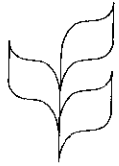




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**CONVENTION ON  
BIOLOGICAL DIVERSITY**

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REPORT OF THE EUROPEAN WORKSHOP ON  
GENETIC RESOURCES ISSUES AND RELATED ASPECTS

(Submitted by Germany)

**DOCUMENTS OF THE  
EUROPEAN WORKSHOP ON  
GENETIC RESOURCES ISSUES AND RELATED  
ASPECTS**

**\* ACCESS AND BENEFIT SHARING \*  
\* INTELLECTUAL PROPERTY RIGHTS \* EX-SITU  
COLLECTIONS \***

Heidelberg, Germany, 6 - 7 May 1999

organized by Prof. Dr. Rüdiger Wolfrum, Director at the Max Planck Institute for  
Comparative Public Law and International Law,  
sponsored by the German Federal Ministry for Environment, Nature Protection and  
Nuclear Safety / German Federal Environmental Agency

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## INTRODUCTION

In 1997, a project was initiated by the German Federal Environmental Agency concerning "Model Contracts and other Means to Guide Bioprospecting under the Convention on Biological Diversity". The vast and rapid developments in this area soon suggested to additionally consider aspects of intellectual property rights, of tendencies to protect the rights of indigenous people at international level and questions concerning ex-situ-collections. The project included a workshop to discuss the results of the project, which have been submitted recently. The Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity decided to hold an Intersessional Meeting on the Operations of the Convention and to discuss issues which we had dealt with in the project. We thus considered it useful to focus the workshop on that meeting and to provide for an opportunity for discussion in an European setting.

It has been the objective of the project to give young researchers an opportunity to study those very new and pertinent questions and to follow closely the developments. Among them were Carolina Carbuccia, Anja Meyer, Kerrin Schillhorn and Jessica Suplie. They prepared in their personal responsibility the following English draft papers as a basis for discussion at the workshop, which reflect the findings of the project. They have presented those papers at the workshop and later on will further elaborate and edit them, taking into account the discussions in Heidelberg. We intend to publish them together with other contributions from the workshop.

Rüdiger Wolfrum

Tobias Stoll

## **THE INTERSESSIONAL MEETING AND ITS AGENDA CONCERNING ACCESS TO GENETIC RESOURCES**

Dr. Peter-Tobias Stoll, Research Fellow, Max Planck Institute

At its fourth meeting in May 1998, the Conference of the Parties (COP) of the Convention on Biological Diversity (CBD) decided (Decision IV/16. Institutional matters and the program of work) to

"hold an open-ended meeting to consider possible arrangements to improve preparations for and conduct of the meetings of the Conference of the Parties, taking into account proposals made at the fourth meeting of the Conference of the Parties, including a preparatory discussion of the item on access to genetic resources on the agenda of the fifth meeting of the Conference of the Parties. This meeting will be of three days duration and is to be held in conjunction with one of the meetings planned for 1999."

The President of the Conference of the Parties and the Bureau decided later, that this meeting should be held immediately after the fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), from 28 to 30 June 1999, in Montreal, Canada.

According to the Provisional Agenda as issued on 11 March 1999, the review of the operations of the Convention and the program of work - often referred to as "modus operandi" - will play an important role in the meeting (agenda item 3). However, agenda item 4 relates to "access to genetic resources and benefit-sharing" and thus reflects the mentioning of the "item on access to genetic resources" as stipulated by decision IV/16.

It is very likely that this will include the following issues which were referred to the Intersessional Meeting by other decisions of the fourth meeting of the COP.

### **1. Access and Benefit-sharing**

Decision IV/8 "Access and benefit-sharing" in para. 1 states:

"The Conference of the Parties

1. Requests the intersessional open-ended meeting referred to in decision IV/16, paragraph 2, to explore options for access and benefit-sharing mechanisms ..."

This probably has to be seen in the context of para. 3 of that decision which establishes a

- "regionally balanced panel of experts
- appointed by Governments,
- reporting to the next meeting of the Conference of the Parties,



- with the mandate: to draw upon all relevant sources ... in the development of a common understanding of basic concepts and to explore all options for access and benefit sharing on mutually agreed terms ..."

The expert panel has been scheduled for 3-8 October 1999. There has not been a decision on its structure and composition so far.

## **2. Intellectual Property Rights**

Decision IV/8 para. 1 also calls upon the intersessional meeting ... "to start work on paragraph 10 of decision IV/15 and to make recommendations for future work"...

Decision IV/15 relates to "the relationship of the convention with the Commission on Sustainable Development and biodiversity-related conventions, other international agreements, institutions and processes of relevance" and in para. 10 states, that the COP...

10. ... "emphasizes that further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity."

The COP has already discussed issues concerning access to genetic resources and benefit-sharing at its third meeting in 1997 (Decision III/15). According to Art. 27 para. 3 lit. b of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs-Agreement) of the World Trade Organization (WTO), that provision shall be reviewed in 1999. The WTO Council for Trade-related Aspects of Intellectual Property Rights will have several meetings this year, where the review may be discussed.

## **3. The Issue of Ex-Situ-Collections Acquired Prior to the Entry into Force of the CBD**

Decision IV/8 furthermore reads:

2. "Requests the Executive Secretary to invite information from Parties and relevant organizations in time for the intersessional meeting in respect of those ex situ collections which were acquired prior to the entry into force of the Convention on Biological Diversity and which are not addressed by the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization, to help the intersessional meeting to make recommendations to the fifth meeting of the

Conference of the Parties for future work on resolving the issue of such ex situ collections, with due regard to the provisions of the Convention; ..."

**ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING:  
PROSPECTS FOR GUIDANCE BY THE CBD-SYSTEM:  
ASSESSMENT - THE CURRENT SITUATION AND SHORTCOMINGS**

Tobias Stoll

**1. Access to Genetic Resources and Benefit-sharing - the Legal Basis**

**1.1. Rights as to Genetic Resources**

As Art. 2 of the CBD stipulates, the term genetic resources means "any material of plant, animal, microbial or other origin containing functional units of heredity" which has an "actual or potential value". At the international level, rights as to those resources are assigned to States on the basis of the sovereign right of States to their natural resources, a long-standing principle of international law which is recognized and affirmed by Art. 15 para. 1 CBD. It is the very essence of State sovereignty over genetic resources that States can freely use such resources for their own purposes and provide it to third parties on terms and conditions they may deem appropriate. This provision is referred to as access. At the national level, comparable legal concepts which cover genetic resources might exist. Property in land or tangibles may be considered in this regard. It may be in the hands of individuals or groups, including indigenous and local communities. However, it should be noted that the CBD does not call for entitlements of the latter in this regard but only refers to their knowledge and practices.

Rather than newly creating a State's right, the CBD contains procedural safeguards in this regard: It refers to a determination of Governments - Art. 15 para. 1, envisages that such access shall be on mutually agreed terms - para. 4, and requires prior informed consent of the relevant Contracting Party unless determined otherwise - para. 5.

**1.2. Benefit-sharing: The Call for a Mutually Beneficial Relationship**

The CBD envisages an international order for the utilization of genetic resources which is basically defined by Art. 1 CBD. This provision refers to a "fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding." Thereby, CBD is heading for a more comprehensive, reliable and mutually beneficial system based on sovereign rights over genetic resources. This concept is further dealt with in the Convention as follows:

Art. 1 elements:	further ruled upon in the Convention ...
Fair and equitable sharing of the benefits arising out of the utilization of genetic resources	<p>carrying out scientific research, with full participation of, and where possible in Contracting parties providing the resources ...(Art. 15 para. 6, 19 para. 2)</p> <p>sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources (Art. 15 para. 7, 19 para. 2)</p>
Appropriate access to genetic resources	<p>facilitate access to genetic resources ... and not to impose restrictions that run counter to the objectives of this Convention. (Art. 15 para. 2)</p>
Appropriate transfer of relevant technologies	<p>access to and transfer of technologies relevant to the conservation and sustainable use of biological diversity or make use of genetic resources ... (Art. 16 para. 1-4)</p> <p>see also: exchange of information (Art. 17 para. 1), technical and scientific co-operation (Art. 18 para. 1)</p>
Appropriate funding	financial mechanism, Art. 21, 22

Altogether, the provisions have a common structure. They:

- address States with regard to obligations and as beneficiaries,
- they envisage benefits to flow and terms of exchange at inter-state level, they refer without much distinction to means of cooperation between States, the financial mechanism of the Convention and private transactions as means and agents of achieving these objectives,
- yet the interactions sought are widely those between private entities, only in some instances do they call on States to urge the private sector to achieve the objectives sought.
- They do not directly address the private sector their relationships.

## 2. Further Implementation and Developments

From the outset, the CBD process including the drafting of the Convention and discussions on its implementation has been deeply inspired by some remarkable bioprospecting agreements. The Merck/INBio agreement has often been cited in this context. Indeed, such agreements have had a decisive impact on the discussion. Obviously, very high expectations have been placed in the CBD as laying the ground for, supporting and facilitating the initiation, conclusion and execution of a number of similar agreements around the world. However, these expectations do not seem to have been reached yet. There has been hardly any indication that the exchange of genetic resources and benefits among States parties has intensified.

### 2.1. Concerns and Uncertainties

The reasons for this have been discussed extensively. Inter alia, the Directorate General (DG XI) of the European Commission and the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety co-sponsored a workshop from 15 - 16 January 1998 in Cordoba, Spain on 'Best Practices for Access to Genetic Resources'. As a result, the conclusion formulated at the workshop was that potential providers and users of genetic resources consider the following factors as constituting uncertainties which may hinder mutually beneficial relationships:

#### Concerns of Providers ...

lack of information/control of genetic resources once outside providers' jurisdiction,  
 lack of clarity of the market structure for genetic resources,  
 uncertainty as to the value of biological diversity and biological resources,  
 unapproved use of genetic resources in academia and ex situ collections,  
 lack of negotiating and contractual capacities,  
 lack of institutional capacity,  
 lack of confidence in existing IPR regimes.  
 Inadequacy of existing IPR regimes to support the implementation of the Convention's objectives.

#### ... and Users

Users need a clear contact point and to know of institutions authorized to grant access to genetic resources in provider countries  
 Users need legal certainty on access  
 Users need clarity on ownership/tenure/ related rights  
 Access regulations need to distinguish between different genetic resources and different uses (scientific/ commercial)

These concerns are subject to and may be addressed by a number of developments and measures. Economic and technological developments are to be taken into account at this point as well as

developments concerning the general legal framework, including the system of intellectual property rights. Also, measures and projects of capacity building, business development, marketing promotion and general international cooperation might be considered. More particular and focusing on the legal perspective, resource state legislation, model contract provisions and non-legally binding principles and statements are relevant.

## **2.2. Access Legislation**

In theory, according to Art. 15 para. 1 CBD, States - or even more precisely: Governments - can decide upon access to genetic resources on a case by case basis on their own. However, from the national point of view, in most cases more than one stakeholder potentially may claim a right to benefit from and determine the conditions of granting access to genetic resources. This may include: different government departments, public agencies, nature conservation governing boards, municipalities and academic institutions, indigenous and local groups and land owners. In most cases some clarification is needed as to the validity of those claims and their procedural interplay at the national level. This at the same time is necessary in order to enable potential users of genetic resources to address the duly authorized entity when seeking access.

The competence of States to rule upon access to its natural resources is one of the major and most important elements of the principle of sovereignty over natural resources as mentioned above. Moreover, Art. 15 para. 2 may be understood as calling upon States to develop and maintain a legal structure, as an appropriate legal setting is an important condition for facilitating access to genetic resources.

As specified in the "Updated Survey on Access Legislation to Genetic Resources and Benefit Sharing", many States gradually implement the CBD internally, but only few of them have actually enacted such legislation.

The few laws already enacted met with some criticism concerning their practicability and the burdensome procedures a potential user has to undergo in order to obtain access. In sum, the legislation gives a number of different entities a say in the process. A general sort of administrative pathway is defined. This however, includes procedural requirements which consider each of the different stakeholders involved. Those requirements - especially in view of local and indigenous communities or municipalities - call for public information by media in the local language or dialect - if appropriate. Sometimes, a public hearing has to be undertaken. A potential user has to obtain the consent of all relevant stakeholders and has to negotiate benefit-sharing arrangements concerning each of them.

## **2.3. Model Contracts**

There have been some suggestions to draft and discuss model contract terms for access and benefit-sharing. However, as has often been indicated, the drafting of model contract terms cannot be considered very helpful for the time being:

If considered as a means of cutting down transaction costs by standardization, model terms might scarcely be relevant, as the exercise of drafting an agreement is only a minor concern in this

regard: Confidence building and negotiations in an environment of uncertainty are considered far more relevant, burdensome and detrimental factors. Also, it is considered to be likely that model terms fail to properly address the variety of possible arrangements - especially in view of possibly different approaches mandated by applicable national laws.

If considered as an instrument to indicate wishful and acceptable solutions, however, model terms seem to be premature in most cases, as the necessary consensus on such solutions will probably have to develop on the basis of more general ideas and statements in the first place.

#### **2.4. Principles and Positions to be Voiced by Individual Stakeholders or Groups**

Having this in mind, it might be considered a good idea if stakeholders individually, or within their organizations, or even between them, would develop and make public their expectations and suggestions. Those statements could already be quite useful and facilitate negotiations on access and benefit-sharing.

#### **2.5. Developments within a Multi-layered Process?**

As this short overview may indicate, States and stakeholders have a number of options determining how to contribute to achieving more favorable conditions for engaging in mutually beneficial relationships regarding the utilization of genetic resources. As is often the case, such activities may and to some extent do take place simultaneously. Such a multi-layered process has a number of merits: it may be widely driven by those interested in the field and may lead to a subsequent development of positions and standpoints. However, such a process requires a proper reflection and representation of the interests at stake and all participants must have sufficient means and capacities to engage in it. Also, one has to keep in mind, that stakeholders may be in a competitive situation where any statements may have implications for their market position.

#### **2.6. Actions by States as Considered within the CBD**

Finally, it should be noted that the CBD in its endeavor to foster a mutually beneficial use of genetic resources not only relies on private entities but also addresses States. As the intensive discussions on access and benefit-sharing within meetings of the Conference of the Parties may indicate, a high State interest is involved in this area. Decision III/15 of 1996 in this regard voiced an interest in further information and studies. To the more, however, it encouraged "States and regional economic integration organizations ... to explore and develop, ... guidelines and practices ... to ensure mutual benefits to providers and users of access measures and to implement them effectively at the national, regional or international level, as appropriate; ...". In doing so, however, Decision III/15 addresses States individually.

The 1998 Bratislava decision (IV/8), which primarily focuses on establishing a panel of experts, takes a somewhat different approach. The mandate of the panel clearly points out that the Panel shall develop "a common understanding of basic concepts and to explore all options for access

and benefit sharing on mutually agreed terms including guiding principles, guidelines, and codes of best practice for access and benefit-sharing arrangements."



## **NATIONAL ACCESS LEGISLATION: AN UPDATED SURVEY**

Carolina Carbuccia, LL.M (Manchester), project staff

### **1. Executive Summary**

Several initiatives for implementing the CBD have taken place to a higher or lower degree in different countries. Regulations are often restrictive and bureaucratic, due to the complexity of factors that interact in accessing genetic resources and benefit sharing.

The Andean Pact countries have established a Common Regime (Decision 391) on Access to Genetic Resources since 17 July 1996 which is the first regional effort to develop the CBD. To access genetic resources an application form must be filed and published by the Competent National Authority in a Public Register. If access is granted, an access contract is negotiated and signed, and a resolution is published. Each Member State is to determine which National Authority should have the competence to grant access through internal legislation, and may afford special importance to specific concerns, benefit sharing, technology and know-how transfers. Each State may also compensate indigenous and local communities for their knowledge.

In Mexico, the National Commission for the Knowledge and Use of Biodiversity (CONABIO) is in charge of developing a policy framework to govern access to Mexico's genetic resources. CONABIO must determine the criteria for the sustainable use and management of biodiversity and the legal procedures regulating access to genetic resources.

Costa Rica enacted Law 7788 (*Ley de Biodiversidad*) on 23 April 1998 to preserve biodiversity and to achieve a sustainable use of resources and a fair sharing of related benefits and costs. The Ministry of Environment and Energy (MINAE) coordinates the administrative bodies in charge of granting access to genetic resources. The National Commission for the Administration of Biodiversity plays the main role through its Technical Office.

In Brazil, Congress is currently in the process of approving *Projecto do Lei do Senado 306/1995*. It has already been approved by the Senate. The distinction between in-situ and ex-situ access is emphasized. In order to access in-situ genetic resources the interested party needs to apply for a research contract, directly or through a Access Agency. If the application is admitted, the parties will proceed with negotiations and will eventually sign an access contract. Concerning access to ex-situ resources of Brazilian origin, confirmation from the Competent Authority is required regarding genetic resources in or outside the national territory. Benefit-sharing can be pecuniary or achieved through in-kind compensation.

In the Philippines access to genetic resources and benefit-sharing are regulated by Executive Order 247, 1995 and Administrative Order 20, 1996. Prior informed consent of concerned local and indigenous communities is mandatory. The collector must enter into a research agreement with the Philippines Government, represented by different departments, depending on the nature of the access project, with the prior recommendation of the Inter-Agency Committee on

Biological and Genetic Resources. Contracting parties are free to choose a means through which to achieve benefit sharing, such as the payment of royalties or technology transfers.

The Indonesia Institute of Science (LIPI) formally developed the "Rules and Procedures Governing Permission from the Government of Indonesia for Foreign Researchers to Conduct Research in Indonesia" on access to genetic resources. However, access to Indonesia's genetic resources is currently defined through individual access contracts. In the field of agriculture, especially regarding access and conservation of plant genetic resources, Regulation 44, 1995 was issued. There are also plans to regulate at the national level.

India's system of Intellectual Property rights makes it difficult for the country to enact legislation regarding access to genetic resources and benefit-sharing. India is currently developing a national system of access to genetic resources and benefit-sharing, but negotiations are not public.

The Organization of African Unity (OAU) is preparing a „Model Law and Declaration Draft on Community Rights and Access to Genetic Resources“ which has not been completed so far. This Law should form the basis for African Nations to develop national legislation on access to genetic resources and benefit sharing. Access is to be provided after prior informed consent, an application form must be filed, and if the application is successful the parties will sign an access agreement. The main institutional body will be an inter-sectorial agency.

Cameroon enacted Law 94/01 in 1994. The Ministry of the Environment and Forestry is in charge of issuing commercial exploitation permits to access genetic resources for commercial purposes. Benefit-sharing can be realized through taxes, employment, infrastructure, or benefits in kind.

In Australia, rules concerning access to genetic resources are dispersed by her individual States, but a National Strategy for the conservation and use of biological diversity has been developing.

Canada has adopted a Biodiversity Strategy that her States may enact by individual jurisdiction in their discretion, while the United States have not ratified the Convention due to pressures from property rights organizations and farm and ranching groups.

The Member States of the European Union are also contracting parties to the Convention on Biodiversity, so they have internally implemented the Convention or are in the process of doing so. The EU as a whole has focused on the protection of its environment and biological diversity.

## **2. Analysis by Geographical Regions**

### **2.1. Introduction**

The Convention on Biological Diversity (CBD), signed by more than 150 governments at the Earth Summit in Brazil, Rio de Janeiro in 1992, states as main goals the conservation of biological diversity, the sustainable use of its components and the fair and equitable distribution of benefits arising from such use.

In accordance with the CBD, access to genetic resources, benefit-sharing and related issues have become an important part of countries' efforts to develop national or regional policies.

The following study will address the main legal developments in Biodiversity around the world, with a special emphasis on the issues of access to genetic resources and benefit-sharing.

We begin Chapter II with a table containing an overview over the main legal developments of the CBD. Then, the development in Latin American countries is emphasized, as most of the advances have taken place here due to the Common Regime enacted by the Andean Pact Members. This regime has also given neighboring countries an impulse to legislate in this field.

We continue with Asia, where we give details on the Philippines' legislation on access to genetic resources and benefit-sharing. Also, a general view of Indonesia and India is given.

Our next stop is Africa, where we discuss the main provisions of the OAU's „Model Law and Declaration on Community Rights and Access to Biological Resources“, and give a reference to Cameroon, an example of a biologically diverse country.

We then conclude this survey of national legislation with a brief reference to some developed countries, namely Australia and countries in North-America and Europe.

In Chapter III, we analyze some economic arguments for the current legislative situation regarding access to genetic resources and benefit-sharing in developing countries.

Chapter IV finally gives a brief reference of the topics developed in this paper and shows future perspectives.

## 2.2. Overview

The following table shows the current legislative situation concerning the development of national legislation based on provisions of the CBD in certain countries or regions, as well as the future planned developments, the institution responsible for access and some feasible methods of benefit-sharing if applicable.

Country or Regional Organization	Legal provisions on access and benefit-sharing	Future planned developments	Institution responsible for access	Benefit-sharing
Andean Pact Countries	Decision 391, Common Access Regime, of 17 July 1996		Competent National Authority, determined by each Member State	-Indigenous & Local Comm. -Technology transfer -National scientists involvement
Mexico		Comisión Nacional para el Conocimiento y Uso de la Diversidad: National Strategy &		

		Action Plan		
Costa Rica	Law 7788 of April 1998		(Ministry of Environment and Energy) Comisión Nacional para la Gestión de la Biodiversidad (Technical Office)	-Payments for legal procedures -Technology transfer -Royalties
Brazil		Projecto do Lei do Senado 306/1995		
The Philippines	Executive Order 247, 1995 Administrative Order 20 of 1996		Inter-Agency Committee (Protected Areas and Wildlife Bureau, PAWB)	-Royalties -Technology transfer -National scientists involvement -Transfer of equipment -Ecological rehabilitation bond
Indonesia	Rules and Procedures Governing Permission from the Government of Indonesia for Foreign Researchers to Conduct Research in Indonesia	Plans to regulate at the national level	Lembaga Ilmu Pengataharian Indonesia, LIPI. (The Indonesian Institute of Science).	
India		Plans to regulate at the national level		
Organization of African Unity (OAU)		Model Law and Declaration on Community Rights and Access to Biological Resources, 21 April 1998		
Cameroon	Law 94/01 of 20 January 1994		Ministry of Environment and Forestry	-Export duties -Taxes -Employment

				-Infrastructure
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## 2.3. Latin America

### 2.3.1. The Andean Pact Countries: Decision 391 of 17 July 1996

#### 2.3.1.1. Overview

The Andean Pact countries Colombia, Ecuador, Peru, Venezuela and Bolivia, have developed a "Common Regime on Access to Biogenetic Resources" in order to implement the CBD.

This Common Regime is formulated in Decision 391, which was published in the Gaceta Oficial del Acuerdo de Cartagena on 17 July 1996 and which entered into force immediately in all Member countries. Each country should develop national legislation within the framework of the Decision.<sup>1</sup>

The Common Regime established in Decision 391 is the first regional effort to develop the Convention on Biological Diversity. Its main objective is to regulate access to genetic resources and derivative products, in order to achieve a fair distribution of benefits, to develop technological capacities, to conserve biodiversity and to strengthen the Members' position when negotiating access.

The principle of national sovereignty over genetic resources is emphasized, and so is the self-determination that local and indigenous communities have over their traditional knowledge in relation to genetic resources.

Member States pledge to grant each other National and Non-Discriminatory Treatment, and any Member State may grant these to third countries which grant them equal treatment (principle of reciprocity).

#### 2.3.1.2. Access to Genetic Resources

The Competent National Authority must detail the documents needed for the access procedure in a public file.<sup>2</sup> Note that this file is public, unless the interested party petitions the Authority for confidentiality in cases where the information could lead to unfair competition from third parties. In this case the collector must justify his petition and summarize his reasons for the petition in a non-confidential document.

In order to access genetic resources in any Member State, a four step procedure must be followed<sup>3</sup>:

1. Presentation, admission, publication and approval of an access application.
2. Negotiation and subscription of an access contract.

<sup>1</sup> Information obtained from Dr. Manuel Ruiz Mueller, Sociedad Peruana de Derecho Ambiental/Gaceta Oficial no. 213

<sup>2</sup> Art. 18, Dec. 391

<sup>3</sup> Art. 16, Dec. 391

3. A resolution is issued and published.
4. Declaratory record of the actions linked with such access.

1. Presentation, admission, publication and approval of an access application

The procedure to access genetic resources begins with the presentation of the access application to the Competent National Authority. This must contain the following information:

- a) Petitioner's identity and, if appropriate, the documents which corroborate the legal capacity
- b) Provider's identity
- c) Determination of the supporting national person or institution
- d) Identification and resume of the person responsible for the project and of his/her team
- e) Access activity requested
- f) Locality or region where access is planned, including geographic coordinates

The project proposal must be attached to the access application.

If the application is complete, the procedure moves forward. If it is incomplete, it will be sent back to the applicant to be completed.

Once the application is confirmed in the Public Register, a summary must be published in two newspapers; one with a national circulation and the other from the place where the resources are being accessed. In the following thirty working days (which can be extended to up to 60 days), the National Authority will issue a technical and legal judgement on whether the application is convenient or not. Based on this examination the Authority will admit or refuse the application.

If the application is not granted, an explanatory decision will be sent to the applicant, which may be appealed according to the laws of the different Member States. If the application is admitted, the applicant will be notified during the following five days, and contract negotiations begin.

2. Negotiation and Subscription of an Access Contract

The Competent Authority and the collector are parties to the contract.

The access contract must consider the interests of the providers of genetic resources. If the genetic resources have an intangible component, the Contract will incorporate an annex which specifies the fair and equitable sharing of benefits.

The Competent Authority may conclude framework access contracts, which support the accomplishment of several projects, with universities, investigation centers or recognized scientists following the provisions laid out in Decision 391 and in the national legislation of each Member.<sup>4</sup> These framework agreements would make the execution of projects which require access to genetic resources possible through more flexible rules. Deposit contracts for genetic

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<sup>4</sup> Art. 36, Dec. 391

resources may also be concluded between these institutions and the Competent Authority, but only if they regulate custody.

Centers for ex-situ conservation which perform activities that may lead to access to genetic resources from any Member State must sign access contracts with the Competent Authority, following the provisions of Decision 391. At the same time, the Competent Authority may conclude access contracts with third parties over genetic resources deposited in such centers, provided that during the extraction of those genetic resources in any Member State the rights of the providers of such resources, derivative products, and/or intangible components were respected.

Accessory contracts may also be negotiated, in order to develop related activities to the access of genetic resources, specially in relation to land owners of the places where the resources are located. These contracts depend on the access contract.

### 3. A resolution is issued and published

Once the access contract is negotiated and signed, a resolution is issued, which will be published together with a summary of the contract in an official journal or in a newspaper with wide national circulation.

### 4. Declaratory Register of the legal acts connected with such access

The Competent National Authority will publish the decisions related to the procedure of access to genetic resources (approval, refusal), termination of access, nullity, sanctions or penalties, Access and Accessory Contracts and any modification to these in a register.

#### **2.3.1.3. Special Reference to Prior Informed Consent**

Although Decision 391 of the Andean Pact countries does not refer expressly to "Prior Informed Consent", it does state that local and indigenous communities have the right to decide over their traditional knowledge associated to genetic resources and derivative products.<sup>5</sup> It also states that the access contract will consider the rights and interests of the providers of genetic resources and derivative products. Whenever the access contract incorporates an intangible component, an annex will develop the fair and equitable distribution of benefits.<sup>6</sup>

From those provisions we can deduct that whenever an access contract involves indigenous and local communities, their interests must be considered. Decision 391 is vague about the way in which this negotiation will take place.

#### **2.3.1.4. Benefit-sharing**

Decision 391 does not develop the issue of benefit sharing in depth. However, it considers the transfer of know-how and technologies as a main factor. This transfer is achieved, among others, by requiring information about the genetic resource that is being accessed, by allotting nationals

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<sup>5</sup> Art. 7, Dec. 391

<sup>6</sup> Art. 34 - 36, Dec. 391

of different countries to the investigation activities and by requiring that a duplicate of the resource collected must be deposited with the designated institutions.

Also, when the genetic resources have an intangible component which is essentially indigenous knowledge, an annex must be incorporated into the access contract. This annex must proscribe how to share the benefits in a fair and equitable manner. Decision 391 does not, however, detail exactly how to achieve the benefit-sharing.

### **2.3.1.5. Brief-reference to Member States**

Some Member States of the Andean Community have adopted internal legislation within the framework of the Decision 391.

Colombia has established through Decree No. 730 of 1997 by the Ministry of Foreign Affairs that the Environment Ministry is the National Authority competent to grant access to genetic resources.<sup>7</sup>

Peru has been working on a draft legislation to regulate the enforcement of Decision 391, which shall be submitted to the Executive Branch for consideration and enacted through a Supreme Decree.<sup>8</sup>

Bolivia has enacted Supreme Decree 24676 of 21 June 1997 "Reglamento de la Decisión 391 sobre Régimen Común de Acceso a los Recursos Genéticos" (By-law to Decision 391). It develops access to Bolivia's genetic resources and regulates a fair and equitable sharing of benefits with the Bolivian Government and with local and indigenous communities. The National Authority is the Ministry of Sustainable Development and Planning (Ministerio de Desarrollo Sostenible y Planificación), and within the Ministry, the Biodiversity General Bureau plays an important role.

Ecuador adopted the "Law which Protects Biodiversity in Ecuador" in 1996. The Ministry of the Environment is the highest National Authority on any topic related to the coordination, execution and supervision of environmental policies.<sup>9</sup>

Venezuela has not yet adopted any regulation specifying Decision 391.

### **2.3.2. Mexico: Comisión Nacional para el Conocimiento y Uso de la Diversidad (CONABIO)**

In order to develop the Convention's objectives, Mexico's Government created La Comisión Nacional para el Conocimiento y Uso de la Diversidad<sup>10</sup> (CONABIO) on 16 March 1992.

<sup>7</sup> Information provided by Paola Ferreira Miani. Coordinator of the Program Investigation in Politics and Legislation. Humboldt Institute-Colombia

<sup>8</sup> Peru: Nation Report to the Convention on Biodiversity

<sup>9</sup> Ecuador: National Report and Comments from Dr. Manuel Ruiz of the Sociedad Peruana de Derecho Ambiental

<sup>10</sup> The National Commission for the Knowledge and Use of Biodiversity



CONABIO's role is to co-ordinate conservation and research efforts in order to preserve biological resources. It is currently in charge of developing a policy framework for governing access to Mexico's genetic resources.<sup>11</sup>

This policy framework has two steps: a) A country study (Estudio del País), which aims at evaluating the current situation of Mexico's biological diversity; b) this study will be the basis for preparing the National Strategy (Estrategia Nacional) and the Action Plan (Plan de Acción).

The National Strategy (NS) will by questioning different sectors of society establish policies and responsibilities in order to access biological resources and use these in a sustainable way following the general principles of the CBD.<sup>12</sup> The objectives of the NS are mainly the following:

- legislate and create incentives in order to support the sustainable use of and access to genetic resources,
- increase the knowledge on ecosystems and their different species. This would include the knowledge of indigenous and local communities, as well as scientific knowledge,
- international cooperation to conserve biodiversity, and
- an equitable sharing of benefits.

The Action Plan will define the obligations of those responsible for implementing the Strategy, the concrete actions, time, sectors and places where they will be developed, the human, institutional and financial means, and a work scheme to implement those actions.

From this brief explanation of CONABIO's responsibilities regarding access to biodiversity we can deduct that it faces a great challenge<sup>13</sup>, as the Commission must determine the criteria for the sustainable use and management of biodiversity and the norms and legal procedures regulating access to genetic resources. It must also continue making inventories of plants and micro-organisms and detailing the biodiversity found in identified priority areas. In compliance with its mission, CONABIO will accomplish these tasks by coordinating scientists, government agencies, NGO's and producers.

### **2.3.3. Costa Rica: Law 7788 of 23 April 1998**

#### **2.3.3.1. Overview**

Costa Rica is a country often cited as a model example due to the positive results of the agreements concluded by the Instituto Nacional de Biodiversidad (INBio), for instance, those with Cornell University, Merck&Co., and the US National Cancer Institute.

INBio, which was created in 1989, is a scientific institution with a social orientation, which sets up an inventory of the country's biological resources and encourages appropriate use of those resources.

<sup>11</sup> See Kagedan, Barbara Laine on "The Biodiversity Convention, Intellectual Property Rights, and Ownership of Genetic Resources: International Developments". Industry Canada, April 1998.

<sup>12</sup> CONABIO: Eleazar Loa, Lucila Neyra y Patricia Schmidtsdorf, Biodiversitas. Ano 3, num.14. Agosto 1997

<sup>13</sup> CONABIO: Internet-page

According to Costa Rica's „Wildlife Conservation Law“ of December 1992, wild plants and fauna belong to the public domain and therefore to the public patrimony. From this point of view, the Ministry of Environment and Energy (MINAE) has the right to grant permits for the access and use of genetic resources. MINAE permits INBio to collect samples for use in scientific research and bioprospecting under specific conditions.

This means that MINAE integrates all activities related to the management and conservation of the country's natural resources. Moreover, a National System of Conservation Areas (SNAC), dependent on MINAE, assures that these resources are adequately managed.

Costa Rica has also been developing the „National Biodiversity Program“ with the aim of conserving the country's biodiversity through the sustainable and equitable use of these resources. This Strategy is based on the framework established at the international level in the "Global Biodiversity Strategy" of 1992 and the UN Earth Summit held in Rio in 1992.

As part of the National Biodiversity Program, a National System for Sustainable Development (Sistema Nacional para el Desarrollo Sostenible, SINADES)<sup>14</sup> has been created, in order to fulfill Costa Rica's obligations according to Chapter 15 of Agenda 21.<sup>15</sup>

It is important to note the activities of the National Advisory Commission on Biodiversity (Comision Nacional Asesora de Biodiversidad, COABIO)<sup>16</sup> within SINADES.

COABIO is an advisory commission of the SINADES which should implement the Convention on Biodiversity and Agenda 21 in Costa Rica, under consideration of the national context. It is worth noting that COABIO was in charge of the preparation of a Draft Law on Biodiversity, which formed the basis for Law 7788 of 23 April 1998.

### **2.3.3.2. Law 7788 of 23 April 1998**

#### **2.3.3.2.1. General Ideas**

The main objectives of Law 7788 are the preservation of biodiversity, the sustainable use of resources, and a fair sharing of related benefits and costs.<sup>17</sup>

It aims at consolidating a clear legal framework in relation to access to genetic resources and the sharing of the social, environmental and economic benefits between all sectors of society,<sup>18</sup> and, at the same time tries to improve public administration in order to create an effective and efficient management of those resources.<sup>19</sup>

<sup>14</sup> Executive Decree n°23671 MIRENEM-MIDEPLAN from 23/9/94

<sup>15</sup> Chapter 15, Agenda 21 states that... "biological resources constitute a capital asset with great potential for yielding sustainable benefits. Urgent and decisive action is needed to conserve and maintain genes, species and ecosystems, with view to the sustainable management and use of biological resources. Capacities for the assessment, study and systematic observation and evaluation of biodiversity need to be reinforced at national and international levels"...

<sup>16</sup> Executive Decree n°24555 - Mirenem - Plan, Gaceta n° 164, 30 August 1995

<sup>17</sup> Law 7788. Art. 1

<sup>18</sup> Law 7788. Art. 10

<sup>19</sup> According to Art. 4, human genetic and biochemical material, exchanges of genetical and biochemical resources between indigenous people without commercial purposes and associated knowledge derived from

In order to achieve these objectives, the Ministry of Environment and Energy (MINAE) coordinates the administrative bodies in charge of the management and conservation of biodiversity, which are integrated by:

- a) Comisión Nacional para la Gestión de la Biodiversidad (National Commission for the Administration of Biodiversity)
- b) Sistema Nacional de Areas de Conservación (National System of Conservation Areas)

#### **2.3.3.2.2. Access to Genetic Resources**

- a) National Commission for the Administration of Biodiversity

One of the main responsibilities of the Commission is to consolidate and coordinate the access to genetic resources and to assure the transfer of technology and a fair distribution of benefits.

The Commission's Technical Office<sup>20</sup> is in charge of handling, approving or rejecting the submissions for access to genetic resources. It must coordinate its activities with the Conservation Areas, the private sector and the local and indigenous communities. The Technical Office must additionally organize and update a register of submissions, ex-situ collections and of natural or corporate persons dedicated to the collection and management of genetic resources.

The Commission will determine access to genetic resources, following these basic conditions<sup>21</sup>:

- prior informed consent from the representatives of the place to be accessed,
- confirmation from the Technical Office of the Commission that such prior informed consent has been acquired,
- definition of the conditions for technology transfer and fair distribution of benefits, if such benefits exist, agreed in the permits, agreements or concessions, as well as the type of protection given to knowledge required by the representatives of the place accessed,
- contribution of those activities to the conservation of species and ecosystems, and
- designation of a legal representative resident in Costa Rica for natural or corporate persons resident in a foreign country.

The Technical Office will follow a summary procedure to access genetic resources, unless third parties may be affected (in this case an ordinary administrative procedure will be followed). Prior informed consent of the owner of the land which access is requested to, of the representative of the indigenous community, or of the Director of the Conservation Area must be attached to the access petition.

Local and indigenous communities have the right to oppose access to genetic resources or associated knowledge for cultural, spiritual, social, economic or other reasons.

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their practices, uses and customs, and the universities' autonomy with respect to biodiversity investigations and teaching without lucrative purposes are all out of the scope of this Law.

<sup>20</sup> Law 7788. Art. 17

<sup>21</sup> Law 7788. Art. 63

The Office will keep an updated register of rights to access genetic resources. This information is public, with the exception of industrial secrets.

The access permit will be granted for a three year period, which is renewable<sup>22</sup>.

Art. 72 of Law 7788 details the formal requirements for requesting access to genetic resources:

- Name and complete information of the petitioner. When the petitioner is not the interested party, the identification of the latter and the type of mandate of the petitioner must be disclosed,
- identification of the scientist or professional responsible,
- exact localization of the place and elements that will be the object of investigation, indicating the owner, administrator or holder of the real estate,
- a descriptive timetable of the investigation's scope and possible environmental impact,
- objectives and goals pursued,
- declaration that the objectives and goals communicated were made under oath,
- place for notifications in the boundaries of the Technical Office, and
- attachment of the prior informed consent.

Before taking any further actions, persons or corporations willing to execute bioprospecting should get registered in the Commission's Register. This act does not grant any rights.

Public universities and other registered centers may periodically sign framework agreements with the Commission to manage the access permits and information on operations.

#### b) The National System of Conservation Areas

The SNAC mainly deals with formulating policies, planning and organizing processes in order to achieve a sustainable use of natural resources in Costa Rica, and with giving its consent to access which should take place in protected areas.

##### **2.3.3.2.3. Special Reference to Prior Informed Consent**

Law 7788 requires the prior informed consent of the representatives of the place to be accessed, which may be the Regional Councils of the Conservation Areas, the land owners or the indigenous authorities.<sup>23</sup> The procedure to obtain prior informed consent is not developed.

##### **2.3.3.2.4. Benefit-sharing**

According to Law 7788 the corporate or natural person must obtain a concession in order to commercialize genetic resources.<sup>24</sup>

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<sup>22</sup> Law 7788. Art. 70

<sup>23</sup> Law 7788. Articles 63 & 65

<sup>24</sup> Law 7788. Art. 75

Concerning benefit sharing, the Technical Office receives a percentage of the benefits defined in the access permits and concessions related to biodiversity.<sup>25</sup> The Office also establishes the interested party's obligation of depositing up to 10% of the investigation's budget and up to 50% of the royalties in favor of the National System of Conservation Areas, the indigenous territory or the private owner who provided the necessary elements for access. It also determines the amount that the interested parties must pay for the legal proceedings in each case, or any other benefit or technology transfer that constitutes a part of the prior informed consent.<sup>26</sup>

### **2.3.4. Brazil: Projecto do Lei do Senado 306/1995**

#### **2.3.4.1. Introduction**

At the federal level in Brazil three projects regarding access to genetic resources are being discussed in Congress. The Project Law 306/1995 by Senator Marina Silva was approved by Senate last year, and it is being discussed in Congress. Other projects from Deputy Jacques Wagner and from the Executive are also being discussed.<sup>27</sup>

At state level, Acre and Amapa have, together with Sao Paulo, enacted laws regarding access to genetic resources.

This section will concentrate on access to genetic resources and benefit-sharing according to Projecto do Lei do Senado 306/1995.

#### **2.3.4.2. Access to Genetic Resources**

Projecto do Lei do Senado 306/95 recognizes Brazil's National Sovereignty over genetic resources and the importance of benefit-sharing with local and indigenous communities and the country itself.

An Administrative Body shall be in charge of access to genetic resources. Decisions of this body must be voted on by a Genetic Resources Commission composed of different sectors of society.

A distinction is made between in-situ and ex-situ access to genetic resources.

Access to in-situ genetic resources is awarded once the following steps have been followed:

##### **1. Application for a Research Contract**

In order to conclude an access contract<sup>28</sup>, the petitioner or Access Agency<sup>29</sup> will first present an application, attaching the access project, with at least the following information<sup>30</sup>:

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<sup>25</sup> Law 7788. Art. 19

<sup>26</sup> Law 7788. Art. 76

<sup>27</sup> Information provided by Cristina do Amaral Azevedo, Environmental Secretariat, Sao Paulo.

<sup>28</sup> See articles 14 to 18, Projecto do Lei do Senado 306/95

<sup>29</sup> The Competent Authority may allow public institutions and non-lucrative private entities, whose activities relate to the conservation and sustainable use of genetic resources, to require access to genetic resources in the name of third parties. These will be known as Access Agencies.

<sup>30</sup> Art. 15, Projecto do Lei do Senado 306/95.

- a) Curricular data and complete identification, including the responsible parties:
  - petitioner, with proved technical capacity, including information of any person or institution involved in the petition for access,
  - Access Agency, including its Land Registry and contract made with the petitioner, if this is the case,
  - holder of the natural resource,
  - provider of the traditional knowledge,
  - public institution resident in Brazil, which will accompany the petitioner/collector.
- b) Timetable and source of funding for the intended project.
- c) Detailed description of the genetic resources, derivative projects, or traditional knowledge which access is requested to, including current and potential uses, environmental sustainability, and risks of access.
- d) Methods and instruments to be employed.
- e) Exact places or regions where access will take place.
- f) Where the material collected will be deposited and its possible future use.
- g) Where access to traditional knowledge is concerned, a confirmation that the local or indigenous communities have been visited shall be attached to the project.
- h) The Competent Authority may require an environmental impact assessment.

## 2. Admission of the Research Contract

If the Application is complete, the Competent Authority takes the following steps:

- Publication of a summary of the application and access project in an official journal.
- Publication thereof in a newspaper with a wide circulation in the region where access is requested in the following three days.
- If the institution which would accompany the collector is not admitted, at least three other institutions will be listed.

If the Application is incomplete, it will be returned to the petitioner in order to be completed.

In the following sixty (60) days, which may be extended after the publications, the Competent Authority will examine the application and access contract, and will decide on their appropriateness.

The Authority shall accept or reject the petition through a justified decision. If the petition is refused, negotiations are closed, but an appeal is possible. If the application is admitted the decision must be communicated to the interested party during the following ten (10) days and

will be published in an official journal and in a newspaper with a wide circulation in the region where access will take place.

### 3. Negotiation of an Access Contract

The Brazilian State, represented by the Competent Authority, the petitioner, the Access Agency, and the provider of the traditional knowledge or agricultural domesticated product are all parties to the access contract.

If the access includes a traditional or an agricultural domesticated product, an annex which establishes a fair sharing of the benefits obtained and indicates the way in which such benefit sharing will take place must be attached to the contract.

Contracts with third persons which are related to the access must be presented to the Competent Authority.

The Contract will contain at least the following terms:

- object of the contract,
- determination of who holds title to property and community rights of products and processes obtained, and requirements to provide licenses,
- an agreement that the genetic resources or derivative products shall not be transmitted to third parties without prior authorization,
- the Access Agency and the petitioner must inform the Competent Authority about the collection and uses of genetic resources and derivative products,
- communication to the Competent Authority of any investigation or publication related to the accessed genetic resources or derivative products,
- disclosure to the Competent Authority of new products or processes which differ from the object of the original contract,
- the Access Agency and the petitioner must inform the Competent Authority about the results achieved,
- the Access Agency and the petitioner must obtain authorization from the Competent Authority to access regions not stipulated in the contract,
- deposit of samples of the genetic resources or derivative products, with an express prohibition of exporting unique samples,
- possible confidentiality agreements,
- possible exclusivity agreements,
- remuneration guarantee in case of violation of the contract,
- compensation clauses in case of contractual and tort liability, and
- submission to national legislation,

The expiry date of the access contract, which is renewable, will be fixed to a maximum period of three years by the Competent Authority.

The Competent Authority may make agreements with scientific institutions, universities or other institutions in Brazil that support the performance of one or more access contracts, according to the procedures developed above, without having to designate an institution to accompany the access team.

#### 4. Provisional and accessory contracts

There is a possibility to sign provisional contracts with the Competent Authority for a one-year period. In such contracts products from genetic resources cannot be commercialized, but once a provisory contract has been signed, the interested party will enjoy preferential treatment when trying to obtain access to the resources in question by means of an access contract.

Accessory contracts are those contracts needed to implement activities connected to access to genetic resources. They are dependent on the access contract.

Concerning access to ex-situ resources of Brazilian origin, the National Agency may sign access contracts to genetic resources in or outside the national territory.

The institution providing those resources must submit an access application, and remuneration may be negotiated. The conservation center and the interested party are allowed to sign an agreement only after confirmation by the Competent National Authority.

#### **2.3.4.3. Special Reference to Prior Informed Consent**

Draft 306/95 states that the provider of the genetic resources or traditional knowledge is a party to the access contract.<sup>31</sup> If the contract wants to make use of traditional knowledge, an annex to the access contract must determine the equitable sharing of benefits.

Local and indigenous communities have exclusive rights to their knowledge. Access to their lands requires their prior informed consent. The procedure for obtaining this prior informed consent is not detailed.<sup>32</sup>

#### **2.3.4.4. Benefit-sharing**

The provisions for payments between the parties should assure fair compensation. This compensation could be monetary or could consist of commercialization rights as defined by the access contracts.

Local and indigenous communities have the right to receive pecuniary or in-kind benefits. The knowledge of these communities will be protected through intellectual property or similar rights, so that the communities can benefit jointly from their knowledge. They also have the right to deny access to genetic resources when it threatens the integrity of their natural or cultural patrimony.

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<sup>31</sup> Art. 19-20, Projecto.

<sup>32</sup> Art. 44, Projecto.



Participation of national scientific institutions is mandatory in any access contract.

## **2.4. Asia**

### **2.4.1. The Philippines: Executive Order 247 of 1995 and Administrative Order 20 of 1996**

On the Philippines, access to genetic resources and benefit sharing are regulated by Executive Order 247, 1995 and Administrative Order 20, 1996 which details the processes by which the Department of Environment and Natural Resources (DENR) and other concerned institutions and agencies will administer Executive Order 247 to regulate the research, collection, and use of biological and genetic resources.

#### **2.4.1.1. Access to Genetic Resources**

A condition for obtaining genetic resources on the Philippines is the prior informed consent of local and indigenous communities concerned.<sup>33</sup> The interested party must, on recommendation of the Inter-Agency Committee on Biological and Genetic Resources, enter into a research agreement with the Philippines Government, represented by the Department of Environment and Natural Resources (DENR), the Department of Health (DOH), the Department of Agriculture (DA) or the Department of Science and Technology (DOST), depending on the nature of the prospecting activity.<sup>34</sup>

There are commercial and academic research agreements. Only Filipino academic institutions and National and Inter-Governmental Agencies can apply for an academic research agreement.

An Inter-Agency approach has been considered an appropriate way of regulating the research, collection, exploitation and use of biological and genetic resources.

The Inter-Agency Committee is composed of representatives from the Department of Environmental and Natural Resources, the Department of Agriculture, two representatives from the academic community, the Department of Health, the Department of Foreign Affairs, one representative from a Non-governmental Organization (NGO), a representative of the National Museum, and one representative from the People's Organization.

As noted above, the Committee is in charge of processing applications for research agreements and recommending them to the Secretary of DENR, DOH, DA or DOST, depending on the nature and character of the prospecting activity. The Committee must ensure that the conditions for the

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<sup>33</sup> Section 1, EO 247, 1995

<sup>34</sup> Section 3, EO 247. According to AO 20, 1996, DENR acts as the primary government agency responsible for the implementation and enforcement of EO 247 and its „Implementing Rules and Regulations“, and assists in the review and evaluation of research proposals pertaining to wildlife resources which it has jurisdiction to manage; DOH assists in the review and evaluation of research proposals in the areas of pharmaceutical/medicinal research and development, including the utilization of extracts, products and by-products and derivatives for commercial and academic purposes; the DA assists in the review and evaluation of proposals in the areas of agricultural, fishery, and other resources which it manages; DOST assists in the review and evaluation of proposals in the areas of germplasm collection, documentation, conservation, evaluation, utilization and related bioprospecting activities.

research agreements are strictly observed. The procedure for requesting access to genetic resources on the Philippines is the following:

#### 1. Application for a Research Agreement

The applicant submits an Application for a research agreement to the Inter-Agency Committee on Biological and Genetic Resources (IACBGR) through the Protected Areas and Wildlife Bureau (PAWB).<sup>35</sup> This must include a research proposal stating the purpose, source of funds, and duration of the research, and a list of biological and genetic materials, including the amount of materials to be extracted.

A copy of the proposal must be submitted to the recognized head of the local or indigenous cultural community or communities that may be affected. Action on the proposal shall be taken no earlier than 60 days after the persons concerned have received a copy of the proposal.

According to Section 5 of Executive Order 247, the commercial research agreement (and academic research agreement) must contain at least these terms:

- a) Limit on samples that the Commercial/Academic Collector may obtain and export. The approved list and amount of samples taken from the area must be followed strictly.
- b) A complete set of all specimens collected shall be deposited by the Commercial/Academic Collector with the National Museum or a duly designated governmental entity, provided that holotypes designated by the author must be maintained at the National Museum.
- c) All Filipino citizens and the Philippine governmental entities shall have access to collected specimens and relevant data whenever these specimens are deposited in depositories abroad.
- d) The Commercial/Academic Collector, or in appropriate cases, his Principal, must inform the Philippine Government, as well as the affected local and indigenous cultural communities of all discoveries made as a result of the activity conducted in the Philippines, if a commercial product is derived from such activity.
- e) The agreement must provide for the payment of royalties to the National Government, local or indigenous cultural community and individual person or designated beneficiary if commercial use is derived from the biological and genetic resources taken. Where appropriate and applicable, other forms of compensation may be negotiated.
- f) There must be a provision that allows the Philippine government to unilaterally terminate the agreement whenever the Commercial/Academic Collector has violated any of its terms. The Agreement may also be revoked on the basis of public interest and welfare.
- g) A status report of the research and the ecological state of the area and/or species concerned shall be submitted to the Inter-Agency Committee regularly.
- h) If the Commercial Collector or its Principal is a foreign person or entity, scientists who are citizens of the Philippines must be actively involved both in the research and collection

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<sup>35</sup> Section 4, EO 247, 1995

process and, where applicable and appropriate, as determined by the Inter-Agency Committee, in the technological development of a product derived from the biological and/or genetic resources taken from any area in the Philippines. This involvement shall be at the cost of the Commercial Collector.

- i) The Commercial Collector and/or its Principal shall be encouraged to use the services of Philippines universities and academic institutions. Where applicable and appropriate, the Commercial Collector and/or its Principal shall be required to transfer equipment to a Philippine institution or entity.
- j) A fixed fee must be paid to the DENR in accordance with a list of fees formulated by the Inter-Agency Committee.
- k) The maximum term for a commercial research agreement shall be three years and it shall be renewable upon review by the Inter-Agency Committee.
- l) In case of endemic species, the technology must be made available to a designated Philippine institution and can be used commercially and locally without paying royalty to a Collector or Principal, provided, however, that where appropriate and applicable, other agreements may be negotiated where appropriate and applicable.

Additionally, concerning academic research agreements, the following terms shall be complied with:

- a) The academic research agreement may be comprehensive in scope and cover as many areas as may be projected. It may stipulate that no scientists and researchers affiliated with a duly recognized university, academic institution, governmental and intergovernmental entity need to apply for a different research agreement but may conduct research and collection activities in accordance with an existing academic research agreement. In such cases, the university, academic institution and governmental entity shall ensure that all terms and conditions of the government are complied with by the affiliated scientist or researcher. In all cases, the university institution or governmental entity must ensure that affected communities have given their prior informed consent to the activities to be undertaken.
- b) There must be a provision requiring the Academic Collector to apply for a commercial research agreement when it becomes clear that the research and collection being done has commercial prospects.
- c) A minimal fee must be paid to the Philippine government in accordance with a list of fees set up by the Inter-Agency Committee.
- d) The maximum term for an academic research agreement shall be five years and this shall be renewable upon review by the Inter-Agency Committee.

When requesting access to genetic resources, the Principal/Collector shall submit the following documents:<sup>36</sup>

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<sup>36</sup> Section 6, AO 96-20

- Letter of Intent addressed to the IACBGR and three (3) copies of a Research Proposal that follows a pre-determined format.
- Duly accomplished Application Form with the following documents attached:
  - ⇒ Letter of Acceptance from Filipino counterpart(s) authorized by or representing the host institutions which cooperate in the activities in the Philippines, where applicable;
  - ⇒ Letter of Endorsement from Head of Institution where applicant is affiliated or reputable Institution, Museum or University;
  - ⇒ Company/Institution/Organization/Agency Profile; and
  - ⇒ Any other document that the government agency concerned may require.
- Prior Informed Consent (PIC) Certificate obtained in accordance with Executive Order 247 from the indigenous or local communities, Protected Area Management Board (PAMB), or, in cases where the prospecting of biological and genetic resources will be undertaken within any of the above mentioned areas, from the private land owner.
- Environmental Impact Assessment (EIA) as determined by the Technical Secretariat.
- Application/Processing fees to be paid upon application:
  - Philippine national — P1,025/application
  - Foreign national — P2,025/application

The IACBGR, through the Technical Secretariat, shall undertake an initial screening of the research proposal to determine whether the research/project activity complies with Executive Order 247. If this is so, the principal/collector shall submit additional documents based on a checklist provided by the Technical Secretariat and other requirements depending on the nature of the bioprospecting activity to be undertaken.

## 2. Approval of the Research Agreement

Within 30 days from receipt of all documents from the Principal/Collector, the Technical Secretariat conducts an initial review and evaluation of the application and documents, and submits the evaluation results including the draft research agreement to the Inter-Agency Committee for a final evaluation.

After the Inter-Agency Committee has completed its final evaluation, it will submit its recommendation to the agency concerned (DENR, DOH, DA or DOST depending on the nature and character of the prospecting activity).

The Secretary of the Agency concerned shall approve the research agreement when it has been favorably recommended by the Inter-Agency Committee. The Agency shall transmit the signed research agreement to the Technical Secretariat who shall send a copy to the principal/collector, indigenous or local Community, protected area or private land owner concerned.

### 2.4.1.2. Special Reference to Prior Informed Consent

AO 96-20 requires a "Prior Informed Consent Certificate" from the indigenous or local communities (IP), the Protected Area Management Board (PAMB), or the private land owner, depending on where the activity will take place. The procedure to obtain PIC for Commercial Agreements is the following:

The Principal/Collector shall inform the concerned representative through various media, first, that he intends to conduct bioprospecting within his particular area, fully disclosing the activity to be undertaken, second, that copy(ies) of a summary of the research proposal fully disclosing the activity has/have been filed with the recognized head of the IP, Municipal or City Mayor of the Local Government Unit, PAMB or Private Land Owner concerned, and third, that an application for a research agreement has been filed with the IACBGR through the Technical Secretariat.

The Principal/Collector shall call for an assembly of the community and shall give the party concerned (a) copy(ies) of a brief summary or outline of the research proposal in a language or dialect understandable to them stating therein the purpose(s), methodology(ies), duration, species/specimen and number/quantity to be used and/or taken, equitable and reciprocal benefits to parties concerned before, during and after the duration of the approved bioprospecting activity and a categorical statement that said activity to be conducted in their area(s) will not in any way affect their traditional use of the resources. Where IPs are concerned, the proposal shall be taken up in accordance with their customary laws/traditions/practices.

The representatives concerned will issue the PIC Certificate. PIC Certificates will not be issued until 60 days after the submission of the proposal.

A representative/s of the IACBGR and/or non-government organizations/people's organizations may participate in activities, and shall sign as witness(es) in the PIC Certificate.

#### **2.4.1.3. Benefit-sharing**

Benefit-sharing will be determined on a case-by-case basis, as „agreements shall include a provision for the payment of royalties to the National Government, local or indigenous cultural community and individual person or designated beneficiary where commercial use is derived from the biological and genetic resources taken. Where appropriate and applicable, other forms of compensation may be negotiated.“<sup>37</sup>

According to Executive Order 20 of 1996, a separate agreement shall be made for the transfer of royalties, technology and other benefits<sup>38</sup>. Such a benefit-sharing agreement must ensure that benefits and results received also go to local and indigenous communities or the Protected Area concerned and are allocated for conservation measures.

If the collector is a foreign person or entity, Filipino scientists must be actively involved in the research and collection process. It is also possible that Filipino scientists must be involved in the technological development of a product derived from the biological and/or genetic resources

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<sup>37</sup> Section 5.e, EO 247, 1995

<sup>38</sup> Section 8.1.14, EO 247, 1995

taken from any area in the Philippines, if the Inter-Agency Committee considers this appropriate. This involvement is at the cost of the collector.

The provision which states that the collector shall donate some of the equipment used in the conduct of the research to the Philippine government agency, institutions or universities concerned is related to this provision.<sup>39</sup>

There is also an obligation to transfer technology to a designated Philippine institution in the case of endemic species. This technology could be used commercially and locally without paying any royalties to the collector. In this case, the Executive Order establishes the possibility to negotiate other agreements, where applicable.

At the same time, all discoveries of commercial product(s) derived from Philippine biological and genetic resources shall be made available to the Philippine government and local communities concerned.

Short, medium or long term benefits which result directly or indirectly from the bioprospecting activities conducted shall be shared equitably and upon mutual consent among the Philippine government, communities concerned and the collector.

If a technology or a commercial product is developed and marketed outside the Philippines, an equity or remittance in an amount to be mutually agreed upon by the parties concerned shall be equitably shared with the Philippine government. If the materials or resources came from protected areas, the amount must be shared with the Integrated Protected Areas Fund. The amount may also have to be shared with the indigenous or local community which gave its PIC or with the individual who supplied material or resources from his private property.

The Principal must also submit a performance, compensation, or ecological rehabilitation bond to be deposited in favor of the government. The amount is to be determined by the Inter-Agency Committee in accordance with the extent and scope of the project.

#### **2.4.2. Indonesia: Brief Reference**

Indonesia is a biologically diverse country, but the development of transparent legal rules regulating access to genetic resources and benefit-sharing is still at an early stage.

Access to genetic resources is formally laid down in the „Rules and Procedures Governing Permission from the Government of Indonesia for Foreign Researchers to Conduct Research in Indonesia“, issued by Lembaga Ilmu Pengataharian Indonesia, LIPI (The Indonesian Institute of Science).

The Indonesian Institute of Science developed this rule in 1968, in order to regulate access to scientific material and sharing of these resources between the assessors and the government through the scientific institutes involved.<sup>40</sup> This rule is not taken into consideration most of the time and, as a matter of fact, access agreements establish the conditions for access. Indonesia's

<sup>39</sup> Section 8.2.3., EO 247, 1995

<sup>40</sup> Indonesia: National Report to the CBD

access agreement with the United States National Cancer Institute is often cited as such an example.

In the field of agriculture, Regulation 44 of 1995 was issued in relation to access and conservation of plant genetic resources.

There are disperse regulations in Indonesia on access to genetic resources and benefit-sharing at a sectoral level. These regulations often contradict each other and, at the same time, create conflicts of interest. For this reason national planning will be developed to provide guidance by the highest national authority.

Indonesia is expected to take further actions towards the management of biodiversity and its sustainable use. The main problem has been insufficient law enforcement.

### 2.4.3. India: Current Status

Although India, with over 45,000 plant species and 81,000 animal species, is considered to be one of the world's 12 mega-biodiversity centers, it has not yet enacted any legislation to implement the Convention on Biodiversity. The CBD was signed by India on 5 June 1992 and ratified on 18 February 1994. It came into force on 19 May 1994.

India has been attempting to formulate a National Biodiversity Action Plan to maintain the ecosystem, species, and genetic diversity through a series of in-situ and ex-situ measures, but strong opinions and the current system on intellectual property rights<sup>41</sup> make it difficult for the country to enact legislation regarding access to genetic resources and benefit-sharing.

Although India is a member of the WTO she has strongly opposed the notion of granting patent rights. But in order to comply with the TRIPs Agreement, India must change existing patent laws. Indian enterprises are urging the Government to actively protect the results of their research, as under the current legislation anybody can get biodiversity products for free, while Indians themselves would pay royalties for these products in any other country.<sup>42</sup>

Intellectual property rights are not part of this paper, but their lack of protection in India shows that there is no coordinated legal framework to govern access and use of genetic resources. The Country considers that Biopiracy<sup>43</sup> is a threat to its biodiversity. It accuses industrialized nations and transnational corporations (TNCs) of claiming intellectual property rights (IPRs) by usurping the country's traditional knowledge systems and genetic resources from the public domain.<sup>44</sup>

This obvious lack of confidence towards industrialized nations makes it difficult for the country to establish a transparent legal system concerning access to genetic resources and benefit-sharing.

<sup>41</sup> See Barbara Laine Kagedan, *op.cit*

<sup>42</sup> Barbara Laine, *op.cit*.

<sup>43</sup> Comments of Dr. Vadana Shiva

<sup>44</sup> A cited example is that of Neem, a tree which has been valued by Indians for over 2000 years for its medicinal and pesticidal qualities. In the last decades, American and Japanese companies, such as the W.R. Grace corporation, have patented compounds based on extracts of the Neem plant. These patents are considered to appropriate what had been common property for millennia in India, transforming a former free resource into a highly priced one.

This is proven by the fact that all negotiations are kept secret, and no specific reference, summary or draft of the type of legislation to be adopted is made available.

To sum up, even though India signed the Biodiversity Convention in 1992, National Biodiversity legislation still has to be developed. Considering the fact that biodiversity is one of India's most important sources of wealth, the enactment of such legislation is urgent.

Biodiversity laws should be based on community ownership, with the state as trustee for non-local, commercial and trade flows of biodiversity and knowledge.

Indigenous knowledge systems need to be recognized, strengthened and defended through the National Biodiversity legislation. At the same time the framework laws should be enacted immediately at the national level, but their implementation and enforcement at the local level should be carried out by local institutions and with full participation of the people.<sup>45</sup>

According to India's 1998 „National Report on the Convention on Biodiversity“<sup>46</sup>, the Government of India is in the process of finalizing a Biodiversity Act, which should provide the legal basis for achieving the objectives of the Convention. A public debate on the subject has been generated. The Government of India is promoting a code of conduct for the users of biological resources to ensure sustainable extraction and equitable benefit-sharing in the spirit of the convention.

## **2.5. Africa**

### **2.5.1. Organization of African Unity: Declaration and Draft on Community Rights and Access to Biological Resources 21 April 1998**

The Scientific, Technical and Research Commission of the Organization of African Unity (OAU/STRC) is developing a „Declaration and Draft on Community Rights and Access to Biological Resources“, which has not been completed yet.

The main objectives are to ensure that local communities continue to control their natural resources, knowledge and technologies, to develop a „Draft African Convention on Genetic Resources“, and to promote appropriate mechanisms for a fair and equitable sharing of benefits.

This model legislation is expected to be the basis on which African nations will develop national legislation on community rights and access to biological resources, community knowledge and technologies.

African States should urgently regulate access to genetic resources, so that a mandatory prior informed consent of the local communities and the States can be established.

The state sovereignty over national genetic resources and the sharing of benefits that arise from such access are both emphasized.

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<sup>45</sup> Comments of Dr. Vadana Shiva

<sup>46</sup> India: National Report 1998, page 41



Concerning requests for access, the draft develops a system quite close to the one established by Decision 391 but with restrictions similar to the Philippines' Executive Order 247.

Access to genetic resources is subject to prior informed consent of the State concerned and of the local or indigenous communities. The Collector shall ask the Competent National Authority for access to genetic and biological resources in a written application that must contain general information (such as: collector's identification, purpose, proposed mechanisms for benefit-sharing, benefits to the country concerned, among others.)

If the application is complete, it will be placed in a public registry by the Competent National Authority. After a certain period of time, which still has to be determined by the draft, the Authority will decide whether or not to grant access, and whether this should be subject to additional conditions.

Once access has been granted, the Authority and the collector sign an access agreement. This will, as a minimum requirement, contain a guarantee to deposit specimens collected, a commitment to inform the Authority of all relevant discoveries, a commitment not to transfer the resources to a third party without previous authorization, payment of royalties to the State concerned, to local communities or to a designated beneficiary or other forms of benefit sharing, a guarantee that the concerned State will participate in all economic, social and environmental benefits arising from these resources, and finally a guarantee of biosafety and a submission of a status report.

It is also noteworthy that the Authority may unilaterally withdraw the access agreement „whenever it has become apparent that the collector has violated any of the mutually agreed terms, or the overriding public interest demands it“.<sup>47</sup>

The rights of local and indigenous communities to their traditional knowledge is stressed, and, consequently, so is the compensation to which they are entitled. Their knowledge may not be used without their prior informed consent. States shall assure that a certain percentage of the benefits obtained from direct or indirect commercial use of biological and genetic resources, which is to be determined, are distributed to these communities.

In relation to the competent institutions, the main body would be an inter-sectoral agency, composed of representatives of the public sector, scientific and professional organizations, NGOs, and local and indigenous communities. This agency should ensure the proper implementation and enforcement of the provisions of this legislation.

A source of funding will be the income derived and fees imposed on bioprospecting arrangements.

It is worthwhile noting that this model law has not been implemented, or even completed.

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<sup>47</sup> OUA Draft, article 4

### **2.5.2. Cameroon: Law 94/01 of 20 January 1994**

Cameroon enacted Law 94/01 of 20 January 1994 for integrated management, conservation and sustainable use of forest, fauna and fisheries, which emphasizes the national sovereignty of the State over biological resources, and requires a mandatory authorization independently from the objectives of this access in order to access the resources.

Concerning access to genetic resources, the country has adopted an inter-agency approach<sup>48</sup> and negotiations on a case-by-case basis. In order to access these resources, collectors must obtain a research permit from the Ministry of Scientific and Technical Research (MINRST). These permits allow the removal of small amounts of flora which is usually free of charge. The Ministry of Environment and Forestry (MINEF) is in charge of issuing the commercial exploitation permits for large scale extractions of genetic resources for commercial purposes. It also negotiates an export tax with the buyer, according to market prices.

Law 94/01 has been considered to be an ineffective means of conserving Cameroon's genetic resources and in ensuring a real sharing of the benefits derived from their access.

Policies concerning benefit-sharing are mainly based on Law 94/01. The policies stipulate that the local communities within which resources are being exploited should be informed, that they should participate in the process, be encouraged through employment and be remunerated through taxes paid to their councils or municipalities. Direct taxes, employment, infrastructure and benefits in kind are possible methods of benefit-sharing.<sup>49</sup>

## **2.6. Australia, North-America and Europe**

### **2.6.1. General Remarks**

With few exceptions, like Australia, which as a developed country is both a provider and a user of genetic resources, the Convention's signatories recognized that most of the world's species are found in poorer, tropical nations.

Nevertheless, an examination of some developed regions is helpful in attaining a general view on the current status of implementation of the Convention in both developing countries and in industrialized countries.

### **2.6.2. Australia**

Australia ratified the Convention on Biodiversity on 18 June 1993. The country is a federation of six self-governing States and two self-governing mainland Territories. Environmental powers are not the sole responsibility of any one level of government, but State and Territory Governments have primary responsibility for land management legislation.<sup>50</sup>

Governments take a cooperative national approach to environmental matters through the Intergovernmental Agreement on the Environment. The private sector, academic institutions, and

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<sup>48</sup> Barbara Laine, *op.cit.*

<sup>49</sup> See Cameroon: National Report to the CBD

<sup>50</sup> Australia: National Report to the CBD

NGOs also play an important role in environmental issues, including biodiversity conservation and sustainable use.

But rules to access genetic resources in Australia are dispersed through the different States. In Western Australia, access to genetic resources is granted by licensing agreements, in Victoria, extracting genetic resources is generally prohibited, unless it is „a good faith research with a previous permit from the Department of Conservation and Natural Resources“. In order to remove protected plants, their location must be disclosed, and a license, permit or order of the Governor in Council must be acquired; acquiring a license is mandatory in the Northern Territory.<sup>51</sup>

Australia stresses its interest in controlling access to genetic resources and in obtaining an appropriate return for any permitted access.

In accordance with the CBD, Australia has set up a „Commonwealth State Working Group on Access to Australia's Biological Resources“ to investigate and report on action required to develop a nationally consistent approach to access to Australia's biological resources.

In this sense, a „National Strategy for the Conservation of Biological Diversity“, which commits Australian Governments to establish a Commonwealth-State working group to investigate on matters relating to access to Australian genetic resources, including the strengthening of existing controls and legislation has been developed.<sup>52</sup>

This working group issued a draft discussion paper, „Managing Access to Australia's Biological Resources: Developing a Nationally Consistent Approach“, which considers the access to Australia's biological resources, and proposes a nationally consistent approach, including principles to grant access and the identification of benefits for the Australian community.

To ensure that the country gains social and economic benefits from the use of genetic material and products derived from Australia's biological diversity is also considered to be a main factor. It can be achieved through participation in research and development and by sharing of the benefits from any commercial opportunity, including the development of biotechnologies that are based on genetic resources collected from areas within Australia's jurisdiction.

Benefits from technologies developed from genetic resources are to be shared with the Parties providing the resources. Australian Governments are committed to ensure that opportunities to increase the level of technology transfer relevant to biological diversity conservation are included in relevant aid programs and projects.

### **2.6.3. North-America: United States of America and Canada**

President Clinton signed the CBD for the United States in 1993, but it has not yet been ratified. The Convention was supported by environmentalists, but property rights groups and farm and ranching organizations complained that the CBD restricts individual freedom, and successfully

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<sup>51</sup> Barbara Laine, op.cit.

<sup>52</sup> Australia: National Report to the CBD

blocked Senate action in 1994.<sup>53</sup> Without Senate ratification, the United States is relegated to „observer“ status at critical meetings.

The provisions for fair sharing of the benefits of genetic resources, the protection of intellectual property rights, and access to native genetic resources on mutually agreed terms have been controversial from the US point of view.

Still, the United States has several federal laws, that are relevant in this context, such as the Endangered Species Act, the Marine Mammal Protection Act, the National Environmental Policy Act, and the National Forest Management Act.

Canada was the first industrialized nation to sign the CBD on 11 June 1992. It was ratified on 4 December 1992, which means that Canada is legally bound to implementing the Convention.<sup>54</sup> The country has implemented the Canadian Biodiversity Strategy, which has been signed by all senior governments in the country. This Strategy was prepared by a federal-provincial-territorial Biodiversity Working Group.

Although the Strategy is quite general and avoids strong commitments in certain places, it does establish some measures and principles that Canada's jurisdictions may address when dealing with biodiversity issues. This means that individual jurisdictions have the discretion to adopt rules in this respect. However, the Canadian Biodiversity Strategy does not necessarily imply progress in implementing the CBD. Coordinated means which include all jurisdictions must be in place.

Jurisdictions need to cooperatively examine their current legislative regime with respect to the goals of this Strategy and take the necessary practical steps which lead to an improved legislative framework that supports the conservation of biodiversity and the sustainable use of biological resources.

#### **2.6.4. The European Union**

The CBD was signed by the European Commission in 1992, and ratified on 21 December 1993. At the same time, the fifteen Member States of the EC are contracting parties to the CBD, so they have developed or are in the process of developing their National Strategies.<sup>55</sup>

Cooperation among States is nevertheless important for the conservation and sustainable use of genetic resources. A coordinated approach in which all institutions, Member States, and the private sector actively participate is appropriate.

In the EC, the CBD is implemented through the work of several Directorate Generals, especially Directorate General XI (for the Environment, Nuclear Safety, and Civil Protection). Within DG-XI, a team exclusively works on the implementation of the CBD.

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<sup>53</sup> United States: Policy Briefing

<sup>54</sup> Canada Biodiversity Working Group Report

<sup>55</sup> European Commission: National Report

The European Union as a whole has focused on the protection of its environment and biological diversity. The main goal is to make a major effort to reduce the threats to Europe's biodiversity and landscapes.<sup>56</sup>

The Community Biodiversity Strategy, adopted by the EC on 4 February 1998, has established a framework to develop Community policies and instruments to comply with the CBD.

### **3. Economic Arguments for Lacking or Excessive Legislation in Developing Countries**

Regulating access to genetic resources and benefit-sharing is a difficult task, because such legislation involves different factors which vary according to demand of genetic resources in the specific country or region, the industrial or R&D partnership needs, and the level of development of the countries involved. It is also important to implement a cost-benefit analysis in any regulatory framework. This means that legislation needs to be transparent and flexible at the same time.

The paradox is that undeveloped, poor countries are often very biologically diverse and press for restrictive access measures in order to satisfy their benefit-sharing expectations, while most developed, rich countries are not very biologically diverse and do not want unnecessary legal, administrative and economic restrictions to access.<sup>57</sup>

As can be seen in the different approaches to the CBD, access to genetic resources and benefit-sharing is so difficult in some developing countries, e.g. the Philippines, that it is hardly economically justifiable, while other countries have been struggling to implement the CBD by creating a coherent legal system for a long time.

The different approaches to the CBD show that, on the one hand, access to genetic resources and benefit-sharing constitutes a burden not justified on economic grounds, due to the complex institutional arrangement in some developing countries, for instance, the Philippines, while, on the other hand, some countries have been struggling to achieve a coherent legal system in order to implement the CBD for a long time.

We can identify the following economic arguments for lacking or excessive regulation, which are common to developing countries to a higher or lower degree:

- High transaction costs
- Conflict of interests
- Free-rider problem

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<sup>56</sup> See Søren Jensen: Danish Environment, Internet Edition, June 1998.

<sup>57</sup> Dr. Manuel Ruiz Mueller, Sociedad Peruana de Derecho Ambiental, : "The Legal Framework on Access to Genetic Resources in the Americas" November 1998

### 3.1. High Transaction Costs

Transaction costs are the costs of any exchange. They include search, bargain and enforcement costs. We will concentrate on bargain and enforcement costs.

Negotiations are simple when detailed information on the costs and benefits of the bargain are available.<sup>58</sup> Developing countries obviously lack confidence in the willingness of developed countries to disclose all information. This translates in the fact that many legislative approaches establish a mandatory disclosure of information, and require that such information is available in public registers. This reflects a general fear that potential collectors may hold back information regarding their real intentions, the benefits they expect from the project, the sample collection, possible technologies advances, and drugs marketing.

There are also concerns that knowledge will be "stolen" from local and indigenous communities by means of patents. India, where there are controversial claims due to alleged biopiracy of traditional knowledge, is such an example.

Many countries question the intellectual property system claiming that it can only benefit richer countries, which will access genetic resources and protect their products with patents, selling them to poorer countries at high prices. In most developing countries, the most essential health products are often not accessible and affordable for the population. Since 1975, only 11 of the 1,219 newly developed drugs that entered the world market focused on tropical diseases.<sup>59</sup> India, where prices for many drugs are 10 to 100 times lower than in developed countries, holds a record, but patent protection is not granted in general, which creates conflicts in the international arena.

Another problem is the lack of experience of provider countries concerning the way in which benefit-sharing may work in practice. Countries try to find a balance between a fair and a non-bureaucratic distribution of benefits.

Providing the possibility of using those resources in an alternative way by establishing protected areas, or dedicating them to research activities, is an unknown cost factor. The cost may be high for developing countries in the short and medium term, even if in the long run the benefits gained from granting access to resources might be higher.

Hostility is also a known obstacle for any bargain. Here, the parties have emotional concerns that interfere with rational agreement. The generally opposing interests between North and South are the cause of such obstacles.

There is a general fear in this type of bargain that the costs to the country providing access to genetic resources may outweigh the social benefits. Even if benefits are uncertain, countries obviously expect them to be higher than the perceived costs. This leads to a non-cooperative

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<sup>58</sup> Cooter and Ulen, "Law & Economics", Cooter and Ulen, Addison Wesley 1996, p.84

<sup>59</sup> Jerome Dumoulin. Pharmaceuticals: The Role of Biotechnology and Patents. *Biotechnology Developing Monitor* 35, June 1998.

solution reflected in the failure to legislate or in restrictive measures which are intended to ensure benefit-sharing.

Enforcement costs arise when the implementation of an agreement takes time.<sup>60</sup> Countries that provide access to their genetic resources have to prevent the unlawful collection of these through efficient institutional arrangements, which requires technical expertise that not every country possesses or can afford. In complex transactions, like negotiating access to genetic resources, monitoring behavior and punishing violations of the agreement can be costly.

### **3.2. Conflict of Interests**

There are many stakeholders concerned with the legislation on access to genetic resources and benefit-sharing, especially, interest groups and bureaucrats.

Interest groups (universities, research institutions, environmentalists, industry sector) have such a powerful influence that they sometimes override more general preferences; bureaucrats have the ability to influence government policy. Additionally, benefit-sharing may create competition within different bureaucracies (competing for budget allocation).

A good example of this is the Inter-Agency Committee established by Executive Order 247 of the Philippines, where search costs for anyone interested in accessing genetic resources in the Philippines lead to a considerable increase in the overall transaction costs.

This potential conflict of interests is another reason for lacking and excessive legislation. This means that effective action for an institutional and legal framework calls for a great level of cooperation and coordination, which is not always simple to achieve.

### **3.3. Free-rider Problem**

Another concern of developing countries is that transfers and negotiations concerning genetic resources may benefit third parties without also benefiting the country where the resource originated.

The prohibition of all transfer of genetic resources to third parties without previous authorization of the country's Competent Authorities shows how cautious most countries are concerning this problem.

## **4. Conclusions**

We have shown in this paper that countries have taken legislative measures to regulate access to genetic resources. This emphasizes the principle of national sovereignty over genetic resources as established in the CBD. The legislative approaches to access genetic resources, or the drafts currently being discussed, have several elements in common. This is a positive development, as the systems may become more coherent in the future.

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<sup>60</sup> Cooter & Ulen, *op.cit.*, p.86

Once experience increases and the value of the transactions associated with access projects becomes easier to assess, the parties will be in a better position to negotiate. So far, the value of these transactions remains unclear. This makes legislation directed at assuring effective benefit-sharing bureaucratic.

From the legislative approaches discussed in this paper we can deduct a general scheme for accessing genetic resources: application for an access contract or research agreement; admission or refusal of the application; concluding of a research contract, and, generally, making public those legal acts, together with the project.

The level of difficulty in accessing genetic resources varies according to the way in which the institutional machinery has been put to play:

Some countries, like the Philippines and Costa Rica, expressly require prior informed consent of the local and indigenous communities. In Brazil's *Projeto de Lei* the provider is a party to the contract, while in the Andean Pact Countries provider's interests must be considered. Where intangible resources are concerned, an annex to the contract will stress benefit-sharing, both in Brazil and Andean Pact countries.

Regarding access to genetic resources for universities and other scientific centers, no foreign institutions of any kind may enter into an academic research agreement in the Philippines. In the Andean Pact Countries and in Costa Rica there is a possibility of signing framework contracts with such centers, while in Brazil institutions resident in Brazil which support the performance of access contracts need not name a local representative to accompany the collector.

In the Andean Pact countries the Competent Authority is defined in each country's legislation. In Brazil it would be an administrative body, as decided by a Genetic Resources Commission; Costa Rica's MINAE approves or rejects applications through the National Commission Technical Office, while on the Philippines a complex inter-action of different administrative bodies has been developed with the IACBGR as the main actor.

In the Andean Pact Countries *ex-situ* access to genetic resources is subject to the same conditions as *in-situ* access established in Decision 391, and to confirmation in the case of Brazil.

Every legislative approach states that benefit-sharing could be in-kind or pecuniary, and establishes fees, royalties or other sorts of payment for granting access and for the procedure itself.

It is important for countries to realize that any regulatory approach must be proportional as the costs should be justified by the benefits. This applies to both parties in any agreement. Flexibility is important in the case of bioprospecting, as this requires continuous movement. A basis for negotiation shall be established with a case-by-case approach. For countries that would like to access genetic resources, it is important that provider countries establish a rational and transparent institutional framework to avoid increasing their transaction costs.

As stated by Dr. Manuel Ruiz Muller, developing countries must define their actual needs, "as most of them require technology transfer, without defining what kind of specific technology the



national interest requires. Probably, not „state of the art technology“, but rather soft technologies which enhance national capacities to conserve and sustainably use biodiversity would be useful.”

Based on the information gathered, countries rich in biodiversity are clearly interested in developing projects to access genetic resources and in guaranteeing benefit-sharing. Legislation and the process itself may be difficult at the beginning and may create considerable bureaucratic burdens, but as experience on such access contracts is gained, confidence obtained from a „repeated-game“ should make the parties reach cooperative solutions.

## 5. List of Abbreviations

AO	Administrative Order
CBD	Convention on Biological Diversity
COABIO	Comisión Nacional Asesora de la Biodiversidad (Costa Rica)
CONABIO	Comisión Nacional para el Uso y Conocimiento de la Biodiversidad (Mexico)
EC	European Commission
EU	European Union
IACGBR	Inter-Agency Committee on Genetic and Biological Resources (The Philippines)
INBio	Instituto Nacional de Biodiversidad (Costa Rica)
LIPI	The Indonesian Institute of Science
MINAE	Ministry of Environment and Energy (Costa Rica)
NGOs	Non-Governmental Organization
OUA	Organization of African Unity
PAWB	Protected Areas and Wildlife Bureau (The Philippines)
PIC	Prior Informed Consent
R&D	Research and Development
SINADES	Sistema Nacional para el Desarrollo Sostenible (Costa Rica)
TRIPs	Trade Related Intellectual Property Rights Agreement

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## **POSSIBLE ELEMENTS OF GUIDANCE - ELEMENTS SUGGESTED**

Tobias Stoll

Issues of access to genetic resources and benefit-sharing have been intensively discussed internationally and a number of studies and papers have been produced. Yet there is no general idea or concept to be seen so far. It would certainly be premature for the time being to develop such a concept or suggestion. However, it seems to be due time to consider some elements discussed so far.

### **1. Sources**

The basis of such a survey of existing suggestions and ideas is heterogeneous. Discussions accompanying the CBD process have resulted in a number of rather general statements. The rather general terms of those statements are probably due to the complexity of those issues and the variety of different situations and factors to be taken into account. Also, there might have been some reluctance to interfere with matters which are to be handled primarily by resource States on the basis of their sovereign rights. Lastly, some practices may be considered confidential business information.

To start with, decision IV/8 para. 3 and annex of the Fourth Meeting of the Conference of the Parties has to be mentioned, which alongside with establishing the panel of experts enumerated some elements that the Expert Panel may address (reproduced in the annex to this paper). Although they are worded in a very general way, those elements are highly relevant, as they reflect an expectation of the Conference of the Parties which the Panel will certainly have to take into account.

Another rather general but useful source are the results of a workshop that the European Commission and the German Federal Ministry for Environment, Nature Protection and Nuclear Safety co-sponsored and which took place in Cordoba in January 1998. The results of the Workshop were submitted to the Fourth Meeting of the Conference of the Parties in May 1998 as an information document together with a letter of transmittal by the two co-sponsors. That letter as well as the results contain a number of relevant elements (full texts reproduced in the Annex to this paper).

There are a number of more specific suggestions, many of which were put forward by professional societies, industry or by indigenous groups. They might be useful to consider, bearing in mind that they have been set up by particular groups or individuals, and often refer to specific interests, commitments or situations. Often they contain specific rights and duties of participants and/or a precise ruling about the planning, authorization and

- initiatives on behalf of or by indigenous people, which in part resulted from consultations sponsored by the United Nations Development Programme (UNDP). They often focus on intellectual property rights but also refer to access to genetic resources and the sharing of benefits,

- initiatives by certain scientific or professional societies and organizations. They often clarify the basic commitments of members of those societies and particularly address cooperation with indigenous communities and rules for bioprospecting,
- policy statements of particular companies,
- practices and guidelines defined by institutions which fund, oversee or directly carry out scientific projects, especially regarding bioprospecting,
- the FAO „International Code of Conduct for Plant Germplasm Collecting and Transfer“, adopted in 1993, which even expressly refers to the CBD. Of course, it primarily relates to the FAO Undertaking on Plant Genetic Resources for Food and Agriculture, which is presently under review and adopts a specific and particular approach. Some of the provisions of the Code of Conduct relate to the Undertaking and thus are not helpful in regard to issues discussed here. However, other provisions refer to more general questions of bioprospecting which are worth while considering.

## **2. Discussion**

### **2.1. Assignment of Rights and Procedures for Obtaining Access and/or Prior Informed Consent**

Sovereignty over genetic resources is a public international law entitlement. It addresses rights and duties of States. States may define on the one hand what entities or subjects will enjoy internally, and on the other, what is considered sovereignty over genetic resources internationally. They could in theory assign rights over resources exclusively to the State and design a rather monolithic mechanism in this regard. However, constitutional rights often require, and a number of policy considerations suggest, that States take into consideration rights and interests of individuals and groups in this regard. Even more, States may internally refrain from claiming any right of their own. In this case, access would be governed entirely by private individuals, groups or entities on the basis of their rights. In most cases, however, States aim at a mixture, where rights of the State are claimed in parallel to private entitlements. Accordingly, most proposals for access mechanisms and indeed the existing legislation envisage an administrative-type access procedure of the State or another public authority accompanied by procedures and mechanisms to obtain the consent of other stakeholders.

In discussing access procedures, a clear distinction thus has to be drawn between those two different elements and the question as to their proper interplay might well become a very pertinent one. This is especially so as a decision upon access does not only entail a „yes“ or „no“ in regard to the taking and use of genetic resources but includes other aspects, especially benefit-sharing.

The Annex of Decision IV/8 addresses this issue as follows:

2. „Clear, established mechanisms to provide such [prior informed] consent [for access to genetic resources and research and development], including, inter alia, legislative, administrative and policy measures, as appropriate.

5. Efficient permitting and regulatory procedures that avoid burdensome procedures.“

The Cordoba workshop results refer to these aspects as follows:

### **Concerns**

Users need a clear contact point and to know of institutions authorized to grant access to genetic resources in provider countries

Users need legal certainty on access

Users need clarity on ownership/ tenure/ related rights

Access regulations need to distinguish between different genetic resources and different uses (scientific/ commercial)

### **Responses**

Establish a Focal Point and competent authority(ies) with clear responsibilities in determining access applications

Create a worldwide list of Focal Points and competent authority(ies) to be accessible through the CHM

Providers authorize relevant institutions to make full ABS arrangements (collection; scientific research and commercialization)

Providers to offer information on rights such as ownership, tenure etc.

Flexible structures

## **2.2. Certainty and Transparency Regarding Origin and Use of Material**

In order to foster certainty and confidence of providers of genetic resources regarding the taking and uses of genetic resources, a number of proposals are made. Some of them relate to intellectual property rights and are discussed elsewhere (see paper by Anja Meyer).

Decision 8/IV, Annex points to aspects of certainty and transparency as follows:

1. „Prior informed consent in provider countries for access to genetic resources and research and development.
2. Reference to the country of origin, where available, in relevant publications and patent applications.“

The Cordoba workshop has resulted in the following findings:

### **Concerns**

lack of information/control of genetic resources once outside providers' jurisdiction,

### **Responses**

ensure the disclosure of the place of origin by putting in place effective

lack of clarity of the market structure for genetic resources,

uncertainty as to the value of biological diversity and biological resources,

unapproved use of genetic resources in academia and ex situ collections,

lack of negotiating and contractual capacities,

lack of institutional capacity, ...

Lack of information about the new CBD ethic of obligations for users

Need for corporate access and benefit-sharing policies by users

Lack of confidence of providers

Insufficient capacity of provider countries to implement access and benefit-sharing laws and agreements

tracking measures,

establish modalities for ensuring evidence of prior informed consent at all stages,

encourage authorized partnerships between providers and users and among providers,

encourage the use of adequate material transfer agreements

users to support BD inventories

build technological and institutional capacity to add value at source,

Focal Point/ competent authority(ies) in user country for providers' queries

Governments and other institutions inform relevant users and providers in their country on the access and benefit-sharing provisions of the CBD

Elaboration of corporate access and benefit-sharing policies, through promotion by governments,

peer pressure, e.g. through professional associations

voluntary policies/measures

Capacity building

Integration into national biodiversity-strategies

Inclusion of information of user measures into reporting under the CBD

Also, a number of specific suggestions are made, including:

- obligations to abide by the CBD and national law, which should effectively apply to staff and others,

- to provide for mechanisms of control of users within their professional organizations,
- an obligation to acquire genetic resources only when accompanied by documentation clearly indicating that rights of providers have been complied with,
- to require potential users demanding access to explain what uses they intend to make of material acquired - especially in the context of users with a non-commercial background,
- safeguard that employees, sub-contractors, field-collectors but also sponsors, clients and customers of an entity seeking access abide by those obligations.

### **2.3. Arrangements for Access and Benefit-sharing Taking into Account Different Uses of Genetic Resources**

Another important issue relates to the possible structure and content of access and benefit - sharing arrangements. This question involves issues regarding the interpretation and implementation of benefit-sharing as called for by the Convention. It involves specific issues regarding indigenous and local communities and contributions to the conservation of biological diversity, which will be discussed elsewhere (see paper by Kerrin Schillhorn).

The main questions regarding those arrangements concern the elements of benefit-sharing as set out by the CBD which shall be included in particular arrangements. The legislation so far enacted, statements and suggestions unanimously leave room for flexibility and call for a differentiated approach in this regard. A major distinction is drawn between access sought by research institutions and public entities for academic research and other non-commercial objectives on the one hand and by companies or research entities for commercial uses on the other hand.

Decision IV/8 refers to this problem area as follows:

„Mutually agreed terms including benefit-sharing and intellectual property rights and technology transfer, where appropriate.“

The letter of transmittal of the Cordoba results in this regard reads:

„Moreover, the discussion during the workshop highlighted the following general points of importance for access to genetic resources:

- the principle of mutually agreed terms is a central aspect of co-operation between providers and users of genetic resources;
- Any guidelines and best practices should facilitate trustful and long-term co-operation of mutual benefit;
- Sharing of benefits can include inter alia scientific and technical co-operation, technology transfer and education know-how transfer, exchange of scientists, participation in research and in results and in the case of successful commercial use economic benefits, e.g. royalties;



- on the provider side, the indigenous and local communities as referred to in Art. 8 lit. j in the CBD should participate directly in the benefits along with the support of the conservation and sustainable use of biological diversity;
- the need for flexibility and the need to distinguish between different genetic resources and uses.“

## **2.4. Rights and Interests of Indigenous and Local Communities and Other Stakeholders**

A number of statements refer to interests, rights and needs of indigenous and local communities. They are dealt with in the paper by Kerrin Schillhorn.

## **2.5. Effects of Genetic Resource Use and Bioprospecting on Biodiversity and Ecosystems**

There are many links between access and benefit-sharing and the conservation of biological diversity:

- Effects on certain species and ecosystems have to be taken into account, when access entails a bioprospecting activity. A number of statements point to concerns in this regard.
- Benefit-sharing may include contributions and measures directly aimed at contributing to conservation efforts. These may include expert advice, capacity building, equipment, the acquisition and documentation of data and - rather specifically - the provision of additional samples with accompanying documentation.
- Also, legislation and practice sometimes envisage that a certain portion of financial benefits shall be devoted directly to conservation measures.

## **3. Observations**

Any more specific guidance will have to carefully consider the variety of different activities in question. Scientific field work, acquisition of material from brokers, independent collectors or ex-situ-collections all have their particularities which must be taken into account.

There is a need to clarify the scope of future work: some aspects are or could be dealt with by different actors or different processes within the CBD framework: It thus has to be determined whether aspects relating to the

- consent and participation of indigenous and local communities and
- possible positive and negative impacts of access activities upon biodiversity, its conservation and the state of ecosystems

shall be dealt with by the expert panel or within other CBD fora.

There is a need for stakeholders and actors to define and communicate their positions and to learn about the preferences and approaches of others. Guidance thus cannot be confined to a rule-oriented approach but also has to address the need for an exchange of information.

## **4. Annex**

### **4.1. COP Decision IV/8 Annex: Elements that the Expert Panel Might Address**

Decision IV/8 para. 3 and annex of the Fourth Meeting of the Conference of the Parties enumerated some elements that the Expert Panel may address:

„Annex

1. Prior informed consent in provider countries for access to genetic resources and research and development.
2. Clear, established mechanisms to provide such consent, including, inter alia, legislative, administrative and policy measures, as appropriate.
3. Reference to the country of origin, where available, in relevant publications and patent applications.
4. Mutually agreed terms including those on benefit-sharing and intellectual property rights and technology transfer, where appropriate.
5. Efficient permitting and regulatory procedures that avoid burdensome procedures involving high transaction costs.
6. Incentive measures to encourage the conclusion of contractual partnerships.“

### **4.2. The Cordoba Workshop and the Letter of Transmittal to COP IV**

In January 1998, the European Commission and the German Federal Ministry for Environment, Nature Protection and Nuclear Safety co-sponsored a workshop in Cordoba, which arrived at a number of conclusions. The results of the Workshop were submitted to the Fourth Meeting of the Conference of the Parties in May 1998 as an information document together with a letter of transmittal by the two co-sponsors. That letter as well as the results contain a number of relevant elements.

The letter of transmittal reads in part:

"Moreover, the discussion during the workshop highlighted the following general points of importance for access to genetic resources:

- the principle of mutually agreed terms is a central aspect of co-operation between providers and users of genetic resources;
- Any guidelines and best practices should facilitate trustful and long-term co-operation of mutual benefit;

- Sharing of benefits can include inter alia scientific and technical co-operation, technology transfer and education know-how transfer, exchange of scientists, participation in research and in results and in the case of successful commercial use economic benefits, e.g. royalties;
- on the provider side, the indigenous and local communities as referred to in Art. 8 lit. j in the CBD should participate directly in the benefits along with the support of the conservation and sustainable use of biological diversity;
- the need for flexibility and the need to distinguish between different genetic resources and uses."

The Workshop results read as follows:

"... Decision III/ 15 of the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) "...encourages Governments and regional economic integration organizations to explore and develop, in collaboration with relevant stakeholders, guidelines and practices to ensure mutual benefits to providers and users of access measures and to implement them effectively at the national, regional or international level, as appropriate". In response, the Directorate General (DG XI) of the European Commission and the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety co-sponsored a workshop on 15 — 16 January 1998 in Cordoba, Spain. A background paper on 'Best Practices for Access to Genetic Resources' served as an entry point to the discussions held in Cordoba. Participants attended in a personal capacity and were selected taking into account the need for regionally balanced participation. 34 experts from Parties to the Convention, the Secretariat of the Convention, non-governmental organizations and the private sector contributed to the discussions. The main findings are the following:

The participants agreed that a number of problems are currently hindering the implementation of the CBD provisions on access to genetic resources and benefit-sharing. A number of concerns and potential responses to these concerns of relevance for providers and users of genetic resources were identified:

### **Providers**

Participants identified a number of cross-cutting issues:

- confidence
- technical and technological capacities,
- IPRs

These cross cutting issues relate to both concerns about access and benefit-sharing and responses to these concerns:

### **Concerns**

### **Responses**

lack of information/control of genetic resources once outside providers jurisdiction,  
 lack of clarity of the market structure for genetic resources,  
 uncertainty as to the value of biological diversity and biological resources,  
 unapproved use of genetic resources in academia and ex situ collections,  
 lack of negotiating and contractual capacities,  
 lack of institutional capacity,  
 lack of confidence in existing IPR regimes.  
 Inadequacy of existing IPR regimes to support the implementation of the Convention's objectives.

ensure the disclosure of the place of origin by putting in place effective tracking measures,  
 establish modalities for ensuring evidence of prior informed consent at all stages,  
 encourage authorized partnerships between providers and users and among providers,  
 encourage the use of adequate material transfer agreements  
 users to support BD inventories  
 build technological and institutional capacity to add value at source,  
 review existing IPR regimes and, if necessary, add to or modify these to make them supportive of the objectives of the CBD.

## **Users**

### **Concerns**

- Users need a clear contact point and to know of institutions authorized to grant access to genetic resources in provider countries

Users need legal certainty on access

Users need clarity on ownership/ tenure/ related rights

Access regulations need to distinguish between different genetic resources and different uses (scientific/ commercial)

- Lack of information about the new CBD ethic of obligations for users

### **Responses**

- Establish a Focal Point and competent authority(ies) with clear responsibilities in determining access applications

Create a worldwide list of Focal Points and competent authority(ies) to be accessible through the CHM

Providers authorize relevant institutions to make full ABS arrangements (collection; scientific research and commercialization)

Providers to offer information on rights such as ownership, tenure etc.

- Flexible structures

Focal Point/ competent authority(ies) in

user country for providers' queries

Governments and other institutions inform relevant users and providers in their country on the access and benefit-sharing provisions of the CBD

- Need for corporate access and benefit-sharing policies by users

Lack of confidence of providers

- Elaboration of corporate access and benefit-sharing policies, through

promotion by governments,

peer pressure, e.g. through professional associations

voluntary policies/measures

Insufficient capacity of provider countries to implement access and benefit-sharing laws and agreements

- Capacity building

Integration into national biodiversity-strategies

Inclusion of information of user

measures into reporting under the CBD

### **Recommendations**

1. The participants at the workshop, representing both providers and users of genetic resources, recognized the need to lower the uncertainty surrounding access and benefit sharing, to build confidence between providers and users and to maintain flexibility.
2. The participants therefore recommend that the COP should initiate a process to support and guide governments and regional economic integration organizations in the implementation of Decision III/15, para 5. The workshop recommends that the concerns and responses identified in the paragraphs above should constitute a basis for initial work."

## **POSSIBLE ELEMENTS OF GUIDANCE - RIGHTS AND INTERESTS OF INDIGENOUS PEOPLES**

Kerrin Schillhorn MIL, Redeker, Schön, Dahs & Sellner (Bonn)

### **1. Definition of Indigenous Peoples**

There is no universal definition of „indigenous peoples“. There are, however, some criteria which are generally met. Indigenous peoples:

- are descendants of the original inhabitants of the land,
- live under foreign domination,
- have their own and particular culture which differs from the dominant culture of the state they live in,
- identify themselves as indigenous.

### **2. Cultural Particularities of Indigenous Peoples**

Indigenous cultures present a multitude of particularities. This applies to the culture itself as well as to the „state of development“ of each indigenous people. Some of them still maintain traditional ways of life whereas others have more or less adapted to western cultures.

Nevertheless, most of the indigenous peoples share cultural particularities in their relationship to their environment:

- Indigenous cultures in general follow a holistic approach with no room for dichotomy between the people and their land/environment, religion/spirituality or their ancestry.
- Indigenous cultures have their own societal structure in which decision making processes and the responsibilities of each member are clearly defined. These structures apply to the groups, not to individuals like in western cultures. Besides human beings, spirits, plants, animals or particular sites of the environment play an important role in these societal structures.
- Indigenous cultures are based on ancient traditional knowledge of the environment, the human beings and the spirituality which is handed down and developed further from generation to generation. Part of this knowledge is secret or restricted to particular members of the group.
- Indigenous cultures in general do not provide for a concept of individual personal property with respect to land and natural resources. Usually, the decision making structures for these issues include a communal process which precludes single persons from taking a decision by themselves. These communal decisions are in general carried out by the elders of each people.

When dealing with indigenous peoples it has to be borne in mind that indigenous cultures have been subject to oppression, assimilation and discrimination for generations. Their land and thus their culture have been taken away. Due to these historic facts, which most of the indigenous

peoples today share, the latest approaches for the recognition of these cultures and the protection of their identity and integrity always carry a high symbolic value.

### **3. International Rights of Indigenous Peoples**

The rights of indigenous peoples under international law are contained in general human rights instruments and in the ILO Convention No. 169 concerning Indigenous and Tribal Peoples in Independent Countries of 1989. This Convention, however, has only been ratified by a few states and is thus only legally binding with respect to these. Also, the Draft Declaration on the Rights of Indigenous Peoples has to be mentioned here. This soft law instrument has been developed by the UN but has not yet found general acceptance as it provides for a number of indigenous rights which the majority of states do not recognize today.

#### **3.1. Protection of Indigenous Culture/Cultural Heritage**

The basic principle of the ILO Convention No. 169 is the recognition of indigenous cultures and the protection of their integrity. The latter can be deduced from a number of provisions in the Convention, for instance the Preamble and Articles 1, 2, 4, 7, 10, and 13. These provisions are based on the notion of group rights acknowledging the particular needs and interests of indigenous peoples in this respect.

In general, however, international human rights instruments follow the individual rights approach. Hence, Art. 27 of the International Convention on Civil and Political Rights (ICCPR) is devoted to the protection of cultural identity of minorities<sup>61</sup> following the individual rights approach. While it has not been decided conclusively how to draw the line between the definition of indigenous peoples and the definition of minorities, today it is generally accepted that the protection by this provision of the ICCPR also extends to members of indigenous peoples and their cultures.

#### **3.2. Land Rights and Rights with Respect to Natural Resources**

The ILO Convention No. 169 is the most important legally binding international treaty in this respect. In its second part (Art. 13 to 19) this Convention provides for a comprehensive protection of indigenous rights with respect to land and natural resources. It has to be pointed out, however, that many states have also regulated indigenous land rights at the national level.

#### **3.3. Protection of Intellectual Property Rights**

The question of the protection of intellectual property rights is treated in detail in the paper by Anja Meyer on "Intellectual Property Rights and the Conservation and Sustainable Use of Biodiversity".

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<sup>61</sup> Art. 27 ICCPR: In those States in which ethnic, religious or linguistic minorities exist, *persons* belonging to such minorities shall not be denied the right, in community with the other members of their group, to enjoy their own culture, to profess and practise their own religion, or to use their own language. (emphasis added).

#### **4. The Relationship Between Indigenous Peoples and the National State**

When undertaking projects which affect or involve indigenous peoples, conflicts with the national state can arise in cases of non-recognition of the respective indigenous peoples.

Such problems might occur in particular with respect to the control over natural resources. If an indigenous people is not recognized by his/her state, that means that his/her rights with respect to the land and natural resources will not be recognized. In this context, reference has to be made to Art. 3 of the CBD and its Preamble which state that national resources are under the sovereignty of states. Thus, it seems doubtful whether an indigenous people can, without the consent of the state, decide on natural resources.

It has to be noted, however, that most negotiations with indigenous peoples will concern indigenous knowledge with respect to natural resources. This knowledge is not part to the national sovereignty, even if the state does not recognize the indigenous people. Such knowledge cannot be claimed to be national knowledge and thus it is only the indigenous people itself which can negotiate and possibly offer the traditional knowledge.

#### **5. Standards Set by Art. 8 lit. j of the CBD**

Art. 8 lit. j of the CBD refers expressly to indigenous and local communities and has become the basis for discussing their rights in this context. The wording and the content of Art. 8 lit. j CBD have, however, been viewed with reservation by indigenous peoples for they fear that this provision cannot ensure an overall protection of their rights and interests.

##### **5.1. Indigenous and Local Communities**

The choice of wording „indigenous and local communities“ in Art. 8 lit. j CBD instead of using the wording „indigenous peoples and local communities“ leaves room for different conclusions. Indigenous peoples view this wording as a backlash vis à vis the ILO Convention No. 169 and the Draft Declaration on the Rights of Indigenous Peoples which employ the term „indigenous peoples“. In this context it should be noted that the symbolic value of the use of different terms cannot be underestimated.

On the other hand the chosen wording could also provide for protection of those communities whose status as a „people“ is not recognized by the state they live in. Many states have been rather hesitant in qualifying indigenous groups as „peoples“ for such a qualification would imply the right to self-determination according to Art. 1 of the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights. These states fear for their territorial integrity and their sovereignty if the right of self-determination, including the option of independence, was to be granted to indigenous peoples.

This dispute has been circumvented by the wording of Art. 8 lit. j CBD. Thus, this provision can also be applicable to groups and communities who have not been recognized by the States they live in.



## **5.2. Traditional Life Styles**

The wording of Art. 8 lit. j CBD with respect to „traditional lifestyles“ suggests that this provision is only applicable to peoples and groups which still maintain a traditional way of life. This has led to the concern of indigenous peoples that they shall be restricted to their tradition and historic state of development without having the right to develop their cultures any further.

It has to be taken into account that indigenous cultures are by no means static but undergo a constant change just as every other culture does. Since this change is based on the traditional culture inherent to the group, a distinction between traditional way of life and modern western way of life is not always possible. Thus, the everyday exercise of traditional cultures can also include modern or western practices.

When applying Art. 8 lit. j CBD in a strict manner, this could lead to the exclusion of peoples who for example have traditionally not exercised any commercial transactions but do so today, whereas others would comply with the criterion "traditional lifestyle" only because they have always carried out such practices. Thus, these distinctions are not viable for most indigenous peoples who have been influenced by different cultures.

In this sense a criterion which does not emphasize the traditionality but rather the content of the culture should be used. As long as indigenous cultures show particular knowledge in relation to their environment based on their traditions they should be deemed to follow traditional lifestyles and thus fall within the scope of Art. 8 lit. j CBD.

## **5.3. Encourage the Equitable Sharing of the Benefits Arising from the Utilization of Such Knowledge, Innovations and Practices**

The wording of Art. 8 lit. j CBD in this respect does not contain a precise obligation of states to equitably share the benefits originating from indigenous peoples' knowledge. Such benefit sharing shall merely be „encouraged“ while a positive obligation to establish a system which ensures such a benefit sharing is lacking. Indigenous peoples have expressed their fears that such vague wording could not be sufficient to ensure appropriate action by the states they live in.

## **5.4. „As far as possible and appropriate“**

The mechanism of protection of Art. 8 lit. j CBD is subject to the reservation „as far as possible and appropriate“. With this phrase the parties to the Convention maintain the possibility of disregarding the presence of indigenous groups and peoples on their territory. The application of the CBD-provisions also depends on the economic or political situation of the different countries on a case-by-case basis. These reservations have to be seen in the light of the CBD as a whole and the obligation to cooperate amongst the parties to the Convention. However, this phrase could serve as a justification of non-compliance with the principles of Art. 8 lit. j CBD.

## 6. Contents of Existing Guidelines

There are already some international guidelines which include provisions with respect to the rights and interests of indigenous peoples in bioprospecting and utilizing genetic resources.

The guidelines considered are the following:

- 1 - Guidelines for and Standards of Practice of the International Society of Ethnobiology (ISE)
- 2 - Draft Code of Ethics and Standards of Practice of the International Society of Ethnobiology
- 3 - International Cooperative Biodiversity Groups (ICBG) Principles, Appendix 1;
- 4 - UN Food and Agriculture Organization (FAO) International Code of Conduct for Plant Germplasm Collecting and Transfer
- 5 - Suggested Ethical Guidelines for Accessing and Exploring Biodiversity (Gupta/Pew Conservation Scholars Initiative)
- 6 - The Global Coalition for Biocultural Diversity Covenant on Intellectual, Cultural and Scientific Resources: A Basic Code of Ethics and Conduct for Equitable Partnerships Between Responsible Corporations, Scientists or Institutions, and Indigenous Groups
- 7 - Guidelines for Equitable Partnerships in New Natural Products Development, Recommendations for a Code of Practice (Cunningham)
- 8 - Commission of the Cartagena Agreement
- 9 - Decision 391 of the Andean Pact Countries
- 10 - Green College Centre for Environmental Policy and Understanding - Findings and Recommendations (Posey)
- 11 - The Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples
- 12 - Principles and Guidelines for the Protection of the Heritage of Indigenous People (UN/Daes)

Some of these guidelines are very accurate and contain explicit rules with respect to the execution of projects which touch upon indigenous peoples and/or local community rights and interests.

### 1. Basic rules

- a) The past and present contribution of indigenous peoples and local communities to biological diversity shall be recognized.
- b) The underlying principle of all planning and executing of projects which affect indigenous peoples and local communities shall be the respect and the recognition of the other culture and a cooperation based on equality shall be aimed at.

- c) To this end an effort shall be made to understand the characteristics of the respective cultures and to have due regard of these cultural peculiarities when executing the project.
- d) The cooperation and the dialogue between the affected peoples or groups and the participants of the project shall be preserved during the whole project.
- e) Human rights, including the right to cultural identity, shall be respected during the execution of the project.

## 2. Preparation of projects

- a) Indigenous peoples and local communities affected by projects should be thoroughly informed about the project in advance, as well as of the possible ways in which the bioprospector may use these results.

It has to be ensured that this information is sufficiently understood by the peoples and groups concerned; linguistic and cultural difficulties in communication have to be taken into account.

Some of the guidelines also foresee information on the organizational structures. The indigenous peoples and local communities shall know in advance the identity of researchers and sponsors of the project.

- b) On the basis of this information the consent of the peoples and local communities concerned shall be sought before the commencement of the project.

It shall be ensured that the indigenous people or the local community can, according to its cultural particularities, decide freely whether or not to accept the project.

The assistance of each of the parties by a legal counsel during the negotiation of the contracts with respect to the project is suggested.

The consent shall be documented in writing or other appropriate form in the official language of the project and the language of the respective people or group.

It shall be ensured that when seeking the consent of the people or group concerned the decision making structures of the respective people or group are respected.

The contracts to be concluded shall not be exclusive, that means the contracting partners shall have the right to conclude contracts with other partners as well.

- c) The question of rights on intellectual property and financial revenues gained by using natural resources, practices and indigenous or local means of using these resources, including publications, shall be subject to a fair and adequate contractual regulation before the project starts or at the earliest possible point of time.

It shall be ensured that each of the intellectual contributions shall be acknowledged in publications concerning the knowledge on genetic resources and their means of utilization.

When traditional knowledge cannot be protected by existing intellectual property rights, it can be necessary to ensure alternative mechanisms of protection for

indigenous and local intellectual property, taking into account the cultural characteristics of the group.

### 3. Execution of projects

- a) Mechanisms should be developed in order to enable indigenous peoples and local communities to control the execution of the project, including a veto right of the people or group concerned with respect to the project or regarding the use of the knowledge or resources gained.

If by continuing the project or by using the knowledge or resources the culture of the respective group is violated, the right of the indigenous people or local community to stop the project at every phase must be ensured.

- b) The execution of the project shall - based on mutual respect - be undertaken in a close cooperation with the affected people or community.
- c) The duty to inform shall also be extended to collections of material during the execution of the project.
- d) Cultural secret knowledge and sacred sites should be respected during the execution of the project and when utilizing the gained results; the regulation of these sensible issues in a contract with the affected group or people before commencing the project is recommended.
- e) All persons participating in the project shall respect the cultural needs of indigenous peoples and/or local communities to keep specific knowledge and sacred sites secret.
- f) The training of members of the indigenous peoples or local groups concerned shall be a part of the project.

### 4. After concluding the project

- a) Indigenous peoples and local groups who have been participating in the project should have access to the results of the project, i.e. publications resulting from the project should be made accessible to the people or group, if possible in their own language.
- b) Indigenous peoples and local communities shall be adequately compensated for their contribution to the project. They shall also be compensated for possible losses and damages in a fair and adequate manner.

To this end, clear and transparent procedures shall be developed according to which the compensation and remuneration shall be executed.

Negotiations on remuneration and compensation shall, if possible, be held with members of the indigenous people or local community itself. If necessary, a negotiation leader should be appointed by the people or group concerned.

The remuneration shall, if possible, include a participation in the expected revenues whereby different criteria such as the value of the knowledge for the development of products or nuisances caused by the project shall be taken into account.

At the beginning of the project, a fraction of the remuneration shall be granted in the way of payments, training or goods.

When deciding on the methods of remuneration and/or compensation the implications for local and indigenous communities of these methods of payment have to be taken into account.

## 5. Supervision

- a) An institution which supervises the compliance of these guidelines by those responsible for the projects should be established.
- b) The ISE has created with its Ethics Committee an institution which controls the compliance with ISE guidelines and is authorized to follow up violations of the guidelines.

Also, according to the FAO Code of Conduct, a system of reports and supervision is provided for.

## 6. Other provisions

In addition, a number of guidelines contain the request to promote indigenous rights and interests. This shall be achieved by political means or in the context of a given project. As part of the projects, promotion of indigenous issues shall be provided for by training measures and/or equipment.

According to the guideline no. 12 (UN/Daes, para. 41) no contracts shall be concluded before indigenous peoples are enabled to supervise and participate in the research planned.

## 7. Evaluation of Existing Guidelines

The examined guidelines contain starting points to develop guidelines for the consideration of indigenous issues in the context of the implementation and application of the CBD. Some requests are justified by the CBD itself or other international norms. Others are justified by means of effectiveness. It is clear that the results which can be achieved in a given case will be better, when there is a respectful, honest and closer cooperation between the participants.

With respect to 1.:

The basic rules more or less reflect the human rights standards as well as the basic preconditions for an effective and successful cooperation with indigenous peoples. It has to be borne in mind, however, that the element of respect and equality has not always been ensured when dealing with indigenous peoples. But it is only under this condition that cooperation is possible, especially when the knowledge of indigenous peoples, i.e. their active participation in the project, is crucial to the success of the project.

In addition, these basic rules have to be considered as a way of interpreting and applying the respective guidelines.

With respect to 2.:

- a) The request to inform the indigenous peoples and local communities concerned before the execution of the project meets with the basic rules under 1., as well as with the content of

Art. 8 lit. j CBD. Only through comprehensive and accessible information about the project can a basis for a cooperation be built.

It remains doubtful to which extent the request for information about the organizational structure of the participants to the project and the sponsors is justified. In addition to the parties of a specific contract, background information on legal or other contexts with respect to the project shall be given, and will have to be decided by the persons responsible for the project taking into account the basic rules laid out under 1.

- b) It seems that the respect for freedom of decision about concluding a contract or consenting to particular projects as referred to under 2.b) does not raise many problems.

A problem could arise, however, when requesting the non-exclusiveness of the contract. For reasons of competition such a regulation may be detrimental to the project.

- c) The recognition of the rights of indigenous peoples with respect to intellectual property protection has not yet been subject to conclusive international regulation. It has to be borne in mind that existing means of protection are not necessarily applicable to indigenous knowledge. This is the reason why the contracts should contain particular means of protection regarding indigenous knowledge. It will have to be decided on a case-by-case basis whether contributions of indigenous peoples/local communities or their members will have to be explicitly referred to in publications.

With respect to 3.:

The regulation of duties on information and cooperation during the execution of the project corresponds to those regulations related to the preparation of projects.

Of particular importance in this context is the protection of indigenous secrets and sacred sights. These are of crucial relevance to indigenous peoples cultures and should be respected in order to preserve their cultural identity. In a given case there shall be an examination on the possibilities of using alternative areas or knowledge.

In this context the veto right proposed has to be seen. Such a provision, however, can endanger the project after beginning the research and thus create a risk which cannot be determined in advance. In this case, a solution which provides respect for the cultural identity of the affected indigenous cultures with its secrets and sacred sites, and at the same time does not place the project solely at the disposal of the indigenous people exercising a veto right, should be found. In such case a compromise has to be sought by using alternative knowledge or alternative areas without prematurely ending the project.

Finally, the training of indigenous peoples as part of the projects can be useful for intensifying the cooperation. There is, however, no legal basis for requesting that the persons responsible for the project provide training to indigenous peoples or local communities apart from the execution of the project and the provision of an adequate remuneration and compensation. In addition, it also remains questionable whether such a provision is in the interest of indigenous peoples and local communities. Thus, the participation in the training during the project should be voluntary.

With respect to 4.:

The guidelines under 4. constitute a more precise regulation of the duty under Art. 8 lit. j CBD, whereby the equal sharing of the benefits is envisaged. A regulation on remuneration and compensation should foresee a clear and transparent procedure which reflects the value of the contribution of indigenous peoples and local communities to the project. This regulation shall be freely negotiated between the persons responsible for the project and the people or group concerned. The determination of the means of remuneration or certain means of fulfilling these obligations could constitute a restriction of the right to self-determination. Meanwhile, it has to be ensured that the financial revenues to the indigenous peoples and local communities do not have detrimental effects. The final decision with respect to the mode of payment and the ways to invest the benefits should be left to the respective people or group.

An institution to supervise the guidelines to be developed has been considered as an effective measure, especially since the guidelines will not have a legally binding character.

## **8. A Synthesis View of the Proposals**

### **8.1. Basic Rules**

- a) The contribution which indigenous peoples and local communities offer to biological diversity is recognized.
- b) The respect for other cultures constitutes the basis of every planning and execution of projects which affect indigenous people and local communities. A cooperation on the basis of equality will be aimed for.
- c) To this end, efforts will be made to understand the characteristics of the culture in question. The cultural characteristics will be taken into account as much as possible during the execution of the project.
- d) Cooperation and dialogue between the concerned people or group and the participants of the project shall be upheld during its execution.
- f) The human rights, including the right to cultural identity, will be respected during the execution of the project.

### **8.2. Preparation**

- a) Information duties
  - (1) Concerned indigenous peoples and local communities shall be comprehensively informed about the project, the possible means of employing the results, including publications, and the possible effects on the respective indigenous people and local community in advance.
  - (2) It must be ensured that the information is adequately understood. Linguistic and cultural communication problems have to be considered.



- b) Prior informed consent
  - (1) On the basis of this information the free consent of the affected indigenous people or local community has to be sought prior to the project.
  - (2) It has to be ensured that indigenous peoples and local communities can make this decision according to their cultural particularities and that they have the option to refuse to the project.
- c) Negotiation and contracts
  - (1) The decision makers of the particular cultures shall participate in the negotiation and in the conclusion of the contract.
  - (2) Consent to the project shall be given in writing or in other documented form and shall also be recorded in the local language of the affected people or group.

The access of each party to legal counsel during the negotiations is recommended.
- d) Protection of intellectual property
  - (1) The question of intellectual property rights and the revenues gained therefrom with respect to natural resources, traditions and traditional means of utilization, including publications, shall be subject to a fair and adequate contract concluded before the commencement of the project or at the earliest possible point of time.
  - (2) It can be necessary to provide particular protection to traditional knowledge which is not subject to existing means of protection of intellectual property.

### **8.3. Execution of the Project**

- a) Cooperation
 

The execution of the project shall, based on mutual respect, be conducted in close cooperation with the respective people or group.
- b) Information
 

Comprehensive information shall also be provided during the execution of the project and shall extend to the compilation of materials.
- c) Protection of secrets and sacred sites
  - (1) Cultural secrets and sacred sites shall be respected during the execution of the project and when using the results gained; it is possible to subordinate these sensitive areas to a contract taking into account the cultural needs of the group affected.
  - (2) If during the execution of the project an unforeseeable conflict arises in relation to cultural secrets or sacred sites, the participants shall cooperate in developing an alternative means to conclude the project without violating the cultural particularities of an indigenous people.
  - (3) All participants to the project shall respect the secrets and sacred sites of indigenous peoples and local communities.

#### **8.4. After Concluding the Project**

a) Access to the research results

Indigenous peoples and local communities which have participated in the project shall have access to the final gains of the project. Publications which result from the project shall be made accessible to the indigenous peoples and local communities, if possible in their own language.

b) Participation in the revenues of the research

- (1) Indigenous peoples and local communities shall be adequately compensated for their contribution to the project. Damages suffered shall be compensated in a fair and adequate manner.
- (2) In order to achieve a fair remuneration and compensation a clear and transparent procedure has to be developed in accordance with the cultural characteristics of indigenous people.
- (3) The negotiations on remuneration and compensation are to be undertaken together with the decision makers of the indigenous people or local communities. If this is not feasible, a representative has to be appointed by the people or group affected.

#### **8.5. Supervision**

An institution which supervises the application of these guidelines shall be established.

### **9. Conclusion**

Currently there are no specific international rules which refer to the recognition and cooperation of indigenous and local communities in CBD-projects. At the same time, the provisions of the CBD itself are not very clear in this respect. The approach taken by the CBD to include indigenous peoples and local communities should however be respected when undertaking bioprospecting. On this basis, the recognition of rights and interests of indigenous peoples and local communities is not only justified on legal grounds but also by its effectiveness. When undertaking research projects affecting indigenous peoples and/or local communities the use of a code of conduct or guidelines to ensure the project's effectiveness and mutual respect is recommended. Due to the reasons discussed above, such guidelines or code of conduct should include the aspects proposed.

## INTELLECTUAL PROPERTY RIGHTS AND THE CONSERVATION AND SUSTAINABLE USE OF BIODIVERSITY

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The commercial potential of genetic resources has been increasing rapidly along with novel developments in modern biotechnology. Concomitantly, the claim has been brought forward to adequately recognize and compensate the contribution of resource states to this scientific progress as they are hosts of the world's largest part of biological diversity.

### 1. The Relevant Provisions of the CBD Concerning the Sustainable Use of Genetic Resources and Intellectual Property Rights

The CBD explicitly confirms each state's sovereign rights over its natural resources. Art. 15 para. 1 CBD provides that each government has the authority to regulate and control access to the state's genetic resources. Genetic Resources are defined in Art. 2 para. 10 CBD as genetic material of actual or potential value.

Other parties of the Convention shall be allowed to access genetic resources (Art. 15 para. 2 CBD). In this context provisions concerning intellectual property rights (IPRs), namely

- Art. 16 para. 5 CBD and
- Art. 8 lit. j CBD,

are of interest.

Art. 16 CBD deals with the access to and the transfer of technology. Art. 16 para. 5 CBD refers to the relationship between intellectual property rights and the CBD by stating that „patents and intellectual property rights may have an influence on the implementation of this Convention, [and therefore Member States] shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives“. This much debated provision is not limited to questions of technology transfer and it is mostly seen as a regulation concerning possible conflicts or the relationship in general between IPRs and the provisions of the CBD.

Art. 8 lit. j CBD firstly demands that indigenous and local communities should be supported with regard to their traditional knowledge. Secondly, it demands a wider application of this knowledge with the necessary consent of the community concerned and with the involvement of the group. Thirdly, the provision includes the responsibility to equitably share the benefits arising from the utilization of the knowledge. Art. 8 lit. j CBD includes a double provision, namely the restriction „as far as possible and appropriate“ and „subject to its national legislation“ which implies that any national legislation will take precedence. Furthermore words like „promote“ and „encourage“, which do not represent precise obligations, are used. Nevertheless, a vivid international debate regarding the rights of indigenous and local communities to their own traditional knowledge of environmentally sound and sustainable uses of natural resources has

started. IPRs on biotechnological inventions might conflict with these rights of indigenous and local communities: The protected invention might rely on traditional knowledge as the initiator of the newly developed biotechnological process or product.

## **2. The Interrelationship Between Rights to Genetic Resources and Intellectual Property Rights**

### **2.1. Rights Concerned and Subject Matter**

Rights to genetic resources are rights to certain materials. According to the definitions laid down in Art. 2 of the CBD genetic resources are "genetic material of actual or potential value" (Art. 2 para. 10 CBD), which means "any material of plant, animal, microbial or other origin containing functional units of heredity" (Art. 2 para. 9 CBD). Although the value of the genetic resources is attributed to the genetic information inherent in the material, the right is still connected to the material itself and not to the information.

Patents and other relevant intellectual property rights protect technical inventions. An invention generally can be defined as a solution to a specific problem in the field of technology. The extent of patentability in the field of biotechnology is controversial and difficult to determine. Patentable inventions include:

- certain isolated substances or processes to produce these substances,
- genes or groups of genes (provided that the protein which is being coded is named),
- processes and findings of genetic engineering,
- microorganisms.

In all these cases biological material is used. This biological material, however, has to be distinguished from the protected invention. Regardless whether the patent protects a certain process or a product, the extent of protection does not in any case include the original genetic material (e.g. the originally collected plant).

While genetic resources rights cover the source material for biotechnological research and development, IPRs apply to the particular outcome: useful processes or products.

The revenues generated by marketing the process or product under patent protection will reward the patent holder. The provider of genetic resources, for his part, will participate in such revenues through royalties or other payments, if agreed so between parties by means of an access and benefit sharing agreement. Such an agreement can be enforced in the courts. If an agreement was not concluded between the parties or turns out to be defective, the provider will have difficulties in enforcing his rights. Private law remedies and criminal sanctions might apply in theory, but are extremely difficult to litigate.

It is also worthwhile to note the situation concerning plant breeder's rights.

Plant breeder's rights protect plant varieties which are distinct, genetically uniform, stable, and novel; the plant breeder has the right to exclude others from breeding and selling the protected variety. Plant variety protection does not require an inventive step but is suitable for any breed or merely discovered variety instead. This opens up the possibility of protecting a plant variety that has been found in a certain country of origin through plant breeder's rights. In parallel, this plant variety may also be subject to the sovereign right to genetic resources of the country concerned. This may lead to conflicts between rights to genetic resources and plant breeder's rights - in a much more evident way than in the case of genetic resource rights and patents. The priority of plant breeder's rights would lead to a de facto erosion of the right to the underlying genetic resource. However, it is beyond the scope of this paper to explore all the implications of this situation.

## **2.2. IPRs and Extended Sovereign Rights to Genetic Resources.**

As explained before, due to the different subject matter of genetic resources and patents, these concepts are not in conflict from a legal point of view.

However, if the right to genetic resources goes beyond the mere protection of the genetic material, a different situation might be given, for instance if the genetic information inherent to the biological material is protected irrespectively of the material as such.

Decision 391 of the Andean Pact can be cited as an example of directly conflicting rights. According to the "Complementary Measures" to Decision 391 of the Andean Pact, which provides a framework for genetic resource access activities, the rights to genetic resources do not only include the right to the actual genetic material but also include rights over derived or synthesized products and intangible associated components of this genetic material. This broad interpretation seems to go beyond the definition in Art. 2 CBD, as only the material itself is enclosed. The products concerned might also be subject to patents, which entails possible conflicts between the right to the genetic resource and the IPR. According to the „Complementary measures“ to Decision 391 this conflict does not occur, as patents will not be granted if the source genetic material has been obtained or used through an access activity which does not comply with Decision 391.

## **2.3. Safeguarding Rights to Genetic Resources in the Patent System**

The fairly limited enforceability of rights over genetic resources has not only resulted in claims for broadening the coverage of those rights concerning derived or even synthesized products as just mentioned. To the more, suggestions have been made to further develop the IPR system in a way which will make it more responsive to those concerns.

Different proposals have been made to include a requirement to disclose at least the origin of genetic material, or even the respective access contract in the patent application procedure. These concepts ask for modifications of the respective patent law proscribing to reveal all necessary

information on the origin of the genetic material used. This would assure the possibility to trace back the origin of the material.

According to provisions in the Brazilian law (Projecto do Lei do Senado 306/95) regulating genetic resource access activities, IPRs are not valid if they were obtained without having fulfilled the requirements of the law. In Costa Rica (Law 7788, 23 April 1998) the granting of an IPR can be objected to if the right implies questions related to biodiversity.

### **3. Current Developments**

Aside from the provisions in national access legislation, as just seen, further developments took place at regional and international level.

#### **3.1. The EC Directive on the Legal Protection of Biotechnological Inventions**

The EC Directive on the Legal Protection of Biotechnological Inventions (98/44) was adopted in July 1998, which takes into consideration the growing importance of the biotechnology industry. The Directive creates harmonized legal protection for biotechnological inventions in EU Member States. It explicitly states that "no prohibition or exclusion exists in national or European patent law (...) which precludes a priori the patentability of biological matter" (Recital 15). However, the directive directly deals neither with the issue of access to biological materials nor with the issue of ownership of those materials, although these questions had been critically debated during deliberations of the directive. The European parliament wanted any applicant for a patent in the EU based upon plant or animal materials to

- specify the origin of those plant and animal materials, and
- prove that those materials have been used in accordance with appropriate access terms.

This request has become established in Recital 27 of the Directive, which states:

„if an invention is based on biological material of plant or animal or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known.“

It is explicitly mentioned in the recital that the validity of patents conferred remains unaffected in any case.

As the Netherlands brought a nullity suit against the directive in November 1998, the further development remains to be seen.

#### **3.2. The WTO Committee on Trade and Environment**

Within the WTO, the Committee on Trade and Environment (CTE) has discussed issues concerning the relationship between the TRIPs Agreement and the CBD within the Report of 1996 to the Ministerial Conference. As conclusion, only a general agreement that further information on the interaction between the two instruments was desirable could be reached.

In 1996, India proposed to amend Art. 29 TRIPs Agreement. According to the proposal, a notification requirement regarding the origins of biological material to the patent procedure should additionally be included. Secondly, India suggested the need for special material transfer agreements which were to be executed by patent applicants involved in the use of biological material or traditional knowledge.

In 1998, another proposal was made by India and Colombia to amend the TRIPs Agreement so as to require that patent applications indicate the origins of genetic samples and include reference whether living organisms have been extracted in accordance with the norms of the country of origin.

These propositions were controversial and have so far had no consequences. No certainty was reached whether the TRIPs Agreement adequately dealt with the issues raised by Art. 16 para. 5 CBD and Art. 8 lit. j CBD.

### **3.3. The Review of Art. 27 para. 3 lit. b TRIPs Agreement**

According to Art. 27 para. 3 lit. b of the TRIPs Agreement „plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes“ may be excluded from patentability. This provision its subject to review in 1999.

With regard to plant varieties, Art. 27 para. 3 lit. b TRIPs proscribes either their patentability or an effective system *sui generis* for their protection. The system provided by the International Union for the Protection of New Varieties of Plants (UPOV) has been widely considered to give adequate and effective protection for plant varieties. An inclusion of the UPOV in the TRIPs Agreement would aim at recognizing plant varieties rights as intellectual property rights which would make them subject to the general principles underlying the TRIPs Agreement. Developing countries are expected to resist this proposal because the UPOV - while strongly protecting the owners of plant varieties - does not fulfil the needs of traditional breeders.

It remains to be seen whether the New Round for the TRIPs Agreement scheduled for the year 2000 will include the debate on the relationship between the TRIPs and other aspects such as competition, environment and its impact on health and welfare.

## **4. Traditional Knowledge of Indigenous and Local Communities**

### **4.1. Protection of Traditional Knowledge**

Art. 8 lit. j CBD, drafted in a rather cautious way, calls for the promotion of the wider application of knowledge with the approval and involvement of the communities concerned, and the encouragement of the equitable sharing of the benefits arising from the utilization of the traditional knowledge, innovations and practices.

Such approval, involvement and benefit sharing can be achieved on the basis of agreements. Know-how licensing terms or service contracts may be and in a number of cases already have

been applied in this regard. Beyond those cases of agreed co-operation on a contractual basis, indigenous groups can hardly exercise any legal control over the knowledge once it has been disclosed. In turn, those who profit from indigenous knowledge in their research and development activities will often succeed in achieving patent protection for the resulting processes or products.

In general, indigenous or local communities cannot reach patent protection or other relevant IPRs. In order to obtain patent protection, the knowledge in question has to constitute an invention. Therefore, it has to include an inventive step, and has to be industrially applicable and novel. Even if the other criteria are met, in most cases the knowledge is not novel but has been known to the specific community for generations. This often means that the knowledge already belongs to the public domain and therefore can be used freely by anyone. Protection of this knowledge is precluded and economically not desirable. Hindering the free use of a certain standard of knowledge presents costs to an economy that do not correspond to the profit of the holder of the right to the knowledge.

Indigenous and local communities will also face de facto difficulties when asserting protection of their knowledge. Very often the internal structures and appreciation of their knowledge by the communities themselves are not compatible with the ideas underlying the patent system, and the disclosure of the knowledge might contravene indigenous customs. Besides, a communal ownership of IPRs is not possible under existing IPR legislation, and the process of acquiring a patent is expensive and will normally require professional legal support.

Protecting traditional knowledge through patents therefore does not seem to be very promising. Indigenous and local communities can keep their knowledge as trade secrets though, if the knowledge is not already in the public domain. Trade secrets protect confidential information or know-how, which provide a competitive advantage to the holder because they are secret. The know-how does not have to be novel and the protection is not subject to a duration limit. Trade secrets can be protected through competition law, tort law, and also as a constitutional property right. Indigenous and local communities can claim compensation for damage or, when their trade secret has been breached, a right to forbearance.

Although there are certain possibilities for indigenous and local communities to protect and defend their knowledge which has a certain value for the biotechnological industry as a trade secret, this value can best be awarded through contractual relations. This is a possibility which is being considered and used, but it lacks an actual obligation or at least precise guidelines that would have to be met.

#### **4.2. The WIPO Initiative „Intellectual Property Rights for New Beneficiaries“**

The WIPO has launched a new initiative called „Intellectual Property Rights for New Beneficiaries“ in 1998 to promote the identification of the needs of holders of traditional knowledge and cultures for intellectual property protection, and to gain greater practical understanding of the relationship between IPRs and multilateral instruments covering other global issues. In July 1998 a „Roundtable on Intellectual Property and Indigenous Peoples“ was



held at Geneva with the aim of facilitating an exchange of views among policymakers and indigenous people concerning both a more effective application and possible improvements of the intellectual property system to protect traditional knowledge. In the beginning of August 1999 another roundtable meeting will be held.

Besides this, the initiative includes a series of fact-finding missions to North America, South and Central America, the South Pacific, West and Southern Africa, and South Asia in order to study current approaches to, and future possibilities for, the protection of traditional knowledge, as well as the feasibility of establishing traditional knowledge databases. Within this biennium the practicability of a regional system for collective management of rights in the Caribbean Basin will be examined for possible application in other regions.

## **5. Intellectual Property Rights and Further Implementation of the CBD**

In sum, it may be stated that the relationship between IPRs and rights to genetic resources and indigenous knowledge is complex. This relationship generally does not give rise to legal problems in the strict sense: With some exceptions, the rights at hand are not in conflict, as they deal with different subject matters. Many concerns address the lack of effective enforceability of rights to inputs into biotechnological research and development - genetic resources and indigenous knowledge - as compared to its results - patents.

Different means have been proposed to address this situation or to make the patent system more responsive in this regard. Of course the relative strength of rights regarding this concept, coverage and enforceability have economic implications. They are again complex. Rights certainly do define market opportunities and the competitive standing. They also predetermine the magnitude of revenues - or: benefits - and their sharing.

## **INTELLECTUAL PROPERTY PROVISIONS IN NATIONAL ACCESS LEGISLATION**

Carolina Carbuccia

### **1. Overview**

In the following pages the provisions of Intellectual Property Rights (IPRs) in the legislation (or drafts) of several countries which have made efforts to implement the CBD into their national legislation, shall be developed. We shall focus on enacted legislation in Costa Rica, Andean Pact Member States and the Philippines, and on draft legislations in Brazil and the OAU.

In every access legislation the issue of IPRs is seen from a double perspective: On the one hand, the rights that may be granted to the potential collectors; on the other, the rights of indigenous and local communities over their traditional knowledge.

Costa Rica's Law 7788 recognizes the need to protect innovations through the use of the adequate legal mechanisms with a few exceptions. Any IPR decision must be congruent with the goals of this Law. Before any administration confers IPRs, there must be a consultation with the Technical Office of the National Commission for the Administration of Biodiversity.

The rights of local and indigenous communities to their knowledge are recognized without these having to be registered. IPRs to this knowledge are not granted.

In the Andean Pact Countries, IPRs cannot be granted when an access activity has not complied with Decision 391 of 1996. Petitioners of IPRs must indicate to the competent Administration the register number of their access contract and provide a copy of the latter. At the same time, Member countries recognize the right of local and indigenous communities to decide over their knowledge.

The Philippines' Executive Order 247/95 leaves an open door for future legislation on IPRs.

According to the Projecto do Lei 306/95, Brazil will only grant IPRs if its provisions have been observed. Local and indigenous communities have exclusive rights to transfer their knowledge.

Finally the Organization of African Unity's „Draft Model Law on Community Rights“ states that the national inter-sectorial body shall recommend new laws on IPRs, and establishes some legislative guidelines for the protection of community intellectual property rights.

### **2. Intellectual Property Rights Provisions in National Access Legislation**

#### **2.1. Costa Rica: Law 7788 of 23 April 1998**

Law 7788 recognizes the need to protect innovations by using adequate legal mechanisms. This protection will be granted through patents, commercial secrets, intellectual community sui generis property rights, author rights, and farmers rights.

There are the following exceptions<sup>62</sup>:

1. sequences of deoxyribonucleic acid per se,
2. plants and animals,
3. non-genetically modified microorganisms,
4. essentially biological procedures to produce animals and plants,
5. natural processes or cycles per se,
6. inventions essentially derived from associated knowledge to biological, traditional or cultural practices in the public domain, and
7. monopolistic exploited inventions, when they affect processes or agropecuary products considered essential for the nourishment and health of the population.

Any intellectual property decision related to biodiversity must be congruent with the objectives of Law 7788. The National Office of Seeds and the Intellectual and Industrial Property Rights Registers must consult the Commission's Technical Office<sup>63</sup>, before granting any right which involves biodiversity. Whenever the Technical Office reasonably objects the right will not be registered.

Persons or corporations who enjoy intellectual or industrial property rights must grant a legal license to the State which it may use to the benefit of the community in declared national emergency without having to pay any remuneration.

The State explicitly recognizes intellectual community sui generis property rights provided by local and indigenous communities. This right is only legally recognized because of the existence of cultural practice or associated knowledge to genetic and biochemical resources. No prior declaration or official register is required to bring the right into existence. This recognition implies that no right to this traditional knowledge will be granted to third parties.

## **2.2. Andean Pact Countries: Decision 391 of 17 July 1996**

Decision 391 does not develop the issue of IPRs over genetic resources in depth.

It establishes that Member States will not recognize any rights, including intellectual property rights, over genetic resources, derived or synthesized products and intangible associated components, when these have been obtained or developed through an access activity which does not comply with Decision 391.

Member States affected may petition nullity and present the necessary legal actions in those countries which had conferred rights or protection titles.<sup>64</sup>

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<sup>62</sup> See Art. 77, Law 7788

<sup>63</sup> The National Commission for the Administration of Biodiversity, an administrative body under the Ministry of Environment and Energy, has a Technical Office which is in charge of handling, approving or rejecting the submissions for access to genetic resources.

<sup>64</sup> See Second Complementary Disposition, Dec. 391

National Offices competent to grant IPRs will ask the petitioner to indicate the register number and to file a copy of the access contract as a prior requirement for granting the pertinent right once they are sure that the processes or products to be protected have been obtained or developed from genetic resources or derivative products originating in any Member State.<sup>65</sup>

With regard to traditional knowledge, Member States recognize the rights of Afro-American, local and indigenous communities to decide over their knowledge, innovations and traditional associated knowledge to genetic resources and derivative products.<sup>66</sup>

### **2.3. The Philippines: Executive Order 247/1995**

Executive Order 247 is almost silent concerning IPRs. It establishes that the Inter-Agency Committee shall study and recommend to the President and Congress appropriate laws on the utilization of biological and genetic resources including new laws on intellectual property rights.<sup>67</sup>

This provision leaves possible future regulations of all possible rights derived from biological and genetic resources including IPRs open.

### **2.4. Brazil: Projecto Do Lei Do Senado 306/95**

Projecto do Lei 306/95 establishes that rights over genetic resources and derivative products will not be recognized whenever the provisions of this law have not been observed. In this it is similar to Decision 391 of the Andean Pact. Intellectual or similar property titles obtained under such conditions are not valid.<sup>68</sup>

The petitioners for intellectual or similar rights based on traditional knowledge must certify the previous approval by such communities and comply with the laws of the country of origin of the genetic resource or traditional knowledge.

Concerning the protection of traditional knowledge, local and indigenous communities have exclusive rights over the transfer of their knowledge through the different contracts provided for in Projecto do Lei 306/95. Intellectual property rights related to traditional knowledge over genetic resources or associated products will not be granted when these provisions are not observed.<sup>69</sup>

### **2.5. Organization of African Unity: Declaration and Draft Model Law on Community Rights and Access to Biological Resources**

The Draft does not state explicitly which IPRs will be granted to the potential collectors. It only states that „the national inter-sectorial coordination body shall...study and recommend policies and laws on the utilization of biological and genetic resources including new laws on intellectual property rights and community rights over their knowledge, innovations and practices

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<sup>65</sup> Third Complementary Disposition, Dec. 391

<sup>66</sup> See Art. 7, Dec. 391

<sup>67</sup> See Section 7.f, EO 247/95

<sup>68</sup> Art. 41, Projecto 306/95

<sup>69</sup> See Art. 44-47 Projecto 306/95

(community intellectual rights) (achievements) relevant to the conservation and sustainable use of biological and genetic resources<sup>70</sup>.

It does, however, refer explicitly to the rights of local and indigenous communities over their traditional knowledge. Art. 5 stresses that States shall recognize and protect the right of the local communities to collectively benefit from their knowledge, innovations and practices acquired by past, present and future generations and to receive compensation for the conservation of biological and genetic resources in accordance with the provisions of this legislation and subsequent regulations.

It also determines that the State shall take regulatory measures to establish a system of collective/community intellectual rights through a process of consultation and participation of the local communities which include the following considerations:

- a) Identification of the types of collective intellectual rights (achievements) that are recognized in each case.
- b) Identification and definition of the requirement and procedure necessary for the recognition of the collective intellectual right (achievement) and the title to it.
- c) Definition of a system of collective registration and specific rights and obligations that arise from the entitlement.
- d) Criteria and mechanisms for the standardization of the procedure.

### **3. Bibliography**

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3. Ley de Biodiversidad 7788 de la República de Costa Rica. April 23, 1998.
4. Organization of African Unity. Declaration and Draft Model Law on Community Rights and Access to Biological Resources, March 1998.
5. Proyecto de Ley del Senado 306/1995. Senadora Marina Silva and Proyecto Substitutivo by Senador Osmar Dias.
6. Ruiz Muller, Manuel: "The Legal Framework on Access to Genetic Resources in the Americas". Sociedad Peruana de Derecho Ambiental. November 1998.
7. The Philippines: Executive Order 247 and Administrative Order 96-20.

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<sup>70</sup> See Art. 6 of OUA Draft

## **EX-SITU COLLECTIONS ACQUIRED PRIOR TO THE ENTRY INTO FORCE OF THE CBD**

By Jessica Suplie, Dipl. pol., project staff, currently with the German Advisory Council on Global Change, scientific team

### **1. Agenda Setting**

The Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity (COP-IV) decided to start work relating to ex-situ collections in the context of the Convention's provisions for access and benefit-sharing. Decision IV/08 „requests the Executive Secretary to invite information from Parties and relevant organizations in time for the intersessional meeting in respect of those ex-situ collections which were acquired prior to the entry into force of the Convention on Biological Diversity and which are not addressed by the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization, to help the intersessional meeting to make recommendations to the fifth meeting of the Conference of the Parties for future work on resolving the issue of such ex-situ collections, with due regard to the provisions of the Convention;...”

Thus, the issue of ex-situ collections acquired prior to the entry into force of the Convention has become part of the Convention's official agenda and will be dealt with during the fifth meeting of the Conference of the Parties which will take place in Nairobi in May 2000.

### **2. Scope and References**

The CBD refers to ex-situ conservation rather than to ex-situ collections. Such conservation is defined by Art. 2 of the Convention as follows: „the conservation of components of biological diversity outside their natural habitats“. It is also dealt with in Art. 9. Certainly, ex-situ collections can be defined by the fact that they conserve or store „components of biological diversity outside their natural habitats“. This holds true for botanical gardens and zoos, which have an explicit mission to conserve such components. However, collections for cultural, ethical, educational and scientific reasons- as well as those that serve the needs of commercial research and developments are also covered. „Components of biodiversity“ also covers various kinds of biological material, tissue-samples and extracts in so-called ‘libraries’.

### **3. The Convention's Approach**

However, as the context of decision IV/8 para. 3 amply shows, the issue of ex-situ collections acquired prior to the entry into force of the CBD focuses on questions of access and benefit-sharing rather than on conservation strategies. The Convention's Art. 9 on ex-situ conservation does not cover this issue. Therefore, the general provisions of Art. 15 et seq. apply. This is true for any activity which entails a transfer of material from the collection, including the original collection in the field, exchanges between botanical gardens or other collections and the transfer of material to third parties for commercial and non-commercial purposes. Here, legal issues play

a critical role, because the discussion so far has focused on bilateral transactions whereas collections, due to their mandate, often have to engage in multiple or subsequent transfers. Solutions for this burdensome legal problem will soon have to be developed.

#### **4. The Issue of Collections Acquired Prior to the Entry into Force of the CBD in Particular**

Even more difficult is the issue of collections acquired prior to the entry into force of the Convention. The initiative to put the issue on the agenda obviously arises from the fact that existing collections may cover a considerable part of the demand for genetic resources, primarily by relying on material acquired before the entry into force of the Convention. Those sources may considerably frustrate efforts of Resource States to offer their material in turn for a sharing of benefits.

Legally, however, the provisions of Art. 15 et seq. of the CBD - as well as the CBD as a whole - do not have a retroactive effect. This is made clear by Art. 28 of the Vienna Convention on the Law of Treaties of 1969, which entered into force in 1980 and is applicable to the CBD. It reads:

„Non-retroactivity of treaties

Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party.“

Thus, the issue falls outside the existing and applicable provisions of the Convention.

#### **5. The FAO-Context and Resolution 3 of the Nairobi Declaration**

The conservation and sustainable use of genetic resources is of particular concern in the area of food and agriculture. The FAO had adopted a legally non-binding „Undertaking for Plant Genetic Resources for Food and Agriculture“ some time before the CBD was negotiated and adopted. This Undertaking, which deals extensively with the rights to genetic resources and also relates to existing ex-situ-collections, takes a somewhat different approach in many regards, which is due, above all, to the particular needs and conditions prevailing in this area and inter alia to the specific international interdependence regarding genetic material. Due to these differences in approach ('common heritage' versus 'national sovereignty') and scope (plant genetic resources for food and agriculture versus other uses), it is important to draw a clear line between CBD and FAO negotiations.

The Nairobi Conference for the Adoption of the Agreed Text of the CBD in May 1992 recognized the role of the FAO and the FAO Global System in dealing with those issues and in addressing them. The FAO inter alia called for the adaptation of the „International Undertaking on Plant Genetic Resources“ in harmony with the CBD and for consideration of access on mutually agreed terms to plant genetic resources, including the issue of collections not addressed

by the Convention. This „issue of collections not addressed by the Convention“ is somewhat similar to the „issue of collections acquired before the entry into force of the convention“ as discussed here. However, it has to be kept in mind that Resolution 3 of the Nairobi Final Act addresses the FAO and has no implication for issues falling outside this scope. On the other hand resolution 3 will certainly be referred to as a precedence for the issue of material stored in collections prior to the entry into force of the Convention.

## **6. Approaches for Dealing with Material Acquired Prior to the Entry into Force of the Convention**

If particular collections or institutions consider treating material acquired before the entry into force of the Convention and material acquired after that date in a similar way, they will face a number of problems. If the origin of material can be determined, an access/benefit-sharing arrangement could be concluded with the original provider. Where the origin remains unclear, there is still the possibility of setting aside a portion of benefits obtained and spending them for conservation projects.

The treatment of pre-CBD-material has so far mainly been discussed among botanical gardens. As far as can be seen, there is a tendency to handle such material in the same way as material acquired under the CBD, where possible. In view of their activities in contributing to conservation Botanical Gardens often do not make any distinction based on the date of acquisition of material.

Concerning individual transactions and access and benefit-sharing, one particular Botanical Garden, the Royal Botanic Gardens of Kew (London), has adopted a „Policy on Access to Genetic Resources and Benefit-sharing“ which contains an Annex 1 on „Policy ... on Benefit-sharing in Connection with Commercial Contracts for Pre-CBD Genetic Resources“. This Annex cautious in the general policy set out in the main document to pre-CBD-material includes the „negotiation and co-ordination of appropriate benefit-sharing mechanisms with Source Countries“. Also, according to the document, commercial development projects will include up-front, medium term and long term benefit-sharing, portions of which will flow to a „benefit-sharing fund“, or to the source country or countries.

## **7. Further Questions**

The following questions could serve as a starting point for further discussion on the issue of ex-situ collections in the CBD-context:

- How can a line be drawn between material collected prior to the entry-into force of the CBD and "new" collections?
- How can expectations in benefit-sharing be met:
  - a) where the source country(ies) or the respective authorized institution is identified,
  - b) where there is no sufficient proof of origin of the concerned material?



- Do users of genetic material prefer to apply negotiated standards for ex-situ collections individually or would a common policy be more appropriate and feasible?

## **PROJECT REPORT: "CONTRIBUTION OF THE GERMAN BOTANIC GARDENS TO THE CONSERVATION OF BIODIVERSITY AND GENETIC RESOURCES"**

On behalf of the Association of Botanic Gardens in Germany (Verband Botanischer Gärten e.V.) and in co-operation with Botanic Gardens Conservation International (BGCI) the project "Contribution of the German Botanic Gardens to the Conservation of Biodiversity and Genetic Resources" is carried out by the Botanic Garden of the University of Bonn. It is financed by the German Federal Ministry for Environment, Nature Conservation and Nuclear Safety (BMU) through the Federal Agency for Nature Conservation (BfN).

The aim of the two-year project is to document the achievements and vast experiences of the German Botanic Gardens in Biodiversity conservation, to identify their potentials and weaknesses and to develop a concept of strategies for achieving a greater contribution to conservation activities on a national and international level. The results show clearly that Botanic Gardens in Germany play an important role in research and conservation of Biodiversity and furthermore that a great potential to strengthen those activities exists. The conclusions of the project will be published in the next months.

94 Botanic Gardens exist in Germany. These are visited by about 14 Million people every year. They probably cultivate more than 50.000 plant species originating from almost all vegetation zones of the world. Beyond the traditional tasks of teaching and research, they take more and more responsibility for nature conservation today.

Already in 1996, the Association of Botanic Gardens in Germany published a declaration on biological diversity in the context of the CBD. One main activity within the project was to initiate a broad discussion on the current and potential contribution of Botanic Gardens to the conservation of biodiversity between the German Botanic Gardens. An important step was a two-day workshop concerning that issue. About 50 representatives from 40 gardens came together to exchange their ideas and experiences concerning the CBD. As a consequence of the workshop two working groups were founded.

One group developed a concept for the "National protected collections" in Germany (see <http://www.botanik.uni-bonn.de/botgart/schutzsamml.htm>). The aim of that concept is to ensure the conservation of valuable ex-situ plant collections. The implementation of the concept, which is supported by the project, will now be initiated.

In response to the Convention on Biological Diversity the second group drafted a voluntary "code of conduct" that outlines how Botanic Gardens should react in regard to the new conditions (see <http://www.botanik.uni-bonn.de/botgart/vregel.htm>). Also, based on that code of conduct, a "Material Supply Agreement" was designed. The aim of these papers is to encourage the German Botanical Gardens to take concerted action on the issue of access to genetic resources and benefit sharing as claimed in the CBD. The project members will act as facilitators of this process.

As participants in an international Botanic Gardens project „Access to Genetic Resources and Benefit Sharing“, initiated and concluded by The Royal Botanic Gardens Kew, the project members contribute to the international discussion on that subject area. Furthermore, discussion on Botanic Gardens and the CBD will be stimulated in Botanic Gardens of Eastern Europe and West and Central Asia.

All project activities intend to enable the Botanic Gardens, above all those in Germany, to exhaust their potentials in being part of the national and international conservation network.