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NATIONAL MEASURES ON ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING - THE CASE OF THE PHILIPPINES

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1 INTRODUCTION

The pace at which global biological wealth has become less diverse has speeded up in recent years, implying severe consequences for the future of the biological chain.[1] In an effort to counter this dangerous trend, states adopted in 1992 the Convention on Biological Diversity (CBD),[2] the first international instrument to address the problem of loss of biodiversity on a global scale. Until then, biodiversity issues were addressed through regional conservation treaties and agreements on the protection of certain species.[3]

The CBD was innovative in its objectives, which, according to Article 1, are not merely the conservation and sustainable use of biological resources, but also the fair and equitable sharing of the benefits arising from their utilisation. The Convention stresses the sovereignty that signatory states exert over the biological wealth within their jurisdiction and calls on them to enact national legislation that will contribute to fleshing out the provisions on access to genetic resources and benefit sharing.

The CBD constitutes an admission by the international community that industrialised countries have historically exploited developing countries' resources without providing adequate compensation. Before the CBD was adopted, countries rich in biological resources were in fact unable to benefit from the use that other countries made of their resources. As a result, many species and crops, like quinine, rubber and cocoa, were effectively smuggled abroad.[4]

Presently, there is a wide range of industries that use genetic resources and are active in 'bioprospecting', in other words active in the exploration and collection of biological resources for commercial purposes.[5] While the most prominent of these are certainly the pharmaceutical and agricultural industries, companies involved in the fields of botanical medicine, cosmetic and personal care, biotechnology, seed and crop protection, chemicals, and horticulture industries also play an important part.[6]

In this context, the term 'biopiracy' has emerged to describe the methods used by corporations from industrialised countries to claim ownership or otherwise take advantage of the genetic resources and traditional knowledge that exist in developing countries. Although broadly used by Non-Governmental Organisations (NGOs) and developing countries, this term remains rather controversial and imprecise, leading some experts to prefer the terms 'illegal access' and 'illegal use', both of which are used in the recently adopted Bonn Guidelines.[7]

The CBD also acknowledges the economic importance of genetic resources and biologically-derived materials, especially in relation to their biotechnological uses and applications, by reaffirming the authority of states to determine the physical access to genetic resources within their jurisdiction and to regulate benefit sharing derived from research on genetic resources. Part of the CBD's intent is to encourage states to preserve the biological resources within their jurisdiction by ensuring that both the state providing the resource and the state receiving it receive some of the profits deriving from its commercialisation. The application of economic incentives in the field of biodiversity has also been supported by the World Bank and, in

[1] E. O. Wilson, *The Diversity of Life* 215 (London: Allen Lane, 1993).

[2] Convention on Biological Diversity, Rio de Janeiro, 5 June 1992, 31 *Int'l Leg. Mat.* 818 (1992) [hereafter Biodiversity Convention].

[3] *See, e.g.*, Convention on International Trade in Endangered Species of Wild Fauna and Flora, Washington, 3 March 1973, 12 *Int'l Leg. Mat.* 1085 (1973), Convention on the Conservation of Migratory Species of Wild Animals, Bonn, 23 June 1979, 19 *Int'l Leg. Mat.* 15 (1980), Convention on Wetlands of International Importance Especially as Waterfowl Habitat, Ramsar, 2 February 1971, 11 *Int'l Leg. Mat.* 963 (1972) and Convention on the Conservation of Antarctic Marine Living Resources, Canberra, 20 March 1980, 19 *Int'l Leg. Mat.* 837 (1980).

[4] W. Lesser, *Sustainable Use of Genetic Resources under the Convention on Biological Diversity: Exploring Access and Benefit Sharing* 13 (New York: CABI Publishing, 1997).

[5] W. V. Reid et al., *Biodiversity Prospecting* (Washington, DC: World Resources Institute, 1993).

[6] K. Ten Kate and S. Laird, *The Commercial Use of Biodiversity – Access to Genetic Resources and Benefit-Sharing* (London: Earthscan, 1999).

[7] Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, *Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity*, UN Doc. UNEP/CBD/COP/6/20 (2002). *See also* G. Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* 52 (London: Earthscan, 2004).

particular, by the Organisation for Economic Cooperation and Development (OECD).[8] Both organisations have recently added biodiversity-related projects and studies to their portfolios.

The Philippines was chosen for this study because it is the first country to have enacted access and benefit sharing legislation. As such, it has the longest experience with this issue and represents a valuable example worth observing and analysing. The aim of this article, however, is to find out whether it is efficient to regulate the access and benefit sharing of any given country's biological resources.

This paper starts by introducing the international access and benefit sharing framework shaped by the CBD and the Bonn Guidelines. After a short reference to the implementation strategies of the CBD's objectives regarding access to biological resources and benefit sharing, the paper describes, discusses, and evaluates the effectiveness of the Filipino legislation, in the hope of providing some guidance to policymakers engaged in similar efforts in other resource-rich countries.

2 ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING

Article 15 of the CBD is the basic article laying down the rules for regulating access to genetic resources and benefit sharing. Access rules to genetic resources regulate the procedures for obtaining the permission to do research on or with biological resources. Granting access to genetic resources does not necessarily imply sharing the benefits of subsequent use of genetic resources, even if the Article calls on negotiating parties to do so 'with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources'.[9] Clearly, it is recommended that access agreements should provide a minimum level of protection of the commercial and non-commercial interests of member states.

The CBD's rules governing access encompass all types of biological and genetic resources irrespective of whether they are wild or domesticated, of animal, plant or microbial origin, situated in private or public land or water. However, there are some important exceptions. Firstly, access rules apply neither to genetic resources collected prior to the CBD's entry into force in a particular state nor to ex situ collections. Secondly, facilitated access to some plant genetic resources used in food and agriculture are subject to the specific rules set out by the International Treaty on Plant Genetic Resources for Food and Agriculture.[10] Thirdly, the Conference of the Parties to the CBD has interpreted the access and benefit sharing provisions in such a way as to exclude human genetic resources.[11]

Above all, Article 15 specifies the rights and obligations of states related to the access to genetic resources and their ultimate utilisation. The article authorises states to provide for the regulation of access to genetic resources, under the condition that national level provisions facilitate 'environmentally sound uses by other Contracting Parties'.[12] Moreover, they must not 'impose restrictions that run counter to the objectives of this Convention'.[13]

Thus, the first two paragraphs of Article 15 establish an equilibrium between these rights and obligations. On the one hand, states have the right to determine the conditions for access to the genetic resources in their territory. On the other hand, they have the obligation to facilitate access of other member states to the genetic resources under their jurisdiction. Furthermore, the CBD states that access 'must be on mutually agreed terms' and 'subject to prior informed consent'.[14] The states are then obliged to set the specific terms and conditions specifying these CBD objectives.

[8] *See* International Bank for Reconstruction and Development, *Ensuring the Future – The World Bank and Biodiversity1998-2004* (Washington, DC: The World Bank, 2004), Organisation for Economic Co-operation and Development, *Handbook of Market Creation for Biodiversity: Issues in Implementation* (Paris: OECD, 2004) and Organisation for Economic Co-operation and Development, *Handbook of Biodiversity Valuation – A Guide for Policy Makers* (Paris: OECD, 2002).

[9] Article 15(7), Biodiversity Convention, note 2 above.

[10] International Treaty on Plant Genetic Resources for Food and Agriculture, Rome, 3 November 2001.

[11] Conference of the Parties to the Convention on Biological Diversity, *Report of the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity*, Decision II/11, Access to Genetic Resources, para.2, UN Doc. UNEP/CBD/COP/3/20 (1996).

[12] Article 15(2), Biodiversity Convention, note 2 above.

[13] *Id.*

[14] Article 15(5), Biodiversity Convention, note 2 above.

These principles provide an international legal basis for a quid pro quo arrangement whereby CBD Contracting Parties grant access to genetic resources in exchange for a fair and equitable share of the benefits derived from their use. Both international and national law are key tools in achieving this goal. It should be noted that the provisions contained in Article 15 are also linked to the provisions on access to and transfer of technology, exchange of information, technical and scientific cooperation, the handling of biotechnology and the distribution of its benefits, and financial resources and financial mechanisms.[15]

2.1 Access to Genetic Resources

Access to genetic resources is premised on the three fundamental principles of state sovereignty over genetic resources, mutually agreed terms, and prior informed consent (PIC).

a. State Sovereignty and the Legal Status of Genetic Resources

Both Article 15 of the CBD and Agenda 21 establish clearly the sovereign right of states over genetic resources found within their borders and stress the duty to conserve biodiversity and promote sustainable development.[16] As explained in Agenda 21, states have the sovereign right to exploit their own biological resources pursuant to their environmental policies.

Before the CBD entered into force, genetic resources were considered part of the common heritage of humankind and thus freely available to everyone. This perception is essentially flawed because biogenetic resources within the territory of a country differ from classic common property resources, such as the high seas and airspace, which are not clearly circumscribed by national borders.[17] Importantly, the view of genetic resources as a common heritage is not compatible with the exercise of state sovereignty.

The CBD reaffirms that states have accepted the greater responsibility that comes from having to regulate and manage access and benefit sharing. This relatively recent willingness to exercise control over biological resources contrasts markedly to past approaches largely due to the fact that states now feel the pressure of scarcity, while not long ago natural assets were perceived as abundant and conservation measures unnecessary.[18]

In view of ongoing changes, the FAO International Undertaking on Plant Genetic Resources[19] was revised in 1991 to align itself to the CBD and thus stated that 'the common heritage of mankind (...) is subject to the sovereignty of the states over their plant genetic resources'.[20]

It should be noted, however, that although the CBD highlights states' sovereign rights over genetic resources within their borders, it does not grant the state property rights over these resources. Issues related to property law are not addressed in the CBD, implying that such considerations should be treated in the relevant national legislation implementing the access provision of the Convention.[21] Thus, property law questions concerning biological resources must be legislated by the state to establish the legal status of genetic resources. Defining the ownership interest issue in access and benefit sharing regulation is particularly crucial because it clarifies who is entitled to negotiate, grant the PIC, and share in the benefits derived from the use of genetic resources.

b. Mutually Agreed Terms

According to Article 15(4) of the CBD, the Contracting Parties need to negotiate and agree on the terms of the access agreement -sometimes called the 'material transfer agreement' or 'academic/commercial research agreement'- that authorises access to genetic resources, controls subsequent use, and establishes the type of benefits to be returned. If the provider country claims ownership over genetic resources, then it is up to the state to negotiate the mutually agreed terms and enter into the agreement. Even if the state is not the owner, it can still exercise a certain

[15] Articles 16, 17, 18, 19, 20 and 21, Biodiversity Convention, note 2 above.

[16] Report of the United Nations Conference on Environment and Development, UN Doc. A/CONF.151/26 (Vol. II) 103 (1992).

[17] Dutfield, note 7 above at p. 10 and L. Glowka, *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources* 4 (Gland: IUCN, 1998).

[18] A.C. Kiss, 'La notion de patrimoine commun de l'humanité', 175 *Recueil des Cours – Académie de droit international* 103, 194 (1983) and Lesser, note 4 above at p. 13.

[19] Article 1, International Undertaking on Plant Genetic Resources, FAO Conference Resolution 8/83, 22nd Session.

[20] FAO Conference Resolution 3/91, 26th Session, International Undertaking on Plant Genetic Resources Annex III.

[21] Glowka, note 17 above at p. 4 and 31.

amount of control over agreements on genetic resources within its jurisdiction stipulated between the user and other private or communal parties by virtue of sovereignty rights.[22]

c. Prior Informed Consent

Article 15(5) of the CBD lays down the conditions regulating access to genetic resources in accordance with the notion of PIC. The potential user must inform the provider country of the intention to access and use genetic resources within the jurisdiction of the country before such activities have begun, and obtain consent to do so. The potential user must, therefore, provide information on the kind and quantity of the resource desired, as well as the time-frame and purpose of the activities. In order to facilitate this process, states must legally define the steps involved in the PIC procedure and designate a supervising administrative body to handle it. The procedure must be clear, ensure that sufficient information is communicated, and pave the way for mutually agreed terms.[23] Finally, PIC procedures should not only regulate access but also benefit sharing, thus fulfilling one of the CBD's main objectives.

The CBD considers the development of a legal PIC procedure as a prerequisite 'unless an individual state determines otherwise'. This exception refers to any access procedures, usually related to research, collection, import and export permits, that some countries may already have had in place before the CBD came into force. Although these pre-existing provisions may already be clear, detailed, and adequately meet the CBD requirements, it is recommended that they be reviewed and revised to take into account the benefit sharing aspect.

2.2 Benefit Sharing and Intellectual Property Rights

The main concern of the CBD is not so much to set the ground for access procedures, but to ensure that benefits arising from the utilisation of natural resources are shared and to address global equity considerations. This is achieved by linking the issues of access with that of the sharing of direct and indirect, monetary and non-monetary benefits. Apart from Articles 1, 15(6) and 15(7), benefit sharing is also dealt with in Articles 16, 19(1) and 19(2). Through these provisions, the CBD calls on member states to carry out scientific research based on shared genetic resources,[24] share the results of research and development efforts and the benefits deriving from the commercial or other use of genetic resources,[25] engage in technology transfer,[26] ensure the participation of provider countries in biotechnological research,[27] and promote and advance priority access, on a fair and equitable basis, to the results and benefits arising from biotechnological research activities.[28]

Prior to the CBD and the introduction of specific international access and benefit sharing requirements, the allocation of benefits deriving from the trade of products developed from genetic material was governed solely by international intellectual property rights (IPR). This meant that patented products developed by the biotechnology industry on the basis of genetic material could reap all the benefits of commercialising the product without having to compensate the country of origin.[29] To a certain extent, the CBD remedies this imbalance by upholding the right of all stakeholders to claim monetary benefits that arise from a (possibly patented) product derived from genetic resources. These include the industry, the provider country and, where applicable, indigenous peoples and other associated individuals/communities.

Like many other international instruments, the CBD offers guidelines to states on how to achieve fair and equitable sharing, but it does not actually require benefit sharing. Moreover, the CBD does not specify what are the benefits to be shared. These are assessed on a case-by-case basis and depend very much on local specificities. The way in which the CBD's principles are adopted and adapted by national legislations is, therefore, crucial in promoting effective and context-specific benefit sharing provisions.

[22] *Id.* at p. 9.

[23] *Id.* at p. 9 and 55.

[24] Article 15(6), Biodiversity Convention, note 2 above.

[25] Article 15(7), Biodiversity Convention, note 2 above.

[26] Article 16(3), Biodiversity Convention, note 2 above.

[27] Article 19(1), Biodiversity Convention, note 2 above.

[28] Article 19(2), Biodiversity Convention, note 2 above.

[29] B. Dhar and R.V. Anuradha, 'Access, Benefit-Sharing and Intellectual Property Rights', 7 *J. World Intellectual Property* 597 (2004), Th. Cottier, 'The Protection of Genetic Resources and Traditional Knowledge: Towards more Specific Rights and Obligations in World Trade Law', 1 *J. Int'l Econ. L.* 555 (1998) and E.J. Asebey and J.D. Kempenaar, 'Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention' 28 *Vanderbilt J. Transnational L.* 711 (1995).

Another limitation of the CBD rests on the fact that it is an inter-governmental document that attempts to regulate access and benefit sharing agreements stipulated between private sector representatives and provider countries. Thus, it is also up to the industry to define what is 'fair and equitable'. Unless these matters are well regulated in national law, conflicts may arise between the user state's commitment to international obligations and its duty to protect the interests of its private sector.[30]

The Bonn Guidelines provide a more complete framework of benefit sharing by outlining procedures, listing the types of benefits that can be shared and the distribution, timing, and mechanisms that allow states to implement the Convention's principles through national legislative measures.[31]

2.3 Indigenous Peoples

The CBD is mindful of the fact that in many countries rich in natural resources indigenous and local communities have, for many generations, been the stewards of biodiversity and developed biodiversity management techniques. As such, they cannot be left at the margins of international access and benefit sharing discussions. In recognition of the contributions to conservation and to the sustainable use of biological diversity made by the traditional practices of many local peoples, Article 8(j) of the CBD contains a provision that encourages, but does not require, the equitable sharing of benefits arising from the utilisation of the knowledge, innovations, and practices of indigenous and local communities. In this context, it is clear that rules regulating indigenous peoples' relationship with the state and with the international community come into play.[32]

Corollary to Article 8(j) is Article 10(c), which calls for the protection and encouragement of 'customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements'.

2.4 The Conference of the Parties and the Bonn Guidelines

Beyond the above-mentioned stipulations, the CBD does not specify or give guidance on how fair and equitable benefit sharing is to be adhered to, which is why the Convention has been criticised for vagueness and lack of clarity. The interpretation and legal implementation of the rules set by the CBD for a "fair and equitable" sharing of benefits is currently a matter of discussion among specialists around the world since terms like 'equity' and 'fairness' raise many questions of a political and philosophical nature. What has become clear is that it is extremely difficult to define in detail the rights and obligations of all parties involved in the commercialisation of genetic resources. Equally clear is the fact that this task must be borne by states.

Having identified the problem, the Conference of the Parties (COP) gave a great deal of attention to the interpretation and implementation of Article 15. A panel of experts on access and benefit sharing was appointed[33] to define a common understanding of basic concepts and to explore all available options, and an Ad Hoc Open-ended Working Group was established with the mandate of developing guidelines.[34] In October 2001, this Group met in Bonn, Germany, and developed a series of guidelines on access and benefit sharing, now known as the Bonn Guidelines, that were subsequently considered and adopted at the sixth meeting of the COP.[35] At the Seventh meeting of the COP a number of states stressed that the Ad Hoc Open-ended Working Group should focus on nego-

[30] Article 15(7), Biodiversity Convention, note 2 above.

[31] Section 1(4), Bonn Guidelines, note 7 above.

[32] See Draft United Nations Declaration on the Rights of Indigenous Peoples, UN Doc. E/CN.4/Sub.2/RES/1994/45 and International Labour Organization Convention No. 169 on Indigenous and Tribal Peoples, 27 June 1989, 28 *Int'l Leg. Mat.*1384 (1989). *See also* Sub-commission on the Promotion and Protection of Human Rights, Final Report of the Special Rapporteur, Erica-Irene A. Daes, Prevention of Discrimination: Prevention of Discrimination and Protection of Indigenous Peoples, Indigenous Peoples' Permanent Sovereignty over Natural Resources, UN Doc. E/CN.4/Sub.2/2004/30 (2004).

[33] Conference of the Parties to the Convention on Biological Diversity, *Report of the Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity*, Decision IV/8, Access to Genetic Resources, UN Doc. UNEP/CBD/COP/4/27 (1998).

[34] Conference of the Parties to the Convention on Biological Diversity, *Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity*, Decision V/26, Access to Genetic Resources, para. 10 and 11, UN Doc. UNEP/CBD/COP/5/23 (2000).

[35] Conference of the Parties to the Convention on Biological Diversity, *Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity*, Decision VI/24, Access and Benefit-sharing as Related to Genetic Resources, UN Doc. UNEP/CBD/COP/6/20 (2002).

tiating an international regime on access and benefit sharing.[36] Such a recommendation was clearly influenced by the outcomes of the 2002 World Summit on Sustainable Development, which called for the development, 'within the framework of the Convention on Biological Diversity [and] bearing in mind the Bonn Guidelines, [of] an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilisation of genetic resources'.[37]

In spite of the difficulties encountered in negotiating such an international regime, the Bonn Guidelines proposed by the Ad Hoc Open-ended Group have been accepted as the major instrument in the field of access and benefit sharing adopted by the Parties to the CBD. They are a non-binding legal instrument that focuses on the enhancement of national policy, administrative, and legal processes concerning access and benefit sharing. They cover most, if not all, of the relevant issues including general provisions, roles and responsibilities, stakeholders' participation, provisions regarding suggested elements for Material Transfer Agreements (MTAs), monetary and non-monetary benefits, as well as draft elements for an action plan for capacity building. They also clearly describe the various steps of the whole access and benefit sharing process and provide elaborate instructions for the development of national legislation capable of addressing issues such as mutually agreed terms, PIC, focal points, and benefit sharing.

Particularly interesting is the stance of the Bonn Guidelines towards the users of genetic resources, because they explicitly state the need for developed countries to ensure that the interests of the provider countries are respected and considered.[38] The common but differentiated responsibility that the CBD assigns to countries calls for an exploration of how users of resources may contribute to the fulfilment of the CBD's access and benefit sharing objectives. The Guidelines suggest that user countries adopt measures that include the PIC procedure and that they oblige would-be patent holders to disclose, in intellectual property rights applications, the origin of resources used. Actions and effective measures in user countries may help to moderate tensions among all countries by reducing the burden of provider countries, which are otherwise forced to exert control through the application of extremely restrictive measures.[39]

Another important aspect of the Bonn Guidelines is that they offer a bilateral solution that complements the multilateral system of the already-mentioned Food and Agriculture Organisation's International Treaty on Plant Genetic Resources, which deals with the administration of plant genetic resources with the objective of ensuring food security.[40]

It should be noted that it was possible to include much more detailed provisions in the Bonn Guidelines than in the CBD because of its non-binding nature as governments are more generous and inclined to accept elaborate rules when these rules are only meant as a guide. Nevertheless, the Guidelines also include many areas that have still not been agreed upon such as the use of terms, the measures for verification of compliance with the Guidelines' provisions on PIC, or how to deal with genetic resources that have been synthesised into another form and then commercialised, like pharmaceuticals.

3 IMPLEMENTATION OPTIONS OF THE CBD ACCESS AND BENEFIT SHARING PROVISIONS

3.1 General Implementation Options

The CBD's objectives could be implemented through the following mechanisms:

[36] Conference of the Parties to the Convention on Biological Diversity, *Report of the Seventh Meeting of the Conference of the Parties to the Convention on Biological Diversity*, Decision VII/19, Access and Benefit-sharing as Related to Genetic Resources (Article 15), UN Doc. UNEP/CBD/COP/7/21 (2004).

[37] Para. 44(o), World Summit on Sustainable Development, Plan of Implementation, 4 September 2002, UN Doc. A/CONF.199/20.

[38] Section II (Roles and Responsibilities in Access and Benefit-Sharing pursuant to Article 15 of the Convention on Biological Diversity) C. Responsibilities, paragraphs 16-17, Bonn Guidelines, note 7 above.

[39] S. Louafi and J. F. Morin, 'International Governance of Biodiversity: Involving all the Users of Genetic Resources', 5 *Les Synthèses de l'IDDRI* (February 2004).

[40] *See* W. B. Chambers, 'Emerging International Rules on the Commercialization of Genetic Resources – The FAO International Plant Genetic Treaty and CBD Bonn Guidelines', 6 *J. World Intellectual Property* 314 (2003).

a) The development of an international binding instrument to regulate access and benefit sharing procedures. Following the call of the World Summit on Sustainable Development for an international access and benefit sharing regime,[41] negotiations have started in various international fora, such as the CBD, the FAO and the World Intellectual Property Organisation (WIPO);

b) Regional agreements/national measures addressing access and benefit sharing;

c) Private practices/professional society standards, such as codes of conduct and research guidelines.

The implementation of the fairness and equity principles of the CBD is especially difficult for several reasons. First of all, concepts of fairness and equity are subjective and have different meanings in different places and at different points in time. Unfortunately, the CBD does not provide a definition of what it considers to be 'fair and equitable'.[42] In the elaboration of more precise rules on access and benefit sharing, this uncertainty on the interpretation of 'fairness and equity' has an impact upon the public policy choices on property and intellectual property rights and influences the final private or public law solutions.[43]

Secondly, there are many stakeholders involved, including states, local communities, the private sector, and civil society, all of whom need to be considered in negotiating agreements. Thirdly, there is the problem of how to define and evaluate the value of genetic resources, which is not intrinsic to the resource itself and must therefore be decided by authorities. The final decision will necessarily affect the regulatory effort.

Overall the final and heaviest burden of regulating access and benefit sharing procedures falls on the state and national legislation.

3.2 National Implementation Options

Several countries have passed laws on access to biological resources or are in the process of doing so.[44] These laws typically focus on research, collection, or exportation, but do not address the key issue of how to ensure the sharing of benefits derived from the use of genetic resources contained in biological specimens. Even 12 years after the CBD came into force, existing or emerging national legal frameworks determining access to genetic resources and benefit sharing continue to experience problems. The Philippines is but one example of this reality.

A variety of strategies have emerged in provider countries with the aim of establishing access and benefit sharing measures within their jurisdiction.[45] The first of these is the introduction of a comprehensive law through either a parliamentary procedure or a presidential or legislative order in accordance with national law.[46]

A second strategy takes the form of a new set of laws for the implementation of a much broader set of objectives, such as the establishment of a basic framework for enacting the CBD or the pursuance of general sustainable development principles, together with the development of special provisions on access and benefit sharing.[47]

A third strategy is to amend existing laws that were initially conceived for other purposes but that touch on access and benefit sharing issues. An example is the Indonesian Government's Regulation on Plant Seed Management. Although its main objective is to ensure the good quality of seeds, its provisions on plant seed management contain clauses concerning the introduction and supply of seeds and the propagation of material to, from, and within the country. The advantage of amending existing laws to include, for example, provisions on PIC and mutually agreed

[41] World Summit on Sustainable Development, note 37 above.

[42] Dutfield, note 7 above at p. 45 and M. Byström, P. Einarsson and G.A. Nycander, Fair and Equitable: Sharing the Benefits from Use of Genetic Resources and Traditional Knowledge (Swedish Scientific Council on Biological Diversity, 1999).

[43] S. Peña-Nera, C. Dieperink, and H. Addink, 'Equitable Sharing Benefits from the Utilization of Natural Genetic Resources: The Brazilian Interpretation of the Convention on Biological Diversity, 6 *Electronic J. Comparative Law* (2002), available at http://www.ejcl.org/63/abs63-2.html.

[44] *See* database on access and benefit sharing measures available at the Convention on Biological Diversity web site at: http://www.biodiv.org/programmes/socio-eco/benefit/measures.aspx. There is a large bibliography on the national implementation of the ABS. *See, e.g.*, J. Mugabe et al. eds., *Access to Genetic Resources – Strategies for Sharing Benefits* 94 (Nairobi: ACTS, 1997), G. Henne, *Genetische Vielfalt als Ressource – Die Regelung ihrer Nutzung* 228 (Baden-Baden: Nomos, 1998), and Lesser, note 4 above at p. 52.

[45] Glowka, note 17 above at p. 23 and Conference of the Parties to the Convention on Biological Diversity, Note by the Executive Secretary, Access to Genetic Resources, UN Doc. UNEP/CBD/COP/3/20 (1996).

[46] *Id.*

[47] *Id.*

terms is that the legal framework is developed on the basis of pre-existing administrative structures, policies, and institutions. Such a solution is clearly cost and time-effective, although one drawback is that internal competencies have to be redrawn.[48]

Fourthly, there are national framework provisions. These can justify an export ban on genetic resources, for example, until the effective national legislation is fully in place. As long as the ban allows the state to achieve a legislation that provides for effective access and benefit sharing control, this action does not contradict Article 15 of the CBD. Given the vast differences in national framework provisions that have been adopted by countries worldwide, it is not possible to draw general conclusions regarding their effectiveness.[49]

A fifth option, one that has been implemented in the absence of national legislation on this matter, has been the stipulation of individual bioprospecting contracts. The major problem with these contracts is that they are conditional on the source country's authority over how genetic resources are disposed of in accordance with domestic law. Furthermore, bioprospecting contracts agreed upon between private persons or entities and local communities, individuals, or scientific institutions do not always guarantee the balanced and fair participation of all signatories.[50]

3.3 Regional Implementation Options

At the regional level, there are currently four agreements related to access and benefit sharing. Firstly, the Andean Pact Decision 391 on the Common Regime on Access to Genetic Resources is a legally binding and elaborate instrument. The next two are the draft Central American Agreement on Access to Genetic Resources and Biochemicals and related Traditional Knowledge and the draft ASEAN framework Agreement on Access to Biological and Genetic Resources. Finally, the African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources provides a model for the African countries and it also addresses issues such as farmers' rights, plant breeders' rights and community rights and responsibilities.[51]

Regional measures are very useful because they allow neighbouring provider countries with similar types of biological wealth to set the same access and benefit sharing conditions to user countries. This group agreement avoids the pitfalls of comparative disadvantage between countries and thus strengthens the regime promoted by the CBD.

3.4 Information Exchange on Access and Benefit Sharing

At its Sixth Meeting in April 2002, the Conference of the Parties invited all member states and relevant organisations to submit information on existing measures on access and benefit sharing.[52] Although most Parties did not respond to this call, the CBD Secretariat carried out research based on official sources and government websites. The results were compiled into a database that, as of October 2004, included information on 26 countries.[53]

The Conference of the Parties also provided the Ad Hoc Open-ended Working Group with the mandate to carry out, 'inter alia, an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing'.[54] The Working Group had its first meeting in Bangkok in February 2005.[55]

[48] *Id.*

[49] *Id.*

[50] *Id.*

[51] Para. 76, Ad Hoc Open-ended Group on Access an Benefit-sharing, Conference of the Parties to the Convention on Biological Diversity, Note by the Executive Secretary, Analysis of Existing National, Regional and International Legal Instruments relating to Access and Benefit-sharing and Experience gained in their Implementation, including Identification of Gaps, UN Doc. UNEP/CBD/WG-ABS/3/2 (2004).

[52] Decision VI/24 D, Paragraph 6, note 35 above.

[53] *See* Database on access and benefit sharing, note 44 above.

[54] *See* Decision VII/19, Section D, Preamble, note 36 above.

[55] Ad Hoc Open-ended Group on Access and Benefit-sharing, note 51 above.

4
ACCESS AND BENEFIT SHARING LEGISLATION IN THE PHILIPPINES

The Philippines is one of the richest Southeast Asian countries in terms of biodiversity but, lately, it has experienced a veritable biological 'meltdown',[56] in part because of illegal bioprospecting activities in 2000, for example, three French scientists masquerading as ecotourists were caught trying to smuggle medicinal plants out of the country.[57]

The Philippines started regulating bioprospecting activities before 1995. The principal agency charged with supervising collection and taxonomy activities is the National Museum of the Philippines. Established in 1901 as an ethnography and natural history museum, its mandate was later broadened to encompass arts and science.[58]

In 1987, the Department of Environment and Natural Resources (DENR) was given increased responsibilities with the creation of the Protected Areas Wildlife Bureau (PAWB). In addition, in 1990, government agencies and academic institutions adopted a memorandum of agreement entitled 'Guidelines for the Collection of Biological Specimens in the Philippines', which was mainly an administrative coordination and permit system. Since this system was far from being a regulatory framework for bioprospecting, the usefulness of the memorandum proved limited.[59] Later, Filipino scientists pushed for the development of bioprospecting legislation that could really put an end to the 'exploitation' of the country's genetic resources by foreigners. This eventually led to the adoption of Presidential Executive Order 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.[60] According to the mandate of Section 15 of the EO 247, the document was further clarified by the Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources (DENR Administrative Order 96-20, 21 June 1996) formulated by the Inter-Agency Committee, in force since June 1996 (Implementing Regulations). Together, the EO 247 and the Implementing Regulations established the first detailed legal framework for bioprospecting and access to biological resources.

The second detailed legal framework in the Philippines was introduced by the 2001 Wildlife Resources Conservation and Protection Act together with its 2004 Implementing Rules and Regulations,[61] and, more recently, by the 2004 Draft Guidelines for Bioprospecting Activities in the Philippines. The Draft Guidelines were issued according to Section 14 of the Wildlife Act and Rule 14(1) or Section 14 of the Implementing Rules to the Wildlife Act, which states that the Department of Environment and Natural Resources, the Department of Agriculture and the Palawan Council for Sustainable Development 'must issue joint guidelines specific for bioprospecting'.

These new laws repeal any conflicting provisions in the EO 247 and are expected to bring about a significant reform to Filipino bioprospecting legislation, especially through the 2004 Draft Guidelines, despite the fact that at the moment they only have the status of a Code of Conduct and are not binding.

In addition, the use of biological resources is affected by a number of other laws, including the Indigenous Peoples' Rights Act, the National Integrated Protected Area System Act, the Traditional and Alternative Healthcare Act, and the National Museum Act.[62] Although these laws usually conform to the EO 247 regime, they could, in some cases, influence the legal force or interpretation of the primary access and benefit sharing law. As will be demonstrated

[56] K. Liebig et al., Governing Biodiversity – Access to Genetic Resources and Approaches to Obtaining Benefits from their Use: The Case of the Philippines 30 (Bonn: German Development Institute, Reports and Working Papers 5/2002, 2002) and C.V. Barber and A.G.M. La Viña, 'Regulating Access: The Philippines Experience', *in* J. Mugabe et al. eds, *Access to Genetic Resources: Strategies for Sharing Benefits* 116, 121 (Nairobi: ACTS, 1997).

[57] R. Dalton, 'Bioprospects less than Golden', 429 *Nature* 598 (2004).

[58] Barber and La Viña, note 56 above at p. 115, 121.

[59] *Id.*

[60] EO 247, 18 May 1995 which entered into force on 18 May 1995. *See also* K. Swiderska, E. Dano and O. Dubois, Developing the Philippines' Executive Order No. 247 on Access to Genetic Resources, Participation in Access and Benefit-Sharing Policy 7 (London: International Institute for Environment and Development, 2001).

[61] The 2001 Republic Act No. 9147 (Section 14) and the 2004 Implementing Rules and Regulations (Chapter III - Section 14) of Republic Act No. 9147 (IRR, Joint DENR-DA-PCSD Administrative Order 01, 18 May 2004).

[62] Respectively, Republic Act 8371, 29 October 1997, Republic Act 7586, 1 June 1992, Republic Act 8423, 9 December 1997 and Republic Act 8492, 12 February 1998.

below, the IPRA has had a particular influence on the Executive Order. Considering that the Draft Guidelines for Bioprospecting are soon going to become law, potential inconsistencies are highlighted here.

Taking into account that the CBD only came into force in 1993, the Philippines enacted access and benefit sharing legislation very quickly and comprehensively, to the point that some foreign bioprospectors have sternly criticised Filipino legislation as over-ambitious.[63]

In the following sections, the access and benefit sharing regulatory environment in the Philippines will be described and evaluated. This regulatory framework is understood as comprising the EO 247, the Indigenous Peoples' Rights Act, and the Wildlife Act with the Draft Guidelines based on the Wildlife Act's Implementing Rules.

4.1 Executive Order 247 and the Implementing Regulations

The preamble of the EO expressly refers to Article 16 of the CBD and to the rights of indigenous cultural communities in the Philippines to preserve their knowledge and practices put, directly or indirectly, to commercial use. The four basic elements in this law involve the establishment of the Inter-Agency Committee (IAC), a scheme for mandatory research agreements, a regulation on achieving PIC from local communities, and requirements on conforming to environmental protection standards.[64]

a. Scope of the law

The scope of the EO is defined in the Implementing Regulations. Accordingly, the EO 247 governs all biological and genetic resources in the 'public domain', namely in the water and lands owned by the state that have not been declared alienable and disposable.[65] Further, it governs naturally-growing plants in private lands that are used for bioprospecting with a view to the discovery, research, or use of resources in the pharmaceutical, agricultural, or other commercial sector irrespective of whether the users are foreign or national individuals, entities, or government or private organisations.[66] Since traditional uses fall beyond the scope of the law, land races and animal races are not contemplated in the Implementing Regulations.[67]

b. The prior informed consent procedure

The concept of PIC plays a key role in the application processes of both academic and commercial research agreements provided for in the EO and detailed in the Implementing Rules.[68]

According to the regulations, the location and legal status of the collection area determine who must be asked for PIC. A copy of the application proposal must be delivered to the local governmental unit responsible for the collection of resources found on communal land. This unit can be represented by the head of the local and/or indigenous cultural community or communities that may be affected, the protected area's management board, or a private landowner. The latter have 60 days to decide whether to raise objections, after which time further action on the application procedure may be taken.

The EO requires that biological and genetic resources prospecting within the borders of ancestral lands and indigenous cultural communities shall be allowed only once the PIC of the concerned communities has been obtained in accordance with their customary laws. The Implementing Regulations define indigenous cultural communities or indigenous peoples as a

> *homogenous society identified by self-ascription and ascription by others who have continuously lived as community on mutually bounded and defined territory, sharing common bonds of language, customs, traditions and other distinctive cultural traits, and who, through resistance to the political, social and cultural inroads of colonization, became historically differentiated from the majority of Filipinos.*[69]

[63] Liebig et al., note 56 above at p. iii.

[64] C.V. Barber, L. Glowka and A.G.M. La Viña,'Developing and Implementing National Policy Measures for Genetic Resources Access Regulation and Benefit-sharing', *in* S.A. Laird ed., *Biodiversity and Traditional Knowledge – Equitable Partnerships in Practice* 363, 404 (London: Earthscan, 2002), Liebig et al., note 56 above at p. 31, Swiderska et al., note 60 above at p. 28 and Henne, note 44 above at p. 230.

[65] Implementing Regulations, Section 2(z).

[66] Implementing Regulations, Section 3.

[67] Implementing Regulations, Section 3(1)b.

[68] EO, Section 4 and Implementing Regulations, Section 2(1)w (PIC definition) and Sections 6(1)3 and 7.

[69] Implementing Regulations, Section 2(1)r.

c. Academic Research Agreements and Commercial Research Agreements

Once the PIC has been obtained and the application for carrying out bioprospecting activities has been accepted, the contracting parties sign either an academic research agreement (ARA) or a commercial research agreement (CRA), depending on the precise nature of the activities envisaged.[70] ARAs deal with prospecting biological and genetic resources for academic purposes and only duly recognised Filipino universities and academic institutions, domestic governmental and intergovernmental entities can apply for this kind of agreement. CRAs, on the other hand, deal with research and collection activities intended, whether directly or indirectly, for commercial purposes and thus encompass all agreements stipulated with private persons, corporations, and foreign or international entities. Clearly, the EO assumes that all bioprospecting agreements other than those undertaken with domestic research institutions and domestic governmental/intergovernmental entities have economic ends.

The starting point for such an assumption is that ARAs can act as a cover for any future commercial use made of the results of academic research, especially when these commercial activities are carried out abroad. In cases where a domestic academic bioprospector detects the possibility of marketing the results of research, s/he must apply for a CRA.[71]

The EO also stipulates minimum terms regarding information, collection, technical cooperation and benefit sharing to be included in ARAs and CRAs.[72]

d. The Inter-Agency Committee

The EO established the Inter-Agency Committee, a body located within the DENR and supported by a technical secretariat.[73] Its work is to coordinate the processing of bioprospecting applications and access and benefit sharing procedures, and to discuss institutional, political, and technological developments related to the EO. A multi-stakeholder approach was chosen to ensure the participation of all the relevant agencies and concerned social groups and to do justice to all the differing interests. Thus, the IAC is composed of representatives from the Department of Environment and from the science and technology, agriculture, and health sectors of the National Museum as well as of representatives from the Ministry of Foreign Affairs, who serve as links with foreign prospectors and supervise any agreements signed with them. Among the other representatives, there is a person from an NGO active in biodiversity protection and a person from a peoples' organisation of indigenous cultural communities.

The IAC also functions as the national focal point for all the access and benefit sharing procedures.

e. Environmental protection requirements

The law further stipulates that all prospecting activities and their results must not, whether directly or indirectly, harm biodiversity, ecological balances, or the inhabitants of the area where resources are being collected. An environmental impact assessment that ensures conformity with these requirements is mandatory for both ARAs and CRAs alike but, in practice, it is the technical secretariat that determines if the assessment actually needs to be conducted. Usually, it is not demanded for ARAs.[74]

f. Other aspects

An appeal against any decision can be lodged before the President within 30 days, after which time the judicial path is open.[75] Prospecting activities without an agreement are considered criminal acts and any behaviour that contradicts the agreement is a reason for cancellation or revocation of the agreement in favour of the government, confiscation of collected material, forfeit of the bond and perpetual ban from prospecting activities in the Philippines without prejudice to administrative sanctions. All breaches are published nationally and internationally.[76]

[70] EO, Section 3.

[71] EO, Section 5(n).

[72] EO, Section 5 and Implementing Regulations, Section 8 (CRAs are required to include additional terms).

[73] EO, Section 6 and Implementing Regulations, Sections 10 & 11.

[74] Implementing Regulations, Section 6(1)4.

[75] Implementing Regulations, Section 13.

[76] Implementing Regulations, Section 14.

4.2 The 1997 Indigenous Peoples' Rights Act

The Indigenous Peoples' Rights Act (IPRA) was enacted in 1997 as a way of recognising, protecting, and promoting the rights of indigenous cultural communities (ICCs) and indigenous peoples (IPs). Today, it is considered as one of the most comprehensive attempts at introducing the principles in Article 8(j) of the CBD into national legislation.[77]

The Act created the National Commission on Indigenous Peoples (NCIP)[78] and upholds indigenous ownership rights over land and resources. The Act includes the basic right of ownership and development of lands and resources, and the right to regulate the entry of migrant settlers and organisations.[79]

Moreover, the Act defines the term 'ancestral domain' and confers property rights to indigenous communities over lands, inland waters, coastal areas, and natural resources contained therein.[80] In this context, indigenous customary laws and existing property rights regimes are expressly recognised[81] and the free and prior informed consent of members of ICCs/IPs is demanded for any activity conducted by outsiders on ancestral domain. Specifically, the Act states that

> *'access to biological and genetic resources and to indigenous knowledge related to the conservation, utilisation and enhancement of these resources, shall be allowed within ancestral domains of the ICCs/IPs only with prior informed consent of such communities, obtained in accordance with customary laws of the concerned community.*[82]

With respect to indigenous knowledge systems and practices, the IPRA acknowledges the full ownership and control of the indigenous peoples over their cultural and intellectual rights, over their sciences and technologies and over derivatives. The IPRA implies that the PIC of the indigenous peoples is always necessary for the grant of any IPR to third parties, based on specific elements of indigenous culture, knowledge and activity.[83]

However, it should be noted that all of the rights listed above are conditional on the obligation to maintain ecological balance and restore denuded areas.[84]

Interestingly, the 'prior informed consent' mentioned in the EO and the 'free prior informed consent' included in the IPRA are not identical. However, since the IPRA supersedes the EO, the PIC procedure provided for in the most recent document should be the modus operandi for all bioprospecting activities in ancestral domains.[85] There is no empirical data on FPIC applications falling under the scope of the EO, but this overlap has now been explicitly resolved with the new Draft Guidelines for Bioprospecting.

4.3 The Wildlife Act and its Implementing Rules (Bioprospecting Undertaking)

The Wildlife Resources Conservation and Protection Act entered into force in 2001 with the primary objective of conserving and ensuring the sustainability of all wildlife resources and habitats in the Philippines.[86] The Act defines bioprospecting as research, collection, and utilisation of biological and genetic resources solely for commercial purposes and deems such activities as legal once the interested party has formally declared, in a Biodiversity Undertaking (BU),[87] its willingness to abide by the terms and conditions set by the Secretary for the protection of biodiversity. The BU requires the interested party to obtain the PIC of concerned indigenous communities and, if the applicant is a foreign individual entity, a local institution must become involved in the agreement. The Secretary of the DENR or the Secretary of the Department of Agriculture (DA) or both, depending on the jurisdictional stipulations of the Act, is charged with coordinating the BU.[88]

[77] Barber et al., note 64 above at p. 384.

[78] IPRA, Chapter VII.

[79] IPRA, Section 7.

[80] *See also* definition of 'ancestral domains' in the EO Implementing Regulations, Section 2(1)c.

[81] IPRA, Section 2.

[82] IPRA, Section 35.

[83] IPRA, Section 34.

[84] IPRA, Section 9.

[85] Liebig et al., note 56 above at p. 33 and 51.

[86] Wildlife Act, Section 2.

[87] Wildlife Act, Section 5(a).

[88] Wildlife Act, Section 4 confers jurisdiction to the DENR over all terrestrial wildlife and to the DA over aquatic wildlife, except for the Province of Palawan, where because of the existing special regime, jurisdiction is vested in the Palawan Council for Sustainable Development. The distribution of jurisdictional powers is elucidated in the Implementing Rules.

It is worth noting that the Draft Guidelines based on the Wildlife Act are only applicable to CRAs since the Act does not consider ARAs to fall under 'bioprospecting activities'. For the ARAs the execution of an affidavit of undertaking or memorandum of agreement by the applicant and the issuance of a gratuitous permit by proper or concerned authorities are necessary.[89]

When it was first implemented, EO 247 evoked negative responses from academic and other research bodies. The pharmaceutical industry, for instance, complained about the long and tedious approval process for concluding research agreements. It soon became clear that the regulatory measures defined by the EO 247 were discouraging the advancement of research on biological resources.

To address these concerns, the Protected Areas Wildlife Bureau (PAWB) of the DENR initiated the development of a Joint DENR-PCSD-DA-NCIP Administrative Order under the title 'Draft Guidelines for Bioprospecting Activities in the Philippines' as part of a project called 'Support to the Implementation of EO 247 in the Philippines' funded by GTZ, Germany's state-owned agency for technical cooperation. The Guidelines form a code of conduct based on the mandate of Rule 14(1) in the Wildlife Act, which provided for the inter-agency issuance of guidelines specifically for bioprospecting. The Guidelines also form an attempt to streamline the access and benefit sharing procedure in the Philippines, facilitate compliance, and establish a cost-effective, transparent, and standardised system.

The Guidelines were drafted by an inter-agency technical group composed of representatives from the policy offices of each signatory agency (DENR, DA, and PCSD) with guidance from legal and technical consultants. The draft underwent three public consultations involving government agencies, academic institutions, NGOs, indigenous peoples' organisations, and representatives of other private and public sector entities. PAWB was also consulted with key stakeholders, especially with experts who have dealt with government agencies on the specific issue of processing applications for bioprospecting. The final draft was reviewed by an inter-agency technical working group created for this purpose.

The most salient changes envisaged in the draft guidelines include

- the exclusively commercial nature of bioprospecting agreements (as mentioned above), which would make ARA conditions and procedures simpler;
- the abolition of the IAC and the strengthening of the Secretary, whose role should be assisted by implementing agencies; and
- importantly, the introduction of detailed guidelines on benefit sharing.

a. Scope of the guidelines

The Guidelines apply to all biological and genetic resources found in the Philippines such as wildlife, private lands, ex situ collections, protected areas, and ancestral domains.[90] They also establish a uniform procedure for evaluating and granting access to biological and genetic resources, thus avoiding any potential problems due to inconsistencies in bioprospecting regulations managed, for example, by different government agencies. Once again, the collection of resources for application in traditional fields falls beyond the scope of the law.[91]

b. Prior Informed Consent procedure

The issue of PIC remains an important element in the framework regulating access and benefit sharing so that, in this sense, the procedures envisaged by the Guidelines are not radically different from those in the EO. However, some changes have been made to the stages of notification and public consultation for the issuance of the PIC certificate:

a) Proposed users of resources now have to inform interested parties of their intention to carry out bioprospecting activities through a letter of intent;

b) A summary or outline of the research proposal must be delivered to the affected community in a language or dialect that is understandable to them, a requirement missing from the EO and the Implementing Regulations;[92]

c) The Guidelines expressly refer to the FPIC process of the IPRA in cases where consent needs to be obtained from indigenous peoples;[93]

d) Concerned agencies or private owners have 30 days to issue the PIC certificate, half the time stipulated in the EO to the community.

[89] Wildlife Act, Section 15 and Implementing Rules.

[90] Draft Guidelines, Section 2.

[91] Implementing Regulations, Sections 4 and 5.

[92] Draft Guidelines, Chapter 5.

[93] Draft Guidelines, Section 4 and 12.

c. Detailed benefit sharing provisions

The introduction of detailed benefit sharing provisions in the Guidelines is significant.[94] The Implementing Regulations of the EO 247 only provide definitions of benefit sharing and equitable sharing.[95] According to these definitions, the results of bioprospecting activities and the utilisation or commercialisation of biological resources are to be fairly and equitably shared between the collector and the indigenous cultural community, local community or the owner of the affected protected area or private land. Apart from these definitions and the indicative list of results, which include payment for access to specimens, royalties, data, technology, capacity building, training and joint research, the EO's Implementing Regulations do not regulate benefit sharing. All that is intended by 'equitable benefit sharing' simply refers to the benefit sharing that was mutually agreed upon by the parties in the research agreement.

In contrast, the draft guidelines significantly limit the freedom of signatories of bioprospecting agreements with regard to the benefits to be shared. The Guidelines also specify every single detail of the process, including the kinds of benefits that can be drawn and the beneficiaries. Thus, equitable sharing is not merely understood as 'benefits equally shared between the collector/user and the provider groups exercising management jurisdiction and/or having rights over the areas where the biological resources were collected',[96] but as a much more complex concept, which explains why the Guidelines devote a whole chapter to the subject.

Equitable sharing further and most importantly means that monetary benefits reach the concerned local community 'and are used solely for biodiversity conservation or environmental protection, including alternative or supplemental livelihood opportunities for community members'.[97] This provision is fully in the spirit of the CBD.

In addition, the Guidelines put in place a mechanism for monitoring the principles of fairness and equity in benefit sharing, with a checklist of suggested indicators.[98]

d. Institutional changes

The role of the IAC was not clear under the Wildlife Act, which conferred responsibility to the Secretaries of the DENR and DA. The Draft Guidelines clarify this issue by expressly dissolving the IAC because, despite its interdisciplinary character and procedures, it was not an efficient body. In the Palawan Province, where decentralised bioprospecting regulations are more appropriate, it is either the DENR/DA Secretaries or the Palawan Council Chairperson who are now assigned the main coordinating tasks and responsibilities. When it comes to evaluating the requirements set by the draft guidelines, they are assisted by technical committees. Whenever bioprospecting involves ancestral domains/lands or involves specimens for medicinal purposes, an NCIP representative and/or a representative from the Philippine Institute for Traditional and Alternative Health Care sits on the committee.[99]

e. Other aspects

The new legislative framework contained in the draft guidelines addresses the deficiencies of previous laws and responds to experiences gained through the application of the EO. In addition to the changes outlined in detail above, it is notable that the draft guidelines set a uniform procedure for accessing genetic resources used for commercial purposes and clarifies previous overlaps between the various legislative instruments. It simplifies the bureaucratic process of reviewing and approving bioprospecting applications,[100] it reduces the bioprospecting fee for local commercial researchers with the aim of promoting research and development in the country and it requires the involvement of a local collaborator in any bioprospecting activity. For the sake of enhanced clarity and simplicity, the draft guidelines also contain eight annexes that lay out a uniform format, for example for the MTAs and for requesting and submitting PIC. The draft guidelines do not, however, make any significant changes to the sanctions and penalties contained in the EO.[101]

[94] Draft Guidelines, Chapter VI.

[95] Implementing Regulations, Sections 2(1)e and n.

[96] Draft Guidelines, Section 19(1).

[97] Draft Guidelines, Section 19(2).

[98] Draft Guidelines, Section 23 and Annex V.

[99] Draft Guidelines, Section 5.4.

[100] Bioprospecting applications must now be reviewed within 15 days instead of 30 and approved/denied within 30 days.

[101] Draft Guidelines, Section 31.

5 EVALUATING ACCESS AND BENEFIT SHARING LEGISLATION IN THE PHILIPPINES

Together with its Implementing Regulations, the EO 247 has established a detailed access and benefit sharing legal framework that is actually based on the CBD principles but that regulates bioprospecting to a much higher degree than required by the Convention. Given its experimental nature, this first access and benefit sharing legal framework has been somewhat problematic.[102] Nonetheless, a considerable effort is being made at the national level to identify the drawbacks and build up the relevant regulatory environment of the Philippines. There is little doubt that the Wildlife Act and its Implementing Rules are going to have a significant effect on the implementation of the EO, as will the draft guidelines issued on 14 May 2004.

In order to evaluate the degree to which Filipino legislation meets the objectives of the CBD, it is necessary to identify its scope and the relevant stakeholders, examine the application of PIC procedures, and detect what the benefits are and to whom they are allocated.

5.1 Scope of the legislation

The EO and its Implementing Regulations did not clearly state whether applicants wishing to access the collections of the International Rice Research Institute (IRRI), an International Agricultural Research Centre (IARC) based in the Philippines, needed to obtain the consent of the Government.

The role of the IRRI is special in that it is a trustee rather than beneficial owner of the plant genetic material in its collections.[103] Obtaining access to IRRI collections, therefore, means concluding a standard MTA that includes a clause prohibiting recipients of IRRI germplasm from claiming either ownership of the material or intellectual property rights over that germplasm or related information.[104]

Furthermore, it was unclear whether such a clause applied only to specimens originating in the Philippines or to all materials in the IRRI collection. In practice, the IRRI has continued to provide access to its collection under its MTA without requesting permission from the authorities.

The draft guidelines have addressed this lack of clarity and extended the jurisdiction of access and benefit sharing provisions to include ex situ collections like those held by the IRRI when they are used for commercial purposes, thus going further than either the CBD or the Bonn Guidelines. This amendment will require the IRRI to change its current procedures and involve the government in transfers of material to a much higher degree than previously.

5.2 The Stakeholders

Possible stakeholders in bioprospecting agreements include the state, local and indigenous communities, scientific institutions, representatives of the industrial sector and NGOs. As has already been mentioned, the Inter-Agency Committee's stake in the process has been totally nullified by the decision to disband this body.

a. The State

According to the CBD, states should exert sovereignty over their genetic resources and should, therefore, be responsible for regulating access to resources in their territory. Clearly, then, the state is a stakeholder in contracts negotiated under access and benefit sharing laws. In the Philippines, the state is represented by competent agencies within the DENR (for terrestrial biodiversity) and the DA (for marine biodiversity).

[102] Liebig et al., note 56 above at p. 30 and 71 and O.B. Zamora, 'The Philippines: A Bridle on Bioprospecting? *GRAIN Seedling* (June 1997), available at http://www.grain.org/seedling/?id=13.

[103] C. Fowler, 'The Status of Public and Proprietary Germplasm and Information: An Assessment of Recent Developments at FAO', *IP Strategy Today* (7-2003).

[104] H. Leung, G.P. Hettel and R.P. Cantrell, 'International Rice Institute: Roles and Challenges as we Enter the Genomics Era', 7 *Trends in Plant Science* 139 (2002) and K. ten Kate and A. Collis, *Benefit Sharing Case Study – The Genetic Resources Recognition Fund of the University of California, Davis* 5 (Submission to the Executive Secretary of the Convention on Biological Diversity by the Royal Botanic Gardens, Kew, 1998).

b. Local and indigenous communities as stakeholders

Local and indigenous communities become stakeholders whenever bioprospecting activities take place on lands that are not designated or protected areas or are not privately owned. In the Philippines, there are two main types of local (non-indigenous) political organisation, the barangays (communities of approximately 500 households) that are represented by a captain and municipalities, represented by a mayor. The representatives of these communities are assigned the responsibility of deciding whether to sign a PIC certificate or not, on the basis of a case-by-case analysis. The active participation of the communities' members rests largely on the local political elite's commitment to involving his/her constituency and on awareness-raising activities carried out by NGOs.[105]

When bioprospecting activities take place on ancestral lands, the situation changes due to the added role of indigenous communities. The Philippines hosts approximately 4.5 million indigenous people representing more than 70 ethnolinguistic groups. Indigenous people can be distinguished not only by their different cultural lifestyles but also because they tend to have an attitude to using and managing natural resources that privileges sustainability and that is based on a holistic perception of the land. Indigenous peoples' experiences with outside interventions such as logging and dam-building have been extremely negative because they have led to violations of rights and exploitation of the affected communities. These experiences, coupled with more recent but equally bitter conflicts over resources on ancestral lands, have made indigenous communities generally sceptical of the potential benefits of bioprospecting.[106]

c. Scientific Institutions

Filipino scientists have long recognised that the exploitation of biodiversity has rarely been beneficial for the country. It was a group of scientists, in fact, whose call for greater regulation in this field led to the development and enactment of EO 247.[107] Their objective was to push political and legal actors to end the exploitation of the country's natural resources by foreigners and to foster domestic technological development. Unfortunately, since the EO 247 has entered into force, only three research agreements have been signed (two CRAs and one ARA) and all with the University of the Philippines in Diliman, Quezon City. Most universities and research institutions refrain from bioprospecting activities in order to avoid possible accusations of biopiracy. The Philippines National Museum, on the other hand disputes that its academic operations fall within the scope of the EO 247.[108]

d. The Industrial Sector

The industrial sector in the Philippines has not shown much interest in bioprospecting, as proven by the fact that only one research agreement has been applied for since 2002. The reason for this is that access and benefit sharing regulations are not of relevance to Filipino companies. The Pharmaceuticals and Healthcare Association of the Philippines, whose members are national and international companies, confirmed the concerns of multinational companies about the long deadlines and processes under the EO 247.[109] It is hoped that the new regulatory environment will better address the needs of the Filipino medicinal sector, in particular the herbal one, and encourage it to be an active user of the country's resources.

e. Non-Governmental Organisations

There are many, very dynamic NGOs in the Philippines, some of which are even appointed by the government to advocate national interests in the country and, in some cases, within international debates. NGOs have played a crucial role in empowering local communities and promoting sustainable development and biodiversity conservation in the Philippines.[110]

With regard to access and benefit sharing, Filipino NGOs tend to follow one of two extreme positions. The first rejects any bioprospecting activities in the country, claiming that they constitute biopiracy and capitalist exploitation. The second is generally supportive of bioprospecting activities, as long as they abide by existing rules. NGOs that hold the second position participate actively in the implementation and enforcement of access and benefit sharing

[105] Liebig et al., note 56 above at p. 34.

[106] *Id.*

[107] Swiderska et al., note 60 above at p. 7.

[108] Liebig et al., note 56 above at p. 35, 63.

[109] *Id.*

[110] Swiderska et al., note 60 above at p. 12.

legislation in the Philippines and have been very involved in the IAC. Due to their competencies, they have acquired a certain degree of power and are considered important actors on the political scene.[111]

5.3 Procedures for Applying for Agreements and Obtaining PIC

Given that, sooner or later, scientific research in the biotechnology sector leads to commercial applications, the distinction made in the EO 247 between academic and commercial research agreements is mainly based on the nature of the institutions applying for the research agreement. While it is clear that monitoring domestic research institutions is easier than monitoring foreign counterparts because there are fewer bureaucratic complications, it is doubtful whether the same can be said about inter-governmental entities.[112] After all, the difficulty of abiding by administrative procedures for the ARAs acted as a disincentive for research.[113]

The issue of PIC is absolutely central to Filipino legislation on access and benefit sharing. The process is based on public notification and sector consultation with the concerned local or indigenous cultural communities to secure consent and thus meets the requirements of Articles 8(j) and 15(3) of the CBD. The principles of local community participation and protection are reflected in both the EO 247 and the draft guidelines.[114]

Despite complying with the CBD, actual implementation of existing PIC mechanisms remains difficult. For example, ensuring the participation of concerned communities is not sufficient if the communities are not aware of their rights and/or of the enforcement procedures. Effective participation means informing and instructing the affected populations in a language they understand, as well as allowing them to reflect and make a decision. Finally, efforts must be made to promote the democratic nature of consultative procedures by avoiding undue influence being given to tribal leaders and families who enjoy exceptional privileges, thus hindering the fairness of the PIC process.

Given the problems encountered in obtaining PIC from indigenous communities, it has been proposed that anyone seeking to carry out bioprospecting activities on ancestral domains or lands should presume that such activities are not possible and that they should work to counter this presumption by presenting the authorities with clear and convincing evidence that the affected indigenous community(ies) want the activity to take place.[115] Despite this 'presumption of impossibility', drug industries continue to show the greatest interest in biological resources located within indigenous territories because of the traditional knowledge that the indigenous people possess, which is deemed to be of great value for the conduct of research and development.

Hence, the practice of obtaining PIC is a rather complex task and discourages users, who are required to cooperate on-site with governmental entities, NGOs, and peoples' organisations so as to identify the communities' representatives and, when necessary, to apply the relevant customary law. Any difficulties that might arise from disagreements between the various negotiating parties also need to be overcome. Hopefully, the difficulties currently experienced by users attempting to obtain PIC will be identified and the laws amended with a view of facilitating the whole process.

At the moment, the International Conservation Biodiversity Group (ICBG) is carrying out a drug discovery project in the Philippines. Through this project, Michigan State University is working with several departments of the University of the Philippines to document and explore the therapeutic potential of natural products from documented and undocumented medicinal plants, invertebrates and microbes throughout the Philippines, with the support of local indigenous communities. The effectiveness of the PIC process will be tested in this case.[116]

5.4 Sharing the benefits

The EO set the framework conditions for the sharing of benefits but did not regulate for the subsequent use of these benefits. It did not ensure that any potential monetary or non-monetary benefits would reach the source communities or that they would be used to foster conservation, as required by the CBD. The draft guidelines, however, provide some very specific directions in this sense

[111] Liebig et al., note 56 above at p. 35.

[112] Henne, note 44 above at p. 234.

[113] Zamora, note 102 above.

[114] Liebig et al., note 56 above at p. 42 notes that the guidedlines do not introduce considerable changes to the principles formulated in the EO.

[115] Barber and La Viña, note 56 above at p. 129.

[116] *See* ICBG awards at http://www.fic.nih.gov/programs/icbg.html#Introduction.

and cover the gap of the previous legislation. For example, the draft guidelines require Filipino collaborators to always be engaged in bioprospecting activities conducted by foreign users, thus ensuring that they are present once the new product has been developed which can take as long as 8 to 12 years from the initial collection of genetic resource[117]

The two agreements stipulated to date - between the University of the Philippines and the University of Utah, and between the Pascual Laboratory and a British pharmaceutical company - show that there have not been long-term benefits yet and that the short-term benefits go first to the scientific community of the Philippines.[118]

In the case of the collaboration between the Pascual Laboratory and the British pharmaceutical company, a joint venture was created. The medicinal properties of a product called Lagundi were patented by Filipino state agencies and a non-exclusive license was issued to Pascual to commercialise the plant. Pascual is currently negotiating a commercial research agreement with a British company and the benefits will depend on the development from the British company of a standardised herbal medicine .[119]

6 CONCLUDING REMARKS

In theory, regulations affecting application, PIC, and benefit sharing procedures are designed to guarantee transparency, stakeholder participation, and equitable sharing of the benefits. In practice, Filipino laws have been criticised for their long and complex procedures and there have been very few applications for research agreements.[120] The laws have also been hindered by the absence of local and regional officials and of indigenous and local communities from the EO negotiation and drafting process. Lack of funding and time, local political conditions, and difficulties with defining representation among the diverse indigenous peoples and communities have hampered consultation efforts. Hence, officials and indigenous peoples have not even been aware of the EO or have not fully understood it and thus ignored it.[121] The draft guidelines are expected to correct the failures and fill the gaps in the EO, which should be thought of as nothing more than a basic framework for regulating bioprospecting activities in the Philippines.

From the viewpoint of the industry, the main bone of contention is the procedure for obtaining PIC, which is particularly difficult because the Philippines has placed strict protective measures such as the IPRA as a means of safeguarding its indigenous communities. Despite this protective stance, users who are really willing to carry out bioprospecting activities in the Philippines, even on ancestral lands are able to do so.

Although it is certainly true that the Philippines could promote the signing of more agreements by developing procedures that promote research, it is not only the source country that is to blame for the low number of applications. In fact, part of the burden for access and benefit sharing should be shifted from provider countries to user countries. The legal basis for this shift is contained in Article 15(7) of the CBD, which foresees that 'each Contracting Party shall take legislative, administrative or policy measures (...) with the aim of benefit sharing' (emphasis added). Furthermore, the Bonn Guidelines list responsibilities that user countries have with regard to access and benefit sharing, further stressing that providers and users of genetic resources are obliged to take action. To this end, a continuum of measures by the public and private sector should be envisioned. For example, government activities could involve amending national intellectual property regimes to require the identification of the country of origin. Another idea could be to make the application for a patent conditional upon confirmation of PIC. In other words, all parties, providers and users, are responsible for the good functioning of access and benefit sharing mechanisms.

Another step that the Philippines could take is to promote a unified, regional system in the ASEAN context. Although bioprospecting legislation is underway in a number of ASEAN countries, the Philippines regulatory framework sets higher performance standards for industry and research institutions. This means that the Philippines are at a competitive disadvantage vis-à-vis neighbouring countries because users will prefer to invest in less 'complicated' countries with biologically similar environments. While institutions in each of the ASEAN countries could undertake and regulate bioprospecting through independ-

[117] Under Article 5(h) of the EO, Filipino researchers only had to be involved for three years.

[118] Liebig et al., note 56 above at p. 47.

[119] *Id.*

[120] Swiderska et al., note 60 above at p. 7, and Liebig et al., note 56 above at p. 23 and 28.

[121] Swiderska et al., note 60 above at p. 20.

ent agreements, it might be more profitable for some institutions to provide raw materials to a cooperative. The cooperative combines the three principal advantages of economies of scale, vertical integration of services, and bargaining power.[122]

The foundations for fair and equitable benefit sharing in the Philippines have been properly laid and it is a very positive indication that the Philippines monitors the implementation and makes efforts to learn by making its regulations more operational and effective. It is a country that developed its access and benefit sharing regime even before the detailed Bonn Guidelines. What is a priority now for the Philippines is to focus on capacity building, plan better and develop opportunities to add value to the material they provide by fostering research and prioritising non-monetary benefits.

Although the Philippines is the country with the longest tradition on access and benefit sharing regulations, its hands-on experience in this field is still very recent. It is therefore still early to draw conclusions on the effectiveness of the new system developed by the Philippines. However, in view of the rapid progress in the area of access and benefit sharing measures and of the administrative developments to manage biodiversity that have been set up in the past few years, it is hoped that all the necessary conditions will be met in order to allow the legal regime in the Philippines to become increasingly effective.

[122] Barber and La Viña, note 56 above at p. 135.