

Regulating the Access to Genetic Resources: Recent Advances in Latin America

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"The Earth's biological resources are vital to humanity's economic and social development. As a result, there is a growing recognition that biological diversity is a global asset of tremendous value to present and future generations" (Convention on Biological Diversity, 1994). In fact, humanity has already obtained enormous economic benefits from the open access to genetic resources in the form of foods, medicines, and industrial products; but concerns are now being expressed, both about the risks of extinction and future conditions of access. Whereas individual plants, animals, and other living organisms traditionally constitute private goods, the genetic information responsible for their preservation does not. In the latter lies the real value of the resources and there the problems are particularly complex.

Considerable progress has been made in developing an international framework for the protection of intellectual property rights for biotechnology-derived inventions, and for the conservation, use, and access to genetic resources. However, to what extent developing countries, where an important part of biodiversity is concentrated, can profit from sovereign rights contemplated in the Convention on Biological Diversity (CBD) is still not clear. This paper presents an overview of recent advances in the development of the legal and policy framework to regulate access to genetic resources in some Latin American countries.

ACCESS TO GENETIC RESOURCES: FROM A FREE FLOW SYSTEM TO SOVEREIGNTY

Since 1946 the Food and Agriculture Organization of the United Nations (FAO) has been involved in the conservation and use of genetic resources for food and agriculture. The free exchange of germplasm was a major and controversial theme in the debates during FAO Conference meetings in 1979, 1981, and 1983. As a result, FAO established a permanent intergovernmental forum, the Commission on Plant Genetic Resources, and a legal framework, the International Undertaking on Plant Genetic Resources. The Undertaking is a non-binding agreement between countries to cooperate in the conservation of genetic material and to work together for its sustainable development. Regarding the ownership and control over plant genetic resources, the Undertaking declared all germplasm, including breeders' lines and elite varieties, as common heritage.

Major changes concerning access to genetic resources have been taking place within the Commission. According to the 1983 Undertaking, common heritage meant free access. Article 5 of the Undertaking stated that adhering governments and institutions will make genetic resources under their control available "free of charge, on the basis of mutual exchange or on mutually agreed terms." In 1989, the Undertaking was modified through FAO resolution 4.89 on an agreed interpretation of the Undertaking, including a recognition of breeders' rights, and resolution 5.89 on farmers' rights. Resolution 4.89 also clearly stated that the term "free access" did not mean "free of charge." During the 1991 FAO Conference, another amendment to the Undertaking was approved introducing the concept that "nations have sovereign rights over their plant genetic resources and that breeders' lines and farmers' breeding material should only be available at the discretion of their developers during the period of development." (Solleiro, 1995).

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Under these last provisions, countries adhering to the Undertaking agreed to confer access to the samples of genetic materials under their control only for specific purposes, excluding access with an aim to reproducing the materials for commercial purposes, such as for propagating seeds (Correa, 1994).

Conservation, access, and use of plant genetic resources are not the goals of FAO alone. The Convention on Biological Diversity (CBD), adopted at the Earth Summit in Rio de Janeiro in June 1992, represents an attempt to balance the interests of the gene-rich South with those of the gene-poor but technology-rich North. In Dec. 1993, the Convention became, unlike the FAO International Undertaking, a legally binding framework for conserving and utilizing global diversity. It confirmed the principle of the sovereign rights of states over their natural resources, including the authority to determine access to genetic resources by national legislation (Article 15.1). For the first time, Article 1 of the Convention, in which its objectives are set forth, has addressed three distinct issues in a single instrument (Organisation for Economic Co-operation and Development, 1996), namely: "the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies taking into account all rights over those resources and to technologies..."

With the establishment of the Convention, the basic principle of sovereignty over genetic resources was confirmed. Thus, the right of access by other contracting parties is dependent upon the conditions established by the legislation and competent authorities of each country. It is also subject to the country's prior consent, provided further that "mutually agreed terms" are reached between the parties. This effectively implies that future transfers of genetic resources will be made under material transfer agreements designed to protect the source nation's interests in any resulting profits.

Furthermore, the World Action Plan for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture, promoted by FAO and adopted in June 1996, represents an additional international instrument for the successful implementation of the CBD by establishing specific actions for the conservation (in-situ and ex-situ), improvement, and utilization of plant genetic resources, as well as for institutional development and capacity building.

REGULATIONS OF ACCESS TO GENETIC RESOURCES: THE FIRST EXPERIENCES

The first developing country to issue specific regulations for the access to genetic resources was the Philippines. In May 1995, this country adopted a Presidential Executive Order which regulates bioprospecting. "It requires prospectors to negotiate a research agreement with the government, and to seek prior informed consent and to share benefits with national stakeholders such as local communities and indigenous peoples" (ten Kate, 1995). The main provisions of the Order are presented in Table 1.

For most specialists in biodiversity legislation, the Philippine approach is very restrictive and inhibits private investment aimed at developing new businesses from genetic resources, even though the explicit intention of the Philippine government was to establish a clear framework for an equitable share of benefits with potential investors, rather than to erect barriers to them. After 3 years of enforcement of the Executive Order, the Philippines has very little experience in the establishment of bioprospecting agreements with international firms.

Table 1. The Philippine regulatory framework.

- A limit is established on the samples that may be collected and exported.
- A complete set of all specimens shall be deposited with the Philippine National Museum.
- Access to collected specimens and relevant data deposited abroad shall be allowed to all Filipino citizens.
- The Collector or Principal must inform the Philippine government and affected local and indigenous communities if a commercial product is derived from its activities.
- Provisions are established for the payment of negotiated royalties or other forms of compensation to the National Government, local or indigenous cultural community, and individual person or designated beneficiary where there is commercial use.
- The involvement of Filipino scientists in the research and collection process at the cost of the Collector is mandatory.
- Agreements must contemplate the transfer of equipment to a Philippine institute where appropriate.
- A fixed fee must be paid to the Department of Environment and Natural Resources.

In the Rural Advancement Foundation International's Global List of Companies and Intermediaries, only one of 67 bioprospecting agreements involves a Philippine institution. Janssen Pharmaceutica N.V. works in agreement with West Visaya State Univ. (Philippines) and Rijksuniversiteit Gent (Belgium) to collect animals, plants, fungi, and microorganisms (Rural Advancement Foundation International, 1997).

Some Latin American countries, aware of the importance of developing their legal infrastructure for biodiversity management, have recently improved the legal framework for accessing their genetic resources, building capacities to identify, conserve, and use genetic resources, and better negotiating the terms of future agreements. For those countries, the Philippine experience is an excellent case to study. In several meetings (for example in Mexico City in 1995 and in Cali in 1996) Latin American specialists have discussed the potential impacts of adopting similar approaches. The following section shows that the Latin American approach tries to achieve a better balance between conservation, business promotion, and benefit-sharing than does the Philippine approach.

RECENT EXPERIENCES IN LATIN AMERICA

Costa Rica, a Latin American country rich in biological diversity, has followed a different approach without having specific legislation to regulate access. The Law for the Conservation of Wild Life establishes that the use of genetic material is of public interest and the Ministry of Natural Resources (MIRENEM) is the competent body to grant concessions for its exploitation. Through the creation of a private, not-for-profit institution, the National Biodiversity Institute (INBio), Costa Rica has promoted pioneering agreements that provide "significant returns to Costa Rica while simultaneously assigning economic value to natural resources, and providing a new source of income to support the maintenance and development of the country's conservation areas" (Sittenfeld, 1996). In its first agreement INBio agreed to inventory and supply to Merck, on an exclusive basis, over a period of 2 years, samples of plants, microorganisms, and animals from the Costa Rican rain forests in exchange for a down payment of \$1 million and 5% of royalties arising from the sale of products derived from these biological materials. New agreements have been signed with other international companies, and INBio has emphasized building special capacities aimed at adding value to collected materials. For this purpose, INBio has started an important program to train "parataxonomists," Costa Rican farmers who learn to classify collected biological material. Capacity building is also strongly oriented to the development of greater negotiation skills to deal with technology and material transfer agreements. INBio's approach has drawn criticism from many policy analysts in developing countries, mainly because INBio is a private organization and therefore should have no rights to lay claims to what is seen as national heritage.

Costa Rica is now trying to draft a law regulating biodiversity. A sign of the above mentioned criticism is that the first draft, prepared by the Mesoamerican Regional Office of the World Union for Nature for the Environment Commission of the Costa Rican Congress, is very

defensive and very different from Costa Rica's previous experience in managing genetic resources. Surprisingly, Costa Rica, despite being the Latin American country with the strongest experience in negotiations of bioprospecting agreements and business development, has produced a draft legislation intended to limit commercial exploitation of biodiversity. This clearly indicates lack of internal agreement among different groups (particularly environmentalists). The draft law proposes to regulate the access, use, and handling of all living beings, wild and domesticated, present in waters, soil, and air, as well as their impact on human activities. It also would establish special conditions for the granting of patents and other intellectual property rights that are not in accordance with the Trade-Related Intellectual Property Issues (TRIPs) standards of the World Trade Organization. The draft also includes a complete chapter on biosafety that drastically restricts the number and type of biotechnology-based and bioprospecting activities to be conducted in the country. This proposal provoked a heated debate and was not passed by the Congress. Further discussions are expected to develop a more balanced approach in which conservation objectives and promotion of sustainable use can coexist. Table 2 shows the main features of the draft law (Costa Rican Congress, 1996).

In Brazil, the initiative for the Access to Genetic Resources Bill (Senado Federal, 1996) was provided by Senator Marina Silva, representative of the Labour Party in the State of Acre, Amazon Region. The bill is currently under discussion, and is still awaiting passage by the Senate. Table 3 presents the main features of the bill.

The proposed bill is an attempt to implement parts of the CBD. Building on experiences of other Latin American countries, particularly the legislative process of the Andean countries, and on consultation with indigenous communities, the bill is a balanced proposal that establishes provisions to protect national interest without erecting excessive barriers to potential prospectors and investors. Thus, it clearly differs from the Costa Rican proposal. Unlike the Costa Rican draft, the Brazilian approach includes no biosafety regulations or prohibitions to the granting of IPRs that are against TRIPs. Nevertheless, criticisms of the proposal have already been expressed, including:

- "...the subjects of technology transfer and the national capacity building in the field of conservation and utilization of biological resources are barely mentioned.
-the relatively new theme of 'collective intellectual property rights', which refers to the recognition of indigenous and traditional knowledge about biological resources, is a crucial element of the bill; however, it does not give any provision of how to regulate and operationalize these rights...

Table 2. Main provisions of the first draft of Costa Rica's Biodiversity Law.

- The draft contains a statement on the rights of present and future generations: equity, access to information, access to information on biosafety, biosafety, and avoidance of risks.
- A system of collective rights for the intellectual contribution of local communities is established and restrictions to intellectual property rights are indicated.
- A biosafety framework restricts the introduction of biotechnology products.
- The scope of regulations covers ecosystems, all living species, and genes.
- The law creates a new institutional framework for planning, management, oversight, and assessment of its different provisions, including the following new institutions: the National System for Biodiversity Planning, the National Biodiversity Commission and Advisory Councils on Biotechnology, Biosafety, Sustainable Use, Intellectual Property, and Indigenous Matters.
- Access is considered not only when obtaining actual samples of organisms and their parts and derivatives; samples and biochemical extracts; genetic elements; and soil, air, and water, but also in acquiring knowledge, innovations, and practices of indigenous and local communities.
- The law establishes an obligation for signing access contracts with the State (in public land), the private owner of a plot after approval of the State (in the case that genetic resources are in private properties), or the social organization representing indigenous communities.
- The law establishes the requirement of previous informed consent for accessing genetic resources and the explicit prohibition to access human genetic resources and their protection by intellectual property rights (IPR).
- Under the law, the State must assure technology transfer and establish exclusions to the patentability of products and processes considered basic for food and health.
- The law recognizes collective intellectual property rights and creates a Register of *sui generis* IPR.

•the crucial question of benefit sharing still needs more refinement.” (Alencar and van der Ree, 1996).

The Andean countries (Venezuela, Colombia, Ecuador, Bolivia, and Perú) adopted in July 1996 Decision 391 of the Cartagena Agreement regulating access to genetic resources of member countries. The Decision’s objectives are the fair and equitable sharing of benefits derived from the use of genetic resources, the recognition and valuation of genetic resources and their derived products and intangible components, the promotion of biodiversity conservation and sustainable use, and the consolidation and development of local capacities.

As in the cases of Costa Rica and Brazil, Andean countries also confirm sovereignty over genetic resources and derived products, and the principle of recognition of innovations, knowledge, and traditional practices of local communities. Decision 391 explicitly proposes to establish sound mechanisms for: capacity building, research, development and technology transfer; sub-regional cooperation; the prevention of genetic erosion and environmental degradation; the free sub-regional transit of biological resources; and the generation of safe and transparent procedures to enforce regulations.

Under Decision 391, access to genetic resources requires presentation, admission, publication, and subscription of a contract of access. The parties of the contract will be the applicant and the State, but an annex requires, in recognition of the rights and interests of the suppliers of genetic materials, a fair and equitable share of the benefits derived from their use. Table 4 presents the general conditions to access genetic resources under Decision 391.

Mexico has ratified the CBD, and the General Law of Ecological Equilibrium and Environmental Protection, in its amendment of 13 Dec. 1996, requires (Article 87 bis) a license granted by the Secretary of the Environment, Natural Resources and Fisheries for the utilization of wild Mexican flora and fauna as well as other biological resources. This article also requires the previous informed consent of the owner(s) of the plot where such resources are located, and states that the owner(s) will have the right to a fair and equitable share of the benefits derived from the commercial use of the resources.

Article 87 bis provides a basis for the development of specific legislation, but a specific proposal to regulate the access to genetic resources in Mexico is still under development. To develop a draft of such legislation, the United Commissions of the Senate (the Commissions of Agriculture, Science and Technology, the Environment and Promotion of Small and Medium Enterprises) and the National Commission for the Knowledge and Use of Biodiversity (CONABIO) have begun consulting with the different stakeholders. The process is being assisted by an Advisory Committee consisting of nine specialists from industry, academic institutions, and nongovernmental organizations (NGOs) representing interests of indigenous communities. The experiences and the legislative process of Costa Rica, Brazil, and the Andean countries were discussed during a seminar hosted by the Senate in May 1997. They provide answers to important questions, especially those dealing with the main items to be covered by a legislation of access and those that are part of other legal instruments, as in the case of biosafety regulations and intellectual property protection. Assessing the experiences of those countries has provided a basis for reaching a high level of consensus in Mexico on the need for a legislation that protects the sovereign rights of the country over its genetic resources and, at the same time, encourages the sustainable commercial use of Mexico’s biodiversity. Nevertheless, important questions are still unresolved. We still have to find an adequate and effective way to assess the value of traditional knowledge and informal innovations and to protect them through a sound system of collective intellectual property rights. We have to develop a system to compensate local communities for this intellectual contribution and to share with them the benefits of commercial exploitation of genetic resources. We expect that consultation among communities and other stakeholders will provide feasible solutions to these problems.

Table 3. Brazil: Provisions of Bill of Law 306/1995.

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- The State preserves diversity, integrity, and sustainable use of the genetic patrimony.
 - The law confirms principles of sovereignty; participation of local communities and indigenous peoples; national participation in economic and social benefit; priority to undertaking carried out within the national territory; promotion of and support for the various forms of generation of knowledge and technologies; protection and encouragement of cultural diversity; biosafety and food safety; and guarantee for individual and collective rights.
 - Access to genetic resources is subject to: previous authorization by competent body; information about the resources; methods, techniques and collection systems and tools to be used; location of the areas of access; destination of material collected; opinion and participation of populations involved; and monitoring by a Brazilian technical and scientific institution.
 - The law establishes the obligation of payment of financial compensation to the State. Funds are to be assigned to the National Environment Fund.
 - The law defines specific rules for collective IPRs and a system of collective registration.
 - Arrangements shall be made to guarantee and facilitate, for national researchers, the access to, and transfer of, technologies.
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Table 4. Decision 391: Conditions for access to genetic resources.

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- Prospectors and collectors must present previous application to conduct their activities
 - Agreements shall include: participation of citizens of member countries in research activities; support for research in the country of origin; strengthening of technology and knowledge transfer mechanisms; supply of information on the background of the research and the scientific advancement in the specific field of activities to be conducted; measures for capacity building at local institutions; provisions for strengthening and building capacities in indigenous communities; deposit of duplicates of collected material; statement on the obligation to inform the National Competent Authority on results of research; and terms for the eventual transfer of the material to third parties.
 - Confidential treatment of information is granted by the Authority
 - An explicit prohibition of the use of genetic resources and their derivatives for military purposes is established.
 - The Decision recognizes local and Andean biosafety and environmental regulations.
 - The Decision establishes limitations of access to endemic or endangered species, strategic genetic resources, and fragile ecosystems.
 - It also establishes specific measures to restrict activities that may have adverse effects on human health, essential elements of peoples’ cultural identity, the environment, or biosafety regulations, and activities that may cause genetic erosion.
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