Acervo ISA

INSTITUTO SOCIOAMBIENTAL
data ___/___/___
cod. L5D 000 43

The Next Rosy Periwinkle Won't Be Free:

Emerging Legal Frameworks to Implement Article 15 of the Convention on Biological Diversity

A Paper Distributed at the Third Meeting of the Subsidiary Body on Scientific, Technical and Technological Advice of the Convention on Biological Diversity

Montreal, 1-5 September 1997

Lyle Glowka
IUCN Environmental Law Centre

IUCN
The World Conservation Union

Table of Contents

Acervo ISA

Executive Summary

Worldwide since the entry into force of the Convention on Biological Diversity there has been a significant amount of planning and legislative activity at the regional, national and sub-national levels focusing on access to genetic resources. An informal survey indicates activities in the Andean Pact States of Bolivia, Colombia, Ecuador, Peru and Venezuela (both regionally and nationally), Argentina, Australia (at the Commonwealth level and in the states of Western Australia and Queensland), Brazil (including the state of Acre), Cameroon, Costa Rica, Eritrea, Ethiopia, Fiji, The Gambia, Ghana, India, Indonesia, Kenya, Laos PDR, Lesotho, Malawi, Malaysia (including the state of Sarawak), Mexico, Mozambique, Nigeria, Philippines, Seychelles, South Africa, South Korea, Tanzania, Turkey, United States of America and Zimbabwe. A global survey is needed to better ascertain the true extent of legislative action.

A comparative analysis of existing and draft access legislation indicates that access provisions are being incorporated into five groups of legislation. The first group comprises general environmental framework laws. The second group includes framework sustainable development, nature conservation or biodiversity laws. A third group consists of dedicated or stand-alone national laws or decrees on access to genetic resources. A fourth group is characterized by the modification of existing national or sub-national laws and/or regulations to better reflect genetic resource access and benefit-sharing issues. The fifth group includes actions taken at the regional level.

The approaches taken to date with existing or draft access legislation concentrate only on excluding potential users from physically accessing genetic resources located within the jurisdiction of a country without a permit or license. Supplemental measures provide the basis to negotiate mutually agreed terms, limit exports, establish sanctions and penalties, provide for *in-situ* conservation, including environmental impact assessment, and address financial issues.

The outstanding issue now is how these legislative frameworks will work in practice. There is little experience and a lot of anxiety. Will future benefits generated outweigh the heavy transaction costs for both provider States and those seeking access? Is existing legislation too confusing or burdensome? Will it actually dissuade industry and researchers from seeking access in some countries? There are no answers to these questions yet, but simplicity of regulatory process must be the guiding principle for access legislation, while still ensuring a country's benefit-sharing interests.

Early access legislation is far from perfect. In many cases it represents a defensive response to a political and industrial climate which places all of the burden of ensuring benefits on the providing State. As States develop their approaches to implementing article 15, access legislation will need to evolve and be refined over time to keep pace with new developments, needs and demands.

The challenge is to sustain the momentum generated by the States providing genetic resources as they strive to enact and implement access legislation. A firm foundation for more equitable *burden*-sharing between provider and user States could be established within the CBD to ensure PIC and MATs and, ultimately, benefit-sharing for genetic resources accessed. The COP could undertake a study on possible legislative, administrative or policy measures which user States could consider implementing to support steps taken by provider States to regulate access to genetic resources and ensure benefit-sharing. The study could catalyse a process within the COP to examine the issue further. In so doing, good-will be generated to find a proper balance between the rights and obligations of Parties to facilitate access to genetic resources (article 15(2)) and ensure benefit-sharing (article 15(7)).

The Next Rosy Periwinkle Won't Be Free: Emerging Legislative Frameworks to Implement Article 15 of the Convention on Biological Diversity

by
Lyle Glowka*

1.0 Introduction

A major aim of many developing countries in the intergovernmental negotiations which led to the Convention on Biological Diversity (CBD) was to redefine historical benefit flows from the use of genetic resources. Article 15 of the Convention on Biological Diversity defines the rights and obligations of Contracting Parties regarding access to genetic resources and the fair and equitable sharing of benefits derived from their use. It attempts to define in international law the new relationship between the Parties of the CBD which provide and use genetic resources: access to genetic resources in exchange for a share of benefits derived from their use.

The CBD provides the general contours of the new relationship. But the details of article 15's practical implementation will be primarily defined at the national and sub-national levels by creating or adapting legislation, administrative procedures and institutions. Not surprisingly, developing countries have been some of the first to develop such legislation.

Worldwide there has been a significant amount of planning and legislative activity at the regional, national and sub-national levels dealing with access to genetic resources since the Convention on Biological Diversity entered into force. An informal survey indicates activities in the Andean Pact States of Bolivia, Colombia, Ecuador, Peru and Venezuela (both regionally and nationally), Argentina, Australia (at the Commonwealth level and in the states of Western Australia and Queensland), Brazil (including the state of Acre), Cameroon, Costa Rica, Eritrea, Ethiopia, Fiji, The Gambia, Ghana, India, Indonesia, Kenya, Laos PDR, Lesotho, Malawi, Malaysia (including the state of Sarawak), Mexico, Mozambique, Nigeria, Philippines, Seychelles, South Africa, South Korea, Tanzania, Turkey, United States of America and Zimbabwe.

A global survey is surely needed to better ascertain the true extent of legislative action. At its third meeting, the Conference of Parties (COP) called on Parties to provide the Secretariat with information on national, regional and sectoral legislative, administrative and policy measures and guidelines for activities covered by article 15.[1]

A comparative analysis of existing and draft access legislation indicates that access provisions are being incorporated into five groups of legislation. The first group comprises general environmental framework laws. Examples include The Gambia (National Environmental Management Act (1995)), Kenya (Draft Environmental Management and Coordination Bill (1995)), Malawi (Environmental Management Bill (1996)), South Korea (National Environmental Preservation Act (1991) as amended (1994)) and the Uganda (National Environmental Statute (1995)).

These tend only to be enabling in nature. As enabling laws, they all merely charge a competent national authority to examine the issue in order to provide more specific guidelines or regulations sometime in the future. The draft and final African laws are based on a standard model developed by the United Nations Environment Programme. They charge a national authority to develop measures on regulating the export of germplasm, benefit-sharing and access fees. However, with the exception of Malawi, they do not clearly establish the principles that access to genetic resources shall be on mutually agreed terms (MATs) and subject to prior informed consent (PIC).

The second group includes framework sustainable development, nature conservation or biodiversity laws. These include laws in Costa Rica (Wildlife Conservation Law (1992)), Eritrea (Second Draft Eritrean Proclamation on the Conservation of Biological Diversity (1996)), Fiji (Draft Sustainable Development Bill (1997)), Mexico (Environmental Act (1996)) and Peru (Draft Law for the Conservation and Sustainable Use of Biodiversity (1997)). A 1993 FAO Technical Report (TCP/SEY/2253) provided recommendations and drafting instructions for possible conservation and national parks legislation and regulations in Seychelles with a component on bioprospecting.

Generally, the access provisions in this group tend to be more detailed than the framework enabling environmental legislation described earlier. In all cases they clearly establish the MAT and PIC principles. The biodiversity laws are particularly interesting because they are intended to comprehensively implement the Convention on Biological Diversity.

A third group consists of dedicated or stand-alone national laws or decrees on access to genetic resources. This group is characterized by the most comprehensive pieces of ac-

* Legal Officer (Biological Diversity), IUCN Environmental Law Centre, Bonn, Germany. The views expressed here do not necessarily reflect those of IUCN or its members. Many thanks to Patricia F. Moore at the IUCN-ELC for her help with the spanish language texts. This paper was financially supported in part by the generosity of the Government of Germany, Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung (BMZ).

cess legislation surveyed. The only finalized example identified is the Philippines Executive Order 247 (1995) and Department of Environment and Natural Resources Administrative Order 96-20 (Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources) (1996).

A fourth group is characterized by the modification of existing laws and/or regulations to better reflect genetic resource access and benefit-sharing issues. Only two examples have been identified at the national level both regarding national parks. In Nigeria, there is a proposal to modify the National Parks Act of 1991 (Draft National Parks Decree (1996)) to establish prior informed consent prior to bioprospecting in Nigerian national parks. In the US there is a proposal to revise Code of Federal Regulations Title 36(2.5) which deals with research specimens removed from national parks.

At the sub-national level two examples have been identified. In Western Australia legislation has been enacted to explicitly clarify the state government's authority under the Wildlife Conservation Act (1950) and the Conservation and Land Management Act (1984) to enter into exclusive agreements for the removal of forest produce (including soil) or flora to promote the use of flora for therapeutic, scientific or horticultural purposes (Part 3, Conservation and Land Management Amendment Act (1993)). In Malaysia, the state of Sarawak amended its Forest Ordinance to require written approval from the Director of Forests prior to the removal or export of any tree part to be taken from listed areas for producing or developing any pharmaceutical product or medicinal compound (section 65A).

The fifth group includes actions taken at the regional level. The only existing example is the Andean Pact's Decision 391 creating a common regime on access to genetic resources. The Pact Decision, which upon its publication in July 1996 became law in all five member states, provides a minimum set of rules for each member state to implement. More detailed national legislation can be implemented provided it does not fall below the standard set by the Decision.

The approaches taken to date with existing or draft access legislation concentrate only on excluding potential users from physically accessing genetic resources located within the jurisdiction of a country without a permit or license. This is sometimes supplemented with measures to control genetic resource exports.

Creating informational rights (such as intellectual property rights) in wild or "unimproved" domesticated/cultivated genetic resources has not yet been manifested in national law and it is unlikely unless technical problems related to describing genetic resources and accurately identifying rights holders are overcome. At least for the time being, future access legislation will likely to continue to focus on methods of exclusion and embargo.

The final content of access legislation will depend on many State-specific considerations. National planning processes and a State's international legal obligations will influence its content.

While every State is different, comprehensive future access legislation will undoubtedly share many similarities. For example, it will likely:

- specify definitions;
- identify scope of application;
- establish or designate appropriate institutions to determine and enforce access; and
- outline an access determination procedure.

Legislation may also include provisions on export controls, sanctions and penalties, identification and monitoring, conservation and financial issues.

Drawing on the emerging legal frameworks, some of the legislative and institutional approaches States have been taking since the CBD's entry into force will be highlighted.[2]

2.0 Definitions

The access legislation examined typically includes a definitions or use of terms section to define and clarify terms used. In some cases terms and definitions have been taken from CBD article 2.

Andean Pact Decision 391 defines "access" broadly. It includes obtaining and using genetic resources conserved *ex-situ* or *in-situ*, derived products (such as biochemicals) or, where applicable, "intangible components" for research, bioprospecting, conservation, industrial application or commercial use (article 1). Intangible components are all individual or collective knowledge, innovations and practices associated with a particular genetic resource or its derived products, whether or not protected by intellectual property regimes (article 1).

As an alternative to defining access some States have chosen to use the terms "prospecting", "bioprospecting" or "biodiversity prospecting" in their legislation. Focusing on a particular activity such as bioprospecting which results in access to genetic resources may help legislative drafters overcome the conceptual difficulties involved with determining what access to genetic resources is and when it occurs. It may also help to broaden the legislation's scope to include biochemicals, keeping in mind that the Convention only applies to genetic material.[3]

Philippines Executive Order 247 and its accompanying implementation regulations define prospecting and bioprospecting as "research, collection and utilization of biological and genetic resources for purposes of applying the

knowledge derived there from to scientific and/or commercial purposes" (appendix A, Executive Order; section 2.1(h)), Implementation Regulations).

In the draft Fiji Sustainable Development Bill "biodiversity prospecting" is defined as "any activity undertaken to harvest or exploit biological resources for commercial purposes...[including] investigative research and sampling".

All three example demonstrate that the legislation applies to more than just genetic material. Included are biochemicals as well. In addition, if the Fijian legislation was read literally, collecting biological resources for almost *any* type of commercial use might be subject to the access and benefit-sharing legislation. It is unclear whether that was the intent of the drafters because this ambiguity may create uncertainty.

For example, if the blossoms of a plant were harvested as a bulk or "biomass commodity" for direct use in an herbal tea or a cosmetic, and not for their genetic or biochemical informational value in a technological application, would harvesting and export trigger the prior informed consent and mutually agreed terms provisions under the legislation? The blossom's suppliers more than likely have or will negotiate a supply agreement with the user. This will presumably reflect a mutually agreed price to supply a certain quantity of the blossom at a particular price per kilo. They may have to obtain State permits to export the material and the quantity harvested and exported might be subjected to a tax or other levy. Benefits therefore will accrue without creating a new regulatory regime.

However, if for example, cells from the blossoms or seeds from the plants were used as the basis for a cell culture or farm cultivation to mass produce an active ingredient, then they are being used as a genetic resource. Since the process depends on the cell's genetic material and the metabolic processes orchestrated by it to produce the active ingredient, the use would be subject to the CBD's access and benefit-sharing provisions.

The intent of CBD article 15 is to fill in a gap for benefit-sharing when genetic material is used. While States can extend the CBD's spirit to technological applications based on the informational value of useful biochemicals discovered in plants, animals and microorganisms, extending article 15's application to biologically-based commodities which already have a market value, are actively traded and are used in end-products with little human intervention or modification may complicate the operation of access legislation. Simply put, the number of transactions, and therefore access determinations, would be overwhelming. Therefore, the primary dilemma faced by the legislative drafter is how wide to cast the legislation's scope of application.

3.0 Scope of Application

The effectiveness of national legislation will depend on many variables. But properly defining the legislation's scope of application will contribute greatly to its future success. Therefore it is worthwhile to examine how States have been addressing the issue.

Although the actual drafted legislative text may only be one or two lines, defining the scope of application involves determining the legislation's application to particular:

- materials and associated knowledge;
- activities;
- actors; and
- geographical locales.

Exclusions from the legislation should also be considered.

Furthermore, the scope of legislation will be closely related to the nature of a State's sovereign rights, limitations placed on their exercise by international law, the State's property rights system governing ownership of plant, animal and microbial genetic resources, tenure over land and sea areas as well as a number of legal issues related to indigenous and local communities.

Ideally, the legal status of genetic resources would distinguish between rights over the *physical entity* (an organism, its parts, including genetic material, or an environmental sample containing whole organisms or parts) and the *information embodied by or in the physical entity*.[4] It is the informational component which is most valuable to bioprospectors.[5] But until such time as the intangible component of genetic resources can be clearly described with sufficient specificity to allow the creation of an informational rights system, property rights approaches focusing on the physical entity will probably be the primary means of controlling access to genetic resources and ensuring benefit-sharing. This is so even though subsequent access agreements *can* specify how the informational content of the genetic resources collected can be subsequently used and how resulting benefits are to be shared.

In their access legislation, some countries have tried to clarify the legal status of genetic resources. For example, Philippines Executive Order 247 recognizes that section 2, article XII of the State constitution "provides that wildlife, including flora and fauna, among others, is owned by the State and the disposition, development and utilization thereof are under its full control and supervision" (preambular paragraph 1).

From ownership over wildlife, it is must then be inferred that the State also owns wildlife's constituents such as genetic material. This is supported by the statement that ownership of all biological and genetic resources is to remain with the State when materials are removed from the

country (section 8.1(16), Implementation Regulations). The State also owns wild fauna and flora found on private or communal land. Apparently domesticated plants and animals are not owned by the State, although this could have been clearly set out in the legislation to eliminate any possibility of confusion. The legal status of biochemicals is also unclear.

In addition, whether the phrase "among others" enables the interpretation that wild microorganisms are also owned by the State is also not clear. The Executive Order defines biological resources to include "organisms or parts thereof" and "microorganisms" (Appendix A, Executive Order).

The Andean Pact Common Regime specifies that genetic resources and their derived products for which the member state is the "country of origin" are "the goods or patrimony of the Nation or State of each Member Country" (article 6). In other words they can be considered "goods of the State", "patrimony of the Nation", "goods of the Nation" or "patrimony of the State" (article 6). The cumbersome drafting reflects an effort to accommodate the phraseology of the five members' legislation.[6] In all cases, the person seeking access must at minimum enter into an access contract with the competent authority of the member state for access to genetic resources.

The Common Regime is interesting because it goes on to distinguish between the legal status of biological resources and genetic resources. Biological resources which contain the genetic materials sought can be subject to private or collective property rights.

But genetic resources are deemed "inalienable and imprescriptible and cannot be seized, without prejudice to property regimes applicable to the biological resources which contain them, the land on which they are found, or the associated intangible component" (article 6). While existing private or communal property regimes over biological resources containing the genetic material or derivatives sought are not altered by Decision 391, property owners or holders are not entitled to determine access to genetic resources. However, property owners or holders can control access to genetic resources indirectly by controlling a bioprospector's physical access to the areas or materials containing genetic resources. This ability to assert control enables these actors to negotiate a share of benefits via "accessory contracts" (see section 5.2).

3.1 Materials and Associated Knowledge

3.1.1 Types of Genetic Resources

Access legislation's scope of application can be defined according to the types of organisms to be regulated. For example, distinctions could be made between wild species or domesticated or cultivated species.

The Philippines Executive Order (preambular paragraph 1) and the Costa Rican wildlife legislation (article 3) only apply to wild flora and fauna. In contrast, the Andean Pact Decision has a broader scope.

It applies to all genetic resources for which a member state is a "country of origin" (article 6). The country of origin is the country which possesses genetic resources in *in-situ* conditions, including those taken from *in-situ* sources and found *ex-situ* (article 1). Emphasizing the country of origin leaves open the possibility that both wild and domesticated or cultivated species fall within the Decision's scope, whether or not they are publicly, communally or privately owned.

The draft Eritrean law also applies to wild and domesticated genetic resources (article 46(a)). Suggested legislation for Seychelles would apply to "any" species (section 53(1)).

The Andean Pact (article 4(a)) and Eritrean (article 46(a)) laws specifically state that human genetic resources are not within the legislation's scope of application. This parallels a decision by the CBD Conference of Parties which stated that human genetic resources are not within the Convention's scope.[7] Therefore, like the Convention, both States leave open the possibility that human genetic resources are still accessible without prior informed consent of or benefit-sharing with the State or the people targeted.

3.1.2 Sources of Genetic Resources

Related to the question of which genetic resources could be covered is the question of which sources of genetic resources could be covered by the legislation. Genetic resources can be obtained from both *in-situ* and *ex-situ* sources, whether public, communally or privately owned. *In-situ* sources can be terrestrial, aquatic or marine.

The Andean Pact decision applies to all genetic resources for which the member state is a country of origin, whether these are found in *in-situ* or *ex-situ* conditions within the territory of the State (article 1; article 3).

Article 5 of the Costa Rican Wildlife Conservation Law applies to wild fauna and flora which are located *in-situ* and *ex-situ*. These respectively remain state owned or national patrimony, therefore access to them would require authorization from the State.

The scope of application of the Eritrean Proclamation on Biodiversity also includes all genetic resources located *in-situ* or *ex-situ* (article 46(a)).

Protected areas are potentially very good *in-situ* sources of genetic resources. Some access legislation specifically mentions genetic resources located in protected areas. Section 27 of Nigeria's draft National Parks Decree applies to biological materials found in any Nigerian national park. No person is to prospect for genetic material, or remove any biological materials from any national park, without written prior informed consent of a designated minister (article 27(1)).

The legislation of other countries also make special reference to protected areas. Genetic resources can be removed from Costa Rican national parks with prior authorization (article 43). In the Philippines, bioprospecting of biological and genetic resources is allowed in all categories of protected areas with prior authorization in conformity with other national law and the protected area's rules and regulations (sections 4.1 and 4.2, Implementation Regulations).

Though it is not a party to the Convention on Biological Diversity, biological materials removed from national parks in the United States of America remain the property of the US government and are not to be used commercially. As a result of commercial bioprospecting for hyperthermophilic microorganisms in Yellowstone National Park modifications to the US Code of Federal Regulations (Title 36 (2.5)) and the individual research permit issued by each park superintendent have been proposed.[8] They would allow, for example, the Yellowstone microorganisms to be collected from its geothermal pools for subsequent commercial use in biotechnological applications. Materials could only be removed from the parks with the prior consent of the individual park superintendent.[9]

3.1.3 Derivatives

The benefit-sharing provisions of the Convention on Biological Diversity only apply to genetic material, the consequence being that potentially valuable materials, such as biochemicals, sometimes (and confusingly) referred to as "derivatives", are not covered by the CBD's access and benefit-sharing provisions. Even though the CBD's scope is limited, States are drafting access legislation to ensure benefit-sharing for useful biochemicals found in the materials for which access is sought. There are two contexts in which the term "derivative" is applicable.

In the first context, derivatives could be described as unimproved or unmodified chemical compounds, other than DNA or RNA, merely associated with targeted biological material, but formed by the organism's metabolic processes. Like DNA or RNA, these exist in a sample of biological material when it is obtained from an *in-situ* or *ex-situ* source. For example, derivatives in this context might be biologically active chemical compounds found within plant material which is collected, but which are yet to be extracted, modified and used in a technological application.

In the second context, derivatives may refer to DNA or RNA, or a chemical compound, modified, created or synthesized from materials originally obtained from an *in-situ* or *ex-situ* source. The resulting end-product, for example, might be a breeder's hybrid seed, a traditional healer's medicine or a pharmaceutical company's synthetic version of an extracted biochemical. These, then, are end-products derived from genetic or biochemical resources through human intervention.

Access legislation could be extended to derivatives used in the first context. This is because the ultimate source of the derivative material is likely to be biological or other materials obtained from an *in-situ* or *ex-situ* source within the State's jurisdiction. Therefore the State only needs to ensure that the scope of legislation clearly specifies this. Then it can regulate access to the materials containing the chemical compounds just as it would for genetic material. Regulating access would enable appropriate benefit-sharing arrangements to be negotiated for any subsequent use of the materials taken and used.

Access legislation would be very difficult to extend to derivatives in the second context because the government would in reality be regulating access to technologies. While in theory it is possible to regulate access to all products *subsequently* derived from the genetic material or biochemicals removed from the original source material, in practice it would not seem to be technically or politically feasible.

For example, if in the second context the government's prior informed consent is required every time a derivative end-product is proposed to be transferred commercially, then it will be practically impossible for the State to control. The technology is likely to be proprietary and may also be subject to intellectual property rights. Furthermore, there is probably no practical way to monitor the transactions, except by putting all public and private research and development, as well as commercial activities, under governmental scrutiny. Another limitation is that there would be no way for the government to subject activities involving the derived products to its regulatory control once they are located beyond the limits of national jurisdiction.

The end-products derived from genetic material or biochemicals removed from *in-situ* or *ex-situ* sources can however be the subject of benefit-sharing arrangements established at the time of the original request for access. Products derived from genetic material or biochemicals supplied pursuant to an access agreement should certainly entitle the provider to benefit-sharing.

In both cases, therefore, it is expedient to ensure that benefit-sharing agreements cover materials originally derived from materials provided from *in-situ* and *ex-situ* sources. Attention should be focused on regulating activities such as collecting to ensure that a State's interests in benefit-sharing are protected when materials are removed and subsequently used.

In the Andean Pact access has been defined to include access to "derived products" from genetic resources (article 1). Derived products include molecules, combinations or mixtures of natural molecules including raw extracts of living or dead organisms (article 1). Early drafts of the Decision extended the scope of application to end-products synthesized from genetic resources. The final Decision does not subject synthesized products to the access regime.[10]

3.1.4 Associated Knowledge

In many cases, knowledge or information associated with genetic resources is quite valuable. Legislative approaches to date have focused on the knowledge of indigenous and local communities.

By adopting Andean Pact Decision 391, member states "recognize and value the rights and the power of decision of indigenous, Afroamerican and local communities over their traditional knowledge, innovations and practices associated with genetic resources and derivative products thereof" (article 7). This is to be accomplished through national legislation complementing the Decision. Article 1 defines these communities as "human groups whose social, cultural and economic conditions distinguish them from other sectors of the national community, which are governed totally or partially by their own customs or traditions or by special legislation, and which, regardless of their legal status, conserve their own social, economic, cultural, and political institutions or parts thereof".

It is important to note that the Common Regime only applies to traditional knowledge where it is associated with the genetic resources and derivatives sought. Application is indirect and there is no explicit provision referring to the provider's prior informed consent. Where genetic resources have an associated "intangible component" an access contract with the State must incorporate an annex which has terms for fair and equitable benefit-sharing (article 35). This is to be signed by the provider, the applicant and, depending on national legislation, the competent national authority. The annex presumably demonstrates the provider's consent to use the knowledge. The rights of providers of associated knowledge are to be "safeguarded" by the competent national authorities of member states (article 50(d)).

Most importantly, the Decision requires the Governing Board of the Andean Pact to prepare within 1 year of the Decision's entry into force a proposal for establishing a special regime or norm to strengthen protection of the knowledge, innovations and practices of indigenous, Afroamerican and local communities (eighth temporary provision). The Governing Board's work is contingent upon member states first submitting national studies. The member states will also design a training programme for these communities to strengthen their capacity to negotiate accessory contracts regarding their knowledge, innovations and practices associated with genetic resources (ninth temporary provision). Therefore the application of Decision 391 to traditional knowledge could change depending on the outcome of the Governing Board's future work.

The draft Fijian Sustainable Development Bill provides that the Conservation and National Parks Authority, the competent national authority overseeing bioprospecting activities, is to ensure that a legally binding agreement for the "harvesting of traditional knowledge" is concluded with the "registered owners" of a targeted resource (section 254(6)(a)). The term registered owners is not defined in the Bill.

The second preambular paragraph of the Philippines Executive Order recognizes that it is in "the interest of the State's conservation efforts to...identify and recognize the rights of indigenous cultural communities and other Philippine communities to their traditional knowledge and practices when this information is directly or indirectly put to commercial use". Indigenous cultural communities or Indigenous Peoples are "a homogenous society identified by self-ascription and ascription by others, who have continuously lived as [a] community on communally bounded and defined territory, sharing common bonds of languages, customs, traditions and other distinctive cultural traits, and who, through resistance to the political, social and cultural inroads of colonization, became historically differentiated from the majority of Filipinos" (section 2.1(r), Implementation Regulations). Local communities are "the basic political unit wherein the biological and genetic resources are located (section 2.1(u), Implementation Regulations)." The Inter-Agency Committee tasked with processing access applications is entrusted with ensuring the rights of indigenous and local communities where collecting and research are being undertaken (section 7(e)).

Access legislation suggested in a 1993 technical report for the Seychelles covers "any species, its parts or elements of genetic or biochemical activity" (section 53(1)).

In the Philippines, the situation is a little less clear. The Philippines legislation defines "by-product" as any part taken from biological or genetic resources including compounds indirectly produced in a biochemical process or cycle (Appendix A, Executive Order; section 2(j), Implementation Regulations). "Derivatives" include extracts from biological or genetic resources such as blood, oils, resins, genes, spores and pollen taken from or modified from a source product (section 2(m), Implementation Regulations). However, neither term appears to be actually used in the legislation's substantive provisions making their application somewhat unclear.

By reference to the Convention on Biological Diversity's non-binding preamble, the Order's Implementation Regulations recognize "the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices" (section 1.3). Prospecting within the areas of local communities, including Indigenous Peoples, is to be with their consent. However, the definition of prospecting does not include knowledge associated with biological or genetic resources (section 5). These deficiencies could be ameliorated if the collector or principal fully disclose the scope of the research activity in the access application process.

The scope of the Eritrean Draft Proclamation's provisions on access to genetic resources apply to associated traditional knowledge (article 46). However, no explicit provisions on consent from the holders of traditional knowledge are provided for. Consent is only explicitly required for genetic resources sought (article 49).

3.2 Activities

The activities regulated by the access legislation are very much related to the ultimate purposes or objectives of physical access to genetic resources, in others words, why the genetic resources are sought. Genetic resources will be sought for commercial and non-commercial reasons.

Even with the blurred lines between non-commercial and commercial activities, the Costa Rican (article 50) and Philippine (section 3, Executive Order; sections 7 and 8 Implementation Regulations) laws do make the distinction. They set out different requirements for each.

In general, non-commercial uses of genetic resources are subject to less rigorous rules than uses with commercial intent. Typically non-commercial research is to be undertaken by an institution accredited with the national government as is the case in the Philippines (section 3, Executive Order). This implies the creation of an accreditation procedure, and the existence of a list of approved institutes. These do not seem to be provided for in the legislation examined to date.

Aside from applying to activities related to the physical access to genetic resources, another activity to which some legislation applies is the export of genetic resources (see below).

3.3 Actors

Ideally, access legislation should apply to both nationals and non-nationals because genetic resources can generate benefits when used within the country or outside, even if endogenous technological capabilities are not far advanced. In addition, the distinction between nationals and non-nationals may be blurred especially when transnational corporations are involved.

The South Korean legislation (article 25-4) only applies to foreigners hoping to access genetic resources. Other than the draft Kenyan law (section 38(1)) which apparently applies only to non-citizens of Kenya, it is unclear whether the other African enabling laws described earlier apply only to foreigners, although in all cases developing guidelines on germplasm export seems to be the primary focus.

The draft Fijian legislation (section 254(3)), draft Nigerian National Parks Decree (section 27(a)) and the Philippines Executive Order (section 3) apply to both nationals and non-nationals. This is also suggested in the legal technical report for the Seychelles (section 53(1)).

The Philippines legislation subjects the agreement between a commercial collector and its principal to scrutiny as part of the access determination procedure (section 3, Executive Order). In addition, the legislation clearly applies to natural and legal persons as well as governmental institutions (section 3.1(a), Implementation Regulations). The Implementation Regulations are quite comprehensive and apply to "foreign and local individuals, entities, organizations, whether government or private" (section 3.1(a)).

In some cases, for instance in Costa Rica, nationals may be entitled to special treatment. This includes being subject to lower licensing fees or being authorized for access longer than for non-nationals (article 39).

In the Philippines only "duly recognized" national institutions can enter into non-commercial research agreements with the government (section 3, Executive Order). Foreign entities, whether legal or natural persons, must enter into a commercial research agreement (section 3, Executive Order).

3.4 Geographical Locales

Access legislation should clarify which geographical areas (land and sea) within the State's jurisdiction it applies to. Depending on the circumstances within the State, access legislation should also indicate whether it applies to communal land and sea territories and private property. References might be made as to whether or not the owner, holder or usufructuary's consent is required prior to access.

Acervo ISA

The draft Fijian legislation is a succinct example. It provides that biodiversity prospecting in any marine or terrestrial area is prohibited without prior approval via a special permit (section 254(2)). In addition, the application procedure includes submitting "any agreement concluded with native land owners concerning...access to land or resources on such land" (section 254(4)(vii)(A)).

The Philippines Executive Order is limited to prospecting of all biological and genetic resources in the "public domain, including natural growths in private lands" (section 3, Implementation Regulations). The public domain comprises the "waters and lands owned by the State that have not been declared alienable and disposable" (article 2.1(z), Implementation Regulations). What constitutes "natural growths" is not clarified.

Prospecting is "allowed within the ancestral lands and domains of indigenous cultural communities only with [their] prior informed consent" (section 2(a), Executive Order). The prior informed consent of "concerned local communities" is also required but the requirement is not explicitly linked to geographical locale (section 2(b), Executive Order).

The Andean Pact Decision speaks more generally in terms of genetic resources found in the member states' territories (article 3). For purposes of the Common Regime, the legal status of genetic resources is distinct from that of biological resources. The property regime over a particular area in which are found biological resources containing the genetic material or derivatives sought only entitles the owner, occupier or administrator to enter into accessory contracts (article 41(a)). They cannot grant access to genetic resources and derivatives. This is reserved for the competent national authority. However, the rights of communal or private landholders from which biological resources are sought as genetic resources are to be safeguarded by each member state's competent national authority (article 50(d)).

Eritrea's Second Draft Proclamation on the Conservation of Biological Diversity applies to the areas under national jurisdiction. This includes land subject to a private right of use and "land used by pastoralists or other communities or groups with traditional interests in that land" (article 49(a) and (b)). Consent of the usufructuary or the communities/groups involved is required for access to resources located on these lands.

3.5 Exclusions

Another aspect of the legislation's scope which could be considered by a State is whether to include explicit exclusions to the law's application. In other words, what will not be regulated by the legislation. Three possibilities might be considered. These are (1) customary use of genetic resources (2) specific uses of biological resources and (3) genetic resources obtained prior to the legislation's enactment (retroactivity).

Article 10(c) of the Convention on Biological Diversity requires each Party to protect and encourage customary use of biological resources compatible with conservation and sustainable use of biological diversity. Use must be in accordance with traditional cultural practices.

Article 4(b) of the Andean Pact Decision 391 is perhaps most comprehensive. It excludes from the Decision's scope the biological and genetic resources exchanged among indigenous and local communities when these are used for their own consumption and in their daily practices. Included as well are derived products, such as molecules, mixtures and raw extracts (article 1)).

The draft Eritrean biodiversity proclamation excludes genetic resource exchanges among local communities for traditional, non-commercial purposes (article 46(b)). A customary use exclusion is provided for in the Philippines Implementation Regulations (section 3.1(b)).

The existing examples of access legislation usually specify what intended genetic resource uses will trigger the prior informed consent requirement. Typically the trigger is "access" or "bioprospecting". These are then defined to include certain activities such as research, collection or use for particular commercial or non-commercial purposes. Specifying which uses or activities trigger the legislation's prior informed consent procedure, implicitly highlights those that do not[11].

The Andean Pact Decision clarifies State authority over genetic resources and derived products. The procedures triggered do not prejudice the property regimes already in place over biological resources in the member states (article 6). At the same time it provides that concessions or approvals to use biological resources for purposes other than those involving genetic resources do not permit subsequent use of these materials for purposes of access (article 23).

Legal rules as a general rule do not to apply to past actions. In other words they are not retroactive. State practice seems to be going in the opposite direction however. There are two situations.

The first situation is not truly retroactive. The Philippines (section 11, Implementation Regulations) and the Andean Pact (article 50(j)) have illustrative legislation. Both require existing agreements to be renegotiated to conform to the principles specified in their respective laws within some period after the legislations' entry into force. In the Philippines existing research can continue pending the negotiation of a new agreement.

Whether the second situation, which only exists in the Andean Pact, is retroactive depends on how one interprets the legal status of genetic resources prior to Decision 391's entry into force.[12] Pursuant to the first temporary provision at the end of Decision 391, where genetic resources

within the Pact have been collected prior to the Decision's entry into force, a negotiation for an access contract for those genetic resources must take place. This provision has implications for legal and natural persons, for example *ex-situ* conservation facilities, both within and outside the Andean Pact.

4.0 Institutions to Oversee Access to Genetic Resources

An institution with authority to process access determination applications will need to be designated or established to regulate access to genetic resources to ensure benefit-sharing. This could be at the national or sub-national level depending on the State's constitutional system.

A number of examples exist. The Philippines illustrates a comprehensive approach.

Executive Order 247 recognizes "an inter-agency approach [as] the most appropriate way of regulating the research, collection, exploitation and use of biological and genetic resources" in the Philippines (preambular paragraph 1). Section 6 creates the Inter-Agency Committee on Biological and Genetic Resources. The Committee is located within the Philippines Department of Environment and Natural Resources (DENR). It oversees the Executive Order's implementation.

The Committee's membership includes representatives from the Departments of Environment and Natural Resources, Science and Technology, Agriculture, Health and Foreign Affairs. Membership also includes two permanent representatives from the Philippine science community, one from the National Museum, one from a non-governmental organization and one from a "peoples'" organization representing indigenous cultural communities and/or their organizations. Each member serves for a three year period.

A technical secretariat, headed by the Philippine Protected Areas and Wildlife Bureau of the DENR, supports the Inter-Agency Committee. Its functions include initially screening proposals submitted for academic and commercial research agreements.

The Inter-Agency Committee neither makes access determinations nor enters into research agreements. Individual access determinations are made and research agreements entered into at the line agency level upon the Inter-agency's recommendation. Competency over genetic resources, which are owned by the State, remains with the relevant sectoral line agencies (Executive Order, section 7(a); section 6.2.6, Implementation Regulations).

For example, upon the Committee's recommendation, the Secretary of the Department of Agriculture, who sits on the Committee, signs and approves agreements related to agricultural and fishery biological resources (section 10.3.1 (c), Implementation Regulations). The Secretary of the Department of Health signs and approves agreements related to activities on pharmaceutical or medicinal research especially involving extracts and compounds produced by metabolic processes (by-products and derivatives) (section 10.3.4 (b), Implementation Regulations). The Secretary of the Department of Environment and Natural Resources signs and approves agreements related to terrestrial wildlife (section 10.3.5 (c), Implementation Regulations).

The signed agreements are then furnished to the local communities involved and the collector. The Protected Areas and Wildlife Bureau which monitors their implementation also receives a copy (sections 8, Implementing Regulations).

Other functions of the Philippine Inter-Agency Committee are clearly specified in the Executive Order's Implementation Regulations. They include ensuring that the conditions of the research agreement are strictly observed (section 10.2.b), deputizing and training appropriate agencies to control exports of genetic resources without an agreement (section 10.2.d), ensuring the rights of indigenous and local communities in whose territories bioprospecting activities will occur (section 10.2.e) and developing a conceptual framework for using research agreements to increase knowledge of Philippines biodiversity (section 10.2.h).

In the Andean Pact, Decision 391 sets out some of the minimum functions of each member state's national competent authority. They decide the authority's ultimate composition and function (article 50).

Some functions are self evident. For example, the competent authorities are to negotiate access contracts, make access determinations, modify or suspend the contracts and monitor their implementation (article 50(c), (b), (g) and (i)).

Others are less obvious. For example national competent authorities can "gap fill" in areas that the Decision does not cover (article 50(a)). They are to "safeguard" the rights of the providers of biological resources which contain genetic resources sought and the rights of the providers of associated knowledge (article 50(d)). They can also review accessory contracts between the applicant and third parties (article 50(j)).

In addition, they are to supervise the status of targeted biological resources and maintain a national inventory of genetic resources (article 50(l) and (n)). They are also to establish permanent contact with the intellectual property authorities in the member state and establish appropriate information systems (article 50(o)).

The draft Fijian legislation would designate the Conservation and National Parks Authority to establish a system

to regulate biodiversity prospecting (section 254(1)). The Authority will not be an inter-agency body.

The Authority will have a number of primary functions. For example, when an application is received it will collect the views of other agencies and the public. It will consult with other agencies including the Native Land Trust Board, the Departments of Health and Customs and the ministry responsible for fisheries (section 254(5)(a)(i)). If necessary, the Authority would be able to extend the consultative process to other government ministries, departments or statutory bodies (section 254(5)(a)(i)). The public's views would be solicited upon a public notice's release (section 254(5)(a)(ii)).

Another primary function will include ensuring that a legally binding agreement exists between the potential bioprospector and the registered owners of the resource (section 254(6)(a)). It will also ensure that the applicant completes an operational plan for the intended research (section 254(6)(b)). A monitoring plan and a process for undertaking an inventory are also required. An auditing system to verify the applicant's activities must also be ensured (section 254(6)(c)). All requirements must be satisfied before a biodiversity prospecting permit representing consent is issued.

In addition, the Authority also oversees the export of materials collected. Prior to granting an export permit it will verify compliance with "the conditions of any authority granted" (section 254(14)(a)) prior to granting an export permit. Prior to granting an export permit, it will also inspect the specimens collected to confirm compliance with any CITES requirements (section 254(14)(b)). The Authority will have the power to issue directives when the permit is not being complied with (section 254(16)).

5.0 Prior Informed Consent: The Access Determination Process

Prior informed consent of a competent authority implies that an administrative "access determination process" is created to handle requests for access to genetic resources. The process is a manifestation of the State's sovereign rights over genetic resources within its jurisdiction.

The access determination process could have four primary components:

- application submitted to a designated institutional competent authority;
- reviewing the application;
- access determination (denial of or consent to access); and
- appeal.

5.1 Access Application To A Competent Authority

The information required for an access determination can be supplied to the competent authority via an application form. The application's receipt would trigger the access determination process.

Andean Pact Decision 391 sets out the minimum information that each member state should require as part of an access application (articles 17 and 26). This information contributes to the criteria against which the application is evaluated. It will also provide the basis for ultimately conditioning any access contract granted.

For example, the application should address participation of nationals from the Pact region in the proposed activity and how the proposal will support research in the particular member state or the region. Mechanisms to strengthen technology transfer and build regional, national or local capacity are to be described. Information on the deposit of samples and third-party transfer is also required (article 17).

In addition to the more self-evident requirements such as the applicant's name and the genetic resource provider's identity, Decision 391 also requires the applicant to demonstrate its legal capacity to enter into an access contract (article 26(a)). The identity of a national collaborating person or institution must be provided (article 26(c)). A proposal is to be submitted describing the activity and the areas for which access is sought (article 26(e) and 8(f)).

The Pact will establish a common project proposal format (article 26). The Andean Committee on Genetic Resources will prepare an explanatory guide to the Decision (article 51(j)). In addition, the Pact will develop models for access applications (final disposition 10).

Complete applications result in the file being registered. Incomplete applications are returned with a rationale (article 27).

The draft Eritrean Biodiversity Proclamation states that an application for access to *in-situ* or *ex-situ* genetic resources should provide a description of the specimens to be taken and their intended use (article 48(b) and (c)). For access to *in-situ* sources, work sites are to be identified. A description of the proposed activities, including collection methods and sample amounts, as well as the results of an environmental impact assessment, are to be provided along with the conservation status of the species or organisms sought (article 48(d)). Access to *ex-situ* sources requires the institution's identification (article 48(e)). A copy of the material transfer agreement is to be submitted with the application (article 48(e)).

Under the draft Fijian legislation, the information to be submitted reflects many of the same elements as legislation from other States. One unique requirement, however, is that the applicant is to provide information on "the nature of any intellectual property rights that may be affected concerning the traditional use of any biological resource" (section 254(4)(b)(iv)).

The Philippines have created a standard application form for an academic or commercial research agreement. When completed, signed and notarized, the applicant certifies statements made are correct and truthful and that the applicant will abide by the decision of the Inter-Agency Committee (annex B, Implementation Regulations).

In addition to a letter of intent and a research proposal (section 6.1.1, Implementation Regulations), some other information requested includes a list of foreign and local researchers collaborating in the undertaking (annex A, Implementation Regulations). Letters of acceptance from counterparts in Filipino institutions and letters of endorsement from the head of the applicant's institution, or that from another reputable institution, are also required (sections 6.1.2 (a) and (b), Implementation Regulations). The Implementation Regulations provide a standard format for research proposals (annex A, Implementation Regulations).

Submitting the application triggers an initial screening by the technical secretariat to determine whether the proposed activity is within the scope of the Executive Order (section 6.2.1, Implementation Regulations). If it is, then additional information is requested pursuant to a checklist. For example, an environmental impact assessment may be required by the technical secretariat (section 6.1.4, Implementation Regulations). In addition, when a commercial research agreement is requested, a "prior informed consent certificate", obtained from the relevant holder or ultimate provider of genetic resources must also be submitted to the technical secretariat to complete the application (section 6.2.3 and annex E, Implementation Regulations).

The entire application process is facilitated by a short publication which disseminates and describes the relevant legislation and provides background information for applicants. The access determination process is schematically represented to enable the applicant to visually understand the process.[13]

5.2 Reviewing the Access Application

The access determination process could provide the opportunity for the competent authority to gather information relevant to making an access determination. Depending on the circumstances, the access determination process may also be the point where mutually agreed terms are negotiated and concluded between the government and someone seeking access. The application's review might be broken down into two primary elements:

- public notification; and
- reaching mutually agreed terms.

Existing and proposed national and regional legislation covering the elements of the application review procedure provide good examples of different levels of regulatory complexity.

In Eritrea, the draft biodiversity proclamation does not include provisions for public notification. The application for an access permit would ultimately lead to the conclusion of mutually agreed terms between the applicant and the State. An access permit would reflect mutually agreed terms (article 50).

In Eritrea all land is owned by the State. However, where access is sought to land where a private right of use has been granted, consent of the usufructuary would be required (article 49(a)). Similarly, access to land used by pastoralists or other communities or groups with traditional land interests would also require their consent (article 49(b)). In both cases, any future access permit issued by the State would need to include terms to ensure benefit-sharing with these individuals or groups. No criteria are provided.

In addition, the legislation does not clarify whether access agreements providing a share of benefits can be negotiated with individuals or communities in addition to the access permit issued by the State. If a permit is issued for access to Eritrean genetic resources it would "contain" the consent of any group or community. It would also include terms on the duration of consent, restrictions on future use, third party transfer, benefit-sharing requirements, research participation, reporting requirements or conservation measures (article 50(6,4,7-10,12 and 13)).

Under the proposed draft Fijian legislation, an application for a special permit for biodiversity prospecting would trigger (1) a consultative process among governmental agencies and (2) a public notice, both of which are to be undertaken by the Conservation and National Parks Authority (section 254(5)(a)(i) and (ii)). The draft bill does not give any details on the nature of the inter-agency consultation.

The public notice would be published in daily newspapers in Fiji's three principal languages (section 254(5)(b)). It would include a description of the activity and its nature, the activity's methodology and the date to be undertaken, a statement on impacts to human, marine or environmental health and plans for environmental monitoring and management (section 254(5)(b)(i-v)). A provision in the public notice would state that any person may make a written submission on the application. It would also provide the closing date for submissions (at least 30 days from

the notice's publication) and the address where submissions could be sent (section 254(5)(vi-viii). A copy of the public notice would be submitted to the National Council for Sustainable Development (section 254(5)(c)).

In both cases the draft bill does not clarify the extent to which the Authority would have to consider comments derived from the governmental consultative or the public notification processes. Rather, the submissions would only have to be considered before a decision on the permit is made.

The draft Fijian legislation has very broad confidentiality provisions. Upon the applicant's written request any information contained in the application must be kept confidential by the Authority (section 254(4)(c)) until the Authority is notified by the applicant in writing that the "confidentiality is no longer required" (section 254(4)(d)). Therefore the Authority will have no discretion to decide the validity of the request. In effect all the information in the application could be removed from public scrutiny, except of course that required for the public notice.

The Fiji bill is interesting because land in Fiji is owned communally by registered groups defined roughly according to customary law principles.[14] "Native ownership" is a trust relationship with the government.[15]

Prior to making any decision on the application, the Authority is required to ensure that the applicant and the registered owners of the targeted resource conclude a legally binding agreement (section 254(6)). The terms of the agreement would include (1) rights of access, (2) limitations on sample exploitation and removal, (3) harvesting or specimens or traditional knowledge and (4) fees for any concessions granted (section 254(6)(a)(i-iv)). It does not appear that the Authority can negotiate a benefit-sharing agreement on behalf of the government itself.

The Authority's approval of the application would be conditioned upon the applicant submitting a legally binding agreement to "negotiate and conclude suitable royalty agreements with the resource owner upon the registry of any patent or copyright by the applicant" (section 254(7)). If a permit is issued, the conditions stipulated would include (1) the species sought and quantities that could be harvested, (2) the methods of scientific evaluation, sampling or harvesting, (3) methods for storage and transport and (4) any environmental monitoring or management plans needed (section 254(9)(c)). A full description of the bioprospecting activity and its location is also required (section 254(9)(a) and (b)).

In the Andean Pact, submitting an access application to a member state will trigger a review procedure in the state *prior* to the negotiation of an access contract. Within six days of receiving a complete access application, an extract of the application will be published nationally, and locally in the targeted region. This will publicly announce the application's receipt and solicit comments (article 28).

The member state's competent national authority will issue a technical and legal opinion on the appropriateness of the application within a time frame specified by a member state's national law (article 29). The competent authority will consider the comments submitted pursuant to the public notice. During this time a field visit to the targeted area to confer with potentially affected communities may also take place.

The national authority accepts or denies the application (article 30). Applications denied are done so without prejudice. This means that the applicant could revise the application and re-submit it at a later date. A rationale for denial is to be provided by the competent national authority. One reason for denying the application might be that an environmental impact assessment needs to be undertaken (article 31).

If the application is accepted, the applicant is notified within 5 working days. Negotiations for an access contract then begin (article 30).

Decision 391 acknowledges that in some cases it may be desirable to make exceptions to the general rule that all access procedure documents are to be placed in the public record and made accessible to anyone (article 18). The Decision allows member states to keep some information or aspects of an access contract confidential. The primary criterion is whether the information could provide the basis for unfair commercial use by third parties, unless the information is already public knowledge or is necessary to protect social or environmental interests (article 19).

The applicant must justify why certain information must be kept confidential, while providing a non-confidential summary of the application which would be placed in the publicly available file (article 19). Some information, such as the applicant's identity, cannot be made confidential (articles 18 and 19). The competent authority will keep a reserved file for confidential information (article 19).

In addition to notifying the general public, the member state is also obliged to notify the other member states of all access applications (article 48). It is unclear, however, what information is to be supplied as part of the notification and whether confidential information can be withheld.

The Pact Decision supports the possibility of at least two types of contract through which mutually agreed terms can be immortalized: (1) "access contracts" between the applicant and the national competent authority (Title V, Chapter III), and (2) "accessory contracts" (Title VI) between the applicant and either a (1) landholder or owner, (2) an *ex-situ* conservation facility, (3) the holder or owner of biological resources containing genetic resources or (4) a national support institute.

The access contract governs the terms and conditions of access to genetic resources and derivatives. The minimum

terms of the access contract between the applicant and the competent national authority are to be in accordance with the Decision and national implementing legislation (article 33).

The access contract is to take into "account the rights and interests of the suppliers of the genetic resources and their derivative products, of the biological resources which contain them and of the intangible component in accordance with the corresponding contracts" (article 34).

In addition, every access contract is to have an annex which refers to benefit-sharing when there is knowledge or information associated with the genetic resources provided (article 35). The annex is actually a third type of contract possible under the Decision.[16] It becomes an integral part of the access contract upon the contract's approval (article 35). The annex is to be signed by the provider of the associated knowledge and the applicant. National legislation will decide whether the competent authority will also sign the annex (article 35). A possible tripartite agreement seems designed to protect indigenous and local communities which may not have the resources to enforce the annex.

Accessory contracts apply to activities associated with access to genetic resources (or derivatives).[17] For example, the applicant may need to negotiate an accessory contract to enter land on which genetic resources are found.

The minimum terms and conditions for accessory contracts are suggested (article 17) but it is unclear whether they are mandatory. It appears the parties to the accessory contract have flexibility to freely contract perhaps while drawing on article 17 for guidance. The minimum terms refer to such issues as research participation, capacity building for indigenous and local communities, deposit of duplicate samples, reporting on research results and terms on third party transfer of materials.

The execution and enforcement of the accessory contract is the complete responsibility of the parties to it (article 42). The accessory contract must have a "suspense clause" (article 42). The suspense clause prevents the accessory contract's entry into force until certain conditions are fulfilled. The accessory contract becomes effective when the access contract is approved. Nullifying the access contract between the competent authority and the applicant nullifies the accessory contract (article 44).

In the Philippines, PIC is two-tiered. It is sought at the national level and at the local level. Therefore reviewing the access application and reaching mutually agreed terms must necessarily occur at both levels.

After the initial screen of the application by the Inter-Agency Committee's technical secretariat, the applicant is to seek a "prior informed consent certificate" from a local provider to complete the application. The location of the proposed activity will determine whose prior informed consent must be sought. Prior informed consent will be required either from the recognized head of an indigenous community, head of local government in a community, the local or district office of the Philippine Protected Area Management Board or a private land owner.

The procedure to secure prior informed consent at the local level varies depending on whether a commercial or academic research agreement is sought (section 7, Executive Order and annex D, Implementation Regulations). The primary distinction turns on when the PIC certificate is obtained in relation to the activity's commencement.

For commercial agreements, PIC must be secured as a condition of the Inter-Agency Committee's further processing of the application and a subsequent recommendation in favour of a commercial research agreement (section 7.1, Implementation Regulations). In contrast, for academic agreements, PIC only needs to be secured prior to the bioprospecting activity's commencement (section 7.2, Implementation Regulations).

The PIC procedure has two basic components. One is public notification. The other is sector consultation. In both cases the applicant has the burden of initiating the processes.

As part of the public notification for a commercial agreement, the principal or collector must inform the recognized head of an indigenous community, head of government in a local community, the Protected Area Management Board or private land owner through various media (section 7.1.1, Implementation Regulations). Notification could include newspaper, radio or television advertisements. These are to be designed to (1) notify the applicant's intent to collect within specified areas and fully disclose the activity, (2) state that a summary of the research proposal has been filed locally with the relevant provider of genetic resources and (3) highlight that a research agreement application has been filed with the Inter-Agency Committee (for a commercial research agreement (section 6.2.2, Implementation Regulations). The regulations do not specify how long the comment period is and to whom comments are to be submitted. However, no PIC certificate will be issued until after 60 days have elapsed from the date the proposal was submitted (section 7.1.3, Implementation Regulations).

Public notification for academic agreements is similar, but the option is given for "direct communication" in lieu of media advertisements. Additionally, notification can include either information that an application has been made for an academic research agreement or that an academic research agreement already exists between the applicant and "the agency concerned" (section 7.2.1, Implementation Regulations). The last qualification is not clarified in the regulations.

The sector consultation is essentially a community level public hearing in the area where bioprospecting will occur (sections 7.1.2 and 7.2.2, Implementation Regulations).

Notice of the consultation is to be conspicuous and made at least one week before the assembly. A brief summary of the proposal, in the local language or dialect, is to be submitted to the appropriate person or institution mentioned earlier.

The summary is to include the purpose and methodology of the activity, duration, species or specimens and quantity taken or used. It must also describe the benefits to be shared during and after the activity. In addition, a categorical statement is to be included that the proposed activity will not in any way affect the traditional use of resources. Where Indigenous Peoples are involved, the sector consultation for a commercial research agreement is to be vetted according to their customary laws and traditional practices.

Sector consultations are not required for the academic research of undergraduate, masters or doctoral students, where their research is not funded by a commercial entity (section 7.2.5, Implementation Regulations)

The recognized head of the indigenous community, head of government in a local community, the Protected Area Management Board or private land owner signs and issues the PIC certificate when public notification and sector consultation have been complied with (sections 7.1.3 and 7.2.3, Implementation Regulations). A standardized form for the certificate is provided. Signature certifies the project's implications have been understood. It also demonstrates that the respective constituencies have been contacted and do not oppose the project (annex E, Implementation Regulations).

The Implementation Regulations present at least two discrepancies. First, even though private landowners are required to issue a PIC certificate, the certificate form does not appear to be tailored to their circumstances.

Second, the regulations do not provide how opposition to the proposal is to be considered in the decision for a prior informed consent certificate (section 7.2.3, Implementation Regulations), although it appears from the PIC certificate form that the certificate can only be issued where there is no objection. In fact, the only reference the regulations make to opposition is raised in the provisions for the academic research agreement.

The Implementation Regulations outline a research agreement's minimum terms and conditions (section 8). General terms for all research agreements are listed. Specific terms for commercial and academic research agreements are then provided.

For example, all Filipino citizens and any Philippine governmental entities are to have complete access to specimens deposited at an internationally recognized *ex-situ* depository (section 8.1(4)). All commercial discoveries are to be available to the Philippine government and local communities (section 8.1(9)). Most interestingly, technologies developed from Philippine endemic species are to be made available to the Philippine Government for commercial and local use without requiring a royalty (section 8.1(13)). The details could be negotiated however.

All bioprospecting research by foreign legal and natural persons is to be undertaken in collaboration or cooperation with Philippine scientists. The expenses are to be borne by the collector (section 8.1(12)). Another condition requires a separate benefit-sharing agreement to be negotiated in addition to the research agreement (section 8.1(14)). When this is to occur however is not clear.

When the commercial or academic collector is an agent for another legal or natural person, the agency agreement between them must be reviewed by the Inter-Agency Committee to ensure its consistency with the Executive Order (section 8.1(17)).

Commercial agreements are limited to 3 years' duration. In addition, the applicant must submit "a performance, compensation, ecological rehabilitation bond" deposited in favour of the government (section 8.2(4)). If the terms of the research agreement are broken the bond is forfeited (section 14.3).

Academic research agreements are valid for 5 years and can be used by affiliates of the institution awarded the agreement provided they secure a PIC certificate (section 8.3(7) and (2)). Data or materials collected cannot be transferred to a commercial entity without the academic agreement's reclassification as a commercial agreement (section 8.2(6)).

5.3 The Access Determination

The actual access determination will be simply a decision to deny or grant consent to access genetic resources. It is essentially a yes or no answer. For purposes of transparency and possible appeal, criteria for the competent authority to make the determination should be specified in the access legislation or accompanying regulations. In addition, a written rationale for the decision should be provided and made publicly available.

Decision 391 of the Andean Pact provides a number of criteria which may be used in the access determination process. Many will be considered early on when the application is first submitted and before the applicant is allowed to enter into negotiations for an access contract. A good example is the Decision's short list of situations where, pursuant to national legislation, the member state can impose limitations on access for environmental reasons (article 45).

Another interesting example is the prohibition placed on using genetic resources from the Andean Pact in biological warfare applications (article 24). This is a good example of how the qualification in CBD article 15(2) on facilitating access for environmentally sound uses could be applied in practice.

Early screening of these details should make the access determination process more efficient because efforts to ensure the application's acceptability are expended up-front. This should lower the risk that the application will be rejected late in the process, when the applicant might otherwise have expended considerable resources to follow the process only to have access then denied. This, therefore, may actually facilitate access in the long-run.

The actual access determination in the Pact is called "perfecting the access contract". When the access contract is completed and signed, the competent national authority issues a resolution along with the contract (article 38). The combination manifests consent to access genetic resources. The access determination process is then complete.

A registration number is assigned. The resolution and an abstract of the access contract is published in the member state's official gazette (article 38). The entry into force of the access contract is the publication date. On this date any suspense clause on accessory contracts is lifted and these enter into force immediately (article 42). The Pact member states are to be notified of the decision immediately (article 48).

In the Philippines, after evaluating the application, the Inter-Agency Committee recommends to the secretary of the governmental agency with competence over the particular genetic resources at issue that the agency should approve the research agreement applied for (section 6.2.5, Implementation Regulations).

The agency then is to approve the agreement (section 6.2.6, Implementation Regulations). Upon the Committee's recommendation, the particular agency makes the actual access determination. A signed copy of the agreement is transmitted to the applicant, land owner, head of local government or indigenous community (section 6.2.7, Implementation Regulations).

While the agency seems to be obliged to issue the research agreement upon a positive recommendation from the Inter-Agency Committee, it is unclear what happens to the application if the Inter-Agency Committee does not recommend approval. Neither the Executive Order nor the Implementation Regulations have provisions on the public availability of the agreement or its final terms though the Protected Areas Wildlife Bureau acts as depository of all original and official documents, such as research agreements (section 12, Executive Order). Presumably, therefore, the availability of these documents is subject to Philippines administrative law.

In Fiji, the Conservation and National Parks Authority would first have to consider submissions made pursuant to the public notification process and verify minimum criteria have been met before making an access determination. There are three possibilities for a decision: (1) refuse the permit, (2) require an environmental impact assessment or (3) issue the permit with specific conditions (section 254(8)). Within seven days of issuing a permit, the Authority would submit a copy of the public notice and a copy of the permit to a public registry (section 254(11)).

5.4 Appeal

An administrative appeals process could be instituted as part of the access determination procedure. Appeals could be handled through existing administrative procedures.

The Philippines Executive Order provides for appeal. Individual agency decisions to approve, disapprove or rescind a research agreement can be appealed to the office of the Philippines president within 30 days of the decision's receipt (section 9, Executive Order; section 13.1, Implementation Regulations). Recourse to the courts can be sought after all administrative remedies have been exhausted.

The Andean Pact Decision does not create a right of appeal. Denial of the access application is done so without prejudice, but any right of appeal is pursuant to a member state's national legislation (article 30).

6.0 Export Controls

Export controls are a typical feature of the existing and proposed access legislation examined. For example, the enabling legislation either proposed or finalized in The Gambia (section 35(2)(a)), Kenya (section 38(2)(b)), Malawi (section 36(2)(a)) and Uganda (section 45(2)(b)) directs a competent authority to make regulations or guidelines on measures for regulating the export of "germplasm", though germplasm is not defined.

The proposed Eritrean legislation would require a certificate of origin to be issued prior to export (article 51(b)). The certificate of origin would be issued by the competent national authority when compliance monitoring, undertaken in cooperation with local authorities, indicates that some of the access permit's conditions have been fulfilled (article 51(a)). The details of this process would probably be elaborated in subsequent regulations designed to implement the law's section on access to genetic resources.

The export control provisions of the draft Fijian legislation seem to be more elaborate than the provisions to gain access for bioprospecting purposes. Before the bioprospector could export any specimen harvested pursuant to a bioprospecting permit, an application would need to be made for removal and export (section 254(12)(a)).

The application would specify (1) the number and size of the specimen exported and the harvesting location (2) the

manner of export and (3) the impact removal and export would have on other species (section 254(12)(b)(i-iii)). As it considers the application, the Conservation and National Parks Authority would inspect the specimens collected to verify compliance with any authority granted (section 254(14)(a)) and CITES (section 254(14)(b)).

The Authority then decides whether to refuse permission to export or issues an export permit (section 254(13)). The approval of the application would be contingent upon the applicant submitting a legally binding agreement to (1) report regularly on any subsequent scientific research flowing from the bioprospecting activity, (2) notify the Authority when any patents or copyrights are sought or registered and (3) negotiate royalty arrangements with the resource owner upon registry of any patent (section 254(15)(a)(b) and (c)). Financial security to warrant performance could be required by the Authority.

The Andean Pact Decision does not have any explicit provisions on export. The movement of biological resources between the Andean Pact's member states is allowed provided no use of genetic resources is contemplated (article 14). Transfer of genetic resources between member states therefore appears to be prohibited. Sanitary certification for biological resources pursuant to Pact Decision 378 must include the new wording "use as genetic resources is not authorized" (complementary provision 4).

The Philippines Executive Order recognizes the importance of export controls, but does not explicitly ban the export of genetic resources. Instead, without referring to the customs agency, the Inter-Agency Committee is required to deputize and train "appropriate agencies" to ensure that genetic resources are only exported pursuant to valid research agreements (section 7(d)).

The Implementing Regulations also refer to export in the context of the minimum terms and conditions of research agreements. For example, wild animals collected and/or exported are to be free from disease (section 8.1(1)). Exports will be subject to strict quarantine and existing CITES rules (section 8.1(5). Plant germplasm exports need to comply with the Philippine Seed Industry Development Act (1992) (section 8.1(6)). Transport of genetic resources is subject to a transport or postal clearance permit (section 8.1(7)).

7.0 Breaches of the Access Legislation and the Access Agreement

The prior informed consent requirement will be difficult to enforce primarily because of the nature of genetic resources particularly their wide availability, ease of dissemination and replication. It will be impossible to ensure enforcement of prior informed consent for all genetic resource transactions because of the sheer number which can and will take place. The threat of sanctions and penalties for breaches of the access legislation, and recision, modification or suspension of the agreement when its terms are breached, can help bring credibility to the access determination process and increase the likelihood that the access agreement will be honoured.

In the Andean Pact, persons undertaking "access activities" without the required authorization are subject to unspecified sanctions (article 46). Unpermitted transactions involving derivatives, synthesized products or associated knowledge are also grounds for sanctions. Administrative sanctions such as fines, confiscation and barring the violator from applying for access in the future are all possible according to each member state's national legislation (article 47). The competent national authority can apply sanctions in addition to suspending, cancelling or nullifying an access contract, require payment for damage to biological diversity and impose any civil or criminal sanctions which may apply (article 47).

The proposed Fijian legislation would give the Conservation and National Parks Authority the power to issue directives to cease bioprospecting activities, recover samples taken and institute financial proceedings to recover any financial security which may have been deposited if the permit issued is not strictly complied with (section 254(16)(a)-(b)). Criminal and financial penalties for a person's failure to comply with the Conservation and National Park Authority's directives, requirements or conditions can be imposed (section 254(17)).

Financial penalties will range from US $10,000 to US $20,000 (section 279). Liability assessment or the settlement of other disputes will be assigned to a proposed sustainable development tribunal (section 254(18)).

The Philippines Executive Order provides for criminal penalties when activities are undertaken in violation of it (section 10). Prosecution will be under existing criminal laws including the provisions of the National Integrated Protected Areas System Act (1992) and the Revised Forestry Code (section 14.1, Implementation Regulations). For legal persons, such as corporations, liability extends to the corporate head, president or general manager (section 14.2, Implementation Regulations).

The Executive Order allows the government to unilaterally terminate the research agreement when any of the agreement's terms have been violated (section 5(f)). The research agreement can also be revoked for reasons of public interest or welfare. Non-compliance will cause the government to confiscate the collected biological and genetic specimens (section 14.3, Implementation Regulations).

The commercial research agreement holder's performance, compensation and ecological rehabilitation bond, provided as a condition of the research agreement, will be forfeited in the event of non-compliance. In addition to any other administrative sanctions, a perpetual ban on future bioprospecting within the Philippines will be imposed. The violation will also be published in the national and inter-

national media and the Inter-Agency Committee will notify intergovernmental organizations.

The Implementation Regulations also have specific provisions on the research agreement's rescission (section 9). For example, after a prior informed consent certificate has been obtained and the research agreement enters into force, subsequent rescission of the certificate will not be grounds for rescinding the agreement (section 9.1). Exceptions are made, however, when the agreement was obtained fraudulently, the right of indigenous peoples to traditionally use biological resources is impaired or the public interest or welfare would be violated (section 9.1(1-3). Either party's violation of the agreement's terms are grounds for rescission (section 9.2). The principal associated with the agreement can apply for rescission in cases of bankruptcy, force majeure or security problems (section 9.3).

The South Korean National Environmental Preservation Act (1991, as amended in 1994) also has particularly strong provisions on sanctions and penalties for commercial, medical and scientific use of biological resources without prior approval. Persons may be imprisoned for up to one year or fined up to 3 million Won (article 39(3)).

8.0 Identification and Monitoring

The Convention's identification and monitoring provisions are viewed as self-executing.[11] However, some access legislation specifically addresses either identification, monitoring or both.

Under Andean Pact Decision 391 each member state's competent national authority is to maintain a national inventory of genetic resources and derivative products (article 50(n)). Research participation, supporting research and capacity building are all provided for by the Decision (article 17). Explicit provisions on monitoring genetic resources for conservation purposes are not provided, but the competent national authorities are to supervise and monitor the conditions of the access contract (article 50(g)) and "to supervise the conservation status of biological resources which contain genetic resources" (article 50(l)).

The Fijian Draft Sustainable Development Bill does not mention inventories or research. A permit application is to state whether an environmental monitoring or management plan is needed (section 254(4)(b)(ix)). A permit issued would stipulate conditions on monitoring (section 254(9)(c)(iv)).

The Philippines legislation provides a comprehensive example. A Philippine State policy is "to promote the development of local capability in science and technology" in selected areas (section 1, Executive Order).

In the Philippines, the Inter-Agency Committee is to develop a conceptual framework for using research agreements to significantly increase knowledge on Philippine biodiversity (section 7(h), Executive Order). Research participation and other related issues are also to be addressed by the Committee.

9.0 *In-situ* Conservation, Sustainable Use and Environmental Impact Assessment

Collecting activities may threaten biological diversity at the genetic, taxonomic and ecosystem levels. Existing legislation reflects varying degrees of conservation awareness. The Andean Pact Decision is perhaps most comprehensive.

It allows member states to adopt precautionary measures to slow genetic erosion, environmental degradation and natural resource degradation (article 13). Lack of scientific certainty is not to be used as a reason for postponing effective measures. The threshold is "the danger of grave and irreversible damage" (article 13).

The applicant can be compelled to comply with existing environmental provisions in a member state (article 31) which could include EIA for example. The competent national authorities are directed to consider environmental issues in the process leading up to a determination as to whether the access application will be accepted for further review (article 31).

The Common Regime amplifies on the precautionary principle by allowing member states to establish partial or total limitations on access (article 45). Measures taken must be provided "by means of an explicit legal norm" (article 45). They include instances where (1) the species, sub-species variety or race is endemic, rare or threatened with extinction; (2) the access activity could threaten a vulnerable or fragile ecosystem; (3) impacts on ecosystems are undesirable or difficult to control; or (4) access threatens genetic erosion. In addition, competent national authorities are entrusted with supervising the conservation status of biological resources targeted for their genetic resources (article 50(d)). As a group, the member states are to design and implement joint genetic resource conservation programmes (complementary provision 1).

In Fiji, the biodiversity prospecting system developed by the Authority is to ensure that research and exploitation do not do ecological harm and that taking biological samples "does not cause any undesirable impact upon Fiji's biodiversity" (section 254(1)). The permit application requires an accurate description of the biodiversity prospecting activity, a description of the area where it will occur, species sought, quantities harvested, sample and harvest methods, storage methods and a statement on ecological impact (section 254(4)).

Acervo ISA

Comments from the public and other agencies will be solicited (section 254(5)), a monitoring programme will be identified and an auditing system will be established prior to a permit's issuance (section 254(6)). Based on the information it has, the Authority's determination will be either to issue or deny the permit or refer the matter for an EIA pursuant to another section in the Draft Sustainable Development Bill. Permits issued can have conservation-related conditions (section 254(9)(c)).

An application for an export permit also requires conservation related information including "the impact of the removal and export on other species of flora and fauna and the biodiversity of the local, national and regional habitat" (section 254(12). If the materials have already been collected, the usefulness of this information is unclear, unless the export permit application is made concurrently at the time the prospecting permit application is made or prior to undertaking biodiversity prospecting activity itself. Such a requirement might be useful for on-going activities. Prior to an export permit decision verification with the conditions of any authority granted and CITES compliance is undertaken (section 254(14)).

In the Philippines, the State's interest in conservation provides one of the bases for regulating bioprospecting activities (preambular paragraph 2, Executive Order). The State's policy is to regulate bioprospecting of biological and genetic resources to ensure that they are protected and conserved (section 1, Executive Order)

Research agreements are to specify a limit on samples (section 5(a), Executive Order). An approved list and amount of samples is to be drawn-up by the Inter-Agency Committee (section 10.2.c) and strictly adhered to by the permittee. A requisite for research agreements provides that prospecting will not directly or indirectly harm biological diversity and the biological balance of the inhabitants of the targeted site (appendix B, requisite b, Executive Order).

Prospecting in protected areas must comply with the Philippines National Integrated Protected Areas System Act and a protected area's management plan (appendix B, requisite c, Executive Order). Finally, activities must comply with all Philippine environmental laws, including those on EIA where necessary (appendix B, requisite d, Executive Order). Exports are also to comply with CITES rules (section 8.1(5), Implementation Rules).

10.0 Financial Issues

There are at least two financial issues which a State will need to address as it develops its approach to regulating access to genetic resources: (1) financial resources to set-up and run the regulatory programme and (2) creating mechanisms into and from which can flow money generated from the use of genetic resources.

Under the complementary provisions of Decision 391, the member states are to create or strengthen funds or other financial mechanisms for benefits derived from genetic resources (complementary provision 1). This is to be pursuant to national legislation. Additionally, the member states as a group will analyze the "feasibility and convenience" of creating an Andean Fund to conserve genetic resources. Early in the consultative process leading up to Decision 391 it was proposed that a portion of the financial flow generated from species common to two or more member states could be diverted into a regional fund to support regional activities regardless of where they were collected from.[19]

In the Philippines, financial resources for the Inter-Agency Committee can come from a number of sources. The most important appears to be an annual appropriation from each of the participating governmental agencies (section 16.1, Implementation Regulations). The Inter-Agency Committee can also be supported by nominal application processing fees (section 6.1.5, Implementation Regulations). Fees depend on the nationality of the applicant.

In addition, "bioprospecting fees" from research agreements can also support the Committee (section 16.1, Implementation Regulations). The bioprospecting fee is determined by the Inter-Agency Committee. It is to be paid by the principal when a research agreement is approved (section 8.15, Implementation Regulations). The Implementation Regulations do not provide criteria for determining the amount of the bioprospecting fee assessed.

11.0 Conclusions

The emerging legal frameworks on access to genetic resources are bold first steps to implement article 15 of the Convention on Biological Diversity. They are remarkable in many ways. For example, they represent the first tangible legislative evidence that the Convention on Biological Diversity is actually being implemented. The flurry of activity around the world, in mostly developing countries, is impressive especially since access and benefit-sharing are complex issues; few countries - developed or developing - have ever addressed them before.

Also remarkable are the participatory planning and legislative processes that have been spawned. In many cases, legislation was or is being developed in consultation with a variety of interest groups, including indigenous and local communities. Thorny issues such as genetic resources ownership naturally must be addressed. Another important accomplishment is how some of the legislation examined promotes transparent participatory decision-making processes to determine access to genetic resources and ensure benefit-sharing. Local level benefit-sharing is also being promoted.

The outstanding issue now is how these legislative frameworks will work in practice. There is little experience and a lot of anxiety. Will future benefits generated outweigh the heavy transaction costs for both provider States and those seeking access? Is existing legislation too confusing or burdensome? Will it actually dissuade industry and researchers from seeking access in some countries? There are no answers to these questions, but simplicity of regulatory process must be the guiding principle for access legislation, while still ensuring a country's benefit-sharing interests.[20]

Early access legislation may not be perfect, but it should be kept in mind that in many cases it is a defensive response to a political and industrial climate which places all of the burden of ensuring benefits on the providing State. While "perfect" legislation is certainly desirable, many times "decision-makers have to take preliminary action in the common interest in the face of...uncertainty and...review and improve later".[21] As States develop their approaches to implementing article 15, access legislation will probably need to evolve and be refined over time to keep pace with new developments, needs and demands.

The challenge is to sustain the momentum generated by the States providing genetic resources as they strive to enact and implement access legislation. A firm foundation for more equitable *burden*-sharing between provider and user States needs to be established to ensure PIC and MATs and, ultimately, benefit-sharing for genetic resources accessed. To foster this, the COP could undertake a study on possible legislative, administrative or policy measures which user States could consider implementing to support steps taken by provider States to regulate access to genetic resources and ensure benefit-sharing.[22] The study could catalyse a process within the COP to examine the issue further. In so doing, good-will be generated to find a proper balance between the rights and obligations of Parties to facilitate access to genetic resources (article 15(2)) and ensure benefit-sharing (article 15(7)).

Endnotes

1 Conference of the Parties to the Convention on Biological Diversity (COP) 1996. Access to Genetic Resources, Decision III/15, in: Report of the Third Meeting of the Conference of the Parties to the Convention on Biological Diversity (U.N. Doc. UNEP/CBD/COP/3/38).

2 For a more detailed treatment of emerging access regimes see Glowka L. (in press). *A Legislative Guide to Implementing Article 15 of the Convention on Biological Diversity* (IUCN, Gland).

3 Glowka L., Burhenne-Guilmin F. and Synge H. 1994. *A Guide to the Convention on Biological Diversity* (IUCN, Gland).

4 Correa C. M. 1994. Sovereign and Property Rights Over Plant Genetic Resources study commissioned by the Food and Agriculture Organization of the United Nations for the First Extraordinary Session of the FAO Commission on Plant Genetic Resources, Rome, 7-11 November 1994.

5 Correa C. M. 1994. Sovereign and Property Rights Over Plant Genetic Resources study commissioned by the Food and Agriculture Organization of the United Nations for the First Extraordinary Session of the FAO Commission on Plant Genetic Resources, Rome, 7-11 November 1994; Feinsilver J. 1995. Biodiversity Prospecting: Prospects and Realities, in: Zakri, A. H. (ed.). 1995. *Prospects in Biodiversity Prospecting* (Genetics Society of Malaysia, Selangor, Malaysia). Stone C. D. 1995. What To Do About Biodiversity: Properly Rights, Public Goods and the Earth's Biological Riches in: 68 Southern California Law Review 577. Swanson T. 1995. Diversity and Sustainability: Evolution, Information and Institutions, in: Swanson (cd.) 1995. *Intellectual Property Rights and Biodiversity Conservation: An Interdisciplinary Analysis of the Values of Medicinal Plants* (Cambridge University Press, Cambridge). Vogel J. H. 1994. *Genes for Sale: Privatization as a Conservation Policy* (Oxford University Press, New York and Oxford).

6 Ruiz M. M. 1997. Personal Communication with Manuel Ruiz, Peruvian Society for Environmental Law, Lima, 27 February 1997.

7 Conference of the Parties to the Convention on Biological Diversity (COP) 1995. Access to Genetic Resources, Decision II/11, in: Report of the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity (U.N. Doc. UNEP/CBD/COP/2/19).

8 Milstein M. 1994. Yellowstone Managers Eye Profits From Hot Microbes, in: 270 Science 226.

9 Lindstrom B. 1996. Personal Communication with Bob Lindstrom, Yellowstone National Park, Yellowstone, 6 May 1996.

10 Rosell M. (forthcoming 1997). Access to Genetic Resources: A Critical Approach to Decision 391 'Common Regime on Access to Genetic Resources' of the Commission of the Cartagena Agreement, in: Review of European Community and International Environmental Law vol._.

11 IUCN 1994. Toward a Legal Framework to Regulate Access to Genetic Resources In the Andean Pact, Technical Legal Report Prepared by the IUCN Environmental Law Centre for the Board of the Board of the Cartagena Accord in collaboration with the Peruvian Society for Environmental Law (IUCN, Bonn).

12 see for example *Id.* at 10.

13 La Vina A., Caleda M. J. and Baylon L. L. (eds). 1997. *Regulating Access to Biological and Genetic Resources in the Philippines: A Manual on the Implementation of EO 247* (Foundation for Philippine Environment, Manila and World Resources Institute, Washington, DC).

14 Smith R. 1996. Personal Communication with Reed Smith, Rainforest Alliance, New York, 21 August 1996.
15 *Id.*
16 ten Kate K. 1997. The Common Regime on Access to Genetic Resources in the Andean Pact, in: Biopolicy, vol. 2, paper 6 (PY97006) Online Journal - URL: http://www.bdt.org.br/bioline/py (Bioline Publications).
17 *Id.*
18 de Klemm C. 1993. *Biological Diversity Conservation and the Law: Legal Mechanisms for Conserving Species and Ecosystems* (IUCN, Gland).
19 *Id.* at note 11.
20 *Id.* at note 3.
21 Burhenne W. E. 1994. Forward, in: Sanchez V. and Juma C. (eds.). 1994. *Biodiplomacy: Genetic Resources and International Relations* (ACTS Press, Nairobi).
22 Hendrickx F., Koester V. and Prip C. 1993. The Convention on Biological Diversity-Access to Genetic Resources: A Legal Analysis. 23 Environmental Policy and Law 250; Glowka L. *et al.* 1994. *A Guide to the Convention on Biological Diversity* (IUCN, Gland); Tobin B. 1996. Putting the Commercial Cart Before the Cultural Horse: A Study of the International Cooperative Biodiversity Group Program in Peru, in: Zerner C. (forthcoming 1997). *People, Plants and Justice* (Rainforest Alliance, New York).

Acervo FSA

IUCN Environmental Law Centre
Adenauerallee 214
D-53113 Bonn, Germany
Telephone: 49 228/2692 231
Telefax: 49 228/2692 250
Email: iucn-elc@wunsch.com

IUCN Headquarters
Rue Mauverney 28
CH-1196 Gland, Switzerland
Telephone: 41 22/9990 001
Telefax: 41 22/9990 002
Email: mail@hq.iucn.org

IUCN
The World Conservation Union