangements; and
- Commercial users, researchers and national providers of genetic resources of the real consequences of meeting the goals of national ABS frameworks notably the need to integrate ABS regulations into their standard operational procedures.

In particular, articles 7, 12 and 16 of the NP call for appropriate participation of IPLCs in dealing with ABS issues. This would not only require facilitating mutual understanding between these two groups – a prerequisite for valid and sustainable ABS contracts, mutually agreed terms (MAT) and ABS compliant BioTrade value chains – but also the identification of actions to involve IPLCs in ABS related processes and decision-making and the development

of capacity building activities (e.g. the creation of local community groups) and training to reinforce their capacity to implement ABS provisions.

Furthermore, at national level, awareness raising and training of professional associations (e.g. through the chamber of commerce) and sectoral institutions involved in research, development and trade of biological resources to understand issues related to ABS would also be required. This in order to create national knowledge platforms that would facilitate the development of collaborative agreements on the use of biological resources that would be leading to new investments and innovations and related benefit sharing.

#### Making the drafting national ABS regime user-friendly

In drafting national ABS legislation, and to make it a workable ABS regime and facilitate the development of BioTrade initiatives (i.e. translating the national ABS regime into business terms), the following additional questions remain to be addressed with more details:

- How to avoid possible overburdening of ABS administrative regulations, notably with regard to PIC, MAT and benefit sharing processes that will discourage stakeholders to engage in ABS? - i.e. to keep the ABS administrative burden as low as possible;
- How to address the practical implications of ABS measures, notably the cost of compliance for companies and the sharing of responsibilities for ABS requirements among value chain stakeholders? In this context, meeting the NP requirements will require sustainable financial resources for capacity building at different levels, for all stakeholders including in particular IPLCs;
- How to expand/extend the understanding of ABS measures among value chain stakeholders (from government institutions to businesses and IPLCs) and how to apply ABS requirements in practice – and notably what tools, training and technical support would be needed to engage them into interactive ABS processes?

From a pragmatic point of view, raising awareness for extending the concept of ABS will further require more efforts to document some of the strongest international ABS case to serve as best practices as to inform and thus accelerate the ABS processes in other countries and regions.

In that context, the pioneering work done by UEBT is certainly paving the way - in assessing BioTrade value chain ABS requirements and providing support for compliance with legal and ethical requirements. However, as, for the time being, UEBT involvement still remains restricted to some pioneering companies and BioTrade value chains, the question remain open on how to extend ABS awareness beyond those pioneering companies.