

# Overview of the National and Regional Implementation of Measures on Access to Genetic Resources and Benefit-Sharing

Centre for International Sustainable  
Development Law





# **Overview of the National and Regional Implementation of Access to Genetic Resources and Benefit-Sharing Measures**

## **Preliminary Draft**

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The Centre for International Sustainable Development Law (CISDL) is based in the McGill University Faculty of Law. Its mission is to promote sustainable societies and the protection of ecosystems by advancing the understanding, development and implementation of international sustainable development law. CISDL works in cooperation with the McGill School of the Environment, the Université de Montreal Faculty of Law, and the Université de Québec à Montreal. It has guidance from the three Montreal-based multilateral environmental accords (the NAFTA Commission for Environmental Cooperation, the UNEP Biodiversity Convention, and the Montreal Protocol multilateral fund), and is currently involved in two international research projects related to sustainable biodiversity law. CISDL is developing materials and capacity building support for the development of regulatory frameworks for the regional and domestic implementation of the new Cartagena Protocol on Biosafety. CISDL is also developing a research project on the benefits of an international regime on access to genetic resources and benefit sharing for local communities, in collaboration with partners in developing countries.

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## **Executive Summary**

Since agreement to the Convention on Biological Diversity in 1992, numerous countries and regions around the world have begun to implement its provisions on access to genetic resources and benefit-sharing (ABS). As of January 10, 2005, forty-three countries had notified the Secretariat to the Convention of their national focal points or competent national authorities (or both) on ABS. This study reviews the ABS measures of sixteen countries from Latin America and the Caribbean, Asia, the South Pacific, Africa, Europe and North America as well as the regional measures of the Andean Community, ASEAN, the African Union plus discussions in the European Community and the Nordic countries. These reviews examine the relevant laws and policies and their provisions on scope, prior informed consent, mutually agreed terms on benefit-sharing, compliance, and monitoring and enforcement as well as any access agreements that have been granted. The study also examines some recent capacity-building projects related to the implementation of ABS. Overall, the analysis suggests some trends in the implementation of ABS such as common use of certain basic elements, a need to clarify some fundamental legal concepts, new ABS systems accommodating the provisions of the International Treaty on Plant Genetic Resources for Food and Agriculture, a continued lack of user measures, increased awareness of and activity on ABS, and capacity-building focus on ABS analysis in megadiverse countries through bilateral donor support. Finally, two appendices summarize the national and regional ABS measures as well as some capacity-building projects.

This preliminary draft of the study is intended for discussion during the third meeting of the Ad Hoc Open-Ended Working Group on ABS. It will be finalized on the basis of information gathered during the meeting in preparation for the fourth meeting of the Working Group.

# I Introduction

Early work on the implementation of access to genetic resources and benefit-sharing (ABS) under the *Convention on Biological Diversity*<sup>1</sup> (CBD) focused on information gathering. At the fifth Conference of the Parties (COP) to the CBD in 2000, the Parties began to move beyond this stage. The COP requested that Parties designate a national focal point (NFP) and a competent national authority (CNA) to be responsible for and provide information on ABS within the country.<sup>2</sup> To date,<sup>3</sup> of the 188 Parties to the CBD, twelve have designated both an NFP and a CNA, 30 have designated only an NFP, and one has designated only a CNA (see Table 1). All regions of the world are represented including two countries from the Pacific, eight from Asia, 14 from Europe, eight from Latin America and the Caribbean, two from North America, and nine from Africa. While the geographically-diverse nature of this representation is encouraging, less than one quarter of Parties to the CBD are represented which illustrates that there is still a way to go in implementing this past decision.

At COP-5, the Parties also created the Ad Hoc Open-Ended Working Group on Access and Benefit-sharing with the mandate “to develop guidelines and other approaches” on ABS in order to help the Parties and stakeholders.<sup>4</sup> At its first meeting in 2001, the Working Group drafted the “Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization” (Bonn Guidelines). After some amendments, the Bonn Guidelines were adopted at COP-6 in 2002.<sup>5</sup>

In February 2002, a new negotiating block coalesced in the form of the Like-Minded Megadiverse Countries (LMMC).<sup>6</sup> This group of 17 developing countries<sup>7</sup> was frustrated with the slow pace of progress at the CBD on biodiversity issues of concern to them and pushed for the negotiation of a protocol to the CBD on ABS issues.

The first test for the LMMC was at the World Summit on Sustainable Development in Johannesburg in September 2002. The Group was successful in obtaining two commitments on ABS in the *Johannesburg Plan of Implementation*<sup>8</sup>. Chapter IV of the Plan addresses the protection and management of the natural resource base of economic and social development. Paragraph 44 of the chapter focuses on biodiversity, and subsection (n) encourages the implementation and further development of the Bonn Guidelines. Subsection (o) calls for action to “[n]egotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources”.

The CBD’s Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing met for a second time in December 2003 and agreed to recommend to COP-7 that the latter mandate the Working Group to enter into negotiations on an international regime on both access and benefit-sharing.<sup>9</sup> COP-7 was held in February 2004 and the Parties agreed to launch the negotiations and also set the terms of reference on which the negotiations are to be based.<sup>10</sup>

**Table 1 Countries with Designated ABS National Focal Points and Competent National Authorities as of January 10, 2005<sup>11</sup>**

<b>Country</b>	<b>National Focal Point</b>	<b>Competent National Authority</b>
<i>Latin America &amp; Caribbean</i>		
Colombia	•	
Costa Rica	•	•
Dominica	•	
Dominican Republic	•	
Ecuador	•	
Jamaica	•	
Panama	•	
Peru	•	•
<i>Asia</i>		
India	•	
Indonesia	•	
Japan	•	•
Lebanon	•	•
Maldives	•	
Pakistan	•	
Singapore	•	
Turkey	•	
<i>South Pacific</i>		
Australia	•	•
New Zealand	•	
<i>Africa</i>		
Botswana	•	
Central African Republic	•	
Gabon	•	
Ghana	•	
Madagascar	•	
Nigeria	•	•
Rwanda	•	
Senegal	•	
Uganda		•
<i>Europe</i>		
Austria	•	•
Belgium	•	
Croatia	•	
Czech Republic	•	•
Denmark	•	•
Estonia	•	•
European Community	•	
France	•	
Germany	•	
Netherlands	•	•
Norway	•	
Sweden	•	
Switzerland	•	
United Kingdom	•	
<i>North America</i>		
Canada	•	
Mexico	•	•

Throughout this period, various countries and regions have been creating and implementing their own ABS systems. These systems are important because they take the broad terms of the CBD and put them into practice. Experience with implementing ABS laws and policies is crucial in identifying different options and approaches to the various aspects of ABS. The creation and use of national systems helps to illustrate the areas where more information is needed, the strengths and weaknesses of different approaches to ABS, and where international rules could be of assistance. The Parties recognized the significance of experience with ABS systems in the terms of reference they set for the negotiation of the international regime. The process of negotiation is to draw on “*inter alia* an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing, including: access contracts, experiences with their implementation; compliance and enforcement mechanisms; and any other options.”<sup>12</sup> It is only by examining what is and is not already working practice that the Parties can determine how best to proceed with the negotiation of the international regime.

The negotiations on the international regime will begin at the third meeting of the ABS Working Group in February 2005. The study and analysis below will be finalized on the basis of information gathered during this meeting.

## **II National and Regional Implementation of ABS**

### **A. Latin America & the Caribbean**

Latin America is an area of high diversity and similarly high activity on ABS. At the regional level, both the Andean Community and the Central American countries have ABS measures, although the latter is still in draft form. In addition to the four countries discussed below (Brazil, Colombia, Costa Rica and Venezuela), several other Latin American countries are in various stages of creating and implementing ABS measures (see Appendix I). There appears to be a lesser degree of activity in the Caribbean.

#### *Andean Community*

In 1993, the Andean Community of countries<sup>13</sup> (Bolivia, Colombia, Ecuador, Peru and Venezuela) issued Decision 345 on a *Common Regime on Plant Breeder's Rights*. The Decision first expressed the commitment to establish a common regime on ABS in the region. This commitment came to fruition when the Andean Community created the first regional approach to a common access regime in the form of Decision 391, a *Common Regime on Access to Genetic Resources*<sup>14</sup>, in 1996. Once approved, the Decision was directly applicable in the member states of the Andean Community but different factors such as social protests, technical ambiguities, legal differences, and institutional limitations forced the Andean countries to develop national policies and regulations to facilitate the implementation of Decision 391 at the national level.<sup>15</sup>

Decision 391 establishes both general principles and concrete access rules. Among the principles, Decision 391 recognizes national sovereignty over genetic resources, the right of indigenous, Afro-American, and local

communities to decision-making authority over their traditional knowledge, the importance of regional cooperation among Andean countries, and the precautionary principle.

The access regulations in Decision 391 apply to genetic resources, their by-products, their intangible compounds (traditional knowledge, innovation and practices) and the genetic resources of migratory species found within the national territory for natural reasons. The access procedure includes an application, a contract, an official resolution and registration in a public list.

The access contract is signed by the National Authority and the applicant but Decision 391 also requires the contract to take into account the rights and interests of the providers of the genetic resources, by-products of the resources, biological resources containing them, and their intangible compounds.<sup>16</sup> In any case, the applicant might be required to sign accessory contracts with other agents involved in providing access: the landowner where the genetic resource is sought, the entity responsible for *ex situ* conservation, and the owner of the biological resource containing the genetic information. Furthermore, when accessing traditional knowledge, innovation and practices, the access contract is to include an annex regulating the equitable sharing of benefits between the provider of the knowledge and the user.

Applications and contracts may include elements such as the following:

- Participation of local people in research activities;
- Support for research inside the country;
- Transfer of environmentally-friendly technology and knowledge (including biotechnology);
- Supplying information about antecedents, state of the science about resources and products;
- Capacity-building measures;
- Depositing collected materials in national institutions;
- Mention of the country of origin in publications;
- Communicating results of the research to national authorities;
- Conditions of transfer of accessed material to third parties.

Following the provisions in Decision 391, the Board of the Cartagena Agreement approved Resolutions 414 and 415<sup>17</sup>, which establish an application form and a model contract containing the elements necessary to regulate access to genetic resources and benefit-sharing.

According to the Complementary Provisions of Decision 391, intellectual property rights applications could operate as a tracking mechanism. National patent offices of the Andean countries must ask the applicants to submit the access contract when the product or process they want to protect might have been developed from genetic resources or by-products thereof. Intellectual property rights already granted will be void when the access has not observed the legal provisions.

Furthermore, in 2000, the Cartagena Agreement issued Decision 486 on Industrial Property that developed certain compliance provisions anticipated in provisional stipulations of Decision 391. According to Article 26 of Decision 486, applications to patent inventions including genetic material or traditional knowledge originating in countries of the Andean region should present the corresponding access contract or the respective license or authorization of use

of traditional knowledge. These provisions, however, do not limit patenting in other jurisdictions.

In July 2002, the Andean Community adopted a Regional Biodiversity Strategy (Decision 523<sup>18</sup>) which points out the legal and institutional difficulties found by Andean Countries in implementing Decision 391. The Strategy proposes, among other measures, to specify the subject matter under Decision 391, consolidate the administrative mechanisms, build scientific capacity, establish a financial support, and create an information system. To date, the member countries have each been interpreting the Decision in a different manner.<sup>19</sup> This makes it difficult to apply the regulation in a uniform way. Lapeña and Ruiz Müller highlight that one of the main concerns is how to interpret and apply Decision 391 in order to foster research and add value to genetic resources in the Andean Region.<sup>20</sup>

### *Brazil*

Since 1994, there have been several initiatives<sup>21</sup> 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 provoked very strong opposition from some sectors. To mitigate this situation, the federal government passed a Provisional Measure<sup>22</sup> addressing elements involved in access to genetic resources. 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.

Access to the genetic heritage requires prior authorization from the Council. Depending where the resources are expected to be collected (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.

### *Colombia*

The 1991 Colombian Constitution established that the state has responsibility for the movement of genetic resources into and out of the country and only the state is authorized to provide genetic resources.<sup>23</sup> Additionally, the Constitution establishes that the exploitation of natural resources in indigenous territories should only take place if the cultural, social and economic integrity of communities is respected. The 1993 Law 99 made the Ministry of Environment the responsible body for the protection and management of biological and genetic resources. In addition to the commitment in Decision 345 of the Andean Community, discussed above, Colombia's commitment to regulate access to genetic resources was reinforced by the ratification of the CBD in 1994.

In implementing the general provisions of Decision 391, the Colombian government identified the Ministry of Environment, through the 1997 Resolution 620, as the national authority entitled to grant access to genetic resources.<sup>24</sup> The main steps for access include: the filing of an application; its study and approval or rejection by the national authority; and, in the case of approval, the access contract. The entire process is public, although the state may grant confidentiality for information susceptible to unfair competition. The procedure is intended to guarantee transparency and to facilitate civil society participation.

The application must specify the genetic resources to be researched, the access activities required, the proposed geographical area, the identification of the supplier of the biological and genetic resources, the state of the art regarding the genetic material and its application, the resumé of the lead scientist of the project, and a copy of the research project. If the research project includes access to traditional knowledge, the application must identify the provider. The application must also identify a national institution as a research partner. The national authority then considers the technical, economic and legal viability of the proposal. The approval of an application is communicated through an administrative resolution and the process moves to a negotiation phase.

Following Decision 391 and Resolutions 414 and 415 of the Andean Community, an access contract in Colombia establishes the conditions for access to genetic resources, their derivatives and traditional knowledge. It also sets up the distribution of monetary and non-monetary benefits. If the

bioprospecting activities imply access to traditional knowledge, the contract must include an annex containing the provisions for benefit-sharing that have been previously approved by the provider. Depending on the resources to be accessed and their location, the applicant may be required to sign additional agreements with the steward, landowner and the provider of the biological resources where the genetic resources are found, and if necessary, with *ex situ* conservation institutions. A national research partner must be identified as part of the mechanism for technology transfer.

The application of a legal regime on access to genetic resources in Colombia has not been free of difficulties. The low policy profile of genetic resources and the lack of technical expertise are limiting factors. Although the state and international agencies have sponsored at least two technical and comprehensive assessments,<sup>25</sup> the government has yet to take decisive steps to implement the recommendations. Legal measures are emphasized but a substantial redefinition of the institutional framework and capacity building continues to be postponed. As a result, only two applications had been resolved by the end of 2004. In 1997, one application by BioAndes of Colombia S.A. to study plants, animals and microorganisms in national parks with commercial purposes was rejected, while in 2004 another application to access genetic resources of the South American dolphin *Sotalia fluviatilis* for academic purposes was accepted. In the meantime, more than twenty applications are pending.

### *Costa Rica*

Costa Rica's *Biodiversity Law*<sup>26</sup> (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.<sup>27</sup> 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.<sup>28</sup>

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 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<sup>29</sup>) 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.

Research activities where the objective is to conduct an inventory, a taxonomic description, etc., do not fall within the definition of access and are instead regulated by Article 36 of the *Wildlife Conservation Act*.

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.<sup>30</sup>

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)<sup>31</sup> within the Ministry of Environment and Energy (MEE). CONAGEBIO is entrusted with preparing access and benefit-sharing policies and can revoke the rulings of the TO on access issues.<sup>32</sup> The main duty of the TO is to process, reject, and audit applications to access biodiversity<sup>33</sup>; and coordinate with the Conservation Areas, the private sector, indigenous peoples, and peasant communities on actions that relate to access<sup>34</sup>. 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.<sup>35</sup> The Technical Office is expected to collect and update regulations related to the fulfillment of treaties and guidelines on biodiversity issues.<sup>36</sup>

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.<sup>37</sup> 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.<sup>38</sup> Chapter V also establishes the legal procedures to be followed,<sup>39</sup> the Registry of access rights, and the protection of confidential information<sup>40</sup>.

The BL regulates the terms of access permits including their limitations and characteristics;<sup>41</sup> the information required in a permit application;<sup>42</sup> the authorization of agreements with individuals seeking access to genetic and biochemical components by the Technical Office;<sup>43</sup> and the possibility of agreements with universities and other duly registered centres<sup>44</sup>. 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.<sup>45</sup> The Technical Office must also always be consulted in processes where IPRs are granted for components of biodiversity and its decision on these matters is binding.<sup>46</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.<sup>47</sup> 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 MEE 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 to the MEE 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 more than 30 bioprospecting agreements. Four permits have been granted under the Biodiversity Law and its regulations, including one commercial (bioprospecting) access permit granted to INBio and three non-commercial scientific research permits. Several applications are pending approval before the Technical Office of CONAGEBIO.

### *Venezuela*

Access and benefit-sharing in Venezuela is carried out in conformity with Decision 391 of the Andean Community and Chapter VII of the *Biological Diversity Law*<sup>48</sup>, which establishes similar provisions to those in Decision 391. According to the law, all persons seeking access to genetic resources must follow the proper administrative procedure, which includes an application, a contract, a public resolution and a registration of the process. Some factors such as the conservation of endemic species, ecosystem preservation, and human health protection, *inter alia*, can justify limitations to access. Concerning the use of traditional knowledge associated with genetic resources, the State commits itself to promote and protect the rights of indigenous peoples and local communities for their collective rights.

A guarantee is required in order to ensure compliance with the contract. In addition, contravention of the access legislation may be punished with a fine. The law also includes provisions that may act as a tracking mechanism:

- The applicant must provide information about the results, and research conclusions must be provided to the Ministry of Environment.

- Intellectual property rights will not be granted when samples have been acquired illegally or when they make use of the knowledge of indigenous and local communities.
- The National Office of Biological Diversity will examine intellectual property rights granted outside the country, based on national genetic resources, with the purpose of claiming the corresponding royalties or the cancellation of the IPR.
- Since Decision 391 applies in Venezuela, the control of genetic resources through a certificate of origin is also a possibility.

Between April 1998 and May 2004, Venezuela facilitated access to 12 projects and signed five framework agreements with national universities and research centres to carry out bioprospecting activities for non-commercial purposes.<sup>49</sup> In light of these projects, Febres<sup>50</sup> and Cabrera<sup>51</sup> have highlighted some gaps in the Venezuelan law. These include the lack of criteria to implement the legislation, the weakness of monitoring systems, and the lack of coordination between authorities.

## B. Asia

Like Latin America, several Asian countries have been at the forefront of creating and implementing ABS measures. Regionally, the Association of South East Asian Nations (ASEAN) has drafted a Framework Agreement on ABS. Three countries from the region are members of the LMMC – Indonesia, Malaysia, and the Philippines – and all have implemented or are drafting some form of ABS system at the national or sub-national level.

### *The Association of South East Asian Nations*

ASEAN is a regional grouping of ten South East Asian countries that was formed in 1967.<sup>52</sup> In September 1997, at the eighth meeting of the ASEAN Senior Officials on Environment, “the Philippine delegation proposed the formulation of a common protocol among ASEAN member countries on access to genetic resources and IPRs.”<sup>53</sup> Two Technical Expert’s Meetings were held resulting in the draft *ASEAN Framework Agreement on Access to Biological and Genetic Resources* in February 2000.<sup>54</sup> According to the Hanoi Plan of Action adopted during the 6<sup>th</sup> ASEAN Summit in 1998, the draft Framework Agreement was to have been adopted in 2004, although this does not appear to have occurred.<sup>55</sup>

The scope of the Framework Agreement is very broad. It covers biological and genetic resources which are defined to include “genetic materials, organisms and parts thereof, population, or any other biotic component of ecosystems with actual or potential use or value for humanity.”<sup>56</sup> Access may also include access to the traditional knowledge associated with the resources although this is not automatic.<sup>57</sup> The Framework Agreement does not apply to traditional uses of biological and genetic resources by indigenous and local communities.

The Framework Agreement does not establish an access procedure *per se*. It leaves each Member State to determine the nature of the country’s access instrument. Each Member State is required to designate a competent national authority who is responsible for creating and implementing national access legislation, among other things. The Framework Agreement also calls for using an existing ASEAN body as a clearinghouse to implement the Agreement.<sup>58</sup>

The Framework Agreement requires a Member State to grant its prior informed consent before access can take place. It is up to the competent national authority to establish procedures for how this is to be done and also to establish legally-binding procedures for obtaining PIC at the local level. The latter must “provide for the active involvement of indigenous peoples and local communities embodying traditional lifestyles.”<sup>59</sup> In addition, the PIC process must “respect and comply with the customary laws, practices and protocols of indigenous peoples and local communities and the disclosure of any information pertaining to the access shall be in a language understandable to the local communities.”<sup>60</sup>

Under the draft Framework Agreement, all resource providers, and indigenous peoples and local communities in particular, are to be actively involved in the negotiation of benefits. Any benefit-sharing agreements are not to negatively interfere with traditional knowledge systems and practices. The negotiation of benefit-sharing agreements is left to the discretion of Member States although it

must include a minimum set of requirements such as the participation of nationals in research activities and royalty-free access for resource providers of all technologies developed from research on accessed materials.

The draft Framework Agreement leaves it to the individual Member States to establish compliance mechanisms for users within their national access systems. Disputes between Member States, between communities and a Member State, or between communities regarding access, are to be settled through dialogue.<sup>61</sup> Disputes among Member States may also be settled through international arbitration.<sup>62</sup> The Agreement makes no specific mention of monitoring the accessed resources but the regional clearinghouse is required to adopt a warning system for Member States on access applications that have been denied and disseminate information on access applications that have been granted by Member States.

### *The Philippines*

The Philippines is a member of the group of Like-Minded Megadiverse Countries and has a relatively long history of regulating bioprospecting and ABS. Prior to the CBD, a permitting system was in place for the collection of biological samples.<sup>63</sup> In response to the Philippines' ratification of the CBD in 1993, the country began to draft Executive Order 247 (EO 247), "Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By-Products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes", which entered into force on May 18, 1995.<sup>64</sup> It is considered to be the first ABS law anywhere in the world. In 1996, the Department of Environment and Natural Resources (DENR) issued Administrative Order No. 20<sup>65</sup> (DAO No. 20), the implementing rules and regulations for EO 247.

Experience with EO 247 highlighted some difficulties with the Order particularly its broad scope and some of the procedures for prior informed consent. On July 30, 2001, the Philippine Legislature enacted the *Wildlife Resources Conservation and Protection Act*<sup>66</sup> (Wildlife Act) to rectify these problems. The Wildlife Act is a piece of general environmental legislation that codifies existing wildlife laws.<sup>67</sup> Only two parts of the Act address bioprospecting – sections 14 and 15 – but they change the bioprospecting procedures significantly. On May 18, 2004, DENR, the Department of Agriculture (DA), and the Philippine Council for Sustainable Development (PCSD) jointly issued Administrative Order No. 1<sup>68</sup> (AO No. 1) which contains the implementing rules and regulations for the Wildlife Act. There is also a set of draft "Guidelines for Bioprospecting Activities in the Philippines"<sup>69</sup> that will be jointly issued by DENR, DA, PCSD and the National Commission on Indigenous Peoples. EO 247 and DAO No. 20 are now repealed or amended to the extent that they conflict with the Wildlife Act and AO No. 1.<sup>70</sup>

Under the Wildlife Act, bioprospecting is defined as "the research, collection and utilization of biological and genetic resources for purposes of applying the knowledge derived there from solely for commercial purposes."<sup>71</sup> In order to engage in bioprospecting, a proponent must enter into an undertaking (a 'Bioprospecting Undertaking' in the draft Guidelines) that binds it to comply with the terms and conditions imposed by the Secretary of DENR and/or the Secretary of DA.

As part of the procedure for the undertaking, the applicant must have received prior informed consent “from the concerned indigenous cultural communities, local communities, management board under Republic Act No. 7586 or private individual or entity.”<sup>72</sup> It is during the prior informed consent process that the concerned communities can negotiate benefit-sharing terms with the applicant.<sup>73</sup> Neither the Wildlife Act nor AO No. 1 set minimum benefit-sharing requirements but Chapter VI of the proposed Guidelines includes detailed benefit-sharing provisions. These include mandatory bioprospecting fees, royalty payments, and up-front payments as well as other non-monetary benefits that may be agreed to by the users and providers.<sup>74</sup>

The Wildlife Act does not specifically mention liability for illegal bioprospecting but “unauthorized collection, hunting, and possession of wildlife is punishable with imprisonment of up to four (4) years and a fine of up to \$300,000P depending on the species illegally collected, hunted, or possessed.”<sup>75</sup>

Non-commercial research on biological and genetic resources is not exempt from the Wildlife Act. A researcher must enter into an Affidavit of Undertaking or Memorandum of Agreement (MOA) with the Secretary of DENR and/or DA or its authorized representative and the Secretary must issue a gratuitous permit.<sup>76</sup> The applicant must receive the free and prior informed consent of the indigenous peoples, or prior clearance of the concerned local government units (LGUs), the Protected Areas and Wildlife Bureau, private landowner and/or other relevant agencies or institutions where collection is to take place.<sup>77</sup> If the applicant is not Filipino, it must collaborate with a Philippine institution.<sup>78</sup> There are also certain minimum terms for the Affidavit or MOA including that spin-off technology is not to be developed from the results of scientific work; IPRs over the results are not to be applied for without the prior approval of the concerned agency; and the proponent is to submit results and recommended action plans, where applicable, at the conclusion of the research.<sup>79</sup> Finally, existing Academic Research Agreements (ARA) that were issued under EO 247 remain in effect until their expiry date. If proponents wish to renew their agreement, they must do so in conformity with the Wildlife Act.<sup>80</sup>

Chapter VII of the proposed Guidelines sets out how bioprospecting will be monitored. The user must submit annual progress reports covering the status of the procurement of PIC, progress of collection of samples, benefit-sharing negotiations, and progress on payment of benefits or other provisions of the undertaking.<sup>81</sup> The progress report must also include certification of compliance with the proper procurement of PIC, of acceptance by the providers of benefits, and of compliance with the collection quota in the Bioprospecting Undertaking.<sup>82</sup> The Guidelines include a model checklist of indicators to monitor whether benefit-sharing is equitable.<sup>83</sup> The Department of Foreign Affairs and the Department of Science and Technology can assist in overseas monitoring including monitoring inventions and commercialization in foreign countries.<sup>84</sup> Finally, civil society is encouraged to participate in monitoring Bioprospecting Undertakings.<sup>85</sup>

Between 1996 and early 2004, the now-dissolved Inter-Agency Committee on Biological and Genetic Resources processed eight applications for Commercial Research Agreements and 17 applications for ARA under EO 247.<sup>86</sup> Only one CRA and one ARA were granted during that time. The former was between the

Department of Agriculture, the University of Utah and the University of the Philippines to collect “tunicates, sponges, and other invertebrate samples for biological samples to screen for potential bioactive compounds.”<sup>87</sup> The latter was with the University of the Philippines in 1999.<sup>88</sup>

### **C. South Pacific**

ABS activity in the South Pacific appears to be increasing. Australia is finalizing its ABS system and New Zealand has been engaged in consultations on bioprospecting. Numerous of the island states are working towards ABS laws or policies while Samoa has a regulation in place on ABS.<sup>89</sup> The United Nations University’s Institute for Advanced Studies has also been active in capacity-building in this region (see section III, below.)

#### *Australia*

Australia is a megadiverse country.<sup>90</sup> The growing attention to the potential value of Australia’s biodiversity as a source of food, pharmaceutical, medicinal and industrial products and the awareness of ensuring that Australia benefits from such uses, was reflected in Objective 2.8 of the *National Strategy for the Conservation of Australia’s Biological Diversity*. “Ensure that the social and economic benefits of the use of genetic material and products derived from Australia’s biological diversity accrue to Australia”.

Section 301 of the *Environment Protection and Biodiversity Conservation Act of 1999*<sup>91</sup> (EPBCA) established the general framework for future, more specific regulations on access to genetic resources. The section states that “the regulations may provide the control of access to biological resources in Commonwealth areas” and, further, that these regulations may contain provisions on the equitable sharing of benefits arising from the use of biological resources; the facilitation of access; the right to deny access; the granting of access, and the terms and conditions of such access.<sup>92</sup>

With the purpose of designing the regulations under Section 301 and implementing a scheme on access to biological resources, an Inquiry into Access to Biological Resources in Commonwealth Areas was initiated in December 1999. The result of the Inquiry was a report containing recommendations on the creation of an ABS system.<sup>93</sup>

The draft *Environment Protection and Biodiversity Conservation Regulations of 2001*, which are expected to be enacted in 2005, essentially reflect the scheme recommended by the Inquiry. The draft regulations provide for a new Part (Part 8A) to be inserted into the existing regulations under the EPBCA and for amendments to Part 17 (Permits that may be issued under EPBCA).

The regulations will apply to biological resources in Commonwealth areas but not to biological resources in States and Territories which have their own legislation and policies governing access to biological resources.<sup>94</sup> The federal draft ABS regulations apply to any activity that involves taking biological resources of native species for conservation, commercial or industrial application, as well as research on genetic resources or biochemical compounds contained in the biological resources. A person may have access to

biological resources only in accordance with a permit issued under Part 17 of the regulations. An applicant for a permit must enter into a benefit-sharing agreement with each access provider. If the access provider is the owner of indigenous peoples' land or a native title holder for the area, he must have given informed consent to the agreement. The regulations include criteria to evaluate whether the access provider gave informed consent to an agreement. The benefit-sharing agreement must provide for reasonable arrangements, including protection for, recognition of, and valuing of any indigenous knowledge given by the access provider. Division 8A.2 of the draft regulations sets out the procedure to assess the application and the agreement. An environmental assessment may be required as part of this procedure.

The Department of the Environment and Heritage manages compliance with the EPBCA and will thus be responsible for the enforcement of the access regulation. The draft regulation sets a fine of fifty penalty units for contravening the regulation.<sup>95</sup>

In order to establish a coherent legal framework in the Australian federal structure, the 14 Commonwealth, State and Territory Ministers of Australia constituting the Natural Resource Management Ministerial Council, endorsed the *Nationally Consistent Approach for Access to and Utilisation of Australia's Native Genetic and Biochemical Resources* (NCA) on October 11, 2002. The NCA sets general principles that must be applied when developing or reviewing access and benefit-sharing systems established within Australian jurisdictions. These principles include certainty, transparency and accountability for facilitating biodiscovery; sustainable use of biological resources; and equitable sharing of benefits.

#### **D. Africa**

Several African countries have begun to implement at least some general enabling provisions on ABS. Nnadozie *et al.*<sup>96</sup> review the systems of twelve African countries – Cameroon, Egypt, Ethiopia, Ivory Coast, Kenya, Madagascar, Nigeria, Senegal, the Seychelles, South Africa, Uganda and Zambia – as well as the OAU Model Law and initiatives in the Southern African Development Community. In addition to these fourteen national and regional initiatives both the Gambia and Malawi also have some rules and procedures on ABS. Three systems are reviewed below: the OAU Model Law, Kenya, and South Africa.

##### *OAU Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*

The Organization for African Unity (OAU, now the African Union) crafted its Model Law<sup>97</sup> in 2000 in response to the potential for conflicts between the CBD, particularly Article 15, and the *Agreement on Trade-Related Aspects of Intellectual Property Rights*, particularly Article 27.3(b). African countries have consistently expressed the position that they are against the patenting of life forms.<sup>98</sup> The Model Law was thus an effort to create a *sui generis* form of plant protection that complies with the requirements of Article 27.3(b) but also integrates the goals of the CBD. The Model Law is not binding on member states, rather it is intended as a guide and resource tool for African countries as they create their own national systems on ABS.

The Model Law is very broad in scope. It covers a wide range of access activities including the acquisition of biological resources, their derivatives, and community knowledge, innovations, technologies or practices.<sup>99</sup> The definition of 'biological resources' is also very broad and includes genetic resources.<sup>100</sup>

Under the Model Law, access requires the written prior informed consent of a country's National Competent Authority as well as the concerned local communities.<sup>101</sup> The National Competent Authority is to consult with the local communities to determine that their consent has been sought and granted. The Model Law does not provide details on how an applicant should go about soliciting prior informed consent.

Once consent has been obtained, access is to be granted on the basis of a written agreement between the National Competent Authority and the concerned local community/communities, on the one hand, and the applicant on the other.<sup>102</sup> This agreement is to include commitments on the part of the applicant to share benefits and "to contribute economically to the efforts of the State and concerned local community or communities in the regeneration and conservation of the biological resource, and the maintenance of the innovation, practice, knowledge or technology to which access is sought".<sup>103</sup> Further benefit-sharing obligations are set out in section 12. These require the payment of a fee prior to the commencement of collection and entitle the state and the communities concerned to a share of the earnings derived from a biological resource or knowledge.<sup>104</sup> The sum of the initial fee can vary according to whether, *inter alia*, the collection is for commercial purposes.

The Model Law creates distinctions among access for commercial, academic and traditional purposes. The scope of the law states that it is not intended to affect traditional systems of access or "[a]ccess, use and exchange of knowledge and technologies by and between local communities".<sup>105</sup> Section 11 allows the National Competent Authority to set different terms and conditions in the access agreement depending on whether the user is a research institution, a public agency, or an inter-governmental institution. Finally, section 13 creates three types of access permits: the academic research permit, the commercial research permit, and the commercial exploitation permit. The section does not, however, elaborate as to what different rights and responsibilities might accompany each type of permit.

Part VIII of the Model Law includes provisions on sanctions and penalties which complement earlier provisions on prior informed consent. Section 5 makes it an offence to carry out access without the prior informed consent of the state and the concerned local communities. This offence is subject to the penalties in section 67, which includes a list of possible sanctions such as warnings, fines, confiscation of collected material, and a permanent ban from future access in the country.

According to Ekpere, African countries generally fall into one of four categories regarding the implementation of the Model Law in their jurisdiction. Most countries have legislation that is compliant with both TRIPS and the CBD and are only just beginning to consider creating ABS legislation or *sui generis* plant variety protection: "While most [African countries] prefer the Model Law, many are under external pressure not to conform to it."<sup>106</sup> A second category includes

countries like Egypt, Namibia and Zimbabwe that have enacted legislation that includes components of the Model Law. The third category covers countries that have drafted legislation along the lines of the Model Law but have not yet enacted it. This includes Ethiopia and Nigeria. Finally, many Francophone African countries are implementing UPOV-compliant forms of plant variety protection in accordance with the Bangui Accord of the African Intellectual Property Organization.

### *Kenya*

Kenya ratified the CBD in 1994. The country's implementation of the CBD has resulted in some general policy and legislative provisions on ABS but to date, there is no specific law that creates an access and benefit-sharing system. Kenya had some pre-CBD research permitting systems and in the 1990s, there were discussions to develop ABS regulations for the country but these subsequently stalled.<sup>107</sup>

Authority for ABS in Kenya is divided among a number of different agencies and people. Under a broad interpretation of its mandate in the *Wildlife (Conservation and Management) Act* (1977, as amended 1989), the Kenya Wildlife Service (KWS) administers an authorization process for commercial and non-commercial research in the country's parks system.<sup>108</sup> The Office of the President (OP) and the National Council for Science and Technology (NCST) administer a permitting system for any research to be conducted within the country.<sup>109</sup> It is unclear whether private landowners also have ownership and control of the genetic resources found on their property.<sup>110</sup> In addition, a large percentage of Kenyan land is Trust Land which is held in trust for the benefit of the ordinary residents of the land and to which African customary law may apply.<sup>111</sup> Many of the areas traditionally inhabited by pastoralists coincide with Trust Land. While the variety of customary laws between and among different tribes as well as the relative novelty of ABS to customary law makes it difficult to ascertain what customary law would require in the case of someone seeking access to genetic resources on Trust Land, Lettington indicates that it would be likely that the permission of the elders from the regions would be required prior to access.<sup>112</sup>

The most recent law on point is the *Environment Management and Coordination Act (1999)*<sup>113</sup>. It is a general environmental management law and is the primary means by which the CBD is implemented in Kenya.<sup>114</sup> Section 53 of the Act deals directly with ABS. It requires the National Environmental 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."<sup>115</sup> Subsection (2) lists the areas the guidelines or measures are to cover including the import and export of germplasm and benefit-sharing. NEMA has yet to issue the guidelines or measures and "has made it clear the process of implementing section 53 is not imminent because it has not been given high priority and NEMA has limited financial and human resources."<sup>116</sup>

These systems provide informal mechanisms for prior informed consent and benefit-sharing. To the extent that researchers must submit research proposals and receive permits or authorization from KWS or OP/NCST, these agencies can be said to be granting prior informed consent. KWS has negotiated benefit-

sharing in some of its partnerships. In KWS's contract with Diversa, benefits included the promise of royalty-free licenses for products developed from Kenyan resources, financial resources, human and physical capacity-building, and possible milestone and royalty payments.<sup>117</sup> In terms of compliance measures, the Wildlife (Conservation and Management) Act prohibits certain activities within national parks without official authorization, which includes knowingly removing or attempting to remove "any object of geological, prehistoric, archaeological, historic, marine or other scientific interest" or any part thereof from a national park.<sup>118</sup> This prohibition is strictly interpreted and applied.<sup>119</sup>

### *South Africa*

South Africa has had fairly extensive experience with bioprospecting and access and benefit-sharing contracts since approximately the mid-1990s. In 1995, South Africa initiated a biodiversity policy process largely in response to the country's imminent ratification of the CBD.<sup>120</sup> The final result of this process was the release of a "White Paper on the Conservation and Sustainable Use of South Africa's Biological Diversity"<sup>121</sup> in May 1997. One of the goals of the White Paper is to "ensure that benefits derived from the use and development of South Africa's genetic resources serve national interests".<sup>122</sup> Subsequently, the government began drafting the *National Environmental Management: Biodiversity Act*<sup>123</sup> (Biodiversity Act) which became law in June 2004. Chapter 6 of the new law is devoted to regulating bioprospecting, access and benefit-sharing.

The scope of the law is over 'indigenous biological resources' which is defined broadly and includes the genetic material of these resources but excludes most exotic organisms, human genetic material, and indigenous biological resources listed in the *International Treaty on Plant Genetic Resources for Food and Agriculture*.<sup>124</sup> Bioprospecting is defined to include "research on indigenous biological resources for commercial or industrial exploitation", thus purely academic research is excluded from the scope of the legislation.<sup>125</sup>

Interested parties must receive a permit before they can engage in bioprospecting activities.<sup>126</sup> The permit application must protect the interests of two types of stakeholders: the person granting access to the resources, and the indigenous community whose traditional uses or knowledge of the resources will be used in the bioprospecting.<sup>127</sup> These interests are protected by requiring the applicant to receive prior consent from the stakeholder on the basis of disclosure of all material information, and by requiring the applicant and the stakeholder to enter into a benefit-sharing agreement.<sup>128</sup>

The legislation sets general requirements for benefit-sharing agreements – such as they must specify the source and quantity of the resources to be collected, and the manner and extent to which the resources will be used and the stakeholder will share in any benefits – but it does not require any specific forms of benefit-sharing.<sup>129</sup> All benefit-sharing agreements must be approved by the Minister in order to take effect.<sup>130</sup> All money arising from benefit-sharing agreements is to be paid into a 'Bioprospecting Trust Fund'.<sup>131</sup>

Compliance with the law is enforced under Chapter 9 of the Act. It makes it an offence to engage in bioprospecting or export genetic material without a

permit, or to contravene the provisions of an issued permit.<sup>132</sup> The penalties for these offences are a fine and/or imprisonment.<sup>133</sup>

The Act does not establish a central focal point for bioprospecting. By default, the issuing authority for permits under the Act is the minister responsible for national environmental management but this could change if regulations are issued that grant issuing authority to other state authorities.<sup>134</sup> In the past, permitting authority was divided among a number of national and provincial departments depending on the geographic area where access was being sought and the type of resource being accessed.<sup>135</sup>

According to the Government Gazette of 8 October 2004, Chapter 6 of the Biodiversity Act will come into operation on 1 January 2006.<sup>136</sup> This is to allow the Department of Environmental Affairs and Tourism sufficient time to develop the regulations necessary to implement the chapter. All existing ABS contracts will have one year from this date to come into compliance with the new law.<sup>137</sup> In the interim until January 2006, any applications for bioprospecting are being handled under the old system where permitting authority was divided among different agencies. Numerous contracts have been signed under this system in the past including between the Council for Scientific and Industrial Research (CSIR) and Phytopharm on the one hand, and the San people on the other for access and benefit-sharing related to the Hoodia cactus; CSIR and Diversa; and the National Botanical Institute and Kew Gardens.<sup>138</sup> With the pending changes to the ABS system prior to the passage of the Biodiversity Act, the various permitting agencies were somewhat reluctant to grant new permits. This reluctance may persist until Chapter 6 and the new regulations are in force in 2006.<sup>139</sup>

## **E. Europe**

Very few European countries have adopted formal regulations on access to genetic resources. The 1998 *European Community* (EC) Biodiversity Strategy<sup>140</sup> notes the need for the Community to promote appropriate multilateral frameworks for ABS, to encourage the development of voluntary guidelines for ABS and to support countries of origin of genetic resources in developing national strategies on bioprospecting. Directive 98/44/EC on the *Legal Protection of Biotechnology Inventions*<sup>141</sup> also takes ABS considerations into account. Recital 27 encourages patent applications to include information on the geographical origin of biological material. Recital 55 requires Member States to give particular weight, *inter alia*, to Articles 8(j), 16.2 and 16.5 of the CBD when enacting the laws, regulations and administrative provisions necessary to comply with the Directive. Recitals, as such, do not create legally binding obligations on the Member States. However, some EU countries such as *Denmark* and *Spain*<sup>142</sup>, have introduced a requirement for the disclosure of origin of genetic resources in applications for intellectual property rights. Breach of this requirement will not have any consequences for the validity of the patent.

The communication from the Commission to the European Parliament and the Council on "The Implementation by the EC of the Bonn Guidelines on Access to Genetic Resources and Benefit-Sharing under the Convention on Biological Diversity"<sup>143</sup> may work as a guideline for Member States when designing their

ABS regimes according to the Bonn Guidelines. The Communication sets out, *inter alia*, different mechanisms to foster the achievement of users' obligations: material transfer agreements, codes of conduct, disclosure of origin in intellectual property rights applications, certificates of origin, and voluntary certification schemes. The Communication as well as subsequent EC submissions before the World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property, Genetic Resources and Folklore, have emphasised the role of certificates of disclosure, particularly as part of the patent application, as a means to prevent the use of genetic resources obtained without PIC.

The most clear intention to regulate access to genetic resources can be found in *Bulgaria's Biodiversity Law (2002)*<sup>144</sup>, which establishes that "genetic resources may be provided for use to other States on the basis of advance agreement in writing on the terms and manner of sharing the benefits arising from such transfer under mutually advantageous terms" and, further, that the terms and a procedure for provision of access to genetic resources will be established by a regulation adopted by the Council of Ministers. According to this law, genetic resources may be provided for free where the resources are intended for non-commercial purposes such as scientific research, education, conservation of biological diversity, or public health.

*Portugal* has adopted a registration regime for the protection of indigenous plant material of current or potential interest to agrarian, agroforestry and landscape activities,<sup>145</sup> although it excludes varieties protected by intellectual property rights. An application for registration may be filed by any entity representing the interests of the geographical area in which the local variety is most widely found or where the spontaneously occurring indigenous material displays the greatest genetic variability. The entity is responsible for the *in situ* maintenance of the plant material. Once the specific plant material has been registered, it will be included in the National Directory of Registration of Plant Genetic Resources. Traditional knowledge may also be registered in order to prevent reproduction, commercial or industrial use. Accessing the germplasm of plant material and using plants or parts thereof for industrial or biotechnological purposes requires prior authorization from the Technical Council of the Ministry of Agriculture, Rural Development and Fisheries on Agrarian Genetic Resources, Fisheries and Aquaculture. The entity owning the registration of the plant material has the right to be consulted prior to access, and to share in any benefits resulting from the use of the registered variety.

The *Nordic countries* (Denmark, Finland, Iceland, Norway and Sweden) share a common Strategy for Conservation of Genetic Resources in the Nordic Region (2001-2004). As a follow-up to the Strategy's provisions, a Project Group on rights and access to genetic resources was established at the beginning of 2002. The Group prepared a document which proposals for further actions on ABS.<sup>146</sup>

*Norway* is also in the process of reviewing its biodiversity legislation. Recently, a draft Act on the Protection of the Natural Environment, Landscape and Biological Diversity was presented. The text includes some provisions on access to genetic material which call for respect for traditional use by indigenous people and local communities. According to the Norwegian draft law, any person who receives genetic material from public collections must refrain from claiming intellectual property rights or other rights to the material

that would limit its use for food and agriculture. To ensure the legitimacy of foreign resources utilized in Norway, the import of such resources may only be permitted if the consent for collection or export has been given in accordance with the conditions required by the state of origin.

## **F. North America**

None of the three North American countries has implemented a comprehensive ABS system. Furthermore, the United States is a signatory but not a party to the CBD so it does not have the same international obligations on ABS. Both Canada and the U.S. have some ABS activity at the provincial/state level. Canada is also initiating a federal policy process on the issue while Mexico already has some legislation in place.

### *Canada*

The Canadian government is in the process of determining how it wants to proceed in the area of access and benefit-sharing. There are no national laws specifically devoted to ABS and jurisdiction in this area is shared with provincial and territorial governments as well as Aboriginal communities.

Canada's three northern territories – the Yukon, the Northwest Territories (NWT), and Nunavut – have gone the furthest in implementing ABS systems. Each territory has research licensing legislation that serves as a form of access system. All three systems are very similar; the NWT and Nunavut regimes will be examined here, see the table in Appendix I for a summary of the system in the Yukon.

The licensing of research in the NWT and Nunavut is governed by the *Scientists Act*<sup>147</sup>, which was passed in 1974. The Act requires anyone conducting scientific research or collecting specimens for scientific research in the jurisdictions of the territories to obtain a license.<sup>148</sup> Research on wildlife or the collection of specimens of wildlife is exempt as is archaeological work, although these activities require permits under other pieces of legislation.<sup>149</sup> Applications for licenses under the Scientists Act are made to the Aurora Research Institute in the NWT and the Nunavut Research Institute in Nunavut. Both institutes are part of local colleges and they have similar mandates relating to using research and knowledge for the benefit of people in the territories.<sup>150</sup>

The Scientists Act makes no distinction between scientific and commercial research. Both research institutes interpret the scope of the Act in a broad fashion such that a license for 'scientific research' includes areas like social sciences, economics and anthropology as well as biology, contaminants, and engineering.<sup>151</sup> The Act also makes no mention of prior informed consent but the application process requires written prior informed consent for any research that involves interviews with or the clinical participation of people.<sup>152</sup> The application process may also require consultation with and approval from different Inuit communities depending on the location of the research and the activity to be conducted.<sup>153</sup> Obligations for benefit-sharing are largely limited to reporting and sharing research results.<sup>154</sup> Contravention of the Scientists Act, its regulations or the conditions of a license are subject to a fine of no more than \$1,000 and/or imprisonment for no longer than six months.<sup>155</sup>

Both the NWT and Nunavut research licensing systems are frequently used. The Aurora Research Institute documents over 75 licenses issued under the Scientists Act in the year 2000 in areas as diverse as biology, geology, health, social sciences and traditional knowledge.<sup>156</sup> The Nunavut Research Institute counts over 100 research projects undertaken in the territory in 2002 under the Scientists Act in the areas of health, physical sciences, and social sciences and traditional knowledge.<sup>157</sup>

### *United States*

In the U.S., as in Canada, there is no one overarching piece of legislation that governs ABS in the country. Instead, jurisdiction is divided among different federal and state departments and agencies as well as private landowners.<sup>158</sup> That said, a system of access and benefit-sharing has been created for the national parks system.

The U.S. Code of Federal Regulations prohibits the “sale or commercial use of natural products” collected from national parks.<sup>159</sup> It also forbids the taking of plants, fish, wildlife, rocks or minerals from a national park without a specimen collection permit.<sup>160</sup> A distinction is made between research in a park that may or may not lead to commercial applications (which is allowed with a permit), and the direct sale or commercial use of products found in a park (which is prohibited).<sup>161</sup> Applications for a permit are submitted via a centralized internet system but decisions on the applications are made by the staff of the individual park or parks where the proposed research will take place. Applications are evaluated according to their favourable and unfavourable characteristics. The former can include research that will contribute to the understanding of park resources or provides for the sharing of information with park staff or the public. The latter can include activities that will negatively affect the experiences of park visitors or that may have an adverse impact on the park’s resources.<sup>162</sup> Permits can also only be issued to “an official representative of a reputable scientific or educational institution or a State or Federal agency for the purpose of research, baseline inventories, monitoring, impact analysis, group study, or museum display...”.<sup>163</sup> This provision includes corporate institutions and commercial research in its scope.<sup>164</sup>

The Code of Federal Regulations does not mention prior informed consent in the context of collection permits but the “permit application process helps ensure that the permit applicant discloses the information required to enable the park to determine that the proposed research activities are consistent with [National Park Service (NPS)] regulations and policy.”<sup>165</sup> Similarly, the regulations do not refer to the negotiation of mutually agreed terms in the granting of access permits. The permits themselves, however, include general conditions applicable to all research. These conditions include a requirement that any specimens or components of specimens (which includes “genetic materials”) be used for scientific or educational purposes only.<sup>166</sup> Commercial use is only allowed where the permittee has entered into a Cooperative Research and Development Agreement (CRADA) “or other approved benefit-sharing agreement with the NPS”.<sup>167</sup> The use of benefit-sharing agreements in the NPS was spurred by increased interest in the biological materials in Yellowstone National Park, the successful commercial use of an enzyme found in Yellowstone,<sup>168</sup> and the passage of the *National Parks Omnibus Management*

*Act of 1998*, which allows the Secretary of the Interior to “enter into negotiations with the research community and private industry for equitable, efficient benefit-sharing arrangements.”<sup>169</sup> Finally, the general permit conditions also include two standard benefit-sharing requirements: researchers must report annually on their activities, and they must submit any reports and publications resulting from their study.

Under the federal regulations, a permit can be suspended or revoked if its terms are violated. In addition, the general permit conditions provide that if a commercial product results from a permittee’s collection activities and the permittee does not have a CRADA, the NPS is entitled to a royalty of 20% and may also seek other damages.<sup>170</sup>

The permitting system of the NPS is used frequently – approximately 275 research projects per year in Yellowstone National Park alone.<sup>171</sup> One means by which these permits are monitored is by staff accompanying researchers during their specimen collection activities. The permit system has also resulted in the benefit-sharing contract between Yellowstone National Park and Diversa Corporation. This contract was challenged in the courts, and upheld but the Federal court did order the NPS to prepare an environmental impact statement of the effects that the implementation of benefit-sharing arrangements might have on the units of the NPS (i.e., the individual parks, monuments, etc.)<sup>172</sup> This process is currently ongoing but it is anticipated that a draft statement will be available for public review in the spring of 2005.<sup>173</sup>

### *Hawaii*

The state of Hawaii has also initiated efforts to regulate bioprospecting. Both the House of Representatives and the Senate considered bioprospecting bills in their 2004 sessions.<sup>174</sup> There was no agreement on legislation between the two bodies but there are plans to establish a Bioprospecting Advisory Commission early in 2005.<sup>175</sup> The current permitting process for scientific collecting on state lands and waters does not include any provisions for benefit-sharing. The University of Hawaii has entered into a number of access and material transfer agreements including an ABS contract with Diversa. The University has voluntarily decided to follow the ABS provisions of the CBD.<sup>176</sup>

### *Mexico*

Despite being considered a priority area for many people, Mexico lacks a specific and comprehensive regulatory framework for genetic resources. There are two legal initiatives in the Congress which aim to fill this gap, but they have not yet been widely discussed.<sup>177</sup>

The current rules regulating access to genetic resources are found in different federal laws. The *Ecological Equilibrium and Environmental Protection General Act*<sup>178</sup> (General Act) recognizes that the use of genetic resources is considered of public interest. Due to this, the State can regulate individual actions on behalf of the higher interests of society.<sup>179</sup> According to Article 87 of the General Act, scientific collection of biological resources (including genetic resources) for non-biotechnological purposes requires authorization by the Secretariat of Environment and Natural Resources. Research results must be available to the public. When the resources are to be used for the purposes of biotechnology, Article 87bis conditions authorization on the prior consent of

the landowner where the resource is sought. The benefits arising from the use of the resources must be shared with such owner.

The prior consent of the land owner is also required by the *Wildlife General Act*<sup>180</sup> when collecting activities are for scientific purposes. This regulation asks users to submit reports about their activities and to deposit samples of biological material in national research institutions.

In order to complete Article 87, the *Official Mexican Standard Nom-126-ecol-2000* specifies the requirements for scientific collections. If the user changes his purpose from scientific to biotechnological applications, he must submit a new declaration stating the new purpose and setting the stage for new consent and benefit-sharing agreements.

The provisions of the *Sustainable Forestry Development Act* regulating collection for scientific, commercial and biotechnological purposes follow the access scheme in the General Act. The former adds a simplified procedure in case of collections done by the owner of the land or by public agencies. The novel element in this Act is that it recognizes the right of indigenous people over local varieties and related traditional knowledge. This regulation declares void any registration including patents that does not acknowledge the right of indigenous people to the ownership, knowledge and use of local varieties. If traditional knowledge is to be used, there must be recognition of the ownership on behalf of the communities, an access agreement and proof of prior informed consent.

The Mexican Criminal Code explicitly includes illegal collection and traffic of genetic resources, which are punishable by imprisonment and a fine. Furthermore, “additional punishment will be applied... when the... described activities... are executed with a commercial purpose”.

Conflicts of land tenure and resource use in rural areas are important factors that have hindered the establishment and enforcement of an efficient ABS regime in Mexico.<sup>181</sup> Due to uncertainty and distrust felt by some social sectors, bioprospecting activities have been difficult to carry out on some occasions.<sup>182</sup> A clear and comprehensive regulation on access and benefit sharing, taking into account the social problems in some areas of the country, could help to resolve the situation.

### **III Recent ABS Capacity-Building Initiatives**

The growing discussions on ABS have certainly prompted an increase in the number of capacity-building projects on the subject. Decision VII/19 from COP-7 also includes an action plan on capacity-building that is intended to support capacity-building activities for the effective implementation of the ABS provisions of the CBD and the Bonn Guidelines in particular. Many of the major international donors are now funding ABS capacity-building activities. These projects address different aspects of ABS, such as genetic resources policy, intellectual property rights and indigenous knowledge, to name a few. They also involve actors at different levels be it internationally, regionally, nationally or locally. The brief overview below focuses on recent and ongoing

projects related to the implementation of ABS systems and is organized by funder. Please see the table in Appendix II for information on additional projects.

*Swedish International Development Cooperation Agency (Sida)*

In May 2004, the Stockholm Environment Institute, the Swedish Biodiversity Centre (CBM), and Svalöf Weibull AB (a plant breeding and seed group) organized a course on Genetic Resources and Intellectual Property Rights – Pathways for Development, an advanced international training programme. The course was held in Svalöv, Sweden and aimed to assist participants to understand the background to genetic resources and IPRs issues; to find, use and draw conclusions from sources of information related to genetic resources and IPRs; to enhance their managerial ability to address genetic resources and IPR issues; and to improve their ability to instigate the development of IPR policies and implementation of genetic resources frameworks at the national and institutional levels.

*The Swedish International Biodiversity programme (an initiative of Sida & CBM)*

In December 2004, the International Alliance of Indigenous and Tribal Peoples of Tropical Forests (IAITPTF) held an Expert Meeting on Traditional Forest-Related Knowledge in San José, Costa Rica. In preparation for the meeting, a series of national and regional case studies was produced on the extent to which governments have met their commitments on the promotion and protection of traditional forest-related knowledge. The meeting resulted in the Corobici Declaration, which demands recognition of certain principles on forest policy and traditional forest-related knowledge, as well as a series of recommendations. This work was also supported by the United Nations Forum on Forests.

*German Federal Ministry for Economic Cooperation and Development (BMZ)*

BMZ is funding a number of ABS projects including The ABS Project coordinated by IUCN's Environmental Law Programme. The overall goal of the project is to address issues of national, regional and international implementation of ABS concepts in the context of globalization, and the need to ensure that the international ABS regime operates to the benefit of the CBD objectives. Partner organizations include the Peruvian Environmental Law Society (SPDA), INE, INRENA, the International Institute for Sustainable Development (IISD), the International Plant Genetic Resources Institute (IPGRI), and the University of California at Davis. To date, the project has produced a series of information tools for delegates to COP-7 and an in-depth survey of the implementation of ABS law and policy in countries of the Pacific Rim.

BMZ is also funding an ongoing project in the Asia region on Strengthening Local Initiatives at Implementing ABS Regulations in Palawan, Philippines. The project is being conducted by the Palawan NGO Network, Inc. The overall goal of the project is for the responsible political bodies in Palawan to collectively coordinate and implement sound and effective access and benefit-sharing policies and regulations targeted at ascertaining the rights of indigenous and local communities embodying traditional lifestyles.

### *The Darwin Initiative, UK*

The Darwin Initiative is funded and administered by the British Department for Environment, Food and Rural Affairs. The Initiative funds projects related to biodiversity conservation and sustainable use such as the [Access to Genetic Resources, Benefit-Sharing and the Protection of Traditional Knowledge in Chile](#) of the Foundation for International Environmental Law and Development and the *Fundación Sociedades Sustentables*. The project aimed “to raise awareness and promote a policy debate concerning access to genetic resources, the equitable sharing of benefits arising from those resources, and the protection of traditional knowledge in Chile, in accordance with the Convention on Biological Diversity.”

### *The International Development Research Centre (IDRC), Canada*

IDRC is funding a large number of projects related to ABS. One example is the [Laying the Foundation: Global Access, Local Benefits](#) project coordinated by the Centre for International Sustainable Development Law (CISDL). The project includes in-country research on access agreements by the project partners and a junior researchers’ ABS capacity-building workshop. The project partners are Gene Campaign in India, the Southern Environmental and Agricultural Policy Research Institute in Kenya and SPDA in Peru with CISDL’s component of the research being conducted from the University of Costa Rica.

IDRC is also funding Gene Campaign to conduct a project on the [Protection of Indigenous Knowledge of Biodiversity in India](#). The project aims to identify mechanisms that will protect the indigenous knowledge of biological resources in the interests of the local communities. This will be done through a review and analysis, through the lens of protection of indigenous knowledge of rural and *adivasi* communities, of the strengths and weaknesses of existing efforts to document indigenous knowledge, of customary laws and practices, of international instruments, and of national legislation.

### *Governments of Canada & Mexico*

In October 2004, Mexico and Canada co-hosted an [International Expert Workshop on Access to Genetic Resources and Benefit-Sharing](#). The objective of the workshop was to facilitate open discussion on aspects of the international ABS regime and to prepare a report for the upcoming meeting of the CBD’s ABS Working Group. The workshop was organized into a series of panel discussions on subjects ranging from the overall vision of the international regime, including current levels of national ABS implementation, to intellectual property rights and monitoring and compliance. The panel discussions were based on short papers prepared by the panelists. Various departments of the two governments provided funding for the workshop as did the Swiss Agency for the Environment, Forests and Landscape.

### *APEC & the Department of Foreign Affairs and Trade, Australia*

In March 2004, these two bodies held a [Workshop on Trade and the Sustainable Use of Biodiversity](#). Participants exchanged information on trade

and sustainable use of biodiversity in the region and a compilation of proceedings was published.

*United Nations University – Institute of Advanced Studies (UNU/IAS)*

UNU/IAS is funding its own research programme on [Facilitating Global Dialogue on ABS](#). The programme includes three components: ABS governance, integration of traditional knowledge and customary law concerns into ABS policy, and capacity development. The project involves a number of partners in different regions and has produced a variety of reports and workshops to date.

*United Nations Environment Programme (UNEP)*

UNEP is also involved in different ABS capacity-building projects including a project on [The Implementation of the Bonn Guidelines in Africa](#). Approximately six African countries will be selected to participate in the project which will help them develop ABS legislation and provide training on the drafting and implementation of the legislation. The project is also designed to be replicable by regional organizations.

*United Nations Permanent Forum on Indigenous Issues (UNPFII)*

UNPFII held an international workshop on [Methodologies Regarding Free and Prior Informed Consent and Indigenous Peoples](#) in January 2005 at the United Nations headquarters in New York. Included on the agenda were discussion of free and prior informed consent as it relates to special issues such as gender equality, traditional knowledge, and natural resources within the work of intergovernmental organizations; examples of the application of the principle of free and prior informed consent; and lessons and challenges in the application of the principle.

## **IV Discussion on Trends**

Certain trends can be identified from the preceding overview of national and regional measures and capacity-building projects. First, while the details of laws and policies vary from one system to another, there are a number of basic elements that are commonly included. These include the identification of an ABS permitting authority (either as part of an existing organization or through the creation of a new one); a requirement and procedure for obtaining prior informed consent not only from government authorities but other providers such as indigenous people and local communities; and the negotiation of mutually agreed terms, including benefit-sharing provisions, with national authorities and other providers. In many cases, the legislation includes a list of required or potential benefit-sharing provisions. There is also common use of a written agreement or contract that sets out the MAT and benefit-sharing arrangements as well as the establishment of penalties or sanctions in cases of non-compliance. In some countries the IPR system is used as a compliance mechanism and IPRs are refused or revoked if the applicant did not comply with ABS provisions. More work remains to be done on some of these elements, however. The prior informed consent systems in some countries still

lack clarity over questions such as whose consent is needed, when it is needed, and how it is given.

A second trend is the continued evolution of the scope of ABS systems and the continuing need to clarify some fundamental legal issues relating to scope. There has been a move by some countries, such as the Philippines, to make ABS provisions more flexible for scientific/non-commercial research due to criticisms from the research community that the previous requirements were too burdensome and were stifling their activities. The range of access activities is more of a spectrum than a dichotomy between commercial and non-commercial. More work is needed to clarify the meanings of commercial and non-commercial access, how to address the activities that fall in the grey area between the ends of the spectrum, and how to respond to access activities that shift from non-commercial to commercial in focus, or vice versa.

The second area where more clarification is needed is over terms like genetic resources and biological resources. The scope of many access regimes is over genetic resources and biological resources but different systems define these terms differently and there is a lack of clarity over what they include even as defined in the CBD.

Some of the most recent initiatives to create ABS regimes – such as those in South Africa, El Salvador and Bhutan – have also begun to take into account the provisions of the new International Treaty on Plant Genetic Resources for Food and Agriculture. The South African legislation, for example, excludes those resources included in the terms of the ITPGRFA from the scope of its Biodiversity Act. It is expected that this will be a growing trend as more countries ratify the ITPGRFA and have the opportunity to adjust their ABS systems accordingly.

A fourth trend is the continued lack of user measures – such as disclosure of origin requirements in IPR legislation or cooperation to address alleged infringements. Even in the few countries that have begun to implement user measures, these measures are largely limited to the use of the IPR system. It is anticipated that more user measures will be put in place in the near future as more work is done on this subject.

In general, however, there is increased awareness about ABS, and a growing level of activity among countries, particularly the mega-diverse countries. Of the seventeen members of the LMMC, nine have either national or regional laws that specifically create an ABS system (Bolivia, Colombia, Costa Rica, Ecuador, India, Peru, the Philippines, South Africa, and Venezuela), four have no specific ABS law (Brazil, Congo, Kenya and Mexico), and four countries have laws or policies in development (China, Indonesia, Madagascar and Malaysia). Other countries that consider themselves megadiverse, such as Australia and the United States, also have some form of ABS system, be it quite comprehensive at the national, state and territorial level as in Australia, or more limited in geographic coverage such as the NPS system and the initiatives in Hawaii.

While ABS activity is growing, the scope of current capacity-building efforts is still relatively small. Many countries are providing resources for ABS capacity-building activities but multilateral support is largely absent. The Global

Environment Facility (GEF) is the main funding mechanism for the CBD. Decision VII/19 from COP-7 includes guidance to the GEF regarding ABS capacity-building but the GEF appears to be funding few explicitly ABS capacity-building projects. Much of the focus of many of the ongoing capacity-building projects is on increasing analytical capacity in the countries of the project partners or engaging individuals in global dialogue on ABS. Many of these efforts are also focused in megadiverse countries.

## Appendix I – Summary Table of National and Regional ABS Measures

### Latin America

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
Andean Community (Bolivia, Colombia, Ecuador <sup>183</sup> , Perú, Venezuela)	<a href="#">Régimen Común sobre Acceso a Recursos Genéticos</a> Decisión 391 2.7.1996 (and <a href="#">Resolución 415 de Adopción del Modelo Referencial de Contrato de Acceso a Recursos Genéticos</a> )	Public body assigned by member states	Genetic resources, their by-products & their intangible compounds (=traditional knowledge, innovations and practices) & genetic resources of migratory species that for natural reasons are found within national territory	<i>Agents involved</i>	National Authorities (Decision-making capacity of indigenous, Afro-American & local communities over their traditional knowledge, innovations & practices is recognized). Accessory contracts to be signed with <i>ex situ</i> centre & private providers	Contract must regulate: <sup>184</sup> -Participation of nationals in research activities -Support for research inside country -transfer of environmentally-friendly technology & knowledge (biotech included) -supplying info about antecedents, state of science on resources & products -capacity building measures -collected materials must be deposited in national institutions -mention of country of origin in publications -research results must be communicated to national authorities	-Cancellation of contract -Fines -Confiscations -Closure of facilities -Payment of compensation for damages -Civil & criminal sanctions	-Mechanisms to identify and track extracted samples can be required in access contract. -National support institution obliged to collaborate with competent authority -Reports -Continuous contact with national IPR offices <sup>185</sup> -Certificate of origin	-
				<i>Purposes</i>	Research, bioprospecting, conservation, industrial application, commercial use				

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
Bolivia	Decreto Supremo 24676 que aprueba el Reglamento de la Decisión 391	No Competent National Authority (CNA) or National Focal Point (NFP) notified to CBD Secretariat.  Secretaría Nacional de Recursos Naturales y Medio Ambiente	Genetic resources, their by-products, their associated intangible elements, & genetic resources of migratory species that, for natural reasons, are found within national territory	<i>Agents involved</i>	- National Authority (Accessory contract required for access within protected areas & <i>ex situ</i> collections)	- Benefits must be shared with State of Bolivia & rural & indigenous communities providing intangible compounds related to resources. Types of benefits: Transfer of technology & knowledge, scientific & technological capacity-building, royalties. - Reports must be submitted to Institución Nacional de Apoyo & National Authority	- Contract cancellation - Fines -Confiscations -Closure of facilities	Applicant for IPR must submit Resolution given by National Authority as part of IPR application	One commercial access contract signed in 2004 (for potato genetic resource) between Ministry of Sustainable Development & MIGROS (a Swiss organization)
				<i>Purposes</i>	Must be specified on application				
				<i>National / foreigners</i>	Participation of foreign entity only authorized when it is to be in conjunction with public institution, which must be responsible for coordination of activities				

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
Brazil	<p><a href="#">Medida provisória Nº 2186-16</a>,<sup>186</sup> 23.8.2001.</p> <p>Regulamenta o inciso II do §1º e o §4º do art. 225 da Constituição o, os arts. 1º, 8º, alínea “j”, 10, alínea “c”, 15 e 16, alíneas 3 e 4 da Convenção sobre Diversidade Biológica, dispõe sobre o acesso ao patrimônio genético, a proteção e o acesso ao conhecimento tradicional associado, a repartição de benefícios e o acesso à tecnologia e transferência de tecnologia para sua conservação e utilização, e dá outras providências</p>	<p>No CNA or NFP notified to CBD Secretariat.</p> <p><a href="#">Conselho de Gestão do Patrimônio Genético</a></p>	<p>Genetic heritage and related traditional knowledge</p>	Agents involved	<ul style="list-style-type: none"> <li>-National Authority</li> <li>-Indigenous Communities</li> <li>-Protected areas authority</li> <li>-Landowner,</li> <li>-Conselho de Defesa Nacional,</li> <li>-Marine Authorities</li> </ul>	<ul style="list-style-type: none"> <li>-Contract must regulate benefit sharing provisions</li> <li>-Benefit Sharing: division of profits, royalties, tech transfer, license for products or processes, capacity building.</li> </ul>	<ul style="list-style-type: none"> <li>- Contract cancellation</li> <li>- Fines</li> <li>-Confiscation of samples &amp; products</li> <li>-Suspension of sale of products</li> <li>-Closure of facilities</li> <li>- Patent, licenses, authorization suspension &amp; cancellation</li> <li>- prohibition of contracting with public administration</li> <li>-Restriction of tax incentives</li> </ul>	<p>Origin of genetic material &amp; associated traditional knowledge must be specified when applying for IPRs on process or product obtained using samples of genetic heritage</p>	<p>Contract between Bioamazonia &amp; Novartis prior to <i>Medida Provisoria</i> coming into force. Contract subsequently cancelled.</p>
				Purposes					
				National / foreigners	<p>Participation of foreign entity only authorized when it is to be in conjunction with public institution, which must be responsible for coordination of activities</p>				

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
Colombia	Andean Community Decision 391	<a href="#">Ministerio de Medio Ambiente</a> (NFP)  (No CNA notified)	Genetic resources, their by-products and intangible compounds	<i>Agents involved</i>	Ministry of Environment  Indigenous & local communities when traditional knowledge is involved <sup>187</sup>	- Economic (access price & royalties) - non- economic benefits (supplying samples & results to national institutes related to biodiversity research) - For non-commercial research, only non-economic benefits expected)	- Cancellation of contract - Fines - Confiscation - Payment of compensation for damages - Civil & criminal sanctions	Article 26 of Andean Community Decision 486 requires presentation of access contract to genetic resources or authorization for use of traditional knowledge as part of patent application.	BioAndes case has been only access application with commercial purposes. It was denied. Several proposals for non-commercial research have been submitted, only one has been approved by Ministry of Environment <sup>188</sup>
	<i>Purposes</i>			Commercial & non-commercial research					
	Order 309 of 2000 Ministry of Environment Research permits on biological diversity 25.2.2000								
	Resolution 620 of 1997 Ministry of Environment regulating Decision 391 7.7.1997								
	Order 1320 of 1998 Ministry of Interior Previous Consultation with Indigenous & Black Communities for Exploitation of Natural 391 7.7.1997								

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
Costa Rica	<p><a href="#">Biodiversity Law</a> No. 7788 30.4.1998</p> <p>General Rules for the Access to the Genetic and Biochemical Elements and Resources of the Biodiversity Decreto 020 2003 MINAE 15.12.2003</p>	<p><a href="#">Sistema Nacional de Áreas de Conservación</a> SINAC (NFP)</p> <p>Ministerio del ambiente y Energía (CNA)</p> <p><a href="#">Comisión Nacional para la Gestión de la Biodiversidad</a> (CONAGEBIO)</p> <p>Technical Office of CONAGEBIO</p>	Genetic and biochemical resources	Agents involved	<p>- CONAGEBIO</p> <p>Representative from area where activity will take place: public entity (e.g. SINAC), private owner, or indigenous communities. (Local communities &amp; indigenous people can deny access for cultural reasons)</p>	Benefit sharing: - Tech transfer - Price of samples - Participation in environmental economic, social or spiritual benefits, including commercial profit of product or derivative.	<p>-Inspections -Cancellation of access permit -Fine when accessing without permit</p>	<p>-Verification &amp; control -Reports -Certificate of origin (required in patent applications) -IPR offices &amp; National Seeds Office must consult CONAGEBIO before granting IPRs.</p>	<p>INBio agreements include, <i>inter alia</i>, with industry: - Merck - Bristol Myers Squibb - Givaudan - Diversa - Eli Lilly - Akkadix</p> <p>With academia: - University of Strathclyde - University of Guelph - University of Costa Rica</p> <p>Other: -The Chagas Project</p> <p>4 permits granted under Biodiversity Law &amp; Access Norms. Includes one commercial (bioprospecting) access permit granted to INBio &amp; 3 non-commercial scientific research permits. Several applications pending approval.</p>
				Purposes	Commercial & non-commercial bioprospecting				

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
Cuba	<a href="#">Ley del Medio Ambiente</a> L-81 11.07.1997 <a href="#">Regulaciones sobre la Diversidad Biológica</a> R-111-96 CITMA 14.10.1996 <sup>189</sup>	No NFP or CNA notified to CBD Secretariat  <a href="#">Centro de Gestión e Inspección Ambiental</a> (Ministerio de Ciencia, Tecnología y Medio Ambiente)	Biological resources	<i>Agents involved</i>	National Authority	- Benefit sharing provisions - Research activities must be developed inside country & involve Cuban staff	-	-	-
				<i>Purposes</i>	Must be specified on application				
El Salvador	<a href="#">Ley de Medio Ambiente</a> Decreto Legislativo 233, 4.5.1998 <sup>190</sup> <a href="#">Procedimientos Administrativos</a> , 2002	No NFP or CNA notified to CBD Secretariat  Dirección General de Patrimonio Natural del <a href="#">Ministerio de Medio Ambiente y Recursos Naturales</a>	Genetic & biochemical resources	<i>Agents involved</i>	-National Authority -Local communities - Provider	Benefit-sharing elements may be regulated in contract. May include: -Economic benefits (royalties, prices, research inversion) & other benefits (tech transfer, research, capacity building) - deposit materials in national institutions - supplying info about antecedents, state of science on resources & products - Participation of national institutions in collecting, R&D. - Access to research results	Contract cancellation	Certificate of origin	-
				<i>Purposes</i>	Access, research, manipulation, exploitation  Access might be limited for concrete biodiversity conservation reasons				

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
Guatemala	<a href="#">Ley de Áreas Protegidas</a> <sup>191</sup> 4-89 7.11.1996 and its regulations	No NFP or CNA notified to CBD Secretariat  Consejo Nacional de Áreas Protegidas <a href="#">CONAP</a>	Wildlife protected by the Law	<i>Agents involved</i>	CONAP	Some provisions on payment of royalties & sharing benefits	Prison & fine (Ley de Áreas Protegidas)		
				<i>Purposes</i>	- Exploitation (searching, collection, extraction)				
Nicaragua	<a href="#">Ley General de Medio Ambiente y los Recursos Naturales</a> <sup>192</sup> No 217 2.5.1996  <a href="#">Reglamento de la Ley General de Medio Ambiente y de los Recursos Naturales</a> Decreto 9-96 26.7.1996	No NFP or CNA notified to CBD Secretariat  <a href="#">Ministerio del Medio Ambiente y de los Recursos Naturales</a> MARENA	Biological diversity, National genetic heritage, Genetic resources	<i>Agents involved</i>	-MARENA -Indigenous people -Ethnic communities	Must involve local population in research activities (especially those who provide genetic resources) & supply them with info on results	-	All germplasm & native species of country are patented in favour of Nicaraguan State & its people	-
				<i>Purposes</i>	Biotechnology research				

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
Panamá	<a href="#">Ley General del Ambiente</a> <sup>193</sup> No. 41, 1998	<a href="#">Autoridad Nacional del Ambiente</a> ANAM (NFP)  No CNA notified to CBD Secretariat	Biogenetic resources  (rights granted for use of resources do not include rights for use of genetic resources contained therein)	<i>Agents involved</i>	ANAM	Indigenous communities entitled to share of benefits derived from use of natural resources found on their lands			-International Cooperative Biodiversity Groups -Smithsonian Tropical Research Institute; - Laboratorio de Bioorgánica Tropical de la Universidad de Panamá -US National Institutes of Health
				<i>Purposes</i>					

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
Perú	<a href="#">Ley sobre la Conservación y el Aprovechamiento Sostenible de la Diversidad Biológica</a> No. 26839 8.7.1997 <a href="#">Ley de Protección al acceso a la Diversidad Biológica Peruana y a los Conocimientos Colectivos de los Pueblos Indígenas</a> No 28216 1.5.2004 <a href="#">Ley que establece el Régimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas Vinculados a los Recursos Biológicos</a> No 27811 10.8.2002	<a href="#">Consejo Nacional de Medio Ambiente</a> CONAM (NFP)  Ministerio de Pesquería, Instituto Nacional de Investigación Agraria (INIA) & Instituto Nacional de Recursos Naturales (INRENA) CNA	Genetic resources & their by-products	<i>Agents involved</i>	- CONAM - Indigenous communities when accessing their collective knowledge	- Benefits must be shared with indigenous communities when putting on market a product developed from collective indigenous knowledge	Legal action against infringement of indigenous rights	National Commission for protection of access to biodiversity examines IPRs granted outside country that are based on national genetic resources or indigenous collective knowledge	Agreement between Searle Pharmaceuticals and Pueblo Aguaruna, (Amazonas peruano), Washington University, Universidad Cayetano-Heredia, Perú, Museo de Historia Natural de Perú
				<i>Purposes</i>	Access may be limited for purposes of biodiversity conservation				

COUNTRY	Regulation	National Authority	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
Venezuela	<a href="#">Ley de Diversidad Biológica</a> 24.5.2002	No NFP or CNA notified to CBD Secretariat  <a href="#">Oficina Nacional de Diversidad Biológica</a> (Ministry of Environment)	Resources of biological diversity	<i>Agents involved</i>	National Authority	Access contracts must include: -Participation of national researchers in activities -Remaining special advantages that may be offered to Republic for access to resources	-Guarantee of contract accomplishment is required - Fines	-IPRs will not be granted when samples have been acquired illegally or when they make use of knowledge of indigenous & local communities -Information about results & conclusions of research must be provided to Ministry of Environment -National Office of Biological Diversity examines IPRs issued outside country, based on national genetic resources, with purpose of claiming corresponding royalties or their cancellation	About 30 applications have been made & 10 academic/research access contracts have been signed.
				<i>Purposes</i>	Must be specified on application.  Access might be limited for purposes of biodiversity conservation, human protection, or national security.				

## Asia

COUNTRY	Regulation	National Authority	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
<b>ASEAN</b> (Philippines, Thailand, Indonesia, Malaysia, Singapore, Brunei Darissalam, Cambodia, Vietnam, Myanmar, Laos)	Framework Agreement on Access to Biological and Genetic Resources (draft, February 2000)	Up to each Member State to establish CNA.  Regional clearinghouse mechanism – permanent body to be determined, ASEAN Regional Centre for Biodiversity Conservation in interim.	Biological & genetic resources including associated traditional knowledge (includes genetic materials.)  Does not include traditional use of biological & genetic resources by indigenous and local communities	<i>Agents involved</i>	- state - indigenous peoples - local communities	- resource providers, particularly indigenous peoples & local communities to be actively included in negotiation of benefits - minimum benefit-sharing requirements of: - participation of nationals in research activities - sharing research results, including all discoveries - complete set of specimens left in national institutions - access by nationals to national specimens in <i>ex situ</i> collections - royalty-free access for resource providers to all technologies developed from accessed materials - fees, royalties & financial benefits - donation of equipment	- dialogue - national access regulation to set process for resolving dispute between resource user & Member State - dispute among Member States settled through international arbitration	Regional clearinghouse to monitor implementation of national access legislation, disseminate information on access agreements granted & denied, provide legal and technical support to CNAs.	-
				<i>Purpose</i>	Research, bioprospecting, conservation, bioindustrial application or commercial use, among others.				

COUNTRY	Regulation	National Authority	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
<b>The Philippines</b>	Wildlife Resources Conservation and Protection Act 30.07.2001	No NFP or CNA notified to CBD Secretariat	Bioprospecting : commercial research & use of biological & genetic resources	<i>Agents involved</i>	Commercial research: - applicant - indigenous & local communities - management board or private entity	Negotiated during PIC process. Must include bioprospecting fees, royalty & up-front payments. User & provider may also negotiate non-monetary benefits.	Unauthorized collection, hunting & possession of wildlife punishable by fine & imprisonment	Annual progress reports with certification of status of PIC, collection of samples, benefit-sharing negotiations & sharing of benefits.  DFA & DOST can assist in overseas monitoring. Civil society encouraged to participate in monitoring.	Between 1996 & early 2004, one ARA & one CRA granted under EO 247
	DENR-DA-PCSD Administrative Order No. 1 18.05.2004  Guidelines for Bioprospecting Activities in the Philippines  Executive Order 247 18.05.1995  DENR Administrative Order No. 20 21.06.1996				Secretaries of Department of Environment & Natural Resources, & Department of Agriculture				

## South Pacific

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
Australia	<a href="#">Environment Protection and Biodiversity Conservation Act 1999</a> <sup>194</sup>  <a href="#">Nationally Consistent Approach for Access to and Utilisation of Australia's Native Genetic and Biochemical Resources</a>	<a href="#">Department of Environment and Heritage, National Heritage Division</a> (NFP & CNA)	Native genetic & biochemical resources	Agents Involved	- Federal/State Authority - TK must be undertaken with cooperation & approval of holders of knowledge & on mutually agreed terms	Equitable sharing of benefits between access providers & applicants. Examples: Sharing research outcomes, making research outcomes available to public, negotiation of legally binding benefit-sharing agreement between access provider & entity seeking access	-	-	<i>Inter alia</i> , AstraZeneca, Griffith University & Queensland Museum; Australia Institute of Marine Science and Cerylid
				Purposes	Commercial & non-commercial purposes				
Samoa	Conditions for Access to and Benefit Sharing of Samoa's Biodiversity Resources 23.3.2000	No NFP or CNA notified to CBD Secretariat  Director of Land Surveys and Environment	Biodiversity resources	Agents Involved	- National Authority - Relevant land owners	- Relevant TK & practices must be acknowledged & considered in benefit-sharing - Minimum royalty: 2% - Register of all samples must be kept at Division of Environment & Conservation - Ownership of samples remains with Government of Samoa	-	Reports on status &/or analysis of samples must be submitted every 6 months	-
				Purposes	Investigate biodiversity resources				

## Africa

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
South Africa	<a href="#">National Environmental Management: Biodiversity Act. 2004</a> 7.6.2004	No NFP or CNA notified to CBD Secretariat.  Issuing authority in Act is minister responsible for national environmental management.	Indigenous biological resources (includes genetic material but excludes resources listed in ITPGRFA)	<i>Agents involved</i>	-issuing authority -stakeholders: person giving access to resources, and/or indigenous communities	- Person seeking access must sign benefit-sharing agreement with stakeholders in order to receive permit. - Agreement must be approved by Minister. -Act does not set specific benefit-sharing requirements.	Prison and/or fine		<i>Inter alia:</i> - CSIR-Phytopharm - CSIR-San -CSIR-Diversa -NBI-Kew -Strathclyde Institute -Rhodes University- Scripps Institute of Oceanography
				<i>Purposes</i>	- Research on indigenous biological resources for commercial or industrial exploitation				

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
<b>Organization for African Unity</b>	Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources	Up to each country to determine its National Competent Authority (NCA)	Biological resources including genetic resources, organisms or parts thereof, populations, or any other component of ecosystem, including ecosystems themselves with actual or potential use or value for humanity	<i>Agents involved</i>	- National Competent Authority - concerned local communities	<ul style="list-style-type: none"> <li>- applicant must sign agreement with NCA &amp; concerned local community/ies</li> <li>- minimum commitments in agreement:               <ul style="list-style-type: none"> <li>- deposit duplicates of material collected</li> <li>- inform NCA &amp; local community of research findings</li> <li>- benefit-sharing</li> <li>- contribute economically to efforts to regenerate &amp; conserve biological resource &amp; maintain traditional knowledge</li> <li>- try to conduct research in-country</li> <li>- other benefit-sharing requirements include collection fees &amp; state &amp; community entitled to share of earning when resource or knowledge results in product used in production process.</li> </ul> </li> </ul>	<p>Access without PIC of state &amp; community is invalid. Possible sanctions:</p> <ul style="list-style-type: none"> <li>- written warning</li> <li>- fines</li> <li>- cancellation of permission for access</li> <li>- confiscation of collected specimens &amp; equipment</li> <li>- ban on access in that country</li> </ul> <p>Violation must be publicized.</p> <p>Prosecution of violator in cooperation with government with jurisdiction over violator.</p>	Collector must submit regular status report to NCA.	-
				<i>Purposes</i>					

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
Malawi	Procedures and Guidelines for access and collection of genetic resources of Malawi	National Research Council of Malawi through the Genetic Resources and Biotechnology Committee <sup>195</sup>	Genetic resources	<i>Agents involved</i>	Issuing authority  Certifying institutions to ensure that PIC has been obtained from communities/ authorities with jurisdiction over desired genetic resources.  Guidelines sub-divide researchers/ institutions into foreign & local institutions	- Guidelines do not set specific benefit-sharing requirements. - Responsibility of affiliating or certifying institutions to ensure that foreign researchers on field trips are always accompanied by local counterparts & to verify that duplicate specimens of all collections are deposited with appropriate Malawi institution. - Copies of publications arising from collection. - Raw data or redacted subset of data (in case of proprietary research) to be deposited with affiliating institution	Withdrawal of any certificate (permit) granted. Fine &/or imprisonment as prescribed in Environmental Management Act	Certifying & affiliating institutions to monitor progress of investigation. 3 copies of research findings to be sent to National Council	-
				<i>Purposes</i>	Collection &/or export of genetic resources.				

## North America

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
Northwest Territories, Canada	Scientists Act 1974	Aurora Research Institute	Scientific research & collection of specimens for scientific research.	<i>Agents involved</i>	-Aurora Research Institute -Researcher -Indigenous community	- no requirement for MAT.  -researcher must report on & share research results with research institute.	Fine &/or imprisonment	Annual reporting requirement	-Canadian Arctic Plants: Systematics & Evolution -Snare River Aquatic Study -Gwich'in Elders Biographies Research Project
				<i>Purposes</i>					

<b>Nunavut, Canada</b>	Scientists Act 1974/1999	Nunavut Research Institute		<i>Agents involved</i>	-Nunavut Research Institute -researcher				-Flora of Canadian Arctic Archipelago -insect biodiversity & biogeography in Canadian Central Barrens -transmitting spiritual values & shamanic knowledge
				<i>Purposes</i>					
<b>Yukon, Canada</b>	Scientists and Explorers Act 1958	Department of Tourism, Heritage Branch	Social & natural sciences research anywhere in province. (Additional permits may be required for research in some areas or involving certain activities.)	<i>Agents involved</i>	-Heritage Branch officials -researcher -First Nations communities		Fine &/or imprisonment		
				<i>Purposes</i>					

COUNTRY	Regulation	National Authorities	Subject Matter	PIC		MAT on Benefit-Sharing	Compliance Measures	Monitoring access and tracking GR	Applications granted
United States	Code of Federal Regulations  National Parks Omnibus Management Act of 1998	National Park Service Research and Reporting System	Permit system for conducting any research in NPS. Illegal to take plants, fish, wildlife, rocks or minerals without permit	<i>Agents involved</i>	-park authorities -researcher	Use of CRADA to set terms for benefit-sharing.  Researcher must submit reports and publications	Permit can be suspended or revoked if terms violated.  If commercial product results from collection without CRADA, NPS entitled to 20% royalty & can seek other damages.	-annual reporting requirement -staff sometimes accompany researchers on specimen collection trips	Yellowstone & Diversa
				<i>Purposes</i>	To ensure proposed research activities are consistent with regulations & policy				
Mexico	<a href="#">Ley General del Equilibrio Ecológico y la Protección al Ambiente</a> <sup>196</sup> 1.3.1988 <a href="#">Ley General de Vida Silvestre</a> 4.7.2000 <a href="#">Ley General del Desarrollo Forestal Sustentable</a> 26.5.2003	<a href="#">Instituto Nacional de Ecología</a> (NFP)  Comision Nacional para el Conocimiento y Uso de la Biodiversidad (CONABIO) CNA	Biological Resources (includes genetic resources)	<i>Agents involved</i>	- National authority: Secretaría de Medio Ambiente y Recursos Naturales <a href="#">SEMARNAT</a> - Landowner	Landowner has right to equal share of benefits	Prison and fine (Art.420 Criminal Code)	Void any registration, including patents, that do not acknowledge rights of indigenous people on ownership, knowledge or use of local varieties	-UNAM-Diversa -UZACHI-Sandoz -Maya International Cooperative Biodiversity Group
<i>Purposes</i>	-Collection for economic or scientific purposes -Biotechnology								

## Appendix II – Table of Recent ABS Implementation-Related Capacity-Building Projects<sup>197</sup>

Funder	Project	Activities	Project Partners	Target Countries	Timeframe
IDRC, Canada	Global Access, Local Benefits	In-country research; junior researchers workshop	CISDL (coordinator), Gene Campaign, SPDA, SEAPRI	Costa Rica, Peru, Kenya, India	July 2004-February 2005
IDRC	Protection of Indigenous Knowledge of Biodiversity in India	Review & analysis of strengths & weaknesses of existing efforts to document indigenous knowledge, of customary laws & practices, of international instruments, & of national legislation	Gene Campaign	India	December 2003-June 2005
IDRC	Protecting Community Rights over Traditional Knowledge	In-country case studies to inform development of local tools & national policy. Examination of implications for international policy	IIED (coordinator), Development Alliance, Herbal Folklore Research Centre, Centre for Chinese Agricultural Policy, ICIPE, Kechua-Aymara Association for Sustainable Communities (Andes), Fundacion Dobbo Yala.	Peru, Panama, India, China, Kenya	Began May 2004
BMZ, Germany	The ABS Project	Development of the Bonn Guidelines, aiding participation of delegations in ABS negotiations, publications, direct	IUCN Environmental Law Programme (coordinator), SPDA, INE, INRENA, IISD, IPGRI, University of California at Davis	Global	May 2003 – December 2005

		assistance to countries			
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<b>Funder</b>	<b>Project</b>	<b>Activities</b>	<b>Project Partners</b>	<b>Target Countries</b>	<b>Timeframe</b>
BMZ	Strengthening Local Initiatives at Implementing ABS Regulations in Palawan, Philippines	Formulation & adoption of rules, awareness-raising, training programs, public discussions	Palawan NGO Network, Inc.	The Philippines	May 2003 – April 2005
UNU-IAS, multilateral	Facilitating Global Dialogue on ABS	Case studies on ABS governance, research & analysis of user measures, protection of traditional knowledge, identifying best practices on customary law & ABS in the Pacific, promote global ABS network, workshops	UNU-IAS (coordinator)	Global	Began September 2002
Darwin Initiative, UK	Access to Genetic Resources, Benefit-Sharing & the Protection of Traditional Knowledge in Chile	Analysis of Chilean legislation & policy on genetic resources & IPRs as well as access contracts. Research papers analysing relevant international policy & legislation on biodiversity & IPRs issues, including case studies & experiences from other countries & regions.	FIELD & <i>Fundacion Sociedades Sustentables</i>	Chile	April 2002 – May 2004
Swiss Federal Government	Project to Develop a Management Tool for Implementation of Access & Benefit-Sharing	Development of management tool.	IISD & Stratos Inc. (coordinators)	Global	July 2003-May 2004

<b>Funder</b>	<b>Project</b>	<b>Activities</b>	<b>Project Partners</b>	<b>Target Countries</b>	<b>Timeframe</b>
Governments of Canada, Mexico & Switzerland	International Expert Workshop on Access to Genetic Resources & Benefit-Sharing	Discussion workshop			October 2004
Sida	Genetic Resources & Intellectual Property Rights – Pathways for Development: Advanced International Training Programme	Training workshop	Stockholm Environment Institute, Swedish Biodiversity Centre, Svalöf Weibull AB	Global	May 2004
APEC & Department of Foreign Affairs & Trade, Australia	Workshop on Trade & Sustainable Use of Biodiversity	Discussion workshop	Department of Foreign Affairs & Trade, Australia, & Department of Foreign Affairs, Indonesia (organizers)	APEC countries	March 2004
Swedish International Biodiversity Programme	Expert Meeting on Traditional Forest-Related Knowledge	Discussion workshop	International Alliance of Indigenous & Tribal Peoples of Tropical Forests (coordinator)		December 2004
United Nations Permanent Forum on Indigenous Issues	Methodologies Regarding Free and Prior Informed Consent and Indigenous Peoples	Workshop		Global	January 2005
United Nations Environment Programme (UNEP)	Implementation of the Bonn Guidelines in Africa	Drafting of legislation & training		Africa	Began early 2004

<b>Funder</b>	<b>Project</b>	<b>Activities</b>	<b>Project Partners</b>	<b>Target Countries</b>	<b>Timeframe</b>
UNEP	Initiative on Access to Genetic Resources & the Equitable Sharing of Benefits Arising out of their Utilization	Mobilizing resources to assist countries in implementing Bonn Guidelines & other relevant international processes.		Particularly developing countries, SIDS & economies in transition	
IPGRI, IDRC, Rockefeller, BMZ, The Netherlands Ministry of Foreign Affairs, GTZ, CIDA	Genetic Resources Policy Initiative	Dialogue, policy-making, in-country research engaging wide range of stakeholders, training	IPGRI (coordinator)	Egypt, Ethiopia, Nepal, Peru, Vietnam & Zambia, East Africa, West & Central Africa	May 2001 – February 2006

## Endnotes

- <sup>1</sup> *Convention on Biological Diversity*, 5 June 1992, 31 I.L.M. 822 (entered into force 29 December 1993) ["CBD"].
- <sup>2</sup> UN CBD, COP-5, Dec. V/26, "Access to genetic resources" (2000) at Part A, para. 1.
- <sup>3</sup> January 10<sup>th</sup>, 2005.
- <sup>4</sup> Dec. V/26, *supra* note 2 at Part A, para. 11.
- <sup>5</sup> Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising Out of Their Utilization, being the Annex to UN CBD, COP-6, Dec. VI/24A, "Access and benefit-sharing as related to genetic resources" UN Doc. UNEP/CBD/COP/6/20 (2002).
- <sup>6</sup> Cancun Declaration of Like-Minded Megadiverse Countries, 18 February 2002, online: [www.megadiverse.org](http://www.megadiverse.org).
- <sup>7</sup> In 2002, twelve countries formed the LMMC: Brazil, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Mexico, Peru, South Africa and Venezuela. Five other countries have subsequently joined: Bolivia, Congo, Madagascar, Malaysia and the Philippines.
- <sup>8</sup> *Johannesburg Plan of Implementation, Report of the World Summit on Sustainable Development*, 4 September 2002, UN Doc. A/CONF.199/20.
- <sup>9</sup> UN CBD, Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, 2d meeting, "Report of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing on the Work of its Second Meeting" UN Doc. UNEP/CBD/COP/7/6 at rec. 2/4, p. 20, para. 1.
- <sup>10</sup> UN CBD, COP-7, Dec. VII/19, "Access and benefit-sharing as related to genetic resources (Article 15)" UN Doc. UNEP/CBD/COP/7/21 (2004) at Part D, para. 1 & Annex.
- <sup>11</sup> UN CBD, "Access and Benefit Sharing National Focal Points" (10 January 2005), online: Convention on Biological Diversity <http://www.biodiv.org/doc/lists/nfp-abs.pdf> (date accessed: 10 January 2005); UN CBD "Access and Benefit Sharing Competent National Authorities" (10 January 2005), online: Convention on Biological Diversity <http://www.biodiv.org/doc/lists/nfp-abs-cna.pdf> (date accessed: 10 January 2005).
- <sup>12</sup> Dec. VII/19, *supra* note 10 at Part D, Annex, para. (a)(i).
- <sup>13</sup> The Andean Community of countries has its origins in the 1969 *Andean Subregional Integration Agreement* (Cartagena Agreement).
- <sup>14</sup> *Common Regime on Access to Genetic Resources*, Decision 391, 2 July 1996, Official Gazette 17 July 1996.
- <sup>15</sup> Santiago Carrizosa, "Diversity of Policies in Place and in Progress" in Santiago Carrizosa *et al.*, eds., *Assessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity*, IUCN Environmental Policy and Law Paper No. 54 (Gland, Switzerland & Cambridge: IUCN, 2004) at 10, online: IUCN <http://www.iucn.org/themes/law/pdffdocuments/EPLP54EN.pdf> (date accessed: 1 February 2005).
- <sup>16</sup> Decision 391, *supra* note 14 at Art. 34.
- <sup>17</sup> Resolutions 414 & 415, 22 July 1996.
- <sup>18</sup> *Regional Biodiversity Strategy*, Decision 523, 7 July 2002, online: Andean Community <http://www.comunidadandina.org/ingles/treaties/dec/D523e.htm> (date accessed: 1 February 2005).
- <sup>19</sup> See Isabel Lapeña and Manuel Ruiz Müller, eds., *Acceso a Recursos Genéticos, Propuestas e Instrumentos Jurídicos*, (SPDA: San Isidro, Peru, 2004) at 100.
- <sup>20</sup> *Ibid.*
- <sup>21</sup> Bill No 306/95, introduced by Senator Marina Silva and amended by Senator Osmar Dias. Bill No 4579/98, introduced by Deputy Jacques Wagner. The Executive power formulated a third bill in response to Senator Marina's bill. It proposes an amendment to the Constitution.
- <sup>22</sup> Medida provisória Nº 2186-16. 23.8.2001. Regulamenta o inciso II do §1º e o §4º do art. 225 da Constituição o, os arts. 1º, 8º, alínea "j", 10, alínea "c", 15 e 16, alíneas 3 e 4 da Convenção sobre Diversidade Biológica.
- <sup>23</sup> The exclusive right of the Colombian state as a legitimate holder of the genetic resources has been affirmed through judicial decisions of the highest tribunals: Sentence C-137 de 1996 by the Constitutional Court, and Concept August 8 of 1977 by the High Administrative Council.
- <sup>24</sup> The Order 309 of 2000 introduced a more flexible regime to grant research permits on biological diversity. These research permits, however, do not authorize access to genetic resources. This parallel legislation is incoherent and contradictory since genetic resources are contained in biological organisms.

<sup>25</sup> See “Access to Genetic Resources: Technical and Legal Proposal”, (National University of Colombia, Institute of Socio-Legal Research – UNIJUS: Bogotá, 2003), and “Technical Proposal for Policy on Access and Sustainable Use of Genetic Resources in Colombia” (Institute Alexander von Humboldt: Bogotá, 2004).

<sup>26</sup> *Biodiversity Law*, No. 7788, 27 May 1998 [“BL”]. According to Article 117, the law has been fully in force since its publication in April 1998. However, an action to declare the law unconstitutional was brought by the Attorney General’s Office. This claim was admitted for study by the Constitutional Chamber (Unconstitutionality Action Number 98-006524-007-CO-M, admitted by October 1998 Resolution). This action was brought against Articles 14 and 22 of the BL. Article 14 creates NACOMB, one purpose of which is to define the national policies for biodiversity, including access to genetic resources. The chapters dealing with the procedural and substantive aspects of access to genetic resources have not been questioned. As a consequence, if the action succeeds, it would only affect the legal competencies of NACOMB in this matter, not the other applicable provisions. According to Articles 81 and 82 of the Law of the Constitutional Jurisdiction No. 7135, the suit does not suspend the execution of the BL. However, from a political point of view it has definitely delayed NACOMB’s implementation.

<sup>27</sup> BL, *supra* note 26 at Art. 3.

<sup>28</sup> BL, *supra* note 26 at Art. 3. The National Commission for the Management of Biodiversity promulgated regulations, “General Rules for the Access to the Genetic and Biochemical Elements and Resources of the Biodiversity”, under the BL on 3 April 2003 in conformity with Article 62 of the law. The regulations came into effect on 15 December 2003 when they were published in the Official Gazette.

<sup>29</sup> Only the University of Costa Rica developed its own access regulations.

<sup>30</sup> BL, *supra* note 26 at Art. 66.

<sup>31</sup> The acronym derives from the Spanish name, Comisión Nacional para la Gestión de la Biodiversidad.

<sup>32</sup> BL, *supra* note 26 at Art. 14.

<sup>33</sup> BL, *supra* note 26 at Art. 17(a).

<sup>34</sup> BL, *supra* note 26 at Art. 17(b).

<sup>35</sup> BL, *supra* note 26 at Art. 17(c).

<sup>36</sup> BL, *supra* note 26 at Art. 17(d).

<sup>37</sup> BL, *supra* note 26 at Art. 62.

<sup>38</sup> BL, *supra* note 26 at Art. 63.

<sup>39</sup> BL, *supra* note 26 at Art. 64.

<sup>40</sup> BL, *supra* note 26 at Art. 67.

<sup>41</sup> BL, *supra* note 26 at Arts. 70 and 71.

<sup>42</sup> BL, *supra* note 26 at Art. 72.

<sup>43</sup> BL, *supra* note 26 at Art. 74.

<sup>44</sup> *Ibid.*

<sup>45</sup> BL, *supra* note 26 at Art. 76.

<sup>46</sup> BL, *supra* note 26 at Art. 80.

<sup>47</sup> BL, *supra* note 26 at Art. 82 and following.

<sup>48</sup> Ley 4.780, de 24 de mayo de 2000, Official Gazette No. 5468.

<sup>49</sup> Santiago Carrizosa, “Diversity of Policies in Place and in Progress”, *supra* note 15.

<sup>50</sup> María Elisa Febres, “Avances Normativos de Venezuela en Materia de Acceso a Recursos Filogenéticos”, document prepared for the Seminario Regional sobre Acceso a los Recursos Fitogenéticos en la Región Andina, Lima, 2003.

<sup>51</sup> Jorge Cabrera Medaglia, *A Comparative Analysis on the Legislation and Practices on Access to Genetic Resources and Benefit-Sharing (ABS): Critical Aspects for Implementation and Interpretation* (The ABS Project, IUCN: Bonn, 2003), online: IUCN [http://www.iucn.org/themes/law/absdocuments/eng\\_critical\\_aspects.pdf](http://www.iucn.org/themes/law/absdocuments/eng_critical_aspects.pdf) (date accessed: 1 February 2005).

<sup>52</sup> The member countries are Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam.

<sup>53</sup> Paz J. Benavidez II, “Philippines: Evolving Access and Benefit-Sharing Regulations” in Santiago Carrizosa *et al.*, eds., *Assessing Biodiversity and Sharing the Benefits*, *supra* note 15 at 171.

<sup>54</sup> *ASEAN Framework Agreement on Access to Biological and Genetic Resources*, 24 February 2000 (draft) [“Framework Agreement”].

- <sup>55</sup> Hanoi Plan of Action, 6<sup>th</sup> ASEAN Summit 15-16<sup>th</sup> December 1998 at para. 6.11.
- <sup>56</sup> Framework Agreement, *supra* note 54 at Art. 3.
- <sup>57</sup> Framework Agreement, *supra* note 54 at Arts. 3 & 4, para. 1.
- <sup>58</sup> Framework Agreement, *supra* note 54 at Art. 6.
- <sup>59</sup> Framework Agreement, *supra* note 54 at Art. 10, para. 2.
- <sup>60</sup> Framework Agreement, *supra* note 54 at Art. 10, para. 1.
- <sup>61</sup> Framework Agreement, *supra* note 54 at Art. 9.
- <sup>62</sup> *Ibid.*
- <sup>63</sup> Benavidez, *supra* note 53 at 154-155.
- <sup>64</sup> Executive Order No. 247, *Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By-Products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes*, 18 May 1995.
- <sup>65</sup> Department of Environment and Natural Resources Administrative Order No. 20, *Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources*, 21 June 1996.
- <sup>66</sup> Republic Act No. 9147, *Wildlife Resources Conservation and Protection Act*, 30 July 2001 ["Wildlife Act"].
- <sup>67</sup> Benavidez, *supra* note 53 at 165.
- <sup>68</sup> Joint Department of Environment and Natural Resources, Department of Agriculture, Philippine Council for Sustainable Development Administrative Order No. 1, *Joint Implementing Rules and Regulations Pursuant to Republic Act No. 9147*, 18 May 2004 ["AO No. 1"].
- <sup>69</sup> Joint Department of Environment and Natural Resources, Department of Agriculture, Philippine Council for Sustainable Development, National Commission on Indigenous Peoples Administrative Order No. 1 (draft), *Guidelines for Bioprospecting Activities in the Philippines*, 14 May 2004 ["Guidelines"]. The Guidelines have been signed by the four bodies but must still be published in order to come into effect, Paz J. Benavidez II, pers. comm. (25 January 2005).
- <sup>70</sup> Wildlife Act, *supra* note 66 at s. 40.
- <sup>71</sup> Wildlife Act, *supra* note 66 at s. 5(a).
- <sup>72</sup> Wildlife Act, *supra* note 66 at s. 14, para. 2.
- <sup>73</sup> Benavidez, *supra* note 53 at 157.
- <sup>74</sup> Guidelines, *supra* note 69 at s. 14-16.
- <sup>75</sup> Benavidez, *supra* note 53 at 166; Wildlife Act, *supra* note 66 at s. 27(f) & 28.
- <sup>76</sup> AO No. 1, *supra* note 68 at Rule 15.1.
- <sup>77</sup> AO No. 1, *supra* note 68 at Rule 15.2.
- <sup>78</sup> AO No. 1, *supra* note 68 at Rule 15.3.
- <sup>79</sup> AO No. 1, *supra* note 68 at Rule 15.4.
- <sup>80</sup> AO No. 1, *supra* note 68 at Rule 15.11.
- <sup>81</sup> Guidelines, *supra* note 69 at s. 22.1.
- <sup>82</sup> Guidelines, *supra* note 69 at s. 22.2.
- <sup>83</sup> Guidelines, *supra* note 69 at Annex V.
- <sup>84</sup> Guidelines, *supra* note 69 at s. 25.1.
- <sup>85</sup> Guidelines, *supra* note 69 at s. 26.1.
- <sup>86</sup> Benavidez, *supra* note 53 at 157.
- <sup>87</sup> Benavidez, *supra* note 53 at 174, footnote 36.
- <sup>88</sup> Benavidez, *supra* note 53 at 174, footnote 37.
- <sup>89</sup> Santiago Carrizosa, "Diversity of Policies in Place and in Progress", *supra* note 15 at 43-46.
- <sup>90</sup> Although not a member of the LMMC.
- <sup>91</sup> *Environment Protection and Biodiversity Conservation Act of 1999* (Cth.)
- <sup>92</sup> *Ibid.* at s. 301(2).
- <sup>93</sup> For details about the process leading to the regulation see Rally Petherbrige, "Australia: Draft Regulations on Access and Benefit Sharing" in Santiago Carrizosa *et al.*, eds., *Accessing Biodiversity and Sharing the Benefits*, *supra* note 15.
- <sup>94</sup> The Queensland *Biodiversity Act 2004* was passed in August 2004. In September 2004, the Northern Territory released its ABS policy for public comment while South Australia is preparing legislation and Western Australia has announced its intention to draft legislation.
- <sup>95</sup> A penalty unit is defined in sec 4AA of the *Crimes Act 1914* (Cth.) as being equal to \$110.
- <sup>96</sup> Kent Nnadozie *et al.* (eds.) *African Perspectives on Genetic Resources: A Handbook on Laws, Policies, and Institutions* (Environmental Law Institute: Washington, D.C., 2003).

- <sup>97</sup> *Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*, 2000 ["Model Law"].
- <sup>98</sup> J.A. Ekpere, "African Model Law on the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources" in *African Perspectives*, *supra* note 96.
- <sup>99</sup> Model Law, *supra* note 97 at s. 1, definition of 'access'.
- <sup>100</sup> *Ibid.*
- <sup>101</sup> *Ibid.* at s. 5.1.
- <sup>102</sup> *Ibid.* at s. 7.2.
- <sup>103</sup> *Ibid.* at s. 8.1(vi) & (vii).
- <sup>104</sup> *Ibid.* at s. 12.1 & 12.2.
- <sup>105</sup> *Ibid.* at s. 2.2
- <sup>106</sup> Ekpere, *supra* note 98 at 283.
- <sup>107</sup> Robert J.L. Lettington, "Access to Genetic Resources in the Republic of Kenya" in *African Perspectives*, *supra* note 96 at 147-148.
- <sup>108</sup> Lettington, *supra* note 107 at 155.
- <sup>109</sup> Lettington, *supra* note 107 at 148.
- <sup>110</sup> Lettington, *supra* note 107 at 151-153.
- <sup>111</sup> Lettington, *supra* note 107 at 149-150.
- <sup>112</sup> Lettington, *supra* note 107 at 150.
- <sup>113</sup> *Environment Management and Coordination Act (1999)*, no. 8 of 1999, entered into force 14 January 2000 ["EMCA"].
- <sup>114</sup> Lettington, *supra* note 107 at 147.
- <sup>115</sup> EMCA, *supra* note 113 at s. 53(1).
- <sup>116</sup> Lettington, *supra* note 107 at 147.
- <sup>117</sup> Lettington, *supra* note 107 at 140.
- <sup>118</sup> S. 13.3(d) quoted in Lettington, *supra* note 107 at 156.
- <sup>119</sup> Lettington, *supra* note 107 at 156.
- <sup>120</sup> White Paper, *infra* note 121.
- <sup>121</sup> South Africa, Department of Environmental Affairs and Tourism, "White Paper on the Conservation and Sustainable Use of South Africa's Biological Diversity" *Government Gazette* General Notice 1095 of 1997, vol. 385, no. 18163, online: Department of Environmental Affairs and Tourism <http://www.environment.gov.za/PollLeg/WhitePapers/Biodiversity/Contents.htm> (date accessed: 4 January 2005).
- <sup>122</sup> White Paper, *ibid.* at chap. 3(C).
- <sup>123</sup> *National Environmental Management: Biodiversity Act, 2004*, No. 10 of 2004.
- <sup>124</sup> *Ibid.* at s. 80 & s. 1.
- <sup>125</sup> *Ibid.* at s. 1.
- <sup>126</sup> *Ibid.* at s. 81(1).
- <sup>127</sup> *Ibid.* at s. 82(1).
- <sup>128</sup> *Ibid.* at s. 82(2)-(3).
- <sup>129</sup> *Ibid.* at s. 83(1).
- <sup>130</sup> *Ibid.* at s. 83(2)
- <sup>131</sup> *Ibid.* at s. 85(1).
- <sup>132</sup> *Ibid.* at s. 101.
- <sup>133</sup> *Ibid.* at s. 102.
- <sup>134</sup> *Ibid.* at s. 1, definition of 'issuing authority'.
- <sup>135</sup> Rachel Wynberg, *Bioprospecting, Access and Benefit-sharing in South Africa: Towards a Strategic Assessment* (May 2004), online: Department of Environmental Affairs and Tourism <http://www.environment.gov.za/ProjProg/ProjProg/2004Jun10/stocktaking/NBSAP%20stocktaking%20Access%20and%20Benefit%20Sharing%20May%202004.doc> at 24.
- <sup>136</sup> Dr. Maureen M. Wolfson, Director: Research Services, South African National Biodiversity Institute, pers. comm. (18 January 2005).
- <sup>137</sup> Wynberg, *supra* note 135 at 16.
- <sup>138</sup> Wynberg, *supra* note 135 at 28-30.
- <sup>139</sup> Wolfson, *supra* note 136.
- <sup>140</sup> COM (1998) 42.

<sup>141</sup> EC, *Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions*, [1998] OJ L 213/13.

<sup>142</sup> Denmark: *Bekendtgørelse om ændring af bekendtgørelse om patenter og supplerende beskyttelsescertifikater*, Bek. nr. 1086 af 11/12/.2000. Spain: *Ley 10/2002, de 29 de abril, por la que se modifica la Ley 11/1986, de 20 de marzo, de Patentes, para la incorporación al Derecho Español de la Directiva 98/44/CE*. BOE no. 103, 30/4/2002.

<sup>143</sup> Commission of the European Communities, “The Implementation by the EC of the ‘Bonn Guidelines’ on Access to Genetic Resources and Benefit-Sharing Under the Convention on Biological Diversity” Communication from the Commission to the European Parliament and the Council, COM(2003) 821 final, (23 December 2003).

<sup>144</sup> Law on Biological Diversity, State Gazette No. 77/ 9.08.2002.

<sup>145</sup> Decreto Lei Nº 118/2002, DR 93, I-A Série de 2002.04.20, Conselho de Ministros . Estabelece o regime jurídico do registo, conservação, salvaguarda legal e transferência do material vegetal autóctone com interesse para a actividade agrária, agro-florestal e paisagística.

<sup>146</sup> See *Access and Rights to Genetic Resources – A Nordic Approach*, online: Nordic Council, <http://www.norden.org/pub/miljo/miljo/sk/N2003016.asp>.

<sup>147</sup> *Scientists Act*, R.S.N.W.T. 1988, c. S-4, as duplicated by s. 29 of the *Nunavut Act*, S.C. 1993, c. 28. Nunavut came into existence in 1999. Prior to this time, the area that is now Nunavut was part of the Northwest Territories. When the new territory was created, the laws in force in NWT became the laws of Nunavut under s. 29 of the *Nunavut Act*. For this reason, both territories have the same *Scientists Act* governing their research licensing systems.

<sup>148</sup> *Scientists Act*, *supra* note 147 at s. 2.

<sup>149</sup> *Scientists Act*, *supra* note 147 at s. 1 & 2(b)

<sup>150</sup> Aurora Research Institute, *Doing Research in the Northwest Territories: A Guide for Researchers* (Aurora Research Institute: Inuvik, NWT, 2004) at 4 [“NWT Guide”]; Nunavut Research Institute, *Compendium of Research Undertaken in Nunavut 2002* (Nunavut Research Institute: Iqaluit, Nunavut, 2002) at 2 [“Nunavut Compendium”], online: Nunavut Research Institute [http://pooka.nunanet.com/~research/NRI\\_compendium\\_2002.doc](http://pooka.nunanet.com/~research/NRI_compendium_2002.doc) (date accessed: 2 February 2005).

<sup>151</sup> Aurora Research Institute, “Definition of Research”, online: Aurora Research Institute <http://www.nwtresearch.com/definition.aspx> (date accessed: 14 December 2004).

<sup>152</sup> NWT Guide, *supra* note 150 at 7.

<sup>153</sup> NWT Guide, *supra* note 150 at 7.

<sup>154</sup> *Scientists Act*, *supra* note 147 at s. 5(1).

<sup>155</sup> *Scientists Act*, *supra* note 147 at s. 7.

<sup>156</sup> Aurora Research Institute, *Compendium of Research in the Northwest Territories 2000* (Aurora Research Institute: Inuvik, NWT, 2000), online: <http://www.nwtresearch.com/media/comp00.pdf> (date accessed: 2 February 2005).

<sup>157</sup> Nunavut Compendium, *supra* note 150.

<sup>158</sup> Preston T. Scott, “The United States of America: The National Park Service Experience” in Santiago Carrizosa *et al.*, eds., *Assessing Biodiversity and Sharing the Benefits*, *supra* note 15 at 177-178.

<sup>159</sup> 36 C.F.R. §2.1(c)(3)(v).

<sup>160</sup> 36 C.F.R. §2.5(a).

<sup>161</sup> Scott, *supra* note 158 at 185.

<sup>162</sup> United States Department of the Interior, National Park Service, “Application Procedures and Requirements for Scientific Research and Collecting Permits”, online: NPS Research Permit and Reporting System <http://science.nature.nps.gov/research/ac/ResearchIndex> (date accessed: 2 February 2005).

<sup>163</sup> 36 C.F.R. § 2.5(b).

<sup>164</sup> Scott, *supra* note 158 at 184.

<sup>165</sup> Scott, *supra* note 158 at 184.

<sup>166</sup> United States Department of the Interior, National Park Service, “General Conditions for Scientific Research and Collecting Permit”, online: NPS Research Permit and Reporting System <http://science.nature.nps.gov/research/ac/ResearchIndex> (date accessed: 2 February 2005) [“General Conditions”].

<sup>167</sup> *Ibid.*

<sup>168</sup> Scott, *supra* note 158 at 181.

<sup>169</sup> *National Parks Omnibus Management Act of 1998*, Pub. L. 105-391, § 205(d), 112 Stat. 3497 at 3500.

<sup>170</sup> General Conditions, *supra* note 166 at para. 6.

<sup>171</sup> Scott, *supra* note 158 at 184.

<sup>172</sup> National Park Service, “Benefits-Sharing for Conservation? Benefits-Sharing Update” (12 April 2002), online: National Park Service [http://www1.nature.nps.gov/benefitsharing/eis\\_scoping\\_letter.pdf](http://www1.nature.nps.gov/benefitsharing/eis_scoping_letter.pdf) (date accessed: 2 February 2005).

<sup>173</sup> National Park Service, “Benefits-Sharing EIS Update” online: National Park Service <http://www1.nature.nps.gov/benefitsharing/involved.htm> (date accessed: 2 February 2005).

<sup>174</sup> “Hawaii’s Bold Bid for a Bioprospecting Bill” *Seedling* (July 2004) 23.

<sup>175</sup> Elizabeth Corbin, Manager, Department of Business, Economic Development and Tourism, Ocean Resources Branch, pers. comm. (19 January 2005).

<sup>176</sup> Kevin Kelly, University of Hawaii, pers. comm. (24 January 2005).

<sup>177</sup> Initiatives for future legislation currently under evaluation are: PRI Initiative (Ley de Investigación, Desarrollo Biotecnológico y Bioseguridad presentada por el Diputado Alejandro Cruz Gutiérrez, del Grupo Parlamentario del PRI; en la Sesión del Jueves 25 de abril de 2002) and Senator Nordhausen Initiative (Iniciativa del Senador *Jorge Rubén Nordhausen González, del Grupo Parlamentario del Partido Acción Nacional, de Ley para el acceso y aprovechamiento de los recursos biológicos y genéticos*).

<sup>178</sup> *Ley General del Equilibrio Ecológico y la Protección del Ambiente*. Official Gazette, January 28, 1988

<sup>179</sup> Jorge Larson-Guerra *et al.*, “Mexico: Between Legality and Legitimacy” in Santiago Carrizosa *et al.*, eds., *Accessing Biodiversity and Sharing the Benefits*, *supra* note 15 at 123.

<sup>180</sup> *Ley General de Vida Silvestre*, Official Gazette 3 July 2000.

<sup>181</sup> See Jorge Larson-Guerra, *supra* note 179.

<sup>182</sup> Cases of the *Maya Internacional Cooperative Biodiversity Group* and the Agreement between *Diversa Corporation Inc.* and the *Universidad Autónoma de México*.

<sup>183</sup> In 1996, a law for the protection of biodiversity was passed by Ecuador’s Congress. The law includes only one article that determines the State’s ownership of the species that constitute the country’s biological diversity. Commercial exploitation will be subject to special regulations issued by the President. Ecuador has been working on a draft regulation since the ratification of Decision 391. The bill (*Ley para la Conservación y Uso Sustentable de la Biodiversidad*) is currently being discussed in the Congress.

<sup>184</sup> The Referential Contract Model includes other elements that may be also regulated in the contract.

<sup>185</sup> Regimen Común sobre Propiedad Industrial, Decisión 486, requires patent applicants to present a copy of the access contract when the subject matter of the patent application has been obtained or developed from genetic resources or their derivatives of which any of the member countries are countries of origin. If applicable, a copy of the authorization for the use of traditional knowledge from indigenous, Afro-American, and local communities when the subject matter of the patent application has been obtained or developed from such knowledge of which any member country is a country of origin is also required.

<sup>186</sup> The Congress is currently working with three bills addressing the regulation of access to genetic resources. [Bill No 306/95](#), introduced by Senator Marina Silva and [No 4579/98](#), introduced as by Deputy Jacques Wagner. The third bill, introduced by the Executive power, was formulated in response to Senator Marina’s bill.

<sup>187</sup> Indigenous Communities involvement: Ley 21 de 1991 que aprueba el Convenio 169 de la OIT and Ley 70 de 1993: Indigenous Communities must be consulted before taking decisions which might affect them.

<sup>188</sup> See applications for non-commercial purposes submitted up to February 2004 in Paola Ferreira-Miani, “Colombia: Access and Exchange of Genetic Resources” in Santiago Carrizosa *et al.*, eds., *Accessing Biodiversity and Sharing the Benefits*, *supra* note 15.

<sup>189</sup> Cuba is currently in the process of passing: *Proyecto de Decreto Ley sobre Acceso a Recursos Genéticos y Reparto Equitativo de Beneficios*.

<sup>190</sup> El Salvador is currently in the process of passing: *Proyecto de Regulación del Acceso a los recursos genéticos y bioquímicos relacionados con la vida silvestre*.

<sup>191</sup> The Action Plan of the National Strategy for the Conservation and Sustainable Use of Biodiversity addresses the need to develop an ABS policy. A moratorium for the collection of plant

genetic resources material was imposed by regulation (Acuerdo Ministerial) 276/89 del 12 de diciembre de 1989. Apparently this moratorium is still in force but is not implemented in practice.

<sup>192</sup> Nicaragua is currently in the process of passing: *Anteproyecto de Ley de la Diversidad Biológica*. For details, see Santiago Carrizosa, "Diversity of Policies in Place and in Progress", *supra* note 15, and Santiago Carrizosa, "Scenarios of Policymaking Process" in Santiago Carrizosa *et al.*, eds., *Accessing Biodiversity and Sharing the Benefits*, *supra* note 15.

<sup>193</sup> It calls on ANAM to set specific access regulations. National initiatives include draft Law 36 that might create an Institute on Traditional Indigenous Medicine. For details see Santiago Carrizosa, *ibid.*

<sup>194</sup> There are also draft regulations, the Environment Protection and Biodiversity Conservation Regulations of 2001, under the EPBCA that are expected to be passed in 2005. Australia also has activity on ABS at the state and territorial level including Queensland's *Biodiscovery Act 2004*.

<sup>195</sup> According to the Guidelines, if the researchers wish to export genetic resources, they will need to seek an export permit from the Minister of Natural Resources.

<sup>196</sup> Initiatives of future legislation currently under evaluation: [PRI Initiative](#) and [Senator Nordhausen Initiative](#), *supra* note 177.

<sup>197</sup> The information in this table was gathered from a variety of sources including the database of ABS capacity-building projects on the CBD website, online: <http://www.biodiv.org/programmes/socio-economic/benefit/projects.aspx>; the websites of the projects themselves; Kathryn Garforth & Jorge M. Cabrera, *A Scoping Study on Future Research Priorities for Access to Genetic Resources and Benefit-Sharing* (Montreal: CISDL, August 2003), online: [www.cisdl.org](http://www.cisdl.org); and Haruko Okuso, "Summary of ABS Capacity Building Activities" (UNU-IAS, September 2004).