

**UNCTAD BIOTRADE:
Some considerations on Access, Benefit Sharing
and Traditional Knowledge**

Working paper

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for Protecting Traditional Knowledge, Innovations and Practices'*

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EXECUTIVE SUMMARY

In 1996, UNCTAD launched the BIOTRADE Initiative with the objective of stimulating trade and investment in biological resources to promote sustainable development in accordance with the Convention on Biological Diversity (CBD). The initiative enhances the capability of developing countries to produce value-added biodiversity products and services for both domestic and international markets. It is an integrated programme consisting of three complementary components: country and regional programmes; policy development and trade facilitation and Internet services. Programmes are currently being developed in Latin America, particularly in the Amazonian and Andean regions.

This paper provides information on access and benefit sharing, traditional knowledge and intellectual property rights and reflects some of the areas in which BIOTRADE is developing activities as part of the implementation of the country programmes. The first section provides a short overview of some of the issues that countries could consider when developing an integrated strategy for trade and investment in biodiversity products and services. The second section contains an overview of the Andean process, and in particular Decision 391 of the Andean Community of Nations (CAN) on a Common Regime on Access to Genetic Resources. The third section gives a brief overview of the situation in Colombia and Peru with respect to access, benefit sharing and traditional knowledge. As the issues at stake are new and rapidly evolving, BIOTRADE will continue to work towards a better understanding of the scope and implications of the issues for trade and investment in biodiversity products and services.

Section 1: Towards an integrated strategy on trade and biodiversity

Developing countries rich in biodiversity are trying to take advantage of opportunities in the sustainable use of their biological resources, which could generate economic benefits for people whose livelihood depends on biodiversity. New investment and trade opportunities for biodiversity-based products and services include genetic resources, eco-tourism and non-timber forest products, such as natural dyes, oils, medicinal plants. Traditional knowledge of local and indigenous communities sometimes plays an important role in identifying genetic resources and other biodiversity products and services for commercial use.

The CBD established the framework for the conservation of biological diversity, sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of genetic resources. This implies, among other things, the development of adequate policies, legislation, and strategies in the area of access and benefit-sharing arising from the use of genetic resources (ABS), adequate mechanism and tools to protect the associated traditional knowledge, innovations and practices of local and indigenous communities (TK) and related issues of intellectual property rights (IPRs)

Policy integration of the trade, economic, social and environmental sectors is a precondition for the sustainable development of a country, creating a constructive framework for economic growth while attending to social and ecological needs and bringing national legislation in line with international commitments.

National Biodiversity Strategies (NBS) provide a framework for action at all levels, enabling a country to ensure the productivity, diversity and integrity of natural systems, and, as a result, develop within the context of sustainable development. Domestic policy that attempts to make biological resources a viable vehicle for sustainable development should be based upon a clear national biodiversity strategy. When formulating BIOTRADE country programmes, the NBS is normally taken as a point of departure. For the country programmes to be effective, the NBS should elaborate the concepts of trade in biodiversity products and services.

The legal frameworks on use, access and benefit sharing associated with genetic resources are a prerequisite for sustainable trade and investment in biological resources. Legislation is essential to ensure that contractual arrangements serve the strategies and policies set by the Government to comply with the related

provisions of the CBD. To allow for flexibility, transparency and low transaction costs, access laws should be clear, simple, and adapted to the priorities of individual countries. This will facilitate the implementation of laws and commercial arrangements on genetic resources.

With respect to traditional knowledge holders a number of factors influence the degree to which benefits arising from the use of both genetic resources and associated traditional knowledge, innovations and practices are shared fairly and equitably with indigenous and local communities. The socio-political status of the community within the wider societies is perhaps the most important factor influencing the degree to which their basic human rights are respected, and whether their values, cosmic vision and systems of rights and responsibilities are understood and respected.

Section 2: Decision 391 of CAN on a Common Regime on Access to Genetic Resources

UNCTAD, CAN and the Andean Development Corporation (CAF) have elaborated a joint programme to support the development of the BIOTRADE Initiative in the Andean Region. One of the objectives of this programme is to strengthen the formulation of the Andean Biodiversity Strategy in the area of trade and biodiversity. Decision 391 of CAN on a Common Regime on Access to Genetic Resources is essential in this process. It seeks to regulate access to genetic resources of Member States and their derived products with a view to a) establish conditions for a just and equitable participation in the benefits generated from access, b) establish the basis for the recognition and valuation of genetic resources and their derived products as well as of their intangible components, particularly in the case of indigenous communities, c) promote the conservation and sustainable use of biodiversity, d) promote the development and enhancement of local, national and regional scientific, technical and technological capacities, and e) strengthen the negotiating capacities of Member States.

With respect to traditional knowledge, Decision 391, at the sub-regional level, provides formal agreements on covenants, contracts, letters of intent and other instruments for parties to formalise obligations and commitments and is the legal instrument for indigenous people to ensure that their knowledge, innovations and practices are used subject to their consent and to the conditions of benefit sharing.

Nearly four years after being ratified, Decision 391 has yet to be fully implemented in Ecuador, Peru and Bolivia. This delay is due to policy concerns, practical difficulties, legal uncertainties, differing interpretations, institutional limitations, data and informational gaps. These present constraints limit Decision 391 from becoming an effective and efficient legal instrument for these countries. Another challenge is posed by the detailed procedures and terms of the common regime.

Section 3: Colombia and Peru

Colombia acknowledges the relationship between traditional knowledge and the cultural implications of biodiversity use and conservation, and the emphasis needed on a holistic and cultural approach to biodiversity and its associated components. The country recognizes that special measures and tools are needed to protect traditional knowledge, innovations and practices in order for indigenous, Afro-Colombian and local communities to fully exercise their collective rights.

The first BIOTRADE country programme was started in Colombia in 1999 and is coordinated by the Alexander von Humboldt Institute. The programme, called "Biocomercio Sostenible", is developing work along different lines: networking, information systems, business development, market information, investment, and financial mechanisms. A number of demonstration projects are being developed in the areas of medicinal plants and ecotourism. Indigenous communities receive assistance in improving their business skills, in formulating market strategies, and in obtaining market information. Case studies have shown how the protection and use of traditional knowledge, the protection of biodiversity and economic development are inter-connected.

Peru has taken important steps in developing legal instruments to protect the knowledge of indigenous people in the area of biodiversity. The draft proposal on traditional knowledge rests on three main pillars: a) the use of contracts as the legal instrument by which indigenous knowledge related to biodiversity can be negotiated by indigenous peoples themselves and through which their prior informed consent can be obtained, b) the recognition of the collective nature of indigenous knowledge (while acknowledging the fact that within communities individual intellectual efforts are also very important), and c) the possibility for knowledge in the public domain to be subject to contractual provisions upon agreement between parties.

INTRODUCTION

1. New investment and trade opportunities are arising for biodiversity-based products and services, due the emerging biotechnology industry, the increased search by industry for recyclable products, and the renewed interest of consumers from developed countries in 'natural products'. Biodiversity products and services include for example genetic resources, non-timber forest products, ecotourism, and carbon-sequestration. Non-timber forest products are products such as natural dyes, oils and medicinal plants. Genetic resources are used primarily as the source of new economically valuable chemical compounds, genes, or germplasm by industries. Relevant industry sectors include: pharmaceuticals, botanical medicines, major crops, horticulture, crop protection products, applications of biotechnology in fields other than healthcare and agriculture, cosmetic and personal care products. Annual global markets for the products derived from genetic resources are estimated between US\$ 500 billion and US\$ 800 billion¹. The UNCTAD conference in Lyon in 1998 estimated in conservative terms, that the market for extracts and essences taken from tropical biological matter varies between US\$ 30 million and US\$ 60 million annually².

2. The international trade in genetic resources, often referred to as biotrade, involves high economic stakes today. Traditional knowledge of local and indigenous communities can play an important role in identifying genetic resources and biodiversity products and services that have a commercial use. Without this knowledge, many valuable medical products used extensively today, would not exist. To reduce research costs, pharmaceutical, biotechnology and personal care companies sometimes focus their research on plants and animals used by indigenous people for their beneficial qualities³.

3. The Convention on Biological Diversity (CBD) was adopted in 1992, in response to the alarming rate that countries have been losing their biodiversity. The objectives of the CBD include the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of genetic resources. The CBD also introduced the notion of intellectual property rights as a strategy for conserving biodiversity by granting countries sovereign rights over their resources. The value of indigenous knowledge was also acknowledged for the first time in this legally-binding instrument.

4. If trade and investment in biodiversity products and services is to be sustainable and meet the objectives of the CBD, countries need to meet a number of conditions, including legal and policy frameworks directed at the sustainable use of biodiversity, technical and entrepreneurial capabilities, the availability of market information and market access, and biodiversity conservation schemes. Adequate and coherent policies, legislation, and strategies for access and benefit-sharing arising from the use of genetic resources (ABS), intellectual property rights (IPRs), traditional knowledge, innovations and practices of local and indigenous communities (TK), are essential for the sustainable trade and investment in biodiversity

¹ Kerry ten Kate and Laird S. (1999). *The commercial use of biodiversity: access to genetic resources and benefit-sharing*. Earthscan Publications Ltd. London.

² UNCTAD (1998). *Partners for Development Summit: Bio-partnerships for Sustainable Development: commercialisation and the bio-industry challenge*, UNCTAD, BIOTRADE Initiative, 10-12 November, 1998 Lyon, France (see also www.biotrade.org).

³. *Roundtable on Intellectual Property and Traditional Knowledge*. (1999). Geneva, November 1-2, 1999. WIPO/IPTK/RT/99/3.

products. They will help create a stable trading and investment climate, while ensuring sustainability and benefit sharing, balancing the rights of both the users and providers of genetic resources.

5. The BIOTRADE Initiative stimulates trade and investment in biological resources by enhancing the capability of developing countries to produce value-added biodiversity products and services for both domestic and international markets⁴. The country programmes are at the centre of the programme. They identify opportunities and constraints for the sustainable development of biodiversity resources in each country, focusing on bio-business development, bio-partnerships and incentives for conservation, sustainable use and benefit-sharing⁵.

6. The BIOTRADE Initiative, while supporting these programmes, addresses the above issues at various levels. Together with the International Centre for Trade and Sustainable Development (ICTSD), and as a component of the larger mandate of UNCTAD's Trade, Environment and Development Section, it develops mechanisms to identify international processes and negotiations relevant to trade and biodiversity that affect the development of the country programmes⁶. At the regional level, UNCTAD cooperates with the Andean Community (CAN), Andean Development Corporation (CAF), the Amazonian Parliament and the Amazonian Cooperation Treaty, in integrating concepts related to trade in biodiversity within a regional legal and policy framework. At the national level, the BIOTRADE country programmes work to create a favourable environment for trade in biodiversity products and services. The programmes also provide support to projects in facilitating bio-business activities.

7. This paper, prepared for an UNCTAD Expert Meeting on 'Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices', draws on information gathered during the process mentioned in the previous paragraphs, but does not include information on international processes, since these are dealt with in the background paper of the UNCTAD Secretariat (see TD/B/COM.1/EM.13/2). Since these issues are new and rapidly evolving, BIOTRADE, in partnership with private and public institutions, continues working toward a better understanding of the scope and implications of trade and investment issues in biodiversity products and services

8. The document is divided into three sections. The first section provides an overview of some of the issues that countries may consider when developing an integrated strategy for trade and investment in biodiversity products and services. This section is based on the work being carried out in support of the BIOTRADE country programmes. The second section provides an overview of the Andean process, particularly Decision 391 of the Andean Community of Nations (CAN) on a Common Regime on Access to Genetic Resources. This section is based on a paper detailing the projects BIOTRADE is developing to support the formulation of the Andean biodiversity strategy, a process coordinated by CAN. The third section provides a brief overview of the situation in Colombia and Peru on access and benefit sharing with traditional knowledge holders. BIOTRADE country programmes are being implemented in both Colombia and Peru.

9. Finally, this paper integrates the issues of traditional knowledge, access to genetic resources and benefit sharing. The Conference of Parties of the CBD note that, given the connections between genetic resources and indigenous knowledge, innovations and practices, countries may consider implementing Article 8 (j)⁷ on TK, in conjunction with Article 15, which contains the broad framework for access to genetic resources.

⁴. See: (www.biotrade.org)

⁵. BIOTRADE is active in Brazil, Colombia, Ecuador, Peru, and Venezuela. Other regions in the world will follow in the short and medium term. BIOTRADE benefits from funding the United Nations Foundation, (UNF) the Andean Development Corporation (CAF), and the Governments of the Netherlands and Norway.

⁶. BIOTRADE is also working with the ITC (UNCTAD/WTO) on identification of markets and trade facilitation in order to provide market access to biodiversity products and services coming out of the BIOTRADE country programmes.

⁷. Article 8(j) states that: "(Each contracting Party shall, as far as possible and as appropriate,) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity and promote the wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices".

I. TOWARDS AN INTEGRATED STRATEGY ON TRADE AND BIODIVERSITY

10. This section focuses on UNCTADs work in creating a strategy that integrates trade and biodiversity in support of the BIOTRADE country programmes, particularly those in Colombia, Ecuador and Peru. In this paper, there is an emphasis on the issues of access to genetic resources and the rights of traditional knowledge holders.⁸

11. In ratifying the CBD, countries are making a commitment to the conservation of their biological diversity, the sustainable use of its components, and a fair and equitable sharing of the benefits arising from the use of genetic resources. To this end, countries are designing a series of policies and regulations, such as national biodiversity strategies and laws on the access to genetic resources and traditional knowledge.

12. The economic, trade, social and environmental policies, strategies and laws of many countries are often conceived separately. As a consequence, they often run parallel and even work counterproductive to each other, hampering their effective implementation. Moreover, the separate functions of different ministries and agencies can sometimes lead to a lack of coherent policy and make it difficult to integrate policy. The Ministry of Trade may deal with commerce and trade issues while the Patent Office may be concerned with intellectual property rights, the Plant Variety Office, usually located in the Ministry of Agriculture may deal with seeds while a separate ministry or agency may deal with the environment. Policy integration is therefore a precondition to create a constructive framework for economic growth while attending to social and ecological needs. It is also necessary to bring national legislation in line with international commitments. For example, in the area of trade and biodiversity, cross-sectoral policy integration is required to successfully implement the CBD's provision on access and benefit-sharing arising from the use of genetic resources and associated traditional knowledge, and the provisions of the TRIPs agreement⁹.

13. Policy integration and coherence ensures a balanced decision-making process, taking into account the wider impact on parallel ministries and the sectors they are responsible for. This integration should also lead to more affective participation in international negotiations and more informed trade-offs.¹⁰ Such integration would assure the creation of an environment that allows the private sector to take advantage and investment opportunities in biodiversity resources, assuring a clear sustainable development approach.

1. National Biodiversity Strategies

14. Following Article 6 of the CBD, each country shall, in accordance with its particular conditions and capabilities:

(a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, *inter alia*, the measures set out in this Convention relevant to the Contracting Party concerned; and

(b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies.

⁸ Information taken from a draft paper of Anida Yupari. Prepared for UNCTAD BIOTRADE in autumn 2000.

⁹ The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) is part of the package signed by all WTO members in 1994. The TRIPs Agreement ensures that all signatories provide minimum standards of protection in number of different areas of intellectual property law (e.g. patent, copyright, geographical indications, and so on). Of particular relevance to biological diversity is the TRIPs' Article 27.3(b)

¹⁰ Tansey, G. (1999). *Trade, Intellectual Property, Food and Biodiversity. Key issues and options for the 1999 review of Article 27.3 (b) of the TRIPS Agreement*. A discussion Paper.

15. National Biodiversity Strategies (NBS) provide a framework for action at all levels, enhancing the ability of a country to ensure the productivity, diversity and integrity of natural systems, and, as a result, the ability of a country to develop sustainably. Any domestic policy aiming at making biological resources a viable vehicle for sustainable development needs to be based upon a clear national biodiversity strategy.¹¹ For example, measures directed at access and benefit-sharing should be considered in the NBS prior to developing related legislative, policy or administrative measures.
16. According to the UNDP/GEF guide for the preparation of NBS, the strategies may incorporate the following elements¹²:
 - (a) biodiversity conservation;
 - (b) sustainable use of biological resources;
 - (c) equitable sharing of benefits derived from the use of genetic resources;
 - (d) the conservation and sustainable use of agricultural biodiversity;
 - (e) bio-safety.
17. Additionally, they suggest that the NBS address priorities such as:
 - (a) Support for projects and programmes that have national priority status and that fulfill the obligations of the Convention;
 - (b) Development of integrated national strategies for the conservation of biological diversity and the sustainable use of its components;
 - (c) Strengthening the conservation, management and sustainable use of ecosystems and habitats identified as priorities by national Governments;
 - (d) Identification and monitoring of wild and domesticated biodiversity components, in particular those under threat, and implementation of measures for their conservation and sustainable use;
 - (e) Capacity-building, including human resources development and institutional development and/or strengthening, to facilitate the preparation and/or implementation of national strategies, plans for priority programmes and activities for conservation of biological diversity and sustainable use of its components;
 - (f) Development of innovative measures that create economic incentives for biodiversity conservation and that compensate local communities that incur opportunity costs associated with its conservation;
 - (g) Strengthening the involvement of local and indigenous people in the conservation and sustainable use of biodiversity;
 - (h) Conservation and sustainable use of threatened coastal and marine and of the biodiversity of environmentally vulnerable areas such as arid and semi-arid and mountainous areas;
 - (i) The conservation and sustainable use of endemic species;

¹¹. *The link between access and the benefits arising from the use of genetic resources and conservation and sustainable use of biodiversity is important and an important aspect of this link is that the stakeholders take into account the relevant national biodiversity strategies and action plans.* See UNEP/CBD/COP/5/8. Conference of the Parties to the Convention on Biological Diversity. Fifth meeting. Nairobi, 15-26 may 2000. Report of the Panel of Experts on Access and Benefit-Sharing.

¹². Hagan R. (1999). *A guide for Countries Preparing National Biodiversity Strategies and Actions Plans.* Biodiversity Planning Support Programme. UNDP GEF

- (j) The integration of social issues, including those related to poverty, with the conservation and sustainable use of biodiversity.

18. In the formulation of BIOTRADE country programmes, the NBS is normally taken as a point of departure. For the country programme to be effective, the NBS should elaborate the concepts of trade in biodiversity products and services. For example, the Biodiversity Action Plan of Colombia provides a solid base for the country programme, as it makes explicit reference to trade and biodiversity in the sections on 'promotion of systems for sustainable management of natural resources' and 'sustainable development of the economic potential of biodiversity'. Likewise, the proposed NBS of Ecuador includes the objective of "promotion of sustainable and equitable use of biodiversity", and one of the main objectives of the NBS that Peru is formulating is the "economic development promotion based on sustainable use of biodiversity with active involvement of the private sector". In both countries, BIOTRADE seeks to support the implementation of these sections. Finally, CAN with the financial support of the Inter-American Development Bank, has just started the process of formulating a regional biodiversity strategy. With financial support of the Andean Development Corporation (CAF), the Initiative will provide support to the formulation of this strategy in the area of trade and biodiversity.

2. Legal frameworks on access to genetic resources

19. Legal frameworks on use, access and benefit sharing associated with genetic resources are a prerequisite for trade and investment in biological resources. Many countries have made significant progress in developing the legal basis on access and benefit-sharing regimes. Nevertheless, while most countries are still formulating such frameworks, access and benefit-sharing is taking place through contractual arrangement, which can be negotiated to reflect the spirit of the CBD, and achieve its objectives. However, legislation is essential to ensure that contractual arrangements serve the strategies and policies set by the Government to comply with the related provisions of the CBD¹³.

20. The Secretariat of the CBD elaborated some documents to give some orientation to those countries in process or planning to establishing access laws, regulations and policy; and to provide some preliminary standards for users seeking access in countries without any provisions on access. As part of the efforts to assist countries to development of access legislation, the CBD also established a Panel of Experts on Access and Benefit-Sharing. The Convention does not provide model regimes, but rather a set of guidelines and requirements for the enactment of national legislation. The following are the basic principles for the formulation of legislation on access to genetic resources and sharing of benefits derived from its use:

- (a) Each country has the authority to control access to its genetic resources, which is "subject to national legislation", (Article 15.1 of the CBD).
- (b) The CBD (Article 15.2) encourages countries to "create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not impose restrictions that run counter to the objective of the Convention".
- (c) Access to genetic resources "shall be on mutually agreed terms", and "subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party", and it shall be encouraged only if the Party seeking access will put the genetic resources to "environmentally sound uses", (Articles 16.3, Article 19.1,2, , Article 15.2,4,5)¹⁴.

¹³. UNEP/CBD/COP/5/8. Conference of the Parties to the Convention on Biological Diversity. Fifth meeting. Nairobi, 15-26 may 2000. Report of the Panel of Experts on Access and Benefit-Sharing.

¹⁴. UNEP/CBD/COP/2/13. 6 October 1995.

(d) Countries should "take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties on mutually agreed terms", (Article 19.2).

(e) National laws on access to genetic resources may give special attention to the commercial importance of species that contain useful genetic resources. But measures need to be taken to manage it consistently with Article 10 (b), which requires that no harm be done to biological diversity from the use of biological resources.

21. Access legislation should be formulated with conservation goals and sustainable use of biodiversity in mind, as much as with those of access and benefit-sharing. Legislation should ensure that access activities create minimum adverse environmental impact and promote the sustainable use of genetic resources and that fair and equitable benefit-sharing contributes to conservation measures and improves the living standards of local people. Such laws should be clear, simple, and adapted to the priorities of individual countries allowing flexibility, transparency and low transaction costs. This will facilitate further implementation of legislation and future commercial arrangements on genetic resources, ensuring benefits for both recipients and providers of resources¹⁵. Legal frameworks will also require a review of other international agreements relevant to the country, to assure that laws do not restrict nor undermine the position of the country in other ongoing international negotiations and vice versa¹⁶.

22. For countries in the process of enacting legislations on access, the CBD notes¹⁷ that the following points are essential: a preparatory process where the relevant stakeholders are identified and the needs, opportunities, resources and capacities of the countries are assessed for successful implementation.

23. Developing access laws may involve changing existing legislation, either in form of stand-alone legislation or as additions to framework sustainable development laws, nature conservation or biodiversity laws covering a broader range of biodiversity-related issues or legislation relating to a specific sector, such as fisheries, forestry or protected areas. In the case of stand-alone legislation, only certain sets of genetic resources are covered, such as fish genetic resources or genetic resources in protected areas. In practice, these laws have either been changed as appropriate or, in the case of new legislation, included as provisions related to the access to genetic resources and benefit-sharing. When sectoral or issue-specific laws are used, only a certain set of genetic resources are covered, such as fish genetic resources or genetic resources in protected areas. The other approach is to establish stand-alone legislation on access to genetic resources and benefit-sharing.

24. From an analysis of legislation that has been adopted and is being developed, a set of generic elements emerges. This includes the scope of application of the laws, property rights and ownership and definitions, requirements for prior informed consent (PIC), PIC procedures, requirements for mutually agreed terms, partners to the mutually agreed terms and monitoring and enforcement measures¹⁸. The Panel of Experts on Access and Benefit-Sharing also notes the importance in the flexibility of laws, regional cooperation and capacity building to allow all stakeholders to participate effectively in formulating and implementing access legislation¹⁹.

¹⁵. Idem

¹⁶. It is advisable that legislation under development take into account and follow for development of multilateral system for access and benefit-sharing for plant genetic resources for food and agriculture currently being considered in the FAO negotiations.

¹⁷. UNEP/CBD/COP/4/23/Rev.1. 24 March 1999. Review of national, regional and sectoral measures and guidelines for the implementation of Article 15. *The CBD bases the the access regime on the parties to genetic-resource transactions: the providing countries, which are countries of origin or those having acquired the geentic resources in accordance with the Convention, and the users of genetic resources provided by other Parties.* The section of this paper includes a summary of the guidelines for the providers of genetic resources included in the UNEP/CBD document.

¹⁸. UNEP/CBD/COP/4/23/Rev.1

¹⁹. UNEP/CBD/COP/5/8

25. It is also suggested that governments establish a national focal point and one or more competent national authorities to deal with access and benefit-sharing. Appointing competent national institutions, that have clear legal power and competencies, is vital for the execution and implementation of provisions included in the laws. A national focal point would also help improve the coordination of the ABS policy process as well as overseeing the implementation of strategies²⁰.

26. Finally, the Panel suggested that in the absence of legislation for access to genetic resources and benefit-sharing, countries may voluntarily adopt measures and guidelines. Some examples are:

- (a) Common Policy Guidelines for participating in Botanic Gardens, on Access to Genetic Resources and Benefit-sharing;
- (b) Swiss Draft Guidelines on Access and Benefit-Sharing regarding the Utilization of Genetic Resources;
- (c) The Micro Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC);
- (d) The FAO Code of Conduct for Collecting and Transferring Plant Germplasm.

3. Capacity building in the area of traditional knowledge, access and benefit sharing

26. Achieving sustainable development is not primarily a technical or scientific challenge, although there is much to learn about how ecosystems work and respond to human activity. Nor is the challenge merely to manage natural resources more effectively. Rather, it is about dealing with people and their diverse cultures, interests, visions, priorities, and needs²¹. Policies, strategies and laws are only as good as the process through which they are developed. Wide stakeholder involvement in the definition of the objectives of legislation facilitates its implementation and increases its acceptance and practical application. Furthermore, multi-stakeholder partnerships, which could be an effective way to promote the sustainable use of genetic resources and TK, require equal access to relevant information and the acceptance of the diverse values, interests, and knowledge of the parties involved. Civil society, including local and indigenous communities and the private sector, should therefore have a better understanding of how to structure and sustain productive partnerships.

27. A basic requirement for wide stakeholder involvement is the decision making process, including the participation of all possible actors. It stands for strengthening the meaning and reality of the principles of "inclusiveness" (i.e. engaging the relevant stakeholders in a process), "transparency" (openness), and "accountability" (which gives legitimacy to any process and decision reached). Through inclusiveness and accountability, stakeholders, such as local and indigenous communities acquire a true capacity to deal with the changing environment as they enter the transition towards sustainable development. The process requires a growing social awareness, higher levels of social participation, and new insights into the ecological processes of change and self-renewal. Extended responsibilities and competence in the sustainable development approach means "socio-economic, political/educational, technological, and cultural/spiritual changes".

- a) socio-economic competence enables people to obtain a collective responsibility and self – management
- b) political/educational competence provides people with the capacity to grapple with issues of democracy and justice, enhancing their own views to achieve the desired level of well-being;

²⁰. Idem. Annex I includes the minimum functions of the national focal point and competent national authority/authorities.

²¹. The functions of the national focal point and competent national authority/authorities are defined in Panel's Report

- c) technological development and property recognition implies the recognition of endogenous evolutionary knowledge and skills completed by international cooperation for sharing adequate technologies;
- d) cultural and spiritual recognition means a real understanding of the basis of human existence and the foundation of healthy sustainable human society. This point is important in the case of indigenous people.

28. In brief, empowerment for sustainable development means the capacity to access and utilize options such as cultural and spiritual space, recognition and validation of indigenous knowledge, land entitlement and other resources, income, credit, information, training and participation in decision-making to meet daily needs without compromising future options²².

29. A second requirement for wide stakeholder involvement is capacity building. The CBD regards capacity building as essential to fully implement provisions on traditional knowledge, access and benefit sharing. It is necessary to strengthen special capacities in the fields of taxonomy, legal drafting access to genetic resources, negotiation skills, collecting, storage, cataloguing, and economic valuation of genetic resources, as well as develop effective tools for traditional knowledge protection, such as *sui generis* systems and suitable existing IPR regimes²³. Since the CBD came into force, the number of projects to assist developing countries in developing capacities in these areas has been increasing.

29. Multistakeholder involvement is especially necessary in the area of trade and biodiversity, which is relatively new and characterized by the sometimes diverging and opposing views of the actors involved, (e.g. private sector, nature conservation groups, local and indigenous communities). The BIOTRADE country programmes intend to contribute to empowerment and capacity building for the different groups involved in the relevant areas. These areas include: legal and policy frameworks, sustainable use of biodiversity; technical and entrepreneurial capabilities and market information.

4. Traditional knowledge and benefit sharing with indigenous and local communities²⁴

32. Indigenous peoples and local communities embodying traditional lifestyles are referred to in the CBD, but there is no distinction made between the two. Although, one should bear in mind that the two categories have both important differences and similarities. The main rights that are claimed by many indigenous peoples, but normally not claimed by non-indigenous communities, are the right to²⁵:

- (a) under certain conditions, self-determination
- (b) collective ownership of lands and territories;
- (c) exercise customary law according to social and cultural practices;
- (d) be represented legally and politically through their own institutions; and
- (e) to control their own indigenous knowledge.

33. Even though they may act and speak as a community, farmers and other local groups do not claim to be a distinct people. Their demands for land rights concentrate on land tenure rather than rights to territory. Many local farming communities, still operating outside the major commercial arena are also socially, politically and economically marginalised. Both indigenous and local communities have common concerns on issues dealing with the fear of the globalization of trade; farmers' rights; the strengthening of rights over traditional knowledge and knowhow in the light of the forecast of world food shortage.

²². Singh, N and Vangile T. (1995). *Empowerment. Towards Sustainable Development*. Fernwood publishing Ltd. Zed Books.

²³ UNEP/CBD/COP/5/ 8.

²⁴. This section considers briefly some issues that should be taken into account when considering involving local and indigenous communities. The paper gives particular emphasis to indigenous people *strictu sensu*.

²⁵. Identifying Commonalities and Divergencies Between Indigenous Peoples and Farmers Groups. Edited version of a report entitled "Mind Gaps: Identifying Commonalities and Divergencies Between Indigenous Peoples and Farmers Groups.

34. Indigenous peoples²⁶ inhabit large areas of the earth's surface and are spread across the world from the Arctic to the South Pacific. They live in approximately 70 countries, making up 300 million²⁷ people and tend to be among the poorest of the poor²⁸. Indigenous peoples have been particularly vulnerable to the loss of their heritage²⁹ as distinct peoples. Usually viewed as "backward" by Governments, they have been the targets of aggressive policies of cultural assimilation. Indigenous people have struggled to achieve international recognition of their rights to a distinct status and identity, but their knowledge, culture and resources are still not adequately protected from appropriation by outside interests.

35. Indigenous peoples have an intimate cultural relationship with their land and its natural resources, depending on them to meet their physical, social, cultural and spiritual needs. As many authors have noted, indigenous people embody knowledge and wisdom, that is vital to the conservation and the sustainable use of biological diversity. This knowledge may relate to planting and harvesting methods, the use of natural herbs and other material for medicinal purposes, and the understanding of changes that have occurred to local biological features and landscapes. It is the accumulated knowledge and practices of these peoples that have protected and enhanced biodiversity over generations.

36. In general terms, indigenous knowledge is unique, traditional and local knowledge existing within and developed around specific conditions of people indigenous to a particular geographic area. It can also be called traditional and local knowledge³⁰. It is the basis for local decision-making in agriculture, health, natural resource management and other activities. It is also embedded in community practices, institutions, relationships and rituals and is essentially tacit knowledge that is not easily codifiable³¹.

33. Traditional knowledge (TK) associated with biological resources is an intangible component of the resource itself. TK has the potential of being translated into commercial benefits by providing leads for the development of useful products and processes. The valuable leads provided by traditional knowledge save the modern biotech industry time, money and investment in research and product development. Hence, a share of benefits must accrue to holders of TK. One of the three central pillars of the CBD is *the fair and equitable sharing of the benefits arising out of the utilization of genetic resources*. Where does benefit sharing stand in terms of local and indigenous communities? Five years after its CBD's enactment, there is very little to show in new and substantial benefits being accrued by indigenous and local people³².

34. A number of factors influence the degree to which indigenous and local communities benefit from the use of both genetic resources and their knowledge, innovations and practices. The most important factor

²⁶. *Indigenous communities, peoples and nations are those which, having a historical continuity with pre-invasion and pre-colonial societies that developed on their territories, consider themselves distinct from other sectors of the societies now prevailing in those territories, or parts of them. They form at present non-dominant sectors of society and are determined to preserve, develop and transmit to future generations their ancestral territories, and their ethnic identity, as the basis of their continued existence as peoples, in accordance with their own cultural patterns, social institutions and legal systems.* U.N Subcommission on Prevention of Discrimination and Protection of Minorities.

²⁷. In Latin America, the early 1990s, the number of indigenous people based mainly on linguistic classifications, was estimated at approximately 40 million people, or 10.0 percent of the total population, with the largest concentrations in Central America and the Andes. See: Maquette, C. (1996). *Indigenous People and Biodiversity in Latin America: A survey of Current Information*. Key Documents. World Bank.

²⁸. An Assessment of UNDP's Activities Involving Indigenous Peoples. Draft. (1999)

²⁹. "Heritage" of indigenous people includes all moveable cultural property as defined by the relevant conventions of UNESCO; all kinds of literary or artistic creation such as music, dance, song, ceremonies, symbols and designs, narratives and poetry and all forms of documentation of and by indigenous peoples; all kinds of scientific, agricultural, technical, medicinal, biodiversity-related and ecological knowledge, including innovations based upon that knowledge, cultigens, remedies, medicines and the use of flora and fauna; human remains; immoveable cultural property such as sacred sites of cultural, natural and historical significance and burials. Commission on Human Rights. Sub-Commission on the Promotion and Protection of Human Rights Human. Fifty-second session. Item 7 of the provisional agenda. *Rights of Indigenous Peoples. Report of the seminar on the draft principles and guidelines for the protection of the heritage of indigenous people*. (2000). Geneva, 28 February 1 March.

³⁰. See fn 27

³¹. Indigenous Knowledge for Development. A framework for Action. (1998). Knowledge and Learning Center. Africa Region. The World Bank.

³². *Biodiversity for Sale. Dismantling the hype about benefit sharing*. (2000). Global Trade and Biodiversity in Conflict. Issue no.4 ~ April 2000. The Gaia foundation. Genetic Resources Action International. GRAIN

is probably the socio-political status of communities within the society. This will influence the degree to which their basic human rights are respected, and whether their values, cosmivision and systems of rights and responsibilities are understood and respected³³. It also determines the extent to which communities participate in decision making, and the development effect of activities in which they are involved. Some of these factors will be elaborated upon in the following paragraphs.

Respect of basic human rights of indigenous people

34. Access legislation and complementary laws to regulate the use of traditional knowledge, innovations and practices of indigenous communities should consider the human rights of these communities. Provisions included in international legal instruments, such as the ILO Convention 169³⁴, UN Draft Declaration of the Rights of Indigenous Peoples, the Principles and Guidelines for the Protection of the Heritage of Indigenous People and other relevant documents provide some guidelines for the protection of traditional knowledge holders. Some basic rights considered in the ILO Convention on behalf of indigenous communities are:

- (a) Respect for cultures, ways of life, traditions and customary laws of indigenous and tribal peoples;
- (b) Acknowledge that Indigenous peoples will continue to exist as a part of their national society with their own identity, their own structures and their own traditions;
- (c) Necessity to protect structures and ways of life of indigenous peoples;
- (d) Indigenous Peoples have the right to participate in the decision-making process of the countries to which they belong;
- (e) The majority of Indigenous Peoples are able to speak for themselves and take part in the decision-making process as it affects them.

35. Legal framework on ABS may be completed with additional laws in order to safeguard rights of indigenous communities and allow them to reap benefits from programmes involving genetic resources and associated traditional knowledge, innovations and practices fully respecting their rights included in the national and international documents.

Participation

36. Indigenous people have the right to participate in the formulation, implementation and evaluation of the national and regional plans and programmes that directly affect them. Through the consultation process these people have a right to express their points of view and influence the decision-making procedures. Governments must provide the environment and conditions for the meaningful contribution of indigenous people. This can consist, for instance, of helping indigenous people to acquire the skills and capabilities needed to understand and decide upon the existing development options.³⁵

37. Moreover, Article 15 of ILO Convention established the following: *The rights of the peoples concerned to the natural resources pertaining to their lands shall be specially safeguarded. These rights include the right of these peoples to participate in the use, management and conservation of these resources.* This provision holds for access and benefit sharing. Similarly, Decision III/14 of the CBD's Conference of Parties requests the development of national legislation and corresponding strategies for the implementation of Article 8 (j) in consultation with representatives of their indigenous and local communities. Effective

³³. Byström M, Einarsson P and Axelsson G. (1999). *Fair and Equitable. Sharing the benefits from use of genetic resources and traditional knowledge*. Swedish Scientific Council on Biological Diversity.

³⁴. ILO Convention 169 is the most comprehensive and up-to-date international instrument on the conditions of life and work of indigenous and tribal peoples.

³⁵. *Convention No. 169: its nature and fundamental principles*. (1998). Indigenous and Tribal People: A Guide to ILO No. 169 Cont. International Labour Organization.

participation of communities in the law development process may ensure a successful implementation of them and equitable possibilities of benefit-sharing on behalf of them³⁶. National authorities should generate opportunities for indigenous people to express their concerns and create a mechanism for dialogue with grassroots indigenous organizations, including women's institutions.

37. Furthermore, communities should be provided with legal tools and incentives to conserve their traditional knowledge and to be able to decide freely to transfer their knowledge. This transfer should be based on their prior informed consent. Complementary laws should define conditions for such consent. Capacity building and empowerment is necessary to allow them to effectively express their prior informed consent. It also may be completed with legal assistance for the protection of their ancestral lands, resources, conservation and protection of their traditional knowledge.

Social Impacts and Development

38. Indigenous people and local communities who decide freely to share their traditional knowledge should have the opportunity to reap substantial economic benefits, that can be used for community based sustainable projects. Concern has been expressed about the social impact, for instance, of paying large sums of money directly to indigenous communities leaders. Royalty paymentst might increase traditional leaders' power and reduce their accountability to their own people. This might also provoke conflicts between different clans and communities regarding the ownership of traditional knowledge such as in the case where several communities have traditionally used a medicinal plant, but only one of them sells its knowledge to a pharmaceutical company. Moreover, distributing funds through intermediary non-governmental organizations does not resolve these problems; the intermediaries cannot avoid choosing which communities and individuals leaders they will support³⁷.

39. Government authorities and indigenous and local communities should jointly design sustainable projects, to ensure that cash payments for the use of their traditional knowledge contributes to poverty reduction, sustainable livelihoods, social equity and gender equality. Indigenous groups will also need to develop new institutions for dealing effectively with outsiders and external financing. This rather than the development of intermediary institutions should be encouraged through capacity building and empowerment process.

40. Indigenous communities have the right to decide their own development and to exercise control over their own economic, social and cultural development. It means that sustainable use of genetic resources located in indigenous ancestral lands should be planned considering the potential social, cultural and economic impacts on their lifestyles and protection of their traditional knowledge. Programmes should therefore attempt to integrate the holistic cultural views of these populations. Moreover all development projects should be preceded by an assessment , conducted in partnership with the peoples concerned, of the potential impacts on the heritage of indigenous peoples³⁸.

41. 40. BIOTRADE, through its country programmes, seeks to enhance the role played by local and indigenous communities in conserving and using their biological diversity, knowledge, innovations and practices. These programmes promote the wider application of this knowledge, encouraging equitable sharing of benefits arising from the utilization of this knowledge with its holders, as well as adding value to the products and services derived from biodiversity.

³⁶. BIOTRADE country programmes recognize that local and indigenous communities have rich traditions of knowledge associated with their biodiversity and biological resources, as well as practices related to those resources. The programmes seek to enhance the role played by indigenous people and local communities in conserving and using sustainable biological diversity through their knowledge, innovations and practices. The country programmes promote wider application of this knowledge, encouraging equitable sharing of benefits arising from the utilization of this knowledge with its holders, as well as adding value to the products and services derived from biodiversity.

³⁷. Daes, E. *Protection of the Heritage of Indigenous People*. (1997). Office of High Commissioner for Human Rights. Geneva.United Nations. New York and Geneva.

³⁸. Further studies may be necessary to define tools to assess of potential social and cultural impacts that bioprospecting arrangements on indigenous lands might have.

II. THE EXPERIENCE OF THE ANDEAN COMMUNITY OF NATIONS WITH TK AND ABS

41. UNCTAD, CAN and CAF have elaborated a joint programme for the development of the BIOTRADE Initiative in the Andean Region. One of the objectives of this programme is to strengthen the Andean Biodiversity Strategy, which formulation is being coordinated by CAN, in the area of trade and biodiversity. The formulation process includes five workshops, two of which are of particular importance to the Initiative: one in Venezuela on access and benefit sharing, traditional knowledge, and intellectual property rights, and one in Colombia on economic and valuation of biodiversity. With financial support of CAF, BIOTRADE will carry out a number of background studies for these workshops, with a particular emphasis on trade and biodiversity. The study on which this section is based serves as a first background paper for the above process³⁹.

1. Decision 391: Common Regime on Access to Genetic Resources

42. CAN adopted Decision 391 on a Common Regime on Access to Genetic Resources in July 1996, in order to regulate access to genetic resources of Member States and their derived products with a view to a) establish conditions for a just and equitable participation in the benefits generated from access, b) establish the basis for the recognition and valuation of genetic resources and their derived products as well as of their intangible components, particularly in the case of indigenous communities, c) promote the conservation and sustainable use of biodiversity, d) promote the development and enhancement of local, national and regional scientific, technical and technological capacities and e) strengthen the negotiating capacities of Member States.

³⁹. Information taken from the paper of Ruiz, M. (2000) Regulating Bioprospecting and Protecting Indigenous Peoples Knowledge in the Andean Community: Decision 391 and Its Overall Impacts in the Region. Prepared for UNCTAD BIOTRADE in October 2000.

Access procedure

Box [No. 1]

Basic process for obtaining access under Andean Decision 391

Step 1. Review general minimum conditions for access (article 17) to be included in application and / or access contract. Conditions could include: terms of transfer of materials to third parties, submission of research results, support to conservation and sustainable use of biodiversity research, participation of Member State nationals in research activities, among others.

Step 2. Submit an access application to the national competent authority (article 26).

Step 3. Celebrate an accessory contract (between applicant and *ex situ* conservation centre; owner or possessor of land where biological resource is located; owner or possessor of the biological resource or the national support institution) (article 41), and / or an accessory contract (or Annex) between applicant and provider of the intangible component (knowledge, whether from an indigenous community or not) (article 35).

Step 4. Access contract is celebrated between the National Competent Authority and the access applicant. All other contracts are subject to the results of the negotiations of the access contract (article 32). The State will take into account the interests of the providers of the biological resources and the intangible component (article 34). All accessory contracts will only enter into effect once the access contract has been signed (article 42).

Step 5. If bioprospecting is to be carried out by universities or recognised research institutions and researchers and it involves multiple access activities, a framework access agreement must be celebrated with the National Competent Authority (article 36).

Step 6. If *ex situ* centres or other institutions seek to carry out access related activities they must celebrate an access contract with the National Competent Authority. The National Competent Authority may celebrate access contracts with third parties who seek to access resources deposited in these centres of which Member States are countries of origin (article 37).

Step 7. The National Competent Authority may celebrate deposit, administration and inter-mediation contracts with universities or recognised research institutions and researchers (Fifth Complementary Disposition).

Implementation process and practical application

43. Bolivia rapidly adopted Decision 391 through Reglamento de la Decisión 391 Régimen Común de Acceso a Recursos Genéticos in 1997. However, almost three years later, this specific complementary regulation has not yet served its purpose of supporting effective implementation of Decision 391. Recently, Bolivia undertook a national planning process, which included a review to Decision 391, the Reglamento and discussions on how best to ensure implementation of both these norms. The situation in Bolivia proves an important point with regards to Decision 391: the fact that there is secondary and complementary legislation, is not the only or most important condition to ensure an adequate implementation of Decision 391. There are other factors, which play more influential role during this process.

44. Ecuador, Peru and Venezuela have also undertaken national processes to develop secondary and complementary implementing legislation. Ecuador has recently finalised the review of a draft proposal,

whilst Peru, as an annex to the Proposal for a Regime for the Protection of Collective Knowledge of Indigenous Peoples, published for further comment a draft regulation to implement Decision 391. In the case of Venezuela a national biodiversity law has been also recently enacted (2001). This law develops the content of decision 391. It also includes complete regime on acces to genetic resourses and the protection of traditional knowlegede troghtout a collective regime of intellectual property that would be develop in a future regulation of in the national law on industrial property. Colombia Vhas chosen to apply Decision 391 of CAN directly, without applying secondary legislation⁴⁰. Access procedures on genetic resourses therefore follow the provisions stated in Decision 391.

45. A number is reasons exist for the delay in the implementation Decision 391. In the case of Decision 391, reasons for non-implementation have little to do with the fact that Member States have not enacted secondary or implementing legislation. Rather, there are major policy concerns, practical difficulties, legal uncertainties, differing interpretations, institutional limitations, data and informational gaps, among others, which severely limit at present possibilities of Decision 391 to become an effective and efficient legal instrument for countries.

46. The very detailed nature of the common regime in terms of procedures and even detailed terms (procedural periods) for these, poses another challenge. Decision 391 leaves little space for complementary regulations to make it more flexible according to national needs and the nature and characteristics of specific bioprospecting activities.

47. Information regarding all bioprospecting (and related) activities in member States is very much dispersed and has not been fully compiled or systematised to date. There are only a few relatively well-documented cases regarding practical application after implementation of Decision 391⁴¹. Probably the first documented case of bioprospecting where Decision 391 was applied, involved Andes Pharmaceuticals Inc. from the USA. In early 1997, Andes requested access to genetic resources in Colombia. The Ministry of the Environment (the national authority in Colombia) denied the application (Resolution 1030, November 14, 1997) on the grounds that it did not comply with Decision 391 formal and substantial technical, legal and scientific conditions. Official governmental arguments to deny the application differed from those of other sectors who have analysed the application and official response by the Ministry. In any case, most agree on the overall denial of Andes' application by the Government.

48. In 1996 the following institutions: the ICBG⁴² (Washington University, the National Natural History Museum of Peru, Peruvian University Cayetano Heredia, the National Confederation of Amazonian Nationalities of Peru and Searle & Co.), reached an agreement, which was based to an important extent on the CBD and draft Decision 391 principles which at the time where under negotiation. Searle & Co. agreed to a "know how", licence agreement by which indigenous Aguaruna communities of the Alto Marañon in the

49. Peruvian Amazon provided them with knowledge (whether or not in the public domain) related to medicinal plants in exchange for benefits from and restrictions to the use of this knowledge⁴³.

In late 1999, the Ministry of the Environment of Venezuela (the national competent authority) celebrated an access contract with the Eidgenossische Technische Hochschule of Zurich, Switzerland in order for bioprospecting activities to take place in the Alto Orinoco, on Yanomani lands. The Yanomanis were not included in the negotiations although many medicinal plants in the region are well known and used by them. The contract establishes a compensation for indigenous communities who participate in the project. Although the exclusion of the Yanomanis from the negotiations is certainly unacceptable from a moral, cultural and even legal point of view, what remains as very interesting for the purpose of this paper is the

⁴⁰ Law 5468 (Biological Diversity Law) of Venezuela incorporates a chapter on access to genetic resources. However, when reviewing its articles (72 through 78), these are mainly a repetition of provisions contained in Decision 391. Hence, this Law is not truly implementing legislation as such.

⁴¹ The Regional Office for South America of IUCN is currently undertaking a project to determine the number and main features of all bioprospecting projects in South America (not only within Andean Community countries). The information and data will be available towards the end of the year or early 2001.

⁴² The Peruvian International Co-operative Biodiversity Group Project Peru (ICBG).

⁴³ For further details of this project see: Tobin, B. (1997). *Know-how licences: recognising indigenous rights over collective knowledge*. In: Bulletin of the Working Group on Traditional Resource Rights, 4. 17 - 18.

various and often conflicting interpretations given to Decision 391. While the Government considers it has proceeded correctly, many NGO and experts think otherwise.

Future Perspective

50. Although institutional and corporate (private biotechnology companies, pharmaceutical companies, ex situ conservation centres, research institutions) views with regards to the effects of CBD's provisions on ABS legislation, particularly on research and development processes, vary considerably, but they have in common that the more complex ABS policies and regulation are, the greater the disincentives for the establishment of bioprospecting alliances with national institutions. As a result, alternative options usually imply targeting other countries (where no or lesser restrictions are in place) or to seek other sources of biological and genetic materials (i.e. from ex situ conservation centres)⁴⁴. However, they also point out that stringent regulations will not promote the necessary co-operation which is required in all bioprospecting effort. Strict and burdensome regulations imply transaction costs which will probably deter national and international bioprospecting initiatives and research activities in the region in general⁴⁵.

51. At present, there is evidence that a series of bioprospecting initiatives are on hold, on stand by or, in some cases, could be under way but bypassing Decision 391. The physical nature of biological material and the relative ease with which it can be mobilised and even exported certainly plays in favour of those seeking easy, unregulated and uncompensated access to potentially valuable genetic resources. Furthermore, limited systematised information about ongoing projects and geographical features of the Andean and Amazonian region especially, make it extremely difficult to assess the general situation in the field and establish control mechanisms. Box No 2 is a proposed basic and general framework with elements that could be considered when defining a legal ABS regime, whether at the national or regional level.

Box No. 2 Towards a more flexible legal framework on ABS

Step 1. Submission of an access application to a national authority.

Step 2. Submission of the access project (all agreements, covenants, letters of intent, etc. celebrated among participating institutions). Parties are free to negotiate although they will need to take into account general conditions established by the national authority (i.e. necessary participation of a national research institution in field and lab work, need for part of the research and development process to be carried out in the country if facilities and capacities are available, need for a percentage of monetary benefits arising from the commercialisation of a product to be directed to a national research and development fund, need to seek consent of indigenous peoples if field work is carried out on their lands, need to submit copies of all reports to the national authority, etc.).

Step 3. National authority approves overall project after verifying that general conditions are met.

- (a) According to the type of bioprospecting activity, the access project will obviously be more or less complex. The national authority will require certain discretion when assessing applications

⁴⁴. For a comprehensive overview of the different positions of companies and industry in general and research institutions regarding ABS regulations, see: Kate T and Laird S. (1999). *The Commercial Use of Biodiversity. Access to Genetic Resources and Benefit Sharing*. EARTHSCAN. Earthscan Publication Ltd. London.

⁴⁵. During the XVI International Botanical Congress held in St.Louis, USA in August, 1999, a specific session on ABS clearly reflected the views of botanists and scientists in general: although most agreed that in the context of international policy and the CBD in particular, ABS rules were now an integral and unavoidable part of the research process, they highlighted the potential risks of over regulating, restricting and probably unintentionally affecting research. To an important extent, national researchers of developing countries would be affected by declining co-operation and possibilities for institutional partnerships. Furthermore they stressed the importance of not imposing restrictions to taxonomic research. In this context it became clear that a delicate balance must be achieved between the legitimate right of countries to regulate and control access to their resources and the need to ensure and not unduly restrict co-operative, and especially national, research activities.

and projects. Training and capacity building at the national level and for national authority officials is key to ensure the technical soundness of decisions and overall transparency of procedures.

(b) Special procedures apply for ex situ conservation and research institutions. Field work should not be unduly restricted. Restrictions could apply at the stage when deposited materials are transferred to third parties. Standard Material Transfer Agreements could be an instrument to be considered for this purpose.

52. It should also be noted that for a system like this to be operational (basically in Latin American countries) it would have to be assumed that parties (individuals, institutions, the State, indigenous peoples) who have rights to biological resources are entitled to negotiate in regards to the genetic resources and information contained therein. This would not imply that they necessarily have property rights over these resources, but that they are legally entitled to negotiate over them. Conditions of access would then ensure that the interest of the State or Nation is duly respected and taken into account.

53. Benefits for the country would thereby encompass a wide range of possibilities which could include: strengthening of national (private or public) research capacities, promotion of bioprospecting efforts throughout the country, strengthening the negotiation capacities of indigenous communities in as much as they are free to a decide if they want to negotiate and b) decide upon terms of the negotiation process (support by specialised institutions will probably be required), promotion of co-operative projects, continued exchange of scientific information, training of national scientists, of a national research and development capacities throughout the country, etc⁴⁶.

2. Protection of traditional knowledge and IPR in the context of Decision 391

54. The participants in the process of developing Decision 391 recognised that access to biological and genetic resources is in many instances how indigenous peoples study, use and enhance them and the application of intellectual property rights (basically patents and plant breeders rights) over products and processes, directly or indirectly, derived from these resources.

55. Under article 7 of Decision 391, Member States (according to this regulation and their national legislation) "...recognise and value the rights and decision making powers of indigenous, afro-american and local communities over their traditional knowledge, innovations and practices associated to genetic resources and derived products". The decision making power is really a formal and express recognition by the State of powers indigenous peoples had anyway. However its express recognition is still important from a policy perspective. More interestingly, although subject to the national legislation qualifier and to the need for further specific content development, it recognises rights over knowledge, innovations and practices.

56. But Decision 391 goes a little further. Article 35 provides with formal agreements, covenants, contracts, letters of intent, or any other instrument through which parties formalise obligations and commitments, etc. as the legal instruments for indigenous peoples to ensure their knowledge, innovations and practices are used subject to their consent and to benefit sharing conditions⁴⁷.

57. Decision 391 recognised the critical importance of the IPR and indigenous traditional knowledge issue and determines that, upon the submission by Andean countries of national reports, the CAN will

⁴⁶. Before defining a system, countries should assess and take into account legal and practical considerations arising of integrating the different systems already in force to access biological material and samples (i.e. scientific collecting permits, CITES procedures, etc.) or establishing the necessary linkages and complements among them. Whether the national authority is a single entity for all procedures which imply accessing biological material or genetic resources or their derivatives, or, if different procedures are developed for different types of access, its competence and jurisdiction should be clearly identified.

⁴⁷. Article 35 specifically refers to the case where access is sought for resources over which an intangible component is associated. In this situation an Annex (the agreement, contract, etc.) will be integrated into the access contract. This annex will be signed by the applicant and provider of the intangible component. In certain cases (subject to national legislation) the annex could be also signed by the national authority. The intangible component refers to any knowledge, innovation and practices, not necessarily nor exclusively those of indigenous peoples.

prepare a proposal for the "...establishment of a special regime or harmonisation regulation oriented to strengthen the protection of indigenous, afro-american and local communities traditional knowledge, innovations and practices in accordance with article 7 of this Decision, ILO Convention 169 and the CBD". This commitment is still pending since 1996.

58. Even if it might be extreme to argue that in all cases IPR systems are unsuitable to protect all indigenous peoples interests, it seems clear that patents and plant breeders rights in particular are not the ideal instruments through which indigenous peoples might protect their knowledge, innovations and practices⁴⁸. Reasons vary and include the level of novelty required to protect an invention, the way in which innovation is generated within indigenous peoples (collectively but also individually), the complexity of administrative procedures to achieve patent or PBR protection, costs of requesting patent or PBR protection, among others.

III. SOME EXPERIENCES OF COLOMBIA AND PERU RELATED TO TRADITIONAL KNOWLEDGE

59. Many countries are developing activities in the area of traditional knowledge and access and benefit sharing. This section provides a brief overview of the situation in Colombia⁴⁹ and Peru, where BIOTRADE country programmes are being implemented.

1. Colombia

60. The first BIOTRADE country programme was started in Colombia in 1999 under coordination of the Alexander von Humboldt Institute. The programme, called "Biocomercio Sostenible", is developing work along different lines: networking, information systems, business development, market information, investment, and financial mechanisms. A number of demonstration projects are being developed in the areas of medicinal plants and ecotourism. Communities receive assistance in improving their business skills, in formulating market strategies, and in obtaining market information⁵⁰. This section provides a brief overview of the situation in Colombia with respect to access and benefit sharing and traditional knowledge. It also provides an insight in some of the work that the programme Biocomercio Sostenible has carried out in this area.

Legal frameworks on access to genetic resources and traditional knowledge

Communities legislation

61. According to Article 7 of the new Colombian Constitution (1991) the State recognizes and protects the ethnic and cultural diversity of the Colombian nation. Legally, traditional communities are divided in three groups: 1) indigenous communities, 2) afro-colombian communities, and 3) peasant (campesino)

⁴⁸. It should be noted that the concepts of "knowledge", "innovations" and "practices" although used very loosely to refer to indigenous peoples intellectual effort, imply different aspects of this effort and probably have different implications particularly from a legal point of view and more so when undertaking regulatory efforts. This is furthermore relevant as legal frameworks need to be very clear with respect to the object they are seeking to regulate and protect. Knowledge seems to be clearly an intangible element which can certainly be reflected in innovations (if these were limited to tangible products i.e. a traditional medicine) and practices (if these were also circumscribed to a tangible, materialised process or procedure i.e. how to prepare a traditional potion). Other analysts strongly suggest that knowledge, innovations and practices, and resources on which they are based, become a single entity, an intangible and tangible component which cannot be separated and which have to be protected as a whole. In any case, experts and policy makers will need to theorise on how these concepts are defined in a specific protection regime, whether at the national or international level. See: Ruiz M. (1999). *Protecting Indigenous Peoples Knowledge: A Policy and Legal Perspective from Peru*. In: Policy and Environmental Law Series. Peruvian Society for Environmental Law. No. 3, May. Lima, Peru.

⁴⁹ See paper of Pardo, M, Hernandez, A and Ramos, A. (2000). *Algunas Consideraciones sobre la experiencia de Colombia en materia de protección de los conocimientos tradicionales, acceso y distribución de beneficios y derechos de propiedad intelectual* Paper presented at UNCTAD Expert Meeting, October.

⁵⁰. For more information see: www.humboldt.org.co/biocomercio

communities. Over the last years, special legislation was adopted for each group. Colombia ratified the ILO Convention 169 (through Law 21) in 1991, recognizing the basic rights laid down in that Convention for indigenous and afro-colombian communities.

62. The Colombian constitution regards, natural resources as property of the State. However, before granting rights over natural resources in areas where indigenous and afro-colombian communities live, a consultation process needs to be carried out in order to ensure that "the exploitation of natural resources in the indigenous territories shall be without detriment to the cultural, social, and economic integrity of the indigenous communities. In the decisions adopted with respect to that exploitation, the Government shall encourage the participation of the representatives of the respective communities", (Law 99, 1993).

63. In 1996, Colombia created a consultative forum called the "Mesa de Concertación de los Pueblos y Organizaciones Indígenas", (Law 1397). Among the objectives of the forum are:

- (a) the adoption of principles, criteria and procedures related to biological diversity, genetic resources, collective intellectual property and cultural rights associated to them, fully respecting the legislation applicable to indigenous peoples;
- (b) to ensure consensus of indigenous people and their organizations with respect to official proposals for protection of traditional knowledge and access to genetic resources; and
- (c) to review licenses and permissions on exploitation of natural resources on indigenous lands.

Legal issues regarding the protection of traditional knowledge

64. The National Biodiversity Policy Act (1997) recognizes the existing relationship between traditional knowledge and the cultural implications of biodiversity use and conservation, and emphasizes the necessity of considering a holistic and cultural approach to biodiversity and associated components. Furthermore, it recognizes that special measures and tools are needed to protect traditional knowledge, innovations and practices in order for indigenous people to fully exercise their collective rights⁵¹.

64. In response to Decision 391 of the Andean Community of Nations a proposal for the protection of traditional knowledge, innovations and practices of indigenous people is being elaborated by the Alexander von Humboldt Institute. The proposal allows indigenous people to choose the best way to protect their traditional knowledge⁵². The proposal suggests to use one of the following possibilities, or a combination thereof:

- (a) a voluntary national registry system;
- (b) use of existing IPR regimes; and
- (c) keeping traditional knowledge, innovations and practices inside the domain of the communities and indigenous groups.

66. Option "b", includes IPR regimes such as patents, geographical indicators and appellation of origin, to protect traditional knowledge, innovations and practices. However, review of the legal system and legal assistance for traditional knowledge holders would be required in order to allow them to meet conventional national law requirements. For instance, the Colombian patent law requires absolute novelty for a patent to be granted to an invention. This requirement makes it difficult to use patents to protect traditional knowledge, which is often in the public domain already⁵³.

⁵¹. Indigenous affairs are part of the Ministry of the Interior's tasks.

⁵². Pardo M.

⁵³. A patent is an intellectual property right that is available to the inventor of an invention that is new with industrial application. The patent gives the inventor the right to exclude others from making, using, or selling the product, and the right to exclude others from using the process or using or selling the product produced by that process. An invention that is public is not eligible for patenting.

Access procedures over genetic resources

67. Colombia has chosen to apply Decision 391 of CAN directly, without applying secondary legislation. Access procedures on genetic resources therefore follow the provisions stated in Decision 391. According to Decision 391, an access contract needs to be signed between the applicant and the environmental national authority, i.e. the Ministry of the Environment. Contracts involving traditional knowledge must be completed by an agreement between the applicant and provider of the intangible component (i.e. traditional knowledge), which lays down the conditions under which traditional knowledge can be used. Despite the clear access legislation, no access contract has been signed yet. In order to facilitate access for scientific and technological development that adds value to national genetic resources, future arrangements on sustainable uses of genetic resources should be based of flexible access procedures. Strategies and policies on access to genetic resources should be developed with clear and flexible mechanisms.

Example of the work of Biocomercio Sostenible

68. The Colombian BIOTRADE programme 'Biocomercio Sostenible' acts as a facilitator for projects related to trade and biodiversity. Projects are being developed in the area of medicinal plants and ecotourism. One project in which the programme is involved concerns the Nanuya Community in Peña Roja, a small community living in the Amazonian region in the South of Colombia. With support of the Foundation Terra Preta they are exploring the possibility of marketing medicinal and aromatic plants. They identified a number of products they could produce and in which quantities. The programme Biocomercio Sostenible is currently assisting the community to increase their capacity in the areas of: financial analysis, access to seed capital, skills to formulate market strategies and business plans, and market information. A second project in which the programme 'Biocomercio Sostenible' is currently involved concerns a partnership between local and indigenous communities in the indigenous reserve Las Canoas in the West of Colombia. This case will be elaborated upon in box 2.

Box 2: Case of Las Canoas

Actors

-
- Peasant, afro-colombian and indigenous communities of the indigenous reserve Las Canoas, located in the Municipio of Santander de Quilichao, Cauca, close to the city of Cali.
- The Centre for Community Research and Services (Centro de Investigaciones y Servicios Comunitarios (CISEC)). CISEC is part of the Foundation for Sustainable Rural Community Development and develops research on basic health care and productive systems (e.g. agro-forestry and silvi-cultures).
- Labfarve (Laboratorio de Farmacología Vegetal e Investigaciones Asociadas, Universidad de Corpas), Bogota, Colombia. Labfarve is one of the main laboratories in Colombia active in research, production and commercialisation.⁵⁴

Description

The municipality of Santander de Quilichao is populated by afro-colombian, peasant and indigenous communities. The main source of income is agriculture. The area's richness in biodiversity is threatened by practices such as by cultivation of illegal crops, expansion of cattle farming, and unsustainable agricultural practices. At the same time, the knowledge of traditional healers in the region is being gradually lost.

In 1993, CISEC conducted an inventory of the medicinal flora in the region with the purpose of creating a herbarium for the local communities. Within the inventory, two plants that are used to cure nervous diseases such as depression, were found to have a commercial potential. The plants are widely used by traditional healers in the region, but are unknown in the conventional markets. Labfarve has expressed an interest in entering into a partnership with CISEC and the local communities to process the plants and bring them to the market. In 1999, Labfarve and CISEC, on behalf of the local communities, requested Biocomercio Sostenible to assist with research on biological sustainability, capacity building on enterprise management and negotiation on the sharing of benefits derived from the use of the plants, as well as with the marketing of the plants.

The three organisations elaborated an action plan with the aim of sustainable use and commercialisation of medicinal plants in line with the objectives of the CBD. The agreement thus goes beyond the two plants that had been identified to have interesting medicinal properties. The plan, which is currently being carried out, consists of, among others, the following:

- Toxicological studies by Labfarve;
- Creation, by CISEC and the community, of a for profit productive association with social and environmental goals. Benefits generated by the Association are to be used for projects in the area of education and health as well as to support the preservation of traditional medicine in the region. The creation of the Association will assure community participation and community control over which plants and knowledge will be utilized by the Association;
- Negotiation of an agreement between the Association and CISEC for assistance in local processing of medicinal plants;
- Formulation of sustainability criteria for the cultivation of medicinal plants. In order to assure sustainability, the Association will only purchase from those providers that agree with these criteria.
- Support of the programme Biocomercio Sostenible to the Association in elaborating business plans, conducting national and international market research, and identifying seed money.

The above case is an example of an approach in which protection and use of traditional knowledge, biodiversity protection and economic development go together. The creation of a for profit association may be a good way to relate to the private sector. If local communities have sufficient entrepreneurial skills, such mechanisms can contribute their economic and social development while respecting their environment.

2. Towards legal protection of traditional knowledge in Peru

69. In Peru, UNCTAD, together 'Consejo Nacional del Ambiente' (CONAM) the national focal point of BIOTRADE, recently started the process of formulating a country programme. A pre-assessment to describe the baseline situation is currently being carried out.

70. Peru has taken important steps in developing a national policy and legal instruments to protect indigenous peoples knowledge associated with biodiversity⁵⁵. Following the final stages of Decision 391 negotiations reflecting the Peruvian Government commitment towards the issue, article 63 of Legislative Decree 823, the Industrial Property Law, which entered into force in April 1996, established that "... through a Supreme Decree approved by the Ministry of Industry, Tourism, Integration and International Trade Negotiation a special regime for the protection and register of native and campesino communities will be established". This provision (and indeed Decision 391 and the CBD) finally triggered the national policy process regarding indigenous people's knowledge.

71. A proposal for a Regime for the Protection of Collective Knowledge of Indigenous People was published in the official gazette for wide comment and consultation in August 2000. This proposal is in turn based on a previous document also published in the gazette in 1999⁵⁶

72. The proposed draft norm is the result of a three year long process where a multi-disciplinary Working Group led by INDECOPI worked towards the development of a legal instrument to protect indigenous people's knowledge. Meetings, international seminars, workshops, consultation processes with indigenous peoples representative groups, interviews with national and international experts and presentations in international meetings, were all part of an effort to, in the best participatory way possible, construct this legal proposal⁵⁷.

73. In simple terms, this proposal rests on three main pillars: a) the use of contracts (licences) as the legal instrument by which indigenous knowledge related to biodiversity can be negotiated by indigenous peoples themselves and through which their prior informed consent can be obtained, b) the recognition of the collective nature of indigenous knowledge (while acknowledging the fact that within communities individual intellectual efforts are also very important) and c) the possibility for knowledge in the public domain to be subject to contractual provisions upon agreement between parties. The licence referred to in point a) above is, precisely, the annex in article 35 of Decision 391 and will contain provisions regarding up front payments and eventual royalties for communities. Communities will always have a right to oppose bioprospecting or access to their knowledge. Here again an interesting conceptual and practical challenge arises if communities decide not to allow access to or use of their knowledge, with regards to resources over which only the State retains rights.

⁵⁴ Its mission is to provide the population with primary herbal and plant medicines for treatment and prevention of common diseases at low prices.

⁵⁵ Information taken from the paper of Ruiz, M. (2000) Regulating Bioprospecting and Protecting Indigenous Peoples Knowledge in the Andean Community: Decision 391 and Its Overall Impacts in the Region. Prepared for UNCTAD BIOTRADE in October 2000.

⁵⁶ See: Propuesta de Régimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas y Acceso a los Recursos Genéticos. (1999). Working Document. El Peruano, October 21. Both this proposal and Working Document 010-2000 can be accessed at: <http://www.indecopi.gob.pe>

⁵⁷ Among those consulted were: the governmental sector (i.e. National Institute of Traditional Medicine, National Institute of Natural Resources, Ministry of Industry, Ministry of Agriculture), the academic sector (i.e. Prof. Susette Biber Klemm from the University of Basel, Prof. Graham Dutfield from the Oxford Centre for the Environment, Ethics and Society, Prof. Abraham Vaisberg from the Universidad Peruana Cayetano Heredia), indigenous peoples representative organizations (i.e. ANDES, OBAAQ, AIDSESP, CONAP) Congress representatives, NGO's (i.e. SPDA, ADN), international institutions (i.e. International Potato Centre, International Labour Organisation, Swedish International Development Cooperation Agency) and the private sector (i.e. the Association of Pharmaceutical Industries of National Origin and Capital).

74. Whoever has access to and utilises indigenous knowledge (with their consent) has an obligation to provide the Fund for the Development of Indigenous Peoples (Title IX) with a minimum retribution of 0.5 per cent of total sales resulting from the commercialisation of products resulting from the use of this knowledge. Even in the case of knowledge which is in the public domain, applicants will be required to contribute with a maximum of 0.5 per cent of total sales to the Fund (article 12).

75. Equally important in the proposed regime is that indigenous peoples knowledge (which is not in the public domain) remains a trade secret of communities and, in this regard, the burden of proof is placed on the person or institution who unlawfully or without the consent of communities discloses and uses their knowledge to dispute any wrongdoing or misuse. An administrative procedure is established for infractions to the regime (Title XI).

76. A national register and local registers are also incorporated as a means to prevent the loss of indigenous knowledge. This register is confidential and only accessible to communities or third parties if they have their consent. However, certain basic information can be provided to third parties in order for them to initiate contacts with communities. Article 20 establishes that upon request by communities, the information contained in the register can be used by the national authority in order to oppose the granting of patents on the grounds of the prior art requirement.

77. Two important issues remain as practical challenges to be faced by the regime. On one hand, the problem of consent of communities who share similar knowledge. Article 7 and 23 address this and provide a practical option. In order to celebrate a contract or licence agreement, the consent of all communities (who share similar knowledge) is not required (article 23). However, the contacted communities should make the best effort to inform other communities that it is entering into negotiations and take into account their interests, particularly their spiritual and religious concerns (article 7).

78. This option reflects a situation where it will obviously be impossible to obtain prior consent from all communities. Indeed, this poses an additional problem of how much disruption and conflict might arise among communities if some benefit and others don't or even if some want to participate in bioprospecting efforts and others don't. It is hoped that the Fund for the Development of Indigenous Peoples (Title IX), to which all communities are entitled, serves to ensure that even if communities do not participate in a specific bioprospecting project they can benefit from resources available for their development. From a more philosophical but critical perspective, one could speculate as to what effect any form of legal regime could have on indigenous cultures⁵⁸.

79. Finally, another challenge to be overcome refers to whether or not the proposed regime acts as an effective incentive to promote registering of indigenous peoples knowledge and to actively empower communities to participate (or not) with their prior consent, in bioprospecting projects. Certainly, and still to be assessed is whether the regime also creates an environment where researchers, universities and eventually companies have the incentives to enter into agreements with communities.

⁵⁸. Some critics argue that "...alternative rights regimes [for indigenous peoples] are just a more naive form of slippery slope leading inevitably to patent models and transactions ... efforts to legislate indigenous knowledge run against customary practices and threaten the survival of cooperative innovation systems". For further analysis of this issue see: *Seeding Solutions*. Volume 1. Policy Options for Genetic Resources: People, Plants and Patents Revisited. (2000). The Crucible II Group. IDRC, IPGRI & Dag Hammarskjöld Foundation. Rome.

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