



**IDENTIFICATION AND ASSESSMENT OF  
THE ACCESS TO GENETIC RESOURCES  
AND BENEFIT SHARING (ABS)  
NATIONAL AND REGIONAL LAWS AND  
RECOMMENDATION OF EXAMPLES OF  
BEST ABS LAWS**

7 JUNE 2010



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#### **World Future Council**

Mexikoring 29, 22997 Hamburg, Germany.

Tel: +49 40 30 70 914-20/fax: +49 40 30 70 914-14

Email [Info@worldfuturecouncil.org](mailto:Info@worldfuturecouncil.org)/web [www.worldfuturecouncil.org](http://www.worldfuturecouncil.org)

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#### **Centre for International Sustainable Development Law**

3661 Peel Street, McGill Law Faculty, Montreal, Quebec H3A 1X1, Canada. Tel: 001 514 398 8918/fax 001 514 398 8197

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

#### **Authors**

Prof. Jorge Cabrera Medaglia (CISDL Biodiversity Law Lead Council) and Olivier Rukundo (CISDL Senior Research Fellow Biodiversity Law Team)<sup>1</sup>

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<sup>1</sup> The views expressed in this paper are those of the authors.

## **ACRONYMS**

**ABS**

**BL**

**PIC**

**CBD**

**EIA**

**MAT**

**MTA**

**AGREEMENT**

**IPR**

**TK**

**ACCESS AND BENEFIT SHARING**

**BIODIVERSITY LAW**

**PRIOR INFORMED CONSENT**

**CONVENTION ON BIOLOGICAL**

**DIVERSITY**

**ENVIRONMENTAL IMPACT**

**MUTUALLY AGREED TERMS**

**MATERIAL TRANSFER**

**INTELECTUAL PROPERTY RIGHTS**

**TRADITIONAL KNOWLEDGE**

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## **I. INTRODUCTION/TERMS OF REFERENCE.**

This paper provides a legal research on the laws on access to genetic resources and benefit sharing, covering the following aspects:

- \* Review of different existing laws on access and benefit sharing (national and regional) including Ethiopian, Costa Rican, Norwegian and other laws.
- \* Review of existing literatures on ABS case studies (IUCN, CISDL and others study and reference material on ABS).
- \* Comparative survey of the best ABS national or regional legislation (including implementation).
- \* Evaluation of best access and benefit sharing law to be presented as Future Policy Award at the upcoming 10<sup>th</sup> Conference of the Parties to the CBD where a protocol on access and benefit sharing could be adopted.

## **II. BRIEF REFLECTIONS CONCERNING THE CONTENT AND IMPLEMENTATION OF ABS LAWS.**

The Convention on Biological Diversity (CBD) has as its main objectives the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of the benefits derived from the utilisation to genetic resources. The Convention establishes as one of its objectives the fair and equitable sharing of benefits derived from the access to and use of biodiversity, thus regulating the access to these resources (and associated knowledge) and subjecting it to the laws of the country, and to a fair and equitable sharing of the benefits with the country providing the genetic resources<sup>2</sup>.

Since the Convention's entry into effect on December the 29<sup>th</sup> of 1993, one of the most controversial regulatory and public policy issues both in the international and national context, has been that of access to genetic resources and the equitable sharing of the benefits( ABS) arising thereof. Since the promulgation of the Philippines Executive Order in 1995, the first specific legislation centred on the regulation of ABS and

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<sup>2</sup> Arts. 15, 16, and 19.

the first regional framework, Decision 391 “The Common Regime for Access to Genetic Resources” of the Andean Community, numerous studies, seminars, publications, laws and drafts laws have been produced on this subject.

To this date different studies and researches on the efforts of promulgating and implementing legal frameworks on access and benefit sharing at the national and international levels, have been completed.<sup>3</sup> A complete list of the studies revised is provided in the references section of this paper. These studies can, on the basis on the approaches adopted therein, be grouped into four main broad thematic categories:

1. The design of the laws and regulations.
2. The participation of stakeholders in the national or regional processes of drafting ABS laws and policies and eventually, in the negotiation of contractual agreements and other arrangements relative to ABS.
3. Contracts, agreements and other arrangements on ABS
4. Aspects relating to the implementation of the legal provisions.

Before undertaking detailed analysis of the selected ABS laws, it is useful to provide a brief overview of the status of implementation of ABS legislation and measures to better situate the overall context. Although, scant research and very few analytic studies have been done on the state of implementation and of ABS at the national level, it is widely recognized that the level of national ABS implementation is low and often incomplete.<sup>4</sup>

Normand offers the following description:

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<sup>3</sup> For example, even though the scope, methodology, objectives and geographic range of the studies vary, the following documents can be mentioned to guide the design of ABS legislation: Glowka, et al, 1994; Glowka, 1998; Mugabe, et al (eds) 1997. From other perspectives it is also possible to mention: Sheiler, and Dutfield 2001; Bass and Ruiz ( eds), 2000; Caillaux, Ruiz, and Tobin, 1999; Swiderska, 2001; Columbia University School of International Affairs, 1999; Crucible Group II 2001; Secretariat of the Convention on Biological Diversity, Case studies on benefit sharing arrangements, distributed at the Fourth meeting of the Conference of the Parties, Bratislava, 4-15 May, 1998; UNEP-WIPO, 2000; Laird, S.(ed), 2002; and Svarstad, H., and Dhillion, S. ( eds), 2000; Gatforth et al ( 2005); Carrizosa, et al 2004; Cabrera, 2004; IUCN ABS Project books, particularly Cabrera and López, 2007 and Tvet and Young 2007; Dross and Wolff, 2005; Nnadozie et al 2003; Kamau and Winter 2009; UNU, 2008; among others.

<sup>4</sup> Furthermore, experience and documentation over on such implementation is relatively scarce. The information available indicates that the development of national measures has proven difficult for many countries due to a number of factors including a lack of technical expertise, budgetary constraints, weak government structures, and political support, local social conflict and conflict over ownership of genetic resources, see CBD analysis of Existing National, Regional and International Legal Instruments Relating to Access and Benefit-Sharing and Experience Gained in their Implementation, Including Identification of Gaps. Note by the Executive Secretary. UNEP/CBD/WG-ABS/3/2, Convention on Biological Diversity, Montreal, 2005.

"...countries are at different levels of implementation of access and benefit sharing and have adopted different approaches to regulating access and benefit sharing, reflecting their national administrative structures, priorities cultural and social specificities. While certain Countries have only adopted one measure, generally legislation, others have adopted a package of measures, including for example, a national strategy, legislation or regulations or guidelines. A number of countries are still in the process of developing their national systems and therefore the package is often incomplete. In addition, the national procedures and structures are diverse. For example some Countries have different levels of government responsible for regulating ABS, national/ federal and state/provincial level.

A majority of Countries, with national measures included on the CBD database can be divided into three categories:

The first category includes Countries which refer to ABS in their national biodiversity strategy or their environmental or biodiversity legislation but have not yet regulated ABS in any detail. These measures generally provide for the developing of ABS regulations and include some general specifications regarding elements to be addressed.

The second category includes Countries that have a biodiversity or environmental law with some general provisions on ABS or access to biological resources, which may include a provision for the establishment of a regulation on ABS.

The Third category is those which have address ABS in greater detail. They have established competent national authorities, procedures for prior informed consent, procedures for the development of mutually agreed terms, including benefit sharing and compliance measures. The issue of IPR is also generally addressed in various manners and in varying degrees of detail."

With regard the main features of the ABS measures, the provisions vary from one national system to another, although some general underlying elements may be highlighted<sup>5</sup>:

- Competent National Authorities: in some cases the Competent National Authority is an organization already in existence, while in other cases a new organization is created by the ABS measure
- Prior Informed Consent: In each Country some type of application for access has to be made in order to obtain access to genetic resources. These provisions also provide indications regarding specific information on the application should contain and the procedure leading to the approval or refusal. The majority of measures also

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<sup>5</sup> Normand, *op cit.*

require the PIC of the relevant authority/resource provider in the geographical area where the GR are to be accessed. Specificities of some measures include different requirements for access depending on the type of applicant and different requirements depending on whether access is granted for commercial and or non commercial purposes

- **Mutually Agreed Terms:** a majority of existing national systems provide that mutually agreed terms are to be set out in an agreement. Some measures also provide for different type of agreements depending on whether the genetic resources are being accessed for research or commercial purposes. The measures generally provide that the agreement is also to be approved by the National Competent Authority. Measures generally provide for BS with the competent authority or with indigenous peoples and local communities or resources provider and in most cases for both. Indications regarding the types of benefits to be shared vary depending on the measures.
- **Compliance measures:** the measures examined generally include provisions for compliance. Although few address monitoring and enforcement to ensure compliance with ABS measures, they generally provide penalties, sanctions for infractions or offences, such as infractions to the provisions of the legislation, regulation or guideline. These sanctions include fines, seizure of samples, revocation and cancellation of the permission to access, revocation of the agreement, a ban on future bioprospecting and imprisonment.”

She concludes:

“Developments are currently taking place in a number of countries, through national initiatives and capacity building projects, however there is still a lack of relevant awareness and capacity to address access and benefit sharing among relevant actors, in both developed and developing Countries.”

Despite the foregoing, it should be indicated that some countries have been able to apply the legislation -at least in a limited form-.

In order to identify the relevant ABS laws which deserves further scrutiny the consultants developed a set of basic as follows<sup>6</sup>:

- **Level of detail and guidance of the ABS laws:** some of these laws are general in nature ( just setting basic ABS principles) and for that reason they don't provide proper guidance to the different

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<sup>6</sup> Not necessarily the selected abs laws must meet all these criteria but at least one or more of them.

stakeholders; requiring- in practice- additional legal regulations to be properly implemented.

**Legal certainty and clarity (Functionality):** some of the existent measures do not provide enough legal certainty about the scope and requirements of the law or lack of sufficient clarity. Annex I presents the relevant characteristics of functional ABS laws.

- **Level of implementation:** It was said before that many laws have been scarcely implemented for different reasons. One of the criteria used is that there is an adequate implementation of the law or at least a process towards that end, including specific cases in which the abs laws have been applied and interpreted and ABS contracts or permits have been approved.
- **Relevance of the ABS Law for the developing or developed country and the importance of the country in terms of its biodiversity or in terms of its capabilities to support the implementation of ABS Laws in other jurisdictions ( countries of origin of genetic resources).** ABS laws can provide an incentive for biodiversity (including cultural diversity) conservation. Therefore the richness of the country in biodiversity resources of associated traditional knowledge was also considered. In the cases of developed countries an additional criteria used is the capacity of the country to support compliance with national ABS legislation of foreign countries through the enactment of “user measures” such as disclosure or origin in IPR applications and others.
- **Relevance of the ABS Laws/practices for other countries.** If the laws under analysis could be used as a model for the development of other abs measures or could provide valuable lessons to the international and regional legal community.
- **Innovative approaches.** It means to what extent the norms contains innovative approaches or mechanisms, which could be useful and replicated in other legislations.

The consultants reviewed different sources of information in order to select the appropriate ABS laws. The complete references are provided below including ABS data bases; reports and studies on abs laws (design and implementation), CBD documents and papers; book chapters, etc.

After this preliminary review and based on the criteria developed the following laws were selected<sup>7</sup>:

a) Brazil

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<sup>7</sup> Certainly other relevant ABS laws also exist such as the State (Queensland, the Northern Territory) and Federal ABS legal framework of Australia.

- b) Costa Rica
- c) Ethiopia
- d) Kenya
- e) Norway
- f) South Africa.

The study focuses on the above national instruments, because they are thought to provide the best combination of the different criteria identified above.

### **III. SELECTED ABS LAWS FOR FURTHER ANALYSIS.**

#### **BRAZIL**

##### **1. Summary of relevant content, including innovative approaches.<sup>8</sup>**

Brazil was one of the first mega-diverse countries to enact national legislation aimed at implementing the CBD at the national level. Provisional Measure No. 2186-16 of 2001 regulates access to genetic resources, to associated TK, benefit sharing derived from their use, and the transfer of technology for the conservation and use of biodiversity.

There is a complex legal system in place on ABS and the protection of TK. Since 1994, there have been several initiatives to regulate access to Brazilian genetic resources but no law has yet been approved. Currently, the different proposals are being evaluated by commissions under the Congress. In the meantime, the States of Amapa and Acre have passed their own laws regulating access to genetic resources.

The publication in June 2000 of the project between Bioamazonia and Novartis to access, research and develop the genetic heritage of Brazil

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<sup>8</sup> See, Kleba, John, A socio-legal inquiry into the protection of disseminated traditional knowledge-Learning From Brazilian Cases; Santilli, Juliana, Brazil's experience in implementing its ABS Regimen-Suggestions for Reform and relationship with the International Treaty on Plant Genetic Resources both in Kamau and Winter (eds), *Genetic Resources, traditional knowledge and the Law: solutions for access to genetic resources and benefit sharing*, Earthscan, 2009 and also Policies, measures and experiences regarding intellectual property and genetic resources: submission by Brazil to the Intergovernmental Committee on Intellectual Property Rights and Genetic Resources; Traditional Knowledge and Folklore, document wipo/grtkf/ic/16/inf/9, February 19, 2010.

provoked very strong opposition from some sectors. To mitigate this situation, the federal government passed a Provisional Measure addressing elements involved in access to genetic resources.

The Brazilian legal framework enshrining the principles of prior informed consent – PIC, mutually agreed terms – MAT, and access and benefit sharing – ABS includes the following pieces of legislation: a) Law 9.279/96 “Industrial Property Law”; b) Provisional Measure 2.186-16, of 2001; c) decisions by the Industrial Property National Institute (INPI) and by the Managing Council of the Genetic Patrimony (CGEN). The executive bodies of the system are the INPI itself - which is the Brazilian patent office - as well as the CGEN. The Measure establishes a Council for managing Brazilian genetic heritage, *Conselho de Gestao do Patrimonio Genetico*. The Council’s main tasks are to implement national policies on access to genetic resources and traditional knowledge, and develop technical and administrative activities for providing or denying access.

The CGEN in turn is a collective inter-ministerial body that holds monthly meetings. It is chaired by the Ministry of Environment. Its membership includes representatives of other 19 bodies or entities of the Federal Administration, all of them holding the right to vote: Ministry of Environment; Ministry of Science and Technology; Ministry of Health; Ministry of Justice; Ministry of Agriculture, Livestock and Supply; Ministry of Defense; Ministry of Culture; Ministry of External Relations; Ministry of Development, Industry and Foreign Trade; Brazilian Institute for the Environment and Renewable Natural Resources (IBAMA); Research Institute Botanical Garden of Rio de Janeiro; National Council for Scientific and Technological Development (CNPq); National Institute for Amazon Research; Emílio Goeldi Museum of Pará; Brazilian Agricultural Research Corporation (Embrapa); Oswaldo Cruz Foundation; National Foundation for Indigenous People (Funai); INPI and Palmares Cultural Foundation. INPI, therefore, takes part in all CGEN deliberations.

Other than these regular members, some representatives of civil society hold a standing invitation to CGEN meetings with the right to speak, such as the Brazilian Association of Biotechnology Companies (ABRABI) and the Brazilian Society for the Advancement of Science (SBPC).

Access to the genetic heritage requires prior authorization from the Council.<sup>9</sup> Depending where the resources are expected to be collected

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<sup>9</sup> Researchers wishing to have access to the national genetic patrimony or associated traditional knowledge with a view to conducting scientific research, technology development or bio-prospection must request prior authorization to CGEN or to a certified agent. Whenever access to the national genetic patrimony results in the filing of a patent request, applicant must notify to the INPI the number of the corresponding authorization as well as the origin of the genetic patrimony or associated traditional knowledge. In the cases where either a) access occurred prior to the coming into force of Provisional Measure 2116-16 (June, 30<sup>th</sup> 2000) or b) access to

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the national genetic patrimony did not occur; applicants must simply declare to INPI that access did not take place.

**Procedure before CGEN.** According to the applicable national legislation, researchers wishing to be granted access to genetic resources and/or associated traditional knowledge must present to the CGEN a list of documents among which are (i) a research project; (ii) proof of experience in research projects; (iii) proof of technical qualification; (iv) information regarding the destination of the samples; as well as (v) "a contract on the utilization of the genetic patrimony and sharing of benefits".

Contracts referred to under item (v) must contain an explicit provision regarding a proposed scheme for sharing of benefits. This may take different forms, such as profit sharing; payment of royalties; access to and transfer of technology; licensing of products or processes; and human resources training.

Applications are analyzed in accordance with the provisions of decisions n° 34 (associated traditional knowledge) and 96 (access to genetic patrimony) of the CGEN. The evaluation process is divided into two phases: (i) a preliminary analysis; and (ii) final evaluation. In both cases, after the applicant has filed the request, the Executive-Secretariat of CGEB shall conduct a preliminary evaluation in 30 days to ascertain that all requisites mentioned under MP 2.286-16/2001 and Decree 3945/2001 are met. When applicants have failed to fulfill any legal requisites, a delay is granted (120 days to applications under traditional knowledge provisions; and 180 to access to genetic resources provisions) to allow them to comply with the relevant provisions before the application is dismissed.

If the application fulfills all legal requisites for presentation it will be subjected to the preliminary analysis (phase "i") to be undertaken by the Evaluation Committee of Applications (CAP). That Committee is made up by two or more "rapporteurs" "ad hoc" (anthropologists, biologists, chemists, etc.) who are experts in the subject. Experts' reports serve as a basis for the final evaluation of the Council. No more than 70 days must elapse between the preliminary analysis and the issuance of the reports. The presentation of the reports is the last step in the "preliminary analysis" phase.

The preliminary phase may take up to 4 months approximately if the applicant does not present additional information or recourse during the process. If that happens, the preliminary phase may take up to 11 months approximately (applicants have a maximum of seven months available for presenting additional pieces of information or recourse).

The final evaluation phase initiates with the appointment of one counselor as "rapporteur" of the process in the plenary meeting. The other counselors receive a summary of the application process prepared by the Executive Secretariat. After the report is read, all counselors deliberate on the matter and may request to withhold the relevant documentation for further analysis. In case a positive decision is taken, the Executive Secretariat will issue an access authorization.

To sum up: the "preliminary phase" and the final "evaluation phase" altogether can be concluded in less than three months when applicants provide all relevant documents required by law. The procedure before the GCEN protects moreover non-disclosed information as it provides for secrecy in analysis proceedings.

**Procedure before the INPI.** According to Resolutions 207 and 208 of INPI and 34 of CGEN, all of them enacted in April 2009, whenever a patent request is the result of an authorization of access to the national genetic patrimony such request must contain the number of the correspondent authorization. This information may be provided anytime before the beginning of the patent examination procedure.

If evidence is found that the research leading to the patent request may have accessed genetic patrimony, and the applicant did not provide information on access authorization, the competent authority will request the applicant to provide such information within 60 days. The applicant shall provide a written form with the number of the authorization or declare that there was no access to the genetic patrimony. If the applicant fails to meet this deadline the request will be dismissed (Art. 34, II, Law 9.279/96).

If authorities verify that applicants have provided false information regarding access to the genetic patrimony, other than the penal responsibility they may incur in, the sharing of benefits will necessarily be governed by Articles 26 and 30 of Provisional Measure 2.186-16. According to

(indigenous territory, protected area, private land, land indispensable for national security, or jurisdictional water, continental shelf or exclusive economic zone), different agents are called to take part in the authorization granting or denying prior informed consent (indigenous communities, competent authority within the protected area, landowner or the Brazilian maritime authority, respectively). Expeditions for accessing genetic resources must be coordinated by a national institution. Foreign institutions or persons are not allowed to develop such activities by themselves. If the access is for commercial purposes, Article 16 of the Measure establishes that the applicant, besides obtaining the authorization, must sign a contract that sets out how the benefits arising from the commercialization of the resources are to be distributed. Article 25 indicates some ways for sharing the benefits: royalties, technology transfer, free licenses to products or process, and human capacity building. The contract must include, among other elements, the resources accessed, benefit-sharing provisions, rights and obligations, intellectual property rights, contract cancellation clauses and jurisdiction in Brazil for dispute settlement. According to Chapter 8 of the Provisional Measure, non-compliance with the regulation may be punished with different types of penalties such as fines, confiscation of samples and products, suspension of the sale of products, closing down establishments, suspension or cancellation of the registry, patent, license or authorization, prohibition of contracting with the public administration, and restriction of tax incentives. The intellectual property rights (IPRs) application procedure in Brazil may work as a monitoring mechanism. Article 31 of the Provisional Measure requires that the origin of the genetic material and the associated traditional knowledge be specified when applying for IPRs for a process or product obtained using samples of components of the genetic heritage.

Provisional Measure created a legal regime based on 2 main instruments: authorization to access to GR and associated TK and benefit sharing contracts. IBAMA, the Brazilian Institute of Environment and Natural Resources is the responsible for authorizing access to GR for the purpose of scientific research with no potential for economic use and which do not involve access to associated TK. When access to GR is aimed at research with the potential for commercialization or economic use or if it involves access to associated TK, the Council is the responsible.

If access to TK held by indigenous peoples or traditional communities is involved the authorization of access depends on their previous

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Article 26, violators are subject to compensations amounting to 20% of the gross income obtained in the commercialization of the product or of the royalties obtained by violators from third parties as a result of the licensing of products, processes or of the use of technology. According to Article 30, as regulated by Decree 5.459/2005, violators are subjected to fines.

acquiescence, without which the Council can not grant authorization. When there is a prospect of commercial use, a benefit sharing agreement contract must be signed with the indigenous peoples or local communities.

The Brazilian legislation defines access to associated traditional knowledge as “acquisition of **information on individual or collective knowledge or practice** associated to the genetic heritage, from an indigenous community or local community for the purpose of scientific research, technological development or bioprospecting with a view to its industrial or other application” (article 7, V of the Medida Provisoria or MP.) The MP defines local community as a “human group, including descendants of Quilombo communities, differentiated by its cultural conditions, which is traditionally organized along successive generations and having its own customs and preserves its social and economic institutions” (article 7, III). A broader version of the concept is provided by Decree 6040/2007, which institutes the National Policy for Sustainable Development of Traditional Peoples and Communities and whose definition is identical to the draft ABS law: “traditional Peoples and Communities are culturally differentiated groups, who identify themselves as such, possess their own forms of social organization, occupy and use territories and natural resources as a condition for their cultural, social, religious, ancestral and economic reproduction, using knowledge, innovations and practices that are generated and transmitted through tradition ( article 3, I)” .

Under the current law benefit sharing contracts are only required when authorization is requested for access to GR and TK for the purposes of commercial or economic use.

Provisional measure provides authorization of access to GR for bioprospecting purposes requires the prior signing of a benefit sharing contract. A Presidential decree (6159-2007) stipulates that, if the provider agrees, the benefit-sharing contract could be drawn up and signed at a later date as long as it is prior to the development of any commercial product or patent application.

The CGEN has granted authorization of access to TK for the purpose of scientific research with the prior consent of the communities or indigenous peoples organizations. BS is required however, once a possibility of economic exploitation has been identified.

In 2006 the Council approved Resolution 21 which exempts four kinds of research and scientific activities from the need or authorization.

## **2. Evolution of the Brazilian system**

The revision of Brazil ABS legislation is still underway and several draft bills have been discussed by stakeholders. Considering the need to improve regulations, the CGEN initiated a public consultation in 2006 involving a broad participation of local and traditional communities, academic and governmental sectors. The results will be used to define the current legislation project that will replace current MP 2.186-16. The consultation process including questions related to the complex issues of TK and BS.

To improve the current system, the Brazilian Government is currently discussing a draft Presidential Decree that will establish a specific procedure to regularize accesses which occurred without prior authorization by the CGEN. Presently, administrative fines are due when access occurs without authorization. In the project under discussion, such fines would not apply or would be reduced when applicants filled voluntarily a request to regularize the research. Patents request pending the regularization of access are suspended until the publication of the Decree establishing the specific procedure before CGEN.

In 15 September 2009, the Ministry of Environment and the Ministry of Science and Technology signed a Technical Cooperation Agreement which grants the National Council for Scientific and Technological Development (CNPq) the competence to authorize access to the genetic patrimony for research purposes. The partnership between the two Ministries aims at accelerating the administrative procedures in those requests that do not involve access to associated traditional knowledge.

The Medida Provisoria is complemented with a number of Decrees (around 4 Decretos) and Resolutions (more than 15) making the legal framework very complex.<sup>10</sup>

In terms of implementation, a growing number of permits have been granted particularly for non commercial research; and also for commercial research or commercial research utilizing TK.<sup>11</sup>

## **3. Analysis**

Brazil is a Megadiverse Country and one of the richest countries of the world in terms of its biodiversity (and associated TK) and also has

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<sup>10</sup> For further information see [www.mma.gov.br/cgen](http://www.mma.gov.br/cgen).

<sup>11</sup> See [www.mma.gov.br/cgen](http://www.mma.gov.br/cgen)

developed considerable technological capacities in the field of biotechnology. The legal ABS developments in Brazil have attracted a lot of attention from outside the country. The ABS legal system has evolved over the time and covers many additional aspects through resolutions and decrees. It has been difficult to implement the original “Medida Provisoria”, making necessary to draft complementary legal measures clarifying the original terms and scope of the Medida. These changes have created some controversy and negative reactions from some sectors ( mostly the research sector and private companies) which complains about the lack of clarity on the requirements to be meet in the type of permits; the scope of the legislation; and the bureaucratic and time-consuming procedures in place. The system has improved over the last years, but the nature of the Medida (in principle a “provisional legal” solution which has lasted 9 years) and the difficulties encountered in its implementation, makes difficult to select this one as a potential candidate for the Award.

## **COSTA RICA<sup>12</sup>**

### **1. Summary of the relevant provisions of the ABS legal system, including innovative approaches.**

Costa Rica’s Biodiversity Law (BL) of May 27, 1998 applies to the components of biodiversity that are under the sovereignty of the State, as well as to the processes and activities carried out under its jurisdiction or control, independently from those effects manifested inside or outside national jurisdiction. This Law specifically regulates the use and management of the components of biodiversity as well as the associated knowledge, benefit-sharing and derived costs from this utilization.

Article 6 establishes that the biochemical and genetic properties of the components of wild or domesticated biodiversity are part of the public domain. The State authorizes the exploration, research, bioprospecting, and use of biodiversity components which constitute part of public domain, as well as the use of all genetic and biochemical resources, through access standards established in Chapter V of the Law.

Likewise, in accordance with Articles 62 and 69, all research or bioprospecting programs on the genetic or biochemical material of biodiversity that are to be carried out in Costa Rican territory require an

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<sup>12</sup> A more detailed analysis is provided in following Section.

access permit, unless they fall into one of the exceptions provided by Article 4 of the Law. These exceptions include access to human genetic resources; the non-profit exchange of genetic and biochemical resources and the traditional associated knowledge resulting from the traditional practices of indigenous peoples and local communities; and research by public universities, which had one year (until May 7, 1999) to establish their own controls and regulations for research that implies non-profit access to biodiversity. If none of these exceptions apply, all sectors (pharmaceuticals, agriculture, crop protection, biotechnology, ornamental, herbal, etc.) that wish to access genetic components are subject to the Law and must follow the access procedures. The definitions of access and bioprospecting in the Law also restrict its scope.

The access regulations apply to genetic resources in public or private lands, terrestrial or marine environments, under *ex situ* or *in situ* conditions, and in indigenous territories. In addition, the rules of indigenous people should be taken into account for access in their territories as should their *sui generis* community intellectual rights. Similarly it is recognized that communities and indigenous peoples have the right to oppose access to their resources and associated knowledge for cultural, spiritual, economic or other reasons.

The access procedure is set out in two chapters of the BL. The competent body that grants access in the first place is the Technical Office (TO) of the recently created National Biodiversity Administration Committee (CONAGEBIO) within the Ministry of Environment, Energy and Telecommunications (MEET). CONAGEBIO is entrusted with preparing access and benefit-sharing policies and can revoke the rulings of the TO on access issues. The main duty of the TO is to process, reject, and audit applications to access biodiversity; and coordinate with the Conservation Areas, the private sector, indigenous peoples, and peasant communities on actions that relate to access. It is responsible for organizing and updating a register of access applications to the components of biodiversity, *ex situ* collections, and of the natural and legal persons who work on genetic manipulations. The Technical Office is expected to collect and update regulations related to the fulfillment of treaties and guidelines on biodiversity issues.

Chapter V defines the requirements and procedures to access genetic and biochemical components and the protection of the associated knowledge. CONAGEBIO is expected to act as the mandatory consultative body for all application procedures for the protection of intellectual rights related to biodiversity. The Law regulates the basic requirements for access, which include prior informed consent (PIC), benefit-sharing, the protection of associated knowledge, and the way in

which the activities will contribute to conservation. Chapter V also establishes the legal procedures to be followed, the Registry of access rights, and the protection of confidential information.

The BL regulates the terms of access permits including their limitations and characteristics, the information required in a permit application, the authorization of agreements with individuals seeking access to genetic and biochemical components by the Technical Office, and the possibility of agreements with universities and other duly registered centers. It stipulates that up to 10 percent of the royalties must go to the conservation area, private owner, or indigenous territory, in addition to the payment of administrative expenses. The Technical Office must always be consulted in processes where IPRs are granted for components of biodiversity and its decision on these matters is binding.<sup>13</sup>

Lastly, the BL establishes the grounds for the protection of traditional, indigenous and community knowledge and for the establishment of a participatory process for the determination and registration of these *sui generis* intellectual community rights. Article 112 establishes a system of fines for illegal access and there is a section on the framework for sanctions.

Most of the bioprospecting in the country has been conducted by the National Biodiversity Institute (INBio). INBio was created in 1989 as a non-governmental, non-profit association and it has been declared of public good. Its mission is to promote a new awareness of the value of biodiversity, and thereby achieve the conservation and use of biodiversity to improve quality of life. In 1991, INBio developed the concept and practice of "bioprospecting" as one answer to the need for sustainable use of Costa Rican biodiversity to benefit society.

INBio has a formal agreement with the MEET that allows it to carry out specific national inventory activities and use of the biodiversity in the country's protected areas. Research is carried out in collaboration with investigation centers, universities and national and international private companies by means of investigation agreements that include key elements, such as:

- Access: limited in time and quantity
  - Equity and compensation: research budget, benefit-sharing (royalties and milestone payments, etc.), technology transfer, training
  - Non-destructive activities
  - Up-front payment for conservation.
- The agreements specify that 10 percent of the research budgets and 50 percent of the future royalties are donated

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<sup>13</sup> However, this consultation process has been diminished by a regulation to the article 80, enacted as part of the implementation package of the CAFTA-DR Free Trade Agreement.

to the MEET to be reinvested in conservation. The research budget supports the scientific infrastructure in the country as well as added-value activities for the conservation and sustainable use of the biodiversity. INBio has signed over 40 bioprospecting agreements. Several permits have been granted for the Technical Office of CONAGEBIO. More than 120 permits have been granted since 2005 and until 2009, mostly for basic non-commercial research but also for commercial research.<sup>14</sup>

## **2. Analysis**

The Costa Rican experience has provided some of the most relevant examples in terms of obstacles as well as achievements with respect to the regulation on access to genetic resources, intellectual property, and traditional knowledge.

Among the main reasons for the selection for further analysis of the BL are:

- In Costa Rica the income contributed by the biodiversity prospecting program reaches several million U.S. dollars overall and makes important contributions to technology, capacity-training, equipment, the National System of Conservation Areas, and more importantly, to the creation of national capacities and negotiation capacities. Although this last aspect stands out as the most important in relation to acquired benefits, it is important to point out that ecological tourism contributed around \$700 USD million in just one year, making bioprospecting's return seem relatively small with respect to the amount of money obtained.
- The ABS regulations of some countries have demonstrated how this type of focus can result in the lack of compliance with the objectives of the CBD. In this respect, some regulations to date have concentrated more on controlling than promoting access. These types of laws are creating high transaction costs and complicated bureaucratic procedures leading to an absence of access applications without which it is not possible to speak about benefit sharing. The BL has created the necessary legal guarantees, and an ABS regime that is sufficiently flexible and transparent.
- Unfortunately, the evolution of legal regulations on access to genetic resources has been separate from the definition of national policies on conservation and sustainable use of biological diversity. As a result, the

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<sup>14</sup> See [www.conagebio.go.cr](http://www.conagebio.go.cr)

contribution of monetary as well as non-monetary benefits barely touches upon the conservation process. The BL has been able to make a connection between ABS and conservation. The regulations on access are based on the idea of conserving biological diversity, its sustainable use and the fair distribution of its benefits. .

- Participatory processes are important in an area of great national importance such as biological diversity. The process for the development of the BL has been highly participatory, as it will be explained later.

At the same time, the main weaknesses of the BL are as follows:

- The changes in the IPR/Biodiversity section due to the implementing laws ( on IPR) of the Free Trade Agreement between Central America, Dominican Republic and the United States ( CAFTA)
- Almost all the ABS initiatives so far has focused on collecting on protected or private areas as well as marine portions of the country. Almost no ABS initiatives has been proposed and carried out in indigenous territories, therefore no benefits have directly accrued to this population.

## **NORWAY**

### **1. Content of the ABS provisions of the legal system, including innovative approaches.<sup>15</sup>**

Norway is a user of genetic resources more than a country providing them. Therefore its ABS provisions should be analyzed focusing on how a user country (and a developed country) can support the implementation and compliance with ABS laws of providing countries/countries of origin.

One of the aspects that may have had the greatest influence on the decision to negotiate an International Regimen on ABS is the lack of measures by user countries, or their inadequacy to support PIC and the MAT of the countries / communities that provide genetic resources or their associated traditional knowledge. In this regard, it has been said that: "In effect, any international regime will require a cooperative effort between the providers and users of genetic resources and traditional knowledge and will require that both take actions to mutually support

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<sup>15</sup> See *Norway's national report on the Implementation of the Convention on Biological Diversity*, page 51 legal resources. See also Nordic Ministerial Council `declaration of 2003 concerning access and rights to genetic resources.

the common objectives of the CBD relating to fair and equitable benefit-sharing".<sup>16</sup>

The existing problems with current ABS systems justify the establishment of user country measures. Some of the aspects presenting the greatest difficulties for the operation of an ABS system have to do with monitoring of and compliance with the provider country's legal provisions (on which access was granted), as well as with the observance of those provisions.

The main problems with observance of ABS regulations are posed by the possibility of non-compliance with the provider countries' legislative provisions or with provisions in access contracts. The ability of the provider countries to enforce their legal requirements will largely depend on mechanisms for access to justice and the existence of administrative or judicial remedies in foreign jurisdictions. Thus, user country measures would be very useful to support compliance with access conditions, considering the transnational nature of most ABS agreements.

While provider country measures make it possible to control the access phase, user country measures permit control of the phases of use, research and development, patenting of products and processes, etc. That is, they help to close the gap that exists between the resource acquisition phase (access permits or contracts) and the development phase, also reducing the burden and problems that occur in developing countries as a result of monitoring and compliance procedures in their national ABS regulations.<sup>17</sup>

In general, certificates of origin-source-legal provenance and disclosure of origin in IPR applications have been mentioned as mechanisms to facilitate the enforcement of ABS regulations, but the IR may also want to consider other kinds of mechanisms.<sup>18</sup>

These elements would help to build trust in the development of ABS relations, in that they would resolve – at least to a certain degree – the costs and problems associated with access to justice in foreign countries in cases of non-compliance.

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<sup>16</sup> Barber, Charles, et al., *User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit Sharing Provisions of the Convention on Biological Diversity*, UNU/IAS, Japan, 2003.

<sup>17</sup> Fernandez, Jose Carlos, *The Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources: Economic Considerations*, Yokohama Round Table: Towards Fair and Equitable Benefit Sharing. Instruments for the Effective Implementation of the Bonn Guidelines under the Convention on Biological Diversity, UNU-IAS and JBA, March 2005.

<sup>18</sup> Cfr. Walloe, Morten, *Elements for Legislation in User Countries to Meet the Fair and Equitable Benefit Sharing Commitment*, in *Journal of World Intellectual Property*, 2006, Vol. 9 No 2.

## 2. Norway Biodiversity Law user measure approaches

Norway Biodiversity Act<sup>19</sup> (Act relating to the management of biological, geological and landscape diversity) of 2009, contains the following provisions of interest for this research:

- Section 3 (definitions) define genetic material as genes or other hereditary material in any biological material that can be transferred to other organisms with or without the help of technology, except human genetic material.
- Chapter II contains general provisions on sustainable use, including management objectives to maintain the diversity of the habitat types and ecosystems ( article 4); management objectives for species ( article 5); general duty of care ( article 6); principles for official decision making ( section 7); the knowledge base of decision making ( section 8); the precautionary principle ( section 9); the ecosystem approach ( section 10); the users pay principle ( section 11); environmental sound techniques and methods of operation ( section 12); and other important public interests and Sami interest ( section 14).
- Chapter VII regulates access to genetic material. Genetic material obtained from the natural environment is a common resource belonging to the Norwegian Society as whole and managed by the State. It shall be utilized to the greatest possible benefit of the environment and human beings in both a national and international context, also attaching importance to appropriate measures for sharing of the benefits arising out of the utilization of genetic material and in such a way as to safeguard the interest of indigenous peoples and local communities. The King may determine that the collection of biological material from the natural environment for the purpose of utilizing the genetic material or the utilization of such material requires a permit from the Ministry. If a collection permit has been granted no new permit is required for subsequent utilization, but the conditions for the permit apply correspondingly to any person that acquires material or results arising from the collection. This paragraph does not limit the right of any owner or other entitled person to deny access on other grounds:
  - a) to the biological material or

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<sup>19</sup> The Marine Resources Act ( Act of 6 June 2008 No. 37 relating to the management of wild marine resources), includes a Chapter 2 on the conduct of marine bioprospecting, including benefit sharing arising out of the use of marine genetic material.

b) to the land from which the material is obtained

In accordance to section 58, the King may make regulations regarding which information the application shall contain including information regarding use of knowledge of indigenous peoples or local communities. Further provisions may also be in the regulations regarding which conditions may be set, such as conditions to the effect that any benefits arising from the utilization of genetic material collected from the natural environment within Norwegian jurisdiction shall accrue to the state. The regulations may also state how the interest of landowners and indigenous peoples and local communities can be reasonably safeguarded. Conditions may be set for the further utilization of material that is necessary to ensure the promotion of the objective set out in section 57. Section 59 regulates genetic material in public collections, including the obligation of any person that receives genetic material derived from a public collection shall refrain, in Norway or abroad, from claiming intellectual property or other rights to the material that would limit use of the material such as use for food and agricultures, unless the material has been modified in a way that results in a substantial change. If IPR over genetic material are established contrary to the third paragraph, the competent authorities under the Act shall consider taking measures including bringing legal action, to ensure the promotion of the objective set out in section 57. Any person may invoke conditions under that paragraph against any person that, contrary to such conditions, seeks to enforce IPR.

The King may make further regulations regarding removals from collections, including setting such conditions as are mentioned in section 58. With regard to the removal of genetic material covered by the International Treaty on Plant Genetic Resources for Food and Agriculture, the standard conditions laid down under the agreement shall apply

- Section 60 ( genetic material from other countries) contains and spells out a highly innovative approach, making Norway the first country, among developed and developing countries, to enact this kind of user measure. The import for utilization in Norway of genetic material from a state that requires consent for collection or export of such material may only take place in accordance with such consent. The person that has control of the material is bound by the conditions that have been set for consent. The state may enforce the conditions by bringing legal action on behalf of the person that set them.

When genetic material from another country is utilized in Norway for research or commercial purposes, it shall be accompanied by

information regarding the country from which the genetic material has been received (provider country). If national law in the provider country requires consent for the collection of biological material, it shall be accompanied by information to the effect that such consent has been obtained.

If the provider country is a country other than the country of origin of the genetic material, the country of origin shall also be stated. The country of origin means the country in which the material was collected from in situ sources. If national law in the country of origin requires consent for the collection of genetic material, information as to whether such consent has been obtained shall be provided. Information under this paragraph is not known, this shall be stated.

The King may make regulations prescribing that if utilization involves the use of TK of local communities or indigenous peoples, the genetic material shall be accompanied by information to that effect.

When genetic material covered by the International Treaty is utilized in Norway for research or commercial purposes, it shall be accompanied by information to the effect that the material has been acquired in accordance with the Standard Material Transfer Agreement established under the Treaty.

- IPR related issues. The Norwegian Patents Act<sup>20</sup> has since February 1<sup>st</sup> 2004 regulated a patent applicant's obligation both with regard to disclosure of origin of biological material and also prior consent if required in the country of origin. The disclosure obligation was expanded July 1<sup>st</sup> 2009 to also include traditional knowledge. The Norwegian Plant Variety Act Section 4 third paragraph has the similar provision as the Patents Act Section 8 b.

The relevant provisions from the Patents Act are reproduced here:

Section 8 b. If an invention concerns or uses biological material or traditional knowledge, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.

If the providing country is not the same as the country of origin of the biological material or the traditional knowledge, the application shall also state the country of origin. For biological material, the

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<sup>20</sup> The Norwegian Patents Act in full can be accessed at this address:  
[http://www.patentstyret.no/en/english/Legal\\_texts/The-Norwegian-Patents-Act/#chapter%203](http://www.patentstyret.no/en/english/Legal_texts/The-Norwegian-Patents-Act/#chapter%203)

country of origin means the country from which the material was collected from its natural environment and, for traditional knowledge, the country in which the knowledge was developed. If the national law in the country of origin requires that access to biological material or the use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that.

For biological material, the duty to disclose information under the first and second paragraphs applies even where the inventor has altered the structure of the received material. The duty to disclose information does not apply to biological material derived from the human body. If access to biological material has been provided in pursuance of Article 12.2 and Article 12.3 of the International Treaty of 3 November 2001 on Plant Genetic Resources for Food and Agriculture, a copy of the standard material transfer agreement (MTA) stipulated in Article 12.4 of the Treaty shall be enclosed with the patent application instead of the information stipulated in the first and second paragraphs.

Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 166. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

Section 1 third paragraph in fine. Biological material means, for the purpose of this legal text, material that contains genetic information, and can reproduce itself or be reproduced in a biological system.

Section 33 second paragraph, extract. The provisions in sections 8 b and 8 c [human material] do not apply to international applications.

Section 166 of the Civil Penal Code: Any person shall be liable to fines or imprisonment for a term not exceeding two years who gives false testimony in court or before a notary public or in any statement presented to the court by him as a party to or legal representative in a case, or who orally or in writing gives false testimony to any public authority in a case in which he is obliged to give such testimony, or where the testimony is intended to serve as proof.

The same penalty shall apply to any person who causes or is accessory to causing testimony known to him to be false to be given by another person in any of the above-mentioned cases.

Addressing the implementation of these provisions, the recent paper concludes<sup>21</sup>:

"Because the disclosure obligation only applies to national patent applications and also Norway's membership to the European Patent Organisation, we receive very few applications within this field. The experience with regard to disclosure is therefore limited. However, in the national patent applications which concern or use biological material we can report that the experiences are varied. Many applicants do not have problems with submitting the information but we do not have a complete picture of the situation due to the fact that some applications are abandoned for other reasons. We have not received oppositions based on information of disclosure nor experienced other consequences such as prosecution before the courts. We have not yet received any patent application that discloses an invention which concerns or uses traditional knowledge."

### 3. Analysis

The Norway Law provides the most developed user measure system and responds to the call of the International Regime Negotiations and the Draft Protocol on ABS, to support national legislation (including PIC and MAT) of providing countries or countries of origin<sup>22</sup>. However, because

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<sup>21</sup> Policies, measures and experiences regarding intellectual property and genetic resources: submission by Norway to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Wipo/grtkf/ic/16/inf/12, February 19, 2010.

<sup>22</sup> See article 12 of the Draft Protocol (Compliance with national legislation on ABS) "Parties shall take appropriate, effective and proportionate measures to ensure that genetic resources utilized within their jurisdiction have been **obtained/obtained, accessed and used** in accordance with **prior informed consent and that mutually agreed terms have been entered into, as specified in the** national legislation on access and benefit-sharing of the country providing **the genetic** resources.

2. Parties shall take appropriate, effective and proportionate administrative, civil and/or criminal measures to sanction or remedy situations of non-compliance with measures adopted in accordance with paragraph 1.

3. Parties shall cooperate in cases of alleged violation of the national legislation of the country providing genetic resources. See article 14 (Compliance with mutually agreed terms): "Parties shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

3. Parties shall take effective and proportionate measures, as appropriate, to address cases of alleged non-compliance with mutually agreed terms including measures to:

- a) Facilitate access to justice;
- b) Facilitate mutual recognition and enforcement of foreign judgments and arbitral awards;
- c) Facilitate cooperation between Parties; and

the law is new there is not experience in its implementation (regarding these provisions). Other aspects of the ABS legal regime seem to be less developed such as the access component.

## KENYA

### **1. Summary of the relevant provisions of the ABS legal system, including innovative approaches.**

The Environment Management and Co-ordination Act (1999) is Kenya's framework legislation coordinating all environmental management activities in the country.<sup>23</sup> As such, it constitutes the principal implementing legislation for the Convention on Biological Diversity. A number of the provisions of the Act have either direct or indirect bearing on the access and utilisation of Kenya's genetic resources. One such provision is section 53 of the act, which mandates the National Environment Management Authority (NEMA) to "issue guidelines and prescribe measures for the sustainable management and utilisation of genetic resources of Kenya for the benefit of the people of Kenya." Accordingly, the provisions of any guidelines issued or measures prescribed, shall include –

- a) appropriate arrangements for access to genetic resources of Kenya including the issue of licenses and fees to be paid for that access;
- b) measures for regulating the import or export of germplasm;
- c) The sharing of benefits derived from genetic resources of Kenya; and, any other matter that the Authority considers necessary for the better management of the genetic resources of Kenya.

Pursuant to these provisions, the NEMA has issued the relevant regulations, namely the Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations 2006.

The scope of the regulations is fairly broad but the regulation also explicitly outlines a few activities and situations which do not fall within the regulatory ambit of the law. These include:

- a) The exchange of genetic resources, their derivative products, or the intangible components associated with them, which are carried out

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d) Provide assistance to those seeking legal redress.

<sup>23</sup> *Environment Management and Coordination Act (1999)*, no. 8 of 1999, entered into force 14 January 2000.

by a local community of Kenya among themselves and for their own consumption

- b) access to genetic resources derived from plant breeders as defined under the relevant laws relating to plant breeding and plant varieties
- c) human genetic resources
- d) approved research activities intended for educational purposes within recognized Kenyan academic and research institutions that are governed by relevant intellectual property laws.

According to the required, bioprospectors are required to obtain a research clearance certificate, prior informed consent from the community and/or property owners, and enter into a material transfer agreement that includes the sharing of monetary and non-monetary benefits. The provisions contain an exhaustive list of the types and examples of monetary and non-monetary benefits that can be envisaged.

## **2. Analysis**

It can be first noted that the regulation was elaborated through a participatory and consultative process and that it generally forms a comprehensive framework for regulating genetic resources and benefit sharing. The regulation by and large embodies provisions and guidelines of the CBD.

There are certain gaps that can be note. First, though the law contains specific provisions on benefit sharing, none of the provisions clearly articulate how benefits are to be distributed to local community. The law is also quite vague as to who the local communities are and what procedures will be followed to identify them as potential beneficiaries. As regard to its scope, language is ambiguous making unclear if biological resources fall within the purview of the law.

Though the law embodies concepts of MAT and PIC, there is very little detail as to what the contents of PIC and MAT ought to be. The law does not specify the Competent Authorities or the kind of local communities that can grant Prior Informed Consent (PIC) to applicants. It does not specify clauses to be included in an agreement between provider and recipient.

Furthermore, the law does not clearly enunciate a demarcation between the statuses of commercial research versus non-commercial research. This potentially makes it difficult to delineate and calibrate distinctive

enforcement mechanisms for commercial research and non-commercial research should a case of non compliance arise.

## **SOUTH AFRICA**

### **1. Summary of the relevant provisions of the ABS legal system, including innovative approaches.**

The ABS legal framework in South Africa is contained in the National Environmental Management Biodiversity Act. Chapter 6 of the Biodiversity Act, entitled "Bioprospecting, Access and Benefit-Sharing", sets out the framework for the regulation of ABS in South Africa. More specifically, chapter 6 is meant to regulate bioprospecting of genetic resources and "ensure the equitable sharing of benefits arising from the commercialization through bioprospecting of traditional uses or knowledge of indigenous biological resources, with persons or communities practicing these traditional uses or knowledge".

In this perspective, section 80 of the Act provides that the purpose of the chapter is to:

- a) regulate bioprospecting involving indigenous biological resources;
- b) regulate the export from the Republic of indigenous biological resources for the purposes of bioprospecting or any other kind of research; and
- c) provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources.

The following are excluded from the scope of the regulation

- a) Genetic material of human origin
- b) Any exotic animals, plants or other organisms other than those that have been altered with material from indigenous species
- c) Indigenous biological resources listed in terms of the International Treaty on Plant Genetic Resources for Food and Agriculture.

Pursuant to section 77 of the Bill, bioprospectors must have entered into a benefit-sharing agreement in order to use traditional knowledge and these agreements must include certain information. Section 76 requires individuals to have a permit in order to engage in bioprospecting. The law thus mandates that before the application for a permit will be considered the applicant must disclose all information concerning the proposed bioprospecting and the resources that will be used for that purpose. A permit will only be issued if a material transfer agreement

regulating the provision of or access to the resources and a benefit-sharing agreement that provides for sharing by the stakeholders in any future benefits that may be derived from the relevant bioprospecting has been entered into by the applicant and the stakeholder, and the Minister has approved these agreements. If the stakeholder has provided knowledge that will be used for the proposed bioprospecting then a benefit-sharing agreement must be entered into between the applicant and the stakeholder and approved by the Minister before a permit will be granted.

For indigenous biological resources, a Material Transfer Agreement is required between the applicant and 'stakeholder'<sup>24</sup>, as well as a benefit-sharing agreement, prior to permit issuance. For holders of knowledge, a benefit-sharing agreement is required. Ministerial approval of all benefit-sharing or material transfer agreements is required. Those issuing permits may also facilitate negotiations between the applicant and 'stakeholder' to ensure they are on an equal footing, or may be required by the Minister to ensure the arrangement is fair and equitable.<sup>25</sup> In that perspective permits are required to:

- a) Engage in bioprospecting involving any indigenous biological resources
- b) Export any indigenous biological resources for bioprospecting or any other kind of research

Furthermore, pursuant to the law, benefit-sharing agreements must include the following information

- Name the parties to the agreement
- Set out the manner in which and the extent to which the resources are to be used or exploited for bioprospecting
- Set out the manner in which and the extent to which the stakeholder will share in any benefits that may arise
- Provide for a regular review of the agreement

Similarly, the law identifies certain elements that have to be included in Material Transfer Agreements. These include:

- Specify particulars of the provider and exporter or recipient of indigenous biological resources
- Name type of resource to be provided
- Identify the area or source from which the resources are to be collected, obtained or exported
- Specify present potential uses

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<sup>24</sup> "stakeholder" means — (a) a person, an organ of state or a community contemplated in section 82(1)(a); or (b) an indigenous community contemplated in section 82(1)(b)

<sup>25</sup> Section 82(4)(b) and (4)(c).

- Specify conditions under which recipient may provide resources or their progeny to a third party
- Is established into which all monies arising from benefit-sharing agreements and material transfer agreements and due to stakeholders must be paid and from which all payments to, or for the benefit of stakeholders must be paid. The trust money will be managed within the terms of the Public Finance Management Act by the Director General of the Department of Environmental Affairs and Tourism.

## **2. Analysis**

One of the concerns with the South African legislation is the lack of precision with which certain terms are defined. For example the term bioprospection is defined very broadly in the act as “any research on, or development of application of indigenous biological resources for commercial and industrial exploitation and includes:

(a) the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research

(b) the utilisation for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities

(c) Research on, or the application, development or modification of any such traditional use for commercial or industrial exploitation

The following terms and concepts are also not defined precisely in the regulation:

- The term commercialization
- Confidential information – requires a broader definition
- Indigenous biological resources – very broad definition may be necessary to differentiate use - includes *ex situ* collections as well as preserved specimens in herbaria and museums
- Indigenous communities – definition does not help to identify all stakeholder communities
- Traditional use (not defined)
- Indigenous knowledge
- Research – not defined in the regulations or Act
- Prior informed consent is not defined

## ETHIOPIA

### **1. Summary of the relevant provisions of the ABS legal system, including innovative approaches.**

In February 2006, the Federal Government issued the Ethiopian ABS law entitled "A Proclamation to Provide for Access to Genetic Resources and Community Knowledge and Community Rights."<sup>26</sup> The law draws a distinction between biological and genetic resources. The objectives of the law are articulated in article 3 of the Proclamation and are namely to ensure fair and equitable share of benefits arising out of the use of GR and CK for the country and its communities.<sup>27</sup>

The proclamation applies to resources to the access to genetic resources found in:

- *In situ* conditions
- *Ex situ* conditions
- Community knowledge

The definitions section largely adopts the definitions of 'biological resource' and 'genetic resource' from the Convention on Biological Diversity. The regulation goes further by explicitly stating that 'genetic resource' includes derivatives.<sup>28</sup> The regulation provides a definition of derivatives that draws from that articulated in the African Model Law.

### **2. Ownership of genetic resources and community knowledge**

Section 5 of the Proclamation specifically addresses the issue of ownership of genetic resources and community knowledge. This is particularly innovative in that most ABS measures currently in force do not explicitly address the issue of ownership of genetic resources and associated TK. Section 5 of the Proclamation states that:

1. The ownership of genetic resources shall be vested in the state and the Ethiopian people.

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<sup>26</sup> Proclamation No. 482/2006.

<sup>27</sup> Article 3, Proclamation No. 482/2006

<sup>28</sup> Article 2.6, "Genetic resource" means any genetic material containing genetic information of actual or Potent value, including derivatives.

2. The ownership of community knowledge shall be vested in the concerned local community.

The law thus draws a distinction between genetic resources, which vests in the state, and associated “community knowledge”, which is owned by the relevant community holding it. “Community knowledge” is defined as the “knowledge, practices, innovations or technologies created or developed over generations by local communities on the conservation and use of genetic resources”.<sup>29</sup> By virtue of this ownership, the law specifically recognizes the right of local communities “to regulate the access to their community knowledge”, their “inalienable right to use their genetic resources and community knowledge”, and “the right to share from the benefit arising out of the utilization of their genetic resources and community knowledge”.<sup>30</sup> These provisions are in consonance with the Convention and consistent with the reference to “traditional knowledge” in the context of Article 8(j) of the Convention, which provides for the respect, preservation and maintenance of “knowledge, innovations and practices of indigenous and local communities...” and for the “the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices”. The Proclamation does not draw any distinctions between different categories of genetic resources, but Article 15(2) of the Proclamation also provides that:

#### **IV. SELECTED ABS LAWS FOR FURTHER ANALYSIS IN THE LIGHT OF THE “BEST LAW STANDARD”.<sup>31</sup>**

This section analyses the content and implementation of the BL versus the Best Law Standard for Costa Rica and Ethiopia

##### **A. Costa Rica**

- **Principle of sustainable use of natural resources**

This principle is covered for different provisions of the BL. The BL was designed to implement the CBD in Costa Rica.

The general goal of the LB is to promote the conservation and sustainable use of biodiversity and to ensure the fair and equitable

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<sup>29</sup> Article 2.14, Proclamation No. 482/2006.

<sup>30</sup> Article 6, Proclamation No. 482/2006.

<sup>31</sup> See Cordonier Segger et al, *Selecting Best Policies and Law for Future Generations*; Legal Working Paper and worked examples. Final Version, 10 May, 2008, Montreal.

sharing of benefits derived from it (Article 1). The entire LB responds to this goal as put forth by the CBD. For example, it establishes the environmental function of the land (Article 8), general principles of the law (Article 9), objectives (Article 10), criteria for applying the law (Article 11); National System of Conservation Areas administrative structure (including the administration of the national wild protected areas, Articles 22 to 43), the guarantee of environmental safety (biosafety and exotic organisms, Articles 44 to 48), the conservation and the sustainable use of the ecosystems and species (Articles 49 to 61), the regulations on access to genetic resources (Articles 62 to 76), intellectual property rights (Articles 77 to 85), education and public awareness and research and transfer of technology (Articles 86 to 91), environmental impact assessment (Articles 92 to 97), incentives (Articles 98 to 104) and procedures and sanctions (Articles 105 to 113). All of these elements are in accordance with the three objectives of the CBD.

GAP's Article 14 establishes some 'Criteria for the evaluation or approval of the request' based on the public environmental interest criteria embodied in the law (Article 11.3).

Also, GAP's Article 24 allows the imposition of total or partial restrictions on access to the resources to ensure their conservation and sustainable use. These restrictions are issued by the TO in the resolution approving access. In this way, it can prohibit access, set limits, and regulate the methods of collection, in application of the precautionary principle mentioned in LB's Article 11.2.

Once access is authorized, the monitoring and control phase begins (Article 20 of the GAP) at the expense of the TO and in coordination with the authorized representatives of the place where access to the resources is taking place. Applicants will have to follow applicable sanitary and phytosanitary rules for the exportation of the materials.

Finally an environmental impact assessment (EIA) can be requested by the TO based on some general provisions of the LB related to EIA, but not specific to bioprospecting activities (Article 92). The evaluation is the responsibility of the National Technical Secretariat (a body of MEET). To date no EIA has been requested of the National Biodiversity Institute (INBio) or any other bioprospector.

The LB established that, without prejudice to the fulfilment of regulations relative to the trade of endangered species of flora and fauna, the application of sanitary and phytosanitary measures and technical procedures and biosafety, the provisions on access to genetic resources will constitute neither a concealed restriction nor an obstacle to trade (Article 68 general rule of interpretation).

It must be pointed out that there are no binding requirements that benefits must go towards the conservation of the resources. It is perfectly possible that a private owner, public institution, or indigenous territory could grant the PIC without allocating benefits towards conservation since the legal authority of the TO is limited to endorsement. In these circumstances, it is valid to ask whether the TO would have the legal authority to revoke a previous consent because of a lack of benefits towards conservation derived from the access (Article 63). As one might expect, in those cases in which a conservation area grants the permits, it is assumed that the benefit will go in its entirety towards biodiversity conservation.

- **Principle of equity and poverty eradication.**

Equity is a fundamental principle of the BL ( equitable sharing of benefits), including equity towards Indigenous Peoples and the design and implementation of a *sui generis system for the protection of TK*. Poverty eradication “*per se*” is not mentioned, but in principle, benefits accruing from the different ABS initiatives, could serve for this purpose. However, so far the implementation of the ABS provisions of the BL has created few benefits for small farmers and indigenous peoples. Most of the benefits are in the form of creation of technological capabilities, research results and associated information and monetary benefits.

The LB regulates the basic requirements for access, including the PIC, transfer of technology, equitable sharing of benefits, the protection of associated knowledge, and the definition of the ways in which the above mentioned activities will contribute to the conservation of species and ecosystems. It also mandates the designation of a legal representative in the country, when the person or organization requesting access is domiciled abroad (Article 63). The procedure to follow is clearly outlined in Article 64. It includes proof of the PIC of the owner of the property where the activity will be developed, whether it is an indigenous community, a private owner or public entity. Other interesting provisions incorporate the right of cultural objection (Article 66), the registry of access applications and the protection of confidential information, except in the case of biosafety concerns (Article 67).

The access request requirements are name and identification of the interested party, name and identification of the responsible researcher, exact location of the place, and the elements of biodiversity that will be the subject of the investigation, indicating the owner and manager or holder of the premises. The applicant will also have to submit a descriptive chronology of activities, aims, and purposes as well as place

for legal notifications. The application must be accompanied by the PIC (Article 72)<sup>5</sup> and a record of individuals or legal entities, which are to conduct the bioprospecting (Article 73). The TO must also authorize those agreements contemplating access to genetic and biochemical elements (Article 74) signed between individuals, natives, or foreigners, or between them and the institutions registered for such purposes. There is also a possibility to establish framework agreements with universities and other duly authorized centres (Article 74). It is established that up to 10% of the research budget and 50% of royalties will have to go to the conservation area, the private owner, or indigenous community (Article 76). In cases in which the TO authorizes the continuing use of genetic material or of biochemical extracts for commercial purposes, applicants are required to obtain a separate concession from the interested party (Article 75).

The PIC is supposed to contain mutually agreed upon terms that represent the fair and equitable distribution of benefits. Once obtained, this agreement must be endorsed by the TO. Even though the legislation is not clear, it is assumed that the PIC will be formalized in a private contract. The TO limits itself to endorsing the contract rather than negotiating it.

The TO's approval authorizes three fundamental aspects: the PIC's fulfilment of the requirements established in the Technical Guide, the number of samples to be taken and the time frame for the reports to be presented (Article 13).

In any case, the current scheme would leave the negotiation of contracts (by means of the PIC), in the hands of the conservation areas and eventually of other public authorities, insofar as they are the owners of the lands or of the biological resources.

The Costa Rican system for the protection of traditional knowledge is based on the following premises:

- a) The legal access provisions ensure prior informed consent and the sharing of benefits related to traditional knowledge. The Technical Office, and eventually the National Biodiversity Commission itself, has the authority to control, authorize, and review (Art 63, 65, 66, 72, among others) this issue.
- b) Prior Consent and sharing of benefits is a combination between access mechanisms, contracts or licenses and a *sui generis* approach based on registers.
- c) The existence and validity of various forms of knowledge and innovation and the need to protect them using appropriate mechanisms (Art. 77), be they patents, trade secrets, copyrights,

plant improvement rights, *sui generis* community intellectual rights, etc. have been recognized (Art. 78).

The legislation is oriented towards the protection of knowledge by means of a registry system. The collective knowledge of indigenous Peoples and Access to Genetic Resources, among others needs to be acknowledged. Thus an inventory will be made of *sui generis* intellectual community rights that the community's request be protected (Art. 84). However, these registry systems have been criticized for the difficulties that they can cause. The following are the main criticisms against these systems: (i) the need to define "access to information"; (ii) the control exercised over said information; (iii) the possibility that communities that are not involved in the access grant prior consent to use the knowledge registered under the name of others; (iv) limitations of the restriction to the access to information

To define the scope, nature, and requirements of these rights a participative consultative process must be started with the indigenous and peasant communities (Art. 83 of the Law of Biodiversity). This process will determine the manner in which intellectual rights of the community will be used, who will hold the title and identify the ones to receive the benefits (Art. 85).

- **Precautionary Principle approach**

All interested parties can access the genetic and biochemical resources. Nevertheless, GAP's Article 14 establishes the following "Criteria for the evaluation or approval of the request" based on the public environmental interest criteria embodied in the law (Article 11.3):

- Development options for future generations;
- Food safety and sovereignty;
- Conservation of ecosystems;
- Protection of human health;
- Improvement of citizens' quality of life;
- Gender issues; and
- Intellectual property rights not affecting key agricultural products and processes for the nourishment and health of the country's inhabitants. This criterion also includes protection for the resources of local communities and indigenous populations.

Also, GAP's Article 24 allows the imposition of total or partial restrictions on access to the resources to ensure their conservation and sustainable use. These restrictions are issued by the TO in the resolution approving access. In this way, it can prohibit access, set limits, and regulate the methods of collection, in application of the precautionary principle mentioned in LB's Article 11.2. To establish complete or partial restrictions some of the elements that will be considered are:

- The danger of extinction of the species, subspecies, races and varieties.
- Reasons of scarcity and endemic conditions.
- Vulnerability or fragility conditions in the structure or function of the ecosystems.
- Adverse effects on human health, the species, and the ecosystems or on essential elements of the autonomy or cultural identity of peoples and communities.
- Strategic genetic resources or geographical areas qualified as such; and
- The prohibition of access for military purposes or for denaturalization of the resources.

The LB also establishes the environmental function of the land (Article 8), general principles of the law (Article 9), the objectives (Article 10) and the criteria for applying the law (Article 11). Article 11 includes the precautionary approach (11.2).

- **Public Participation and access to information and justice**

The LB creates a self-governed CONAGEBIO (Article 14) as a separate legal entity, but belonging to the Ministry of Environment, Energy and Telecommunications (MEET). CONAGEBIO's duties include: To formulate the policies and responsibilities established in chapters IV and V (Access to genetic and biochemical elements and protection of associated knowledge) and VI of the LB. Furthermore, it has to coordinate these policies with the relevant institutions. Additionally, it has to formulate and coordinate the policy for access to elements of biodiversity and associated knowledge, ensuring a suitable transference of science and technology, as well as the distribution of benefits, which are general procedures under Title V of the Law.

In addition, the Commission will execute its agreements and resolutions and will design its internal procedures by means of the TO's Executive

Director (article 16). This entity has been formed by governmental bodies such as the MEET which presides over it, the Ministry of Foreign Trade, the Ministry of Health, Ministry of Agriculture, IFA, National Commission of University Presidents; Indigenous organization, Farmers organization, National Union of Chambers, the Costa Rican Federation for the Conservation of the Environment (FECON) and the Director of National System of Conservation Areas (Article 15). NGOs are represented by FECON.

In addition, the commission must formulate policies on access and distribution of benefits. It can also revoke the TO's resolutions regarding access matters (Article 14). In conformity with Article 62, the NACOMB must propose policies on access to genetic and biochemical resources of *ex situ* and *in situ* biodiversity. It will also act as an obligatory consultant in procedures related to the protection of intellectual property rights on biodiversity<sup>32</sup>.

### **Analysis of the Process that Led to the Development of the LB**

The formulation process of the LB and the discussion of matters related to access, the protection of associated knowledge and intellectual property rights are particularly relevant. The first draft of the LB was developed in 1996. It generated a negative reaction from different stakeholders that considered it to be especially restrictive and opposed to both the public good and scientific research. Multiple suggestions were made to the Legislative Assembly, including a complete new draft prepared by the Advisory Commission on Biodiversity which was never formally incorporated by the legislative course-

The second draft of the law appeared in January 1997. Even though this draft considered several of the objections made to the first draft, it also repeated several of the concepts and dispositions stated by the first version of the document. Therefore, it met with the same opposition. This situation led to the creation of a Special Commission in the Legislative Assembly. Its mandate was to create a new draft, taking into consideration the old one. The Assembly promised to respect the outcome.

The Commission, led by the National University, was installed in April 1997. It included the main political parties (National Liberation and Social Christian Unity), the Advisory Commission on Biodiversity (COABIO), the National Small Farmers Forum, the National Indigenous

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<sup>32</sup> See comment above on the current situation of this consultation due to an amendment of the IPR laws

Forum, the Union of Chambers for Private Business, the University of Costa Rica (with two representatives), the National University (with two representatives), the Costa Rican Federation for Environmental Conservation (FECON) and INBio. The group was composed of twelve representatives and their alternates, named by sectors including the non-governmental sector, representatives of indigenous peoples and farmers, the private sector, the academic sector, and the government (by means of the Advisory Commission on Biodiversity). The Special Commission met until December 1997 when the new draft was sent to the Parliament. It received the favorable opinion of the Parliament's Commission on Environment, and after minor modifications, the text was finally adopted as law. It was published in The Gazette, the Official Diary, in May 1998 and entered into force as law of the republic the same year. As mentioned before this was a comprehensive legislation and access was only one of the topics covered. No foreign consultants participated in this process.

- **Principle of governance and human security**

In Costa Rica, from the institutional perspective there is a duty (for the TO of the CONAGEBIO) to enforce and inspect with the support of the representatives of the place where access will take place. CONAGEBIO shall rely on a supporting Technical Office for, amongst other functions, the transaction, approval, refusal, and supervision of the applications for access to the elements or biochemical and genetic resources of biodiversity as well as the associated traditional knowledge in the terms of the present regulation (article 5 of the Regulations).

The Technical Office, in coordination with the authorized representatives of the site where the access to the elements or biochemical and genetic resources takes place, and in accordance with the established agreements and contracts in each phase of these rules, shall perform the pertinent tasks of verification and control.

To this effect, the officials shall be able to do inspections in the property or place where the access is materialized, at any moment that the respective permit remains valid or once the activities contemplated in the permit have been concluded. The officials shall raise acts of their control visits. The Technical Office shall also attend any complaints and investigate the possible violation of the terms of the prior informed consent or the terms of the access permit.

Non-compliance with the agreements and commitments shall give rise to the permit's cancellation as stipulated in article 27 of the present rules (article 20 of the GAP, 'verification and control').

The certificate of origin is also a form of monitoring the use of genetic resources (see article 80 of the Biodiversity Law and 19 of the Regulations). To date one certificate has been issued as per the request of the applicant.

In addition, the control and monitoring is carried out by the use of reports. For that reason, in the approval shall be established, among other conditions, the 'the obligation of the interested party to present reports and of their periodicity' (article 13 of the Regulations).

- **Principle of integration and interrelationship, in particular with human rights and social, economic and environmental objectives**

Several articles of the BL also addressed this principle. The focus of these paragraphs is the interrelationships between Intellectual Property Rights, Access to Genetic Resources and TK.

During the process of drafting the LB and, as part of the definition of regulations on access and benefit sharing, the topic of intellectual property rights and their relationship with biodiversity inevitably arose.

Thus, the LB establishes that intellectual property rights shall be congruent with its objectives of the Law by virtue of the principle of integration (Article 79). The Law originally excluded the following: DNA sequences from patent processes; plants and animals; unmodified microorganisms; essential biological processes for plant and animal production; the processes of nature or natural cycles; inventions essentially derived from the knowledge of biological traditional practices or in the public domain; inventions that are produced monopolistically that may affect the processes or basic agricultural products used for food and health purposes (Article 78). However, this article was modified by an amendment of an IPR Law<sup>33</sup> which was enacted to comply with the IPR commitments of the CAFTA-DR. DNA and RNA sequences are excluded from patent protection to the extent they don't fulfill the patent requirements; microorganisms as they are found in nature are not patentable; it was clarify that non biological and microbiological processes can be protected; it was added to the exclusion those inventions whose commercial exploitation shall be

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<sup>33</sup> Law No. 8686 published in La Gaceta November, 26 2008.

impede to protect the public order, the morality, the health or life of human beings and animals and plants and to prevent serious damages to the environment.

Authorities should consult the TO before granting protection of intellectual or industrial property-related innovations that involve biodiversity elements. The submission of the certificate of origin and prior informed consent shall be required. A well-grounded opposition by the TO shall prevent protection from being granted (Article 80)<sup>34</sup>. It has been stated that particular beneficiaries granted protection of intellectual or industrial property rights regarding biodiversity must cede to the State a legal obligatory license. In the event of a justified emergency, this license will allow the use of such rights for the benefit of the community. This provision is aimed at solving an emergency, without involving compensation or royalty payment (Article 81).

- **Principle of common but differentiated obligations**

This principle is also indirectly addressed in the BL

## **B. Ethiopia**

- **Principle of sustainable use of natural resources**

The Proclamation includes among its objectives the integration of conservation and sustainable use of the biodiversity elements into the development of socio-cultural, economic and environmental policies; the promotion of the active participation of all social sectors in the conservation and ecologically sustainable use of biodiversity, in order to attain economic, social and cultural sustainability; the regulation of access to genetic resources and thus to make it possible an equitable sharing of the social, environmental and economic benefits derived from the utilization of such genetic resources, with special attention to the local communities and indigenous peoples.

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<sup>34</sup> Decree No. 34958-MINAET-COMEX, regulation to the article 80 of the BL limits the opposition on the grounds of lack of compliance with the patent requirements. Likewise in the case of non compliance a fine is established. The processing of the applications seems to be allowed even if no certificate of compliance was produced. A constitutional action was brought against this regulation and is pending in the Constitutional Court

- **Principle of equity and poverty eradication.**

The proclamation on Access to Genetic Resources and Community Knowledge, and Community Rights provides communities with the right to receive 50% of the share that the state obtains in monetary form from the use of genetic resources. According to this proclamation, communities have the right to decide over access to their knowledge, while the state has the authority to decide over access to genetic resources - on behalf of the communities. Communities do, however, have the right to disagree in cases where access to genetic resources affects their culture and their well being.

An innovative and equitable feature contained in the Proclamation is the definition ownership over genetic resources and community knowledge (the issue of ownership of genetic resources and associated traditional knowledge is rarely dealt with in other national ABS instruments currently in place). The Proclamation stipulates that the "ownership of genetic resources shall be vested in the state and the people" and that the "ownership of community knowledge shall be vested in the concerned local community."

- **Precautionary Principle approach**

The Proclamation specifies certain conditions upon which partial or total access may be denied. These include situations where access may have adverse effects upon human health or the cultural values of the local community. The Proclamation also foresee that access may be denied in circumstances where access may cause undesirable impact on the environment or in circumstances in which access may be feared to cause danger of loss of ecosystem

- **Public Participation and access to information and justice**

The proclamation accords a specific role to communities in the decision-making process relating to use of their genetic resources and community knowledge. The Preamble of the Proclamation states in this regard that "it is necessary to involve communities in the making of decisions concerning the use of genetic resources and community knowledge and sharing of benefits derived from the utilization thereof".

- **Principle of governance and human security**

Several provisions of the Proclamation indirectly hinge on the issue of governance and human security. This is particularly as regard to the role rights of communities in the use of genetic resources and community knowledge and the various modalities governing the sharing of benefits arising thereof. The Proclamation does by and large encourage broad community participation in the decision making process related to the management of genetic resources and community knowledge.

- **Principle of integration and interrelationship, in particular with human rights and social, economic and environmental objectives**

The Proclamation provides for the right to demand the restriction or withdrawal of the prior informed consent given by the competent authority for access to their genetic resources where they found out that such access is likely to be detrimental to the country's socio-economic life or their natural or cultural heritages. The Proclamation also has a specific provision that calls on the person having access to genetic to provide to the Institute regular status reports of the research; and where genetic resource is to be collected repeatedly, follow up the environmental and socio-economic impact of the access and submit a report thereon;

- **Principle of common but differentiated obligations**

The principle is well articulated in the proclamation. The overarching purpose of the regulation is to integrate of conservation and sustainable use of the biodiversity elements into the development of socio-cultural, economic and environmental policies; the promotion of the active participation of all social sectors in the conservation and ecologically sustainable use of biodiversity, in order to attain economic, social and cultural sustainability. The regulations outlines differentiated obligations and responsibility depending on whether the applicant is a foreigner, a state organ, or a local community.

## V. CONCLUSIONS

As has been *Convention on Biological Diversity* (CBD) provided a mandate for countries to develop national genetic resources access and benefit-sharing (ABS) policies. One overarching observation is that. Since the entry into force of the CBD, countries have encountered multiple obstacles in developing such policies. This brief review of the status of ABS implementation in selected countries has highlighted some of the issues that are the basis of the slow or incomplete implementation of national laws in the reviewed jurisdiction. Some of the issues include but are not limited to;

- Unclear procedure as regard to PIC and MAT
- Ambiguities in the scope of ABS frameworks,
- Lack of clear definitions of certain key terms and concepts
- Lack of adequate coordination mechanisms between the various national institutions/agencies that deal with the question of access and benefit sharing
- Weak or non practical enforcement mechanisms etc.

The legislations of Ethiopia and Costa Rica have been selected because they both provide comprehensive frameworks for regulating access to genetic resources and the sharing of benefits that might arise out their utilization. Furthermore, these countries have experienced practical and palpable cases of ABS which have invoked and put to test both countries' ABS national frameworks

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- CBD Clearing House Mechanism (<http://www.cbd.int/chm/default.shtml>)
- Centre for International Sustainable Development Law ([www.cisd.org](http://www.cisd.org).)
- Environmental Law Centre, IUCN ([www.iucn.org](http://www.iucn.org))
- Genetic Resources Action International ([www.grain.org](http://www.grain.org))
- WIPO data base on legislative text on the protection of TK, traditional cultural expressions and legislative text relevant to genetic resources (<http://www.wipo.int/tk/en/laws/index.html>)
- Focal points/ national competent authorities web sites (<http://www.cbd.int/doc/lists/nfp-cbd.pdf>).
- ABS Capacity Development Initiative for Africa <http://www.abs-africa.info/>

Other Sources of Information

*Databases:*

- ABS measures database of the CBD [www.biodiv.org](http://www.biodiv.org)
- Genetic Resources Action (GRAIN) unofficial database on ABS Measures. [www.grain.org](http://www.grain.org)
- UICN-FAO Ecolex database <http://www.ecolex.org/index.php>

## **Annex. Elements that facilitate ABS implementation through consistency, legal certainty and clarity.**

- Certainty about what transactions and uses are covered by ABS (which transactions involving “genetic resources” requiring compliance with ABS laws and which are biological resources (which use conventional markets and instruments)).
- An effective legal means by each source Country can know of and protect its rights after genetic resources leave the Country;
- Accepted indicators that can be used to “prove” that GR used in one country have come from a different country and that the user has obtained a valid right to use them.
- Key message clarify the meaning of GR and use. CBD negotiations opted not to negotiate clear provisions about what genetic resources are and how they are owned or transferred, leaving the clarification of these matters to national law. Negotiators left countries unguided.
- Operative clarity: consistent understanding is the first issue here as well. User-providers-agencies must know objectively if a genetic or biological resource or use of genetic resources is involved.
- Procedures for obtaining ABS permissions: most countries national legislation already contains procedural systems that can be models for PIC and MAT related procedures in ABS. Country National experience is the first and best guide to applying and implementing these requirements in its governmental, legal, cultural system.
- Remedies-control for ABS compliance. There are fewer existing mechanisms as templates for ABS remedies in light of ambiguity of certain key concepts. With objective ABS standards, it could be possible to use existing tools for ABS compliance.
- Legal assurance: The system must provide certain protections for the Parties involved, including governments, applicants, property owners, middlemen, subsequent transferees, user institutions and other affected parties. This type of legal assurance is promoted where the legal framework clearly and objectively defines protects the right of the provider and user acquire by complying with the System. User protection appears to require: a) a clear distinction of the right granted in the ABS agreement, the limits of those rights and the responsibilities associated to them; b) assurance about how and when and ABS agreement becomes final. Provider Protection appears to depend on; a) the ability to monitor the user or to have certainty regarding post access uses of the GR; b) clear contractual statement, of the source rights if the user violates; c) access to

legal processes and incentive mechanisms where the resources are used

- Enforceability. Some of the challenge that can be met through the regime negotiations, by the adoption of: a) enforcement measures that deter both local and international parties from violating the Law; b) mechanisms for source Countries to obtain jurisdiction over users and or access to justice in user Countries; c) accepted evidentiary requirements enabling source Country officials to make their cases successful in user Countries.
- Enforcement must address two different kinds of actors: users under ABS agreements that are accused of violating those, and bio-pirates who take GR for commercial development without ABS compliance. Many enforceability issues will only rise after the GR leave the source Country. Current abs monitoring seems to rely on reports from the user, raising the question of how does the Country confirm reports?
- Integration with other relevant laws and processes. In this regard ABS presents interesting challenges, including their relationship with: laws on the marketing, purchase, sale, transport, and use of biological resources; the biosafety framework, protection of plant varieties, germplasm, food security, forest, etc; the protection of local communities; national laws relating to ownership of and transactions involving tangible and intangible property; consumer protection and fairness in contractual/business negotiations and operations.
- Incentives: It can be difficult to find ways to enhance the motivation of users, source Countries and other to comply with the system. Few incentives that are offered as mechanisms for promoting ABS meet these test. The public relations benefits of ABS compliance are limited by the fact that few members of the public have even heard of ABS. Patent and other legal rights systems are currently interpreted in a way that does not allow the issuance of patents to depend on disclosure of origin. The advantages of good relationship with sources countries although certainly important, may be less valuable after the user takes GR out of the Source Country. There is no current indication that compliance with ABS will protect against future lawsuits or make other legal processes easier. Currently the market incentives in the ABS real are not clear or compelling”.

Source, Young, Tomme, Gaps and Obstacles, *op cit.* with modifications from the authors.