Law and Policy of Relevance for the Management of Plant Genetic Resources in Latin America¹

(Summary of Presentation)

Introduction

Over the past decade or so, countries in South and Central American have experienced substantial policy and legal developments in regard to biodiversity and related issues, such as access to genetic resources and benefit sharing (ABS), protection of traditional knowledge (TK), biosafety, intellectual property rights (IPR), biotechnology, and biodiversity planning, among other things.

The *Convention on Biological Diversity* (CBD) has played a pivotal role in raising the profile of these issues and streamlining them into environmental and non-environmental agendas at the international, regional, and national levels. As a result, they are now not only part of high-level political discussions but also of daily debates among a broad range of stakeholders, from indigenous communities, NGOs and research institutions to the private industrial and commercial sector interested in products and services derived from biological resources.

The CBD has in some cases inspired new rules and principles in regard to these issues. These in turn have important legal and policy implications that require careful and expert analysis. For instance, the substantial content of the concept of 'prior informed consent' (PIC) or 'mutually agreed terms' or the exact meaning of 'sovereignty' or the implications of intellectual property rights as applied to genetic resources all have numerous and complex legal questions related to them. For people without legal training, such as most scientists and science managers, decisions on how these questions are answered may have a practical and direct impact on their own daily research activities and, ultimately, on the conservation and sustainable use of biodiversity.

In this context, the International Service for National Agricultural Research (ISNAR) and the International Plant Genetic Resources Institute (IPGRI) launched *a Learning Module on Law and Policy of Relevance to the Management of Plant Genetic Resources* in 2003 as a means to train and build a general capacity among managers and those involved in the direct use of genetic resources to deal with these issues. The focus of this Module is legal and policy analysis of issues related to genetic resources, as addressed in international instruments and forums such as the CBD, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (IT), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO).

As part of this effort, this paper focuses the analysis on a regional (Latin American), subregional and national perspective. It offers a brief overview of policy and legal developments and some of the trends currently seen in discussions and debates regarding genetic resources in the region (and individual countries). This will help readers understand the relevance of different issues related to genetic resources and some of the policy and regulatory options countries are taking in view of their broader international obligations.

¹ Background paper prepared by Manuel Ruiz.

Regional progress in the implementation of key international instruments related to biodiversity

The Convention on Biological Diversity (CBD)

All countries in South and Central America have ratified the CBD and most are very active in its implementation and in the CBD negotiation process in general.

Implementation of the CBD has, in most cases, focused on the formulation of biodiversity policies and development of legislation, planning, regulations and administrative measures as well as the execution of a wide range of projects for conservation and sustainable use. The overall results of these efforts have included national biodiversity strategies and plans, general biodiversity laws (or adjustments and amendments to sectoral legislation), biosafety laws and legislation, and administrative measures concerning access to genetic resources and benefit sharing.

Negotiating positions presented by countries in South and Central America at a wide range of international forums, such as the CBD, WIPO, the World Summit for Sustainable Development (WSSD) or WTO, have focused mostly on genetic resources, traditional knowledge and intellectual property. An international regime on access and benefit sharing (COP Decision VII/19), substantive review of article 27.3.b of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), and an international regime for the protection of traditional knowledge are some of the key positions these countries are proposing.²

National Biodiversity Strategies

National biodiversity strategies and action plans (NBSAPs)—and similar instruments—have been developed in most countries in the region. All include specific references (in terms of policy guidelines, mandates, actions, program areas and so on) to access to and use of genetic resources and related issues, such as biosafety, traditional knowledge, etc.

Countries now face the challenge of integrating and mainstreaming NBSAPs into overall national (and sectoral) development policies and plans. This is still an ongoing and complex process where existing legislation, institutional frameworks and governmental policies on natural resources play, in most cases, a decisive role. Biodiversity-related policy and regulatory competence tend to be concentrated in recently created environmental ministries or councils (focal points for CBD), such as CONAM in Peru, CONAGEBIO in Costa Rica, CONADIBIO in Guatemala or CONABIO in Mexico, creating a degree of tension and friction with traditional sectoral jurisdictions over natural resources in general.

Access to legislation on genetic resources

Since the entry into force of the CBD, ABS has steadily become a critical concern for most South and Central American countries. For regional members of the Like-Minded Group of Megadiverse Countries³ and Southern Cone countries (Argentina, Chile, Paraguay and Uruguay), genetic resources represent an important scientific, political and legal issue, even if

² Rosell, M. and M. Ruiz. 2003. Lineamientos técnicos. apoyo a la negociación internacional de los países miembros de la Comunidad Andina en materia de acceso a los recursos genéticos y conocimientos tradicionales. Corporación Andina de Fomento, Comunidad Andina de Naciones, Lima.

³ These are 15 of the most biodiversity-rich countries in the world: Brazil, Bolivia, Costa Rica, China, Colombia, Ecuador, India, Indonesia, Kenya, Malaysia, Mexico, Peru, Philippines, South Africa and Venezuela. Although not formally part of this group, Suriname and Guyana in South America and, possibly, Panama and Belize in Central America could also qualify as megadiverse or at least very diverse.

for varying reasons and interests. All countries in South America and most in Central America have at least one major bio-prospecting project under way, which includes partnerships among industry, academia, indigenous communities and the State and which reflects the interest the region has in biodiversity research and development.

Country (sub-region)	Document	Status
Andean Community of Nations (Bolivia, Colombia, Ecuador, Peru, Venezuela)	Regional Biodiversity Strategy	Approved by Decision 523 in 2002
Argentina	National Biodiversity Strategy	Concluded in 2000
Bolivia	National Biodiversity Strategy	Concluded and approved by Government in January, 2001
Brazil	No NBSAP but a National Biodiversity Policy document	Approved by Decree 4339 (August, 2002)
Colombia	Has National Biodiversity Policy and Technical Proposal for development of a National Biodiversity Action Plan	Not formally approved but being used by the Ministry of the Environment
Chile	NBSAP	Approved in 2002
Costa Rica	National Strategy for the Conservation and Sustainable Use of Biodiversity	Approved in 2000
Guatemala	National Strategy for the Conservation and Use of Biodiversity and Action Plan	Approved in 1999
Ecuador	NBSAP	Published in 1999
El Salvador	NBSAP	Under development
Mexico	NBSAP	Under development
Nicaragua	NBSAP	Finalizad in 2001
Guyana	Biodiversity Action Plan	Completed in 1999
Panama	NBSAP	Under development
Paraguay	National Biodiversity Strategy	Approved in 2003
Peru	NBSAP	Approved through Supreme Decree 102 – 2001 / PCM
Uruguay	NBSAP	Published in 1999
Venezuela	NBSAP	Published by the Ministry of the Environment in 2001

Table 1. Status of National Biodiversity Strategies and Action Plans in South and Central America

Note: Although Mexico is not formally a Central American country, *per se*, it has been included as part of Central America for the purpose of providing extra information on policies and laws in the region regarding ABS, biosafety, etc.

During the early '90s, ABS was closely linked to the promise of reaping considerable economic benefits from access to and the use—especially commercial and industrial—of genetic and biochemical resources in the biotechnological, pharmaceutical, industrial and agro-industrial sectors. The 'great bargain' achieved through the CBD triggered policy and regulatory processes in almost all countries.

The Andean Community of Nations (the Andean Pact at the time, formed by Bolivia, Colombia, Ecuador, Peru and Venezuela) established the first regional set of common, standardized principles and obligations on ABS. *Decision 391 on a Common Regime on Access to Genetic Resources* (July 1996) was the result of the first widely participatory experience in the context of the Andean Community. Decision 391 becomes legally binding

in all five Member States once it has been adopted and published in the official Andean Community Gazette. There is no need for congressional approval or any other formal procedure for its incorporation into national law. Decision 391 has become a milestone in international law, and many conceptual approaches, drafts and even existing legislation elsewhere have incorporated elements and specific ideas from it. Decision 391 operates through a set of mechanisms and instruments that include access to applications for genetic resources, conditions for minimum access, contracts (access contracts with the State and accessory contracts with owners of biological resources) and an administrative procedure overseen by a national competent authority. All genetic resources are under State domain. This means that States have property rights over genetic resources, whether as part of wild or domesticated biodiversity. This domain derives from sovereignty and the formation of States (and their rights over natural resources), which, in turn, derive from principles of Roman/Latin law. Some experts have highlighted the complexities of dealing with, for example, domesticated crops or resources, for which it will be extremely difficult to convince their owners that they don't really own their genetic composition. This could be taken to the absurd if you think of domesticated animals such as dogs or cats.

An Access Contract is signed between the State (as the owner of genetic resources) and the applicant. The applicant will also have to sign an Accessory Contract with the owner of the biological resource (the land on which it may be located), with an *ex situ* conservation centre or with indigenous communities whose biological resources are collected. The substantial benefits to be negotiated will be part of the Access Contract, leaving owners of biological resources with little margin for negotiation.

All types of research (commercial and non-commercial) are covered by Decision 391.⁴ Colombia and Venezuela have been applying Decision 391 without further national regulations and with different degrees of success. Bolivia enacted a specific regulation on ABS (Supreme Decree 24676 [1997]) but, overall, implementation has not been particularly successful. Over the past few years, Ecuador and Peru have been developing national regulations for the implementation of Decision 391.

Following the Andean process in 1997, under the aegis of the Central America Commission for the Environment and Development (and following naturally from the Convention of Biodiversity and the Protection of Wilderness Areas in Central America), Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama developed the Central America Agreement (Protocol) on Access to Genetic and Biochemical Resources and Related Traditional Knowledge. Though still in draft form and not in force, it reflects the interest in ABS and in a regional approach to it.

This draft Agreement or Protocol establishes a set of minimum standards and rules that countries will have to implement at the national level (through laws and regulations), based on the following:

- recognition of sovereignty over genetic and biochemical resources
- the need to regulate access to genetic resources and protect traditional knowledge through *sui generis* rights

⁴ Rosell, M. 1997. Access to genetic resources: a critical approach to Decision 391 – Common Regime on Access to Genetic Resources of the Commission of the Cartagena Accord. *RECIEL* 6(3). Ruiz, M. 2003. The International Treaty on Plant Genetic Resources and Decision 391 of the Andean Community of Nations: Peru, the Andean Region and the International Agriculture Research Centers. Centro Internacional de la Papa (CIP), Lima, Peru. <u>http://www.cipotato.org/library/pdfdocs/AN65154.pdf</u>.

- the need to establish procedures for ABS that include PIC, MAT, public participation, MTAs, cerificates of origin, framework access agreements, etc.
- the establishment of a specialized national competent authority
- the establishment of a Central American Working Group on ABS and TK, among other things

However, individual countries have also developed laws and regulations on ABS throughout South and Central America.

Argentina developed a draft *Law on Access to Genetic Resources of Biological Diversity* (2002). The national authority will issue access permits, and applicants are required to conclude accessory contracts with owners or holders of genetic resources (i.e., private landowners or an *ex situ* centre).

Brazil went through a long and complicated political process to develop its ABS legislation. In 1995 an initial draft proposal (draft Law 306/95) was presented in the Senate. This proposal was substituted by another draft in 1996. In parallel, the Federal Government was preparing its own ABS proposal. The states of Amapa and Acre enacted state-level ABS legislation (State Law 0388 [1997] and State Law 1235 [1997], respectively). A controversial bio-prospecting project involving Novartis Pharma and Bioamazonia (from Brazil) in 2000 and criticism from a wide range of sectors of civil society contributed significantly to the enactment of Provisional Measure 2.126-16 (August, 2001) on access to the genetic patrimony as a means to ensure Brazil's interests in genetic resources and bio-prospecting. This legislation recognizes Federal-level powers over the genetic patrimony of the country and places emphasis on capacity building, technology transfer and direct participation of Brazilian nationals in the processes of collecting, research and development.

Chile and Paraguay are starting policy processes to regulate ABS. In the case of Chile, a process to develop ABS regulations was initiated in 1999 by the National Environmental Council (CONAMA) and was re-launched by Fundación Sustentables in 2003. The National Institute of Agriculture Research has prepared an access proposal oriented mostly to plant genetic resources for food and agriculture.

Costa Rica adopted general ABS provisions as part of Law 7788, Biodiversity Law of 1998. Executive Decree 31524 (2003) General Norms on Access to Biochemical and Genetic Resources of Biodiversity establishes a specific and detailed framework on ABS, which covers all types of resources (marine, terrestrial, *ex situ*) and for all purposes (commercial or non-commercial). As in most countries, genetic resources and biochemicals are under the public domain, and thus, under State control.

Costa Rica is an interesting case, given the activities of the National Biodiversity Institute (INBIO) over the past decade or so. INBIO, a public-private research institution, began its operations under the Law for the Conservation of Wildlife (1992), which had only limited references to genetic resources. INBIO has also operated under a special regime covered by a covenant with the Directorate of Wildlife of the Ministry of the Environment and Energy. It has undertaken research on secondary metabolites, enzymes, proteins, enzyme inhibitors, etc., and has partnered with a wide range of private and public research and for-profit institutions. Benefits have included transfer of technologies to Costa Rica, research budgets of over

US\$800,000 a year, generation of patents, transfer of equipment for over US\$2,000,000, etc. INBIO will now have to adapt its operations to the new legal framework.⁵

Mexico has no specific ABS legislation. However, the Law for Ecological Balance (1996) states that genetic resources are of public interest and establishes a procedure for scientific collecting of materials. Prior informed consent is required from owners of land (where resources may be located) and results of research must remain in the public domain. In the case of biotechnological research, benefits must be shared. The Forest Law also includes references to bio-prospecting.

In the case of Panama, the General Environmental Law (1998) makes general references to genetic resources and bio-prospecting and assigns competence to the National Environmental Authority. The State has property rights over genetic resources, although private parties may exercise rights over *biological* resources that contain them. This legislative feature repeats itself in most Latin American countries as part of a tradition under Roman Law where natural resources in general have been deemed and constitutionally recognized as falling under State domain or property.

El Salvador, Guatemala, Honduras and Nicaragua do not have specific regulations or laws on ABS, although general biodiversity laws, sectoral legislation or policy instruments (i.e., NBSAPs) all address the need to conserve and sustainably use genetic resources and, in some cases, call for the development of specific strategies or legislation to regulate ABS.

Almost 10 years after discussions on ABS began, there are valid concerns in many countries about how economic expectations may have overly influenced the model and structure that most ABS policies and legal approaches have had in the region (and in the world). In the context described in the initial paragraphs above, the idea of control over the movement and flow of genetic resources has resulted in rigid, complex legislation that is very difficult to implement in practice. Basic scientific research (i.e., taxonomy) and *ex situ* conservation centres (i.e., international agricultural research centres in Colombia and Peru and other *ex situ* collections and institutions) have been the first to be affected by ABS legislation, mostly through uncalculated and unwarranted restrictions and limitations on research. This may also have a bearing in countries such as Costa Rica, with INBIO, and other research initiatives.

In the Andean Community, for example, given limited progress in implementing Decision 391, there is now a firm commitment by Member States to undertake an overall assessment of the ABS regime and adapt it to better serve sub-regional interests and promote biodiversity research in general (including commercial and industrial research). Although there is no official mandate as yet, as a result of different meetings in the region, representatives of Member States have recognized the need to start this process immediately. One of the critical issues to be reassessed is how to operationalize a conceptually sound (but in practice very complicated) distinction between genetic resources (property of the State) and the biological resources in which they may be contained (which may be owned by communities, individuals, *ex situ* centres or the State).

Through an initiative of the Group of Like-Minded Megadiverse Countries (see above), efforts are also underway to pursue negotiations on an international regime on ABS. This is

⁵ Reid, W., S. Laird, C. Meyer, R. Gamez, A. Sittenfeld, D. Janzen, M. Gollin and C. Juma. 1993. Biodiversity prospecting: using genetic resources for sustainable development. World Resources Institute (WRI), Washington DC.

partially a result of verifying limitations in national jurisdictions and ABS laws in general. The Cancun Declaration 2002, Cusco Declaration 2003, the declaration during WSSD of the Group and recommendations of the Ad Hoc Open-Ended Working Group on ABS (Montreal, December 2003) all include calls for the negotiation and establishment of an international ABS regime. The Seventh Conference of the Parties of the CBD in Malaysia decided that Parties should commit themselves to the negotiation of an effective international regime on ABS (Kuala Lumpur Ministerial Declaration, 2004).

Given national regulatory experiences in the region, the Like-Minded Group of countries seem inclined to advocate the adoption of legal, policy and administrative measures in countries that traditionally use genetic resources and where biotechnology capacities are concentrated (i.e., European countries, Japan and the United States, even if it has not ratified the CBD).

The Biosafety or Cartagena Protocol

The Biosafety Protocol (adopted in Montreal on 29 January 2000) sets a new international paradigm for the trans-boundary movement, transit, handling and use of living modified organisms (LMOs) that result from modern biotechnology (genetic engineering) and may have an adverse effect on conservation of biodiversity and human health. The Protocol sets up an international procedure by which, in general terms, export and import of LMOs is conditioned to the advanced informed agreement (AIA, a modality of PIC) of importing countries. Provisions for risk assessment and risk management are also included. The Precautionary Principle is recognized as the guiding principle of this international instrument.⁶

South America was clearly divided during negotiations of the Protocol, among countries that were part of the so-called Miami Group (including Chile, Uruguay and Argentina), which were much more inclined to free trade and the safe movement of LMOs, and those that were more cautious and resistant to a free flow of LMOs (whether import or export). This tends to reflect technological and agricultural development and trade interests, where the former countries are producers and exporters of LMOs (in the form of products of genetically modified crops).

Brazil, with advanced biotechnological capacity, has taken a cautious approach and until recently has even prohibited the cultivation of genetically modified soya varieties. This has been the result of very strong citizen resistance and campaigns, including legal action and court decisions.

Of the Miami Group, neither Argentina, Chile nor Uruguay has ratified the Protocol. Likewise, but with considerably different interests, neither have Guyana, Peru, Paraguay or Suriname.

Under Decision 345's Third Transitory Disposition, the Andean Community should develop a common regional regime on biosafety. The *Biodiversity Strategy for Andean/Tropical Countries* (Decision 523, 2002), prepared as part of the Andean Community's overall environmental policy, has also established priority programs and actions in regard to biosafety. Biosafety in the Strategy is broadened to include exotic invasive species and their impact.

In the case of Central America, El Salvador, Nicaragua and Panama have ratified the Cartagena Protocol. Costa Rica and Honduras have only signed and Guatemala and Belize

⁶ Mackenzie, R., F. Burhenne Guilmin, A. La Vina and J. Werksman. 2003. An explanatory guide to the Cartagena Protocol on Biosafety. IUCN Environmental Law and Policy Paper No. 46. IUCN Environmental Law Centre, Cambridge, UK. <u>http://www.iucn.org/themes/law/pdfdocuments/Biosafety-guide.pdf</u>.

have neither signed nor ratified. As table 2 demonstrates, countries in the region have some very specific and mostly sectorial (agricultural) laws and regulations regarding biosafety and genetically modified organisms (GMOs).

Country	Law/regulation	Subject matter
Argentina	Resolution 124/91 (1991)	Creates a National Commission on Agriculture Biotechnology (CONABIO), which regulates research, development, use and release of LMOs
Belize	Agricultural Health Authority Act (Act 47, 1999)	Prohibits the import of all GMOs
Bolivia	Supreme Decree 24676 (1997)	Biosafety regulation: applies to research, manipulation, production, use, commercialization, deposit and release of LMOs. A National Biosafety Committee is created
Brazil	Law 8974/95 (1995)	Biosafety law: establishes measures for use of genetic engineering and containment of LMOs
	Provisional Measure 2.052 (2000)	Gives total power to the National Technical Commission on Biosafety to overview biosafety issues
Chile	Resolution 1523 / 01 (2001)	Regulates import and introduction (release) of plant-derived LMOs
	Resolution 269 / 99 (1999)	Creates a Committee for the Release of Transgenic Organisms
Colombia	Accord 0013 (1998)	Creates a technical committee to overview introduction, production and release of LMOs. The National Agriculture Institute (ICA) is the national competent authority for biosafety
	Resolution 02935 (2001) and Accord 00004 (2002)	Regulate the production and release of LMOs for agricultural use
Costa Rica	Biodiversity Law 7788	Specific chapter with references to biosafety
Ecuador	Article 89 of the Constitution	LMOs should be subject to strict biosafety controls and measures
El Salvador	Environmental Law, Decree 233 (1998)	Refers to safety in biotechnology applications
	A draft Seed Law proposes the establishment of a technical	

Table 2. Key biosafety laws and regulations in South and Central America

	Advisory Group on Biosafety	
Guatemala	Ministerial Agreements 393 – 98 and 476 – 98 (Ministry of Agriculture)	Specifically regulate the release and use of agriculture GMOs
Honduras	Phytosanitary Law (Executive Agreement 1570 – 98)	With opinion of a Biotechnology and Biosafety Committee, GM soya and maize have been released for testing.
Mexico	NOM – 056 – FITO 1995	Regulates import, release and testing of agricultural GMOs
Nicaragua	Regulation 136 (1998)	Risk assessment of GMOs
Paraguay	Decree 18841 (1998)	A Commission of Agriculture Biosafety is created
Peru	Law 27104 (1997)	Seeks to prevent risks related to the use of biotechnology (specifically genetic engineering) and its products
	Supreme Decree 068/2001 PCM (2001)	The National Genetic resources and Biotechnology Program of the National Institute for Agricultural Research is responsible for authorizing imports, exports and use of LMOs (in agriculture)
Uruguay	Resolution of the Ministry of Agriculture, Livestock and Fisheries (1993)	A Commission for Assessment of Risks Related to Transgenic Materials is created
Venezuela	Decree 2375 (2003)	Creates the National Commission on Biosafety
	Decree 2223 (1992)	Regulates the introduction, release into the environment, register, control and monitoring of GMOs (and exotic species in general), especially in the agricultural sector.

Source: Verástegui, J. (Ed.). 2003. La biotecnología en América Latina: Panorama al año 2002. CAMBIOTEC, Ottawa.

Note: This is only an indicative, general list of countries and some of their laws and regulations.

Table 2 also shows that many biosafety laws and regulations were in place *before* the Protocol was adopted. However, the negotiation process for the Protocol and its subsequent adoption have triggered new discussions and debates on biosafety as a whole and will most probably result in modifications and adjustments to pre-Protocol legislation.

The Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (IT) (adopted in Rome by Resolution 3/FAO 2001) seeks to ensure the conservation and sustainable use of all plant genetic resources for food and agriculture (PGRFA), in harmony with the CBD. Within this context, key provisions set the principles and rules for access and benefit sharing for a set of crops and forages of importance for world food security (see lists at the end of this handout). These crops are part of a multilateral system for facilitating access

to genetic resources and sharing the benefits arising from their use. Of this list, potatoes, sweet potatoes, cassava and beans (among others) are of particular importance for the region as a centre of origin and diversity. Other crops that are regionally important, such as wheat and rice, are also on the list and the region can therefore benefit from facilitated access to their genetic resources. Certain crops for which the region is the centre of origin and diversity, such as tomatoes and tropical legume forages, are not on the list. By consensus, Parties to the Treaty can extend the list to cover more crops.

Only recently have countries in South America begun discussing the Treaty's legal and policy implications in light of existing legislation on ABS (i.e., Decision 391).

Of the various complex issues brought forward by the Treaty, countries in the region (especially in the Andean Community) need to address (a) the relationship of the Treaty with existing ABS regimes, (b) IPR provisions in the Treaty, (c) the situation of *ex situ* collections and centres and (d) how to implement an effective farmers' rights regime.

Given that the multilateral system currently applies to a specific set of crops and forages, some countries, especially in the Andean region, are considering the recognition of the PGR Treaty as an *exceptional* regime, which would not be affected by existing ABS policies and rules. In this regard, a specific exclusion would be made in laws and regulations for crops under the PGR Treaty. On the other hand, given that many other different sectors (farm animals, forestry, fisheries and so on) have developed their own practices of access and benefit sharing in harmony with the CBD, and which may seek to formalize these in the same way, the question can be posed as to what is exceptional and what is not.

In regard to IPRs (see the section on TRIPS and WTO, below), the international tendency is to strengthen patent and PBR systems (i.e., through WIPO initiatives), and countries in South America have basically accepted the patenting of biotechnological inventions in general, but IPRs over genetic and biological material as it exists in nature is excluded. In this sense, it is possible to speculate that the interpretation of the Treaty's key IPR provision (regarding seeking IPRs over genetic parts or components of materials in the multilateral system *in the form received*) will maintain the status quo by only allowing rights over *technologically modified* genetic parts or components.

Evidence exists that, in the case of the international agricultural research centres in the region (CIP in Lima and CIAT in Colombia), there is uncertainty in regard to implementation of Decision 391. The general guidelines and principles of the Consultative Group for International Agricultural Research (CGIAR) on ABS⁷ and IPR have in practice guided the operations of these centres in implementing agreements signed by the centres with FAO, based on decisions taken in the early 1990s by the intergovernmental FAO Commission on Plant Genetic Resources. Other *ex situ* centres (i.e., botanical gardens and gene banks) face similar dilemmas.

Finally, in relation to farmers' rights, according to the Treaty, responsibility now rests with national governments to recognize and realize these rights (e.g., through compensation mechanisms and *sui generis* protection). Efforts in the region are centred in (a) ensuring that ABS legislation includes mechanisms to share benefits with communities whose traditional knowledge may be used as part of research and development processes, (b) ensuring that PBR

⁷ CIP. 1998. Genetic resources, biotechnology and intellectual property rights. Centro Internacional de la Papa (CIP), Lima.

legislation establishes and recognizes the Farmers' Privilege and (c) developing policies and legislation to protect traditional knowledge. In some cases (i.e., Peru and Colombia), trust funds are also under consideration as a means of ensuring equitable sharing of benefits among all communities. All these efforts are additionally supported by strongly advocating for an international *sui generis* regime to protect traditional knowledge (particularly in CBD and WIPO forums).

In South America, the FAO Treaty has been ratified by Paraguay and Peru. In Central America, it has been ratified by El Salvador and Nicaragua.

Intellectual property rights and biodiversity in the region

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) of the World Trade Organization (WTO)

Most South and Central American countries have adapted their national legislation to comply with the standards outlined in The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), thereby allowing for legal protection of biotechnological inventions (whether of products or processes). In some cases, through free trade agreements with the US, 'TRIPS-plus' regimes are now in place (as is the case in Central America).

Country	Patent legislation	Basic exclusions in patent legislation*
Andean Community of Nations (Bolivia, Colombia, Ecuador, Peru, Venezuela)	Decision 486 of the Andean Community on a Common Regime on Industrial Property (2002)	 Not considered inventions: all or parts of living beings as found in nature, natural biological processes, biological material existing in nature or isolated, including the genome or germ- plasm of any natural living being
		 Not patentable: plants, animals and essentially biological processes to produce plants or animals unless they are nonbiological or microbiological
		Important, innovative provisions in Decision 486:
		• Protection provided through industrial property tools will be granted, safe- guarding and respecting the biological and genetic patrimony of Member States.
		• A patent application (over a biotech- nological invention) will include a copy of the contract providing access to its genetic resources and the authorization to use indigenous peoples' TK, if relevant. A patent may be deemed invalid if these conditions were not met when granted
Argentina	Law 24.481 (1995), Patent and Utility Models Law	 Biotechnological products and processes may be patented
		 Transgenic plants and animals and microorganisms are patentable

Table 3. Patent legislation in South and Central American countries

	Decree 260/96	 Living matter and substances existing in nature are excluded from patentability
Brazil	Law 9.279 (1996), Patent and Utility Models Law	 All or parts of natural living beings or biological materials found in nature, or even if isolated, including the genome or germplasm of any natural living being and natural biological processes Patents cannot be granted over living beings except for transgenic microorganisms
Chile	Law 17.336, Industrial Property Law	
Uruguay	Law 10.089 (1941), Patent Law Law 14.509 (1976) Utility Models and Industrial Designs	Biological materials are not considered in either law
Free Trade Agreement between Mexico and US (NAFTA) + TRIPS	IP provisions in the NAFTA are in line with TRIPS	 Patent exclusions for essentially biologically derived products or processes biological and genetic materials as found in nature animals the human body and its parts plants
Free Trade Agreement between US and Central American countries (CAFTA - 2004)		Patents are extended over plants Countries must adopt UPOV Convention

Note: This is only an indicative list of legislation in each country and region.

*Patents are granted in all countries over inventions (products and processes that are novel, imply an inventive step and have industrial application).

Given different levels of technological development and economic interests (and trading partners), countries in South America have different positions in negotiation forums, particularly in the TRIPS Council and WIPO. There are, however, key issues that are part of the overall regional IPR agenda. These are included as part of emerging trends in the international IPR agenda (mostly influenced by WIPO) and include broadening subject-matter protection, creating new rights, harmonizing and standardizing IPRs and weakening special and differentiated treatment and technology-transfer clauses in IPR agreements.⁸

Review of article 27.3.b. Brazil and Andean Community countries have been most active in the ongoing process of reviewing article 27.3.b of TRIPS. This process formally began in 1999, and the Ministerial Doha Declaration (2001) further complemented the review by indicating the need to include the relation between TRIPS and the CBD in the review. These countries favour a substantive review and analysis of its provisions in the light of strong ABS and TK interests. They also propose that disclosure requirements in TRIPS be amended to make it obligatory to disclose the origin of the genetic resources contributing to a new invention (IP/C/W/403) and that the *sui generis* regime referred to in article 27.3.b does not

⁸ Vivas, D. 2003. Linkages between the TRIPS Council Agenda and the World Intellectual Property Organization activities. Center for International Environmental Law, Washington DC.

imply a 'UPOV-like' system. Rather, this *sui generis* may also be interpreted to include TK considerations.

Defensive protection. The Andean Community countries, Brazil and Costa Rica have also been very active and explicit in the CBD, WIPO, FAO and WTO (TRIPS Council) forums, calling for the legal recognition and incorporation of 'defensive protection', particularly in IPR legislation worldwide. Defensive protection basically seeks to ensure that prior to granting of an IPR (usually a patent over biotechnological inventions), national ABS and TK legislation is complied with.

The idea behind defensive protection is that countries where patents are mostly sought (representing economic power and market potential) could adopt legal measures to support countries that regularly provide genetic resources and related TK in their efforts to control and monitor the flow of genetic resources (and TK) and, ultimately, to assist in overall achievement of the CBD ABS and TK principles.⁹ Both Brazil and the Andean Community have adopted specific legislation to protect their ABS and patent legislation, respectively (with the jurisdictional and territorial limitations this entails). Costa Rica has also included these kinds of provisions as part of Biodiversity Law 7788. This basically means that if national patent authorities are informed that a certain invention contains genetic resources or derived TK of which these countries are countries of origin, authorities in the Andean Community (or in Brazil or Costa Rica) may declare the granted patents as invalid.

During negotiations for the Patent Law Treaty, Colombia expressly (although unsuccessfully) called for the inclusion of defensive protection measures in the Treaty text. Brazil and Ecuador (as part of a broader group of countries) also presented the TRIPS Council with a specific proposal to require disclosure of origin, evidence of prior informed consent and evidence of the fair and equitable sharing of benefits as part of patent-filing procedures (WTO document IP/C/W/356 [2002]). The *Patent Law Treaty* (2000) and the *Substantive Patent Law Treaty* are two new international IPR agreements being promoted under the aegis of WIPO. Both could further strengthen and consolidate the international patent system.

The Union for the Protection of Plant Varieties (UPOV): PBR protection

Almost all countries in the region have some form of legal protection for new plant varieties or cultivars, based significantly on UPOV-like protection of plant breeders' rights (PBRs). Some countries, such as Argentina, Bolivia, Chile, Colombia, Ecuador, Nicaragua, Mexico, Panama and Uruguay, are parties to the UPOV Convention (Acts of 1978 or 1991).

Key discussions in some countries, especially in the Andean sub-region, have been on the impact that legal protection of new plant varieties may have on biodiversity and the environment in general, as well as on small farming communities. Do PBRs inevitably tend to homogenize agriculture? Is the concept of PBR economically viable and suitable in all countries and for all types of agriculture? Will diversity of ecosystems and traditional farming practices resist new plant varieties? If not, what might the impact on traditional practices and livelihoods of communities be? These are some of the kinds of questions that legal, social, economic and ecological research may need to address when these legal regimes start to be evaluated and assessed on their impact.

⁹ UNU-IAS. 2003. User measures: options for developing measures in user countries to implement the access and benefit-sharing provisions of the Convention on Biological Diversity. Institute of Advanced Studies, United Nations University, Tokyo. <u>http://www.ias.unu.edu/binaries/UNUIAS_UserMeasures_2ndEd.pdf</u>.

Table 4. PBR legislation in the region

Country	Legislation	Basic content (salient features).
Andean Community of Nations	Decision 345 on a Common Regime for the Protection of New	 Applies to 'scientifically developed new plant varieties'
	Plant Varieties (1994)	 Recognizes breeders' and farmers' exemptions
		 Protection of essentially derived varieties is optional for Member States
Argentina	Law 24376/94 (adheres to UPOV Act 1978)	
Brazil	Law 9456/97, Law for the Protection of Cultivars (1997)	 Essentially derived varieties are protected
	Decree 2.366 adheres to UPOV Act 1978	 Farmers' privilege does not apply to sugar farmers
Chile	Law 19.342, Plant Breeders' Rights Law (1994)	Exclusive right to produce, sell, export and import new plant varieties
Mexico	Federal Law on Plant Varieties (1996)	Based on UPOV 1978 principles
Paraguay	Law 385/94, Seed and Cultivar	New cultivars may be registered
	Protection Law (1994)	 Protection does not extend to reproductive material
	Signatory to UPOV Act 1991	 Farmers' privilege and breeders exemptions are recognized
Uruguay	Law 15.173/81 and Law 15.554/84 regulate PBR	
	Adhered to UPOV Act 1978 (1994)	

Protection of indigenous peoples' traditional knowledge

Almost in parallel with ABS discussions, the legal protection of indigenous peoples' TK has become an important element of regional and national environmental and non-environmental (i.e., trade negotiations) policy agendas. Given its vast cultural diversity (intrinsically linked to biodiversity conservation), South America has become an important reference in regard to policy, conceptual and legal developments oriented towards the protection of TK. All countries in the region have, to a greater or lesser extent, made progress on this very sensitive issue. Important discussions and policy processes are also underway in Central America.

Substantive debates on TK can be traced to 1992–1993, when initial efforts were being undertaken in the Andean Community of Nations (at the time of the Andean Pact) to develop sub-regional PBR legislation. Decision 345 provides for the protection of new plant varieties if they comply with typical PBR requirements and if *scientific knowledge* is applied to the improvement of these varieties. Intense discussions arose questioning whether this was an implicit exclusion to other forms of knowledge (i.e., traditional knowledge), which could also generate new varieties.

As a result, Decision 391 of the Andean Community recognizes that indigenous peoples have rights (though not explicitly stated, it probably refers to a *sui generis* intellectual property right) over their knowledge, innovations and practices (TK) (article 7). The use of indigenous peoples' TK is regulated by a contract (an annex to ABS contracts) (article 35). The Eighth Transitory Disposition of Decision 391 calls countries to develop a special regime for the protection of TK. This process is now underway within the Community.

Defensive protection is also recognized in Decision 391. National patent offices will not grant protection to inventions that have not complied with ABS legislation and TK provisions (Second Complementary Disposition). Defensive protection of TK has also been developed in detail in Decision 486 (see table 3, above).

Almost in parallel to the Andean regional process, Brazil initiated debate and discussions in regard to ABS and TK. Provisional Measure 2.186-16 (2001), which regulates ABS, specifically refers to the protection of TK. The State recognizes the rights of communities over their TK (article 8[a]), TK may be registered (article 8[3]) and protection of TK should not affect other forms of IPR (article 8[5]). Brazil has specified and provided substantial content to protection mechanisms for TK. Indigenous communities that create, develop and maintain TK have the right (a) to an indication of the origin of TK in all publications, (b) to prevent unauthorized use of their TK by third parties, and (c) to participate in the benefits that derive from the commercial exploitation of TK. Defensive protection of TK is also made available. Prior to the granting of any IPR, an applicant will have to demonstrate the legal origin of the TK (article 31) and that conditions of Provisional Measure have been met.

It should be noted that as yet, national IP authorities in the Andean Community and Brazil have not implemented these 'defensive protection' provisions and principles. However, in the case of Peru, for example, a national working group (led by the patent office) analyzed a set of US and European patents over Peruvian *Lepidium meyeni* ('maca', an Andean crop used for centuries by indigenous people) and concluded that these patents had not undertaken appropriate novelty nor inventiveness standards (not to mention that no permits exist that legitimize its use, even if recognized as a Peruvian crop). It is not difficult to imagine many other cases in the region where resources and TK have become directly or indirectly part of patented inventions.

Finally, the *National Council on the Genetic Patrimony*, created by the Provisional Measure and regulated by Decree 3.945 (2001), will have jurisdiction over TK issues, including setting criteria for the development of TK registers and monitoring ABS projects that might include the use of related TK (articles I[d] and III).

In 1998, Bolivia initiated a political process towards the development of a TK protection regime. The Ministry for Sustainable Development and the Environment, the National Confederation of Campesino Farmers, and the National Indigenous Peoples' Confederation jointly launched an initiative in this regard. As a result, an initial draft proposal for the protection of TK has been developed and is pending wide discussion and debate among broader sectors of society.

Colombia has also been active in undertaking widely participatory processes for the development of national policies and draft proposals for the *sui generis* protection of TK. As early as 1999, a draft proposal prepared by the Environmental Management Institute was discussed in a national workshop. The Humboldt Institute has also made draft proposals on

the structure of a regime for the legal protection of TK.¹⁰ These proposals focus on the *sui* generis nature of the protection, the collective nature of TK, the potential role of registers, the need to ensure benefit sharing from the use of TK and, ultimately, how these protective mechanisms can assist in strengthening TK-based livelihoods.

Peru has become the first country to adopt a *sui generis* or special regime for the protection of TK. Law 27811, on a *Special Regime for the Protection of Collective Knowledge of Indigenous Peoples As It Relates to Biodiversity* (2002), offers indigenous peoples a series of tools and instruments (i.e., know-how licenses, principles of trade-secret law and competition law, registers, funds) to allow for the protection of their TK. This regime will ensure a degree of control over access to and use of TK and ensure that benefits derived from the use of TK are equitably shared with (and among) communities.

In the case of Central America, most progress has been made in Costa Rica and, especially, Panama. Chapter V, Section III, *Access to Genetic and Biochemical Resources and Related Traditional Knowledge* (Protection of Intellectual Rights), entitles indigenous and local communities to reject access to their lands and traditional knowledge, based on cultural, religious or spiritual considerations. Communities have 'community *sui generis* intellectual rights', which are recognized as their property and may be registered with CONAGEBIO (the National Biodiversity Commission).

Law 26 of Panama (June 2000) creates the first Special Regime for Intellectual Property over Collective Knowledge of Indigenous Peoples for the Protection and Defense of Their Cultural Identity and Their Traditional Knowledge. Executive Decree 12 (2001) established the implementing regulation to this Law. This regime seeks to protect the creations of indigenous Panamanian peoples over their arts, music, literature, costumes, garments, embroidery techniques, religious ceremonies, folklore expressions and all of the product of their traditional knowledge (whether or not directly or indirectly related to biodiversity). Their intellectual creations are recognised as *collective* in nature and a Collective Register of IP is managed by the National Directorate of Copyright of the Ministry of Education. The rights granted allow indigenous peoples to exclude third parties from the use and exploitation (in Panama) of the registered (protected) creation.¹¹

Indigenous peoples' organizations have also been active in making specific proposals on TK protection.¹² Most of these organizations have, over time, opposed patents over life forms in general; however, given that a prohibition on these patents seems highly unlikely and politically very complicated for countries, Coordinadora de las Organizaciones Indígenas de la Cuenca Amazonica (COICA) and others (i.e., COPPIP in Peru) have recognized that fighting bio-piracy through 'defensive protection' measures is one alternative to defend their cultural needs and interests.

¹⁰ Ferreira, P., M. Flores, M. del Pilar Pardo and E. Sanchez. 2000. Protección del conocimiento tradicional: elementos conceptuales para una propuesta de reglamentación (El Caso de Colombia). Instituto Humboldt, Bogotá.

¹¹ UNU-IAS. 2004. The role of registers and databases in the protection of traditional knowledge: a comparative analysis. Institute of Advanced Studies, United Nations University, Tokyo. http://www.ias.unu.edu/binaries/UNUIAS_TKRegistersReport.pdf.

¹² De la Cruz, R., N. Paymal and E. Sarmiento Meneses. 1999. *Biodiversidad, Derechos Colectivos y Régimen Sui Generis de Propiedad Intelectual*. Coordinadora de las Organizaciones Indígenas de la Cuenca Amazonica (COICA), Quito, Ecuador.

A clear trend in South and Central America (and also reflected in WIPO and CBD negotiations) is to consider the protection of TK through the use of existing legal tools, modified and adapted to suit the particular needs and interests of indigenous peoples. Some of the most complex matters that arise as these regimes start to develop include how to address TK that is in the public domain (in the case of Peru, interested users of TK in the public domain are encouraged to seek authorization of and share benefits with communities) or how prior informed consent can be achieved when TK is shared (the Peruvian law proposes best efforts to be made to ensure the widest possible consultation with potentially affected communities) or how individual creative efforts within communities are recognized (the Peruvian law leaves this to traditional and customary practices within indigenous communities).

As the Collective Register (of TK) in Panama shows, jurisdictional limitations of national protection are also a factor that impedes universal recognition and protection of indigenous peoples' collective rights. This is one of the reasons an international regime for TK protection is being proposed and sought by many countries.

Passing the practical realities of the livelihoods of indigenous peoples (characterized by isolation and marginalization, poverty—in economic terms—and limited access to formal administrative and bureaucratic structures, among other things) to the law on paper will require extremely careful analysis and evaluation of the best available legal options and opportunities to fit and adequately satisfy these needs.

Other relevant agreements and tools

Phytosanitary agreements

Phytosanitary legislation is abundant in the region, especially in the context of the Andean Community and Mercosur (and in national laws). Some of the most important agreements include the *International Plant Protection Convention* (1989), of which the Regional Phytosanitary Committee is its institutional branch. Its members are Argentina, Brazil, Chile, Paraguay and Uruguay. This Committee seeks to harmonize phytosanitary protection within the Mercosur Agreement and adjust to the WTO's mandates.

As part of sub-regional efforts to free and open markets and trade (including agricultural products and sub-products), the Andean Community has produced extensive phytosanitary legislation. Resolution 431, for example, establishes the Andean norm on phytosanitary requirements (i.e., free of diseases) for trade in agricultural products (1996). This Resolution includes an exhaustive list of products covered by its provisions. Decision 515 establishes the *Andean System for Plant Health* (2002). Its objectives include prevention of plagues and diseases in countries and the sub-region, assisting in the harmonization of phytosanitary legislation, promoting agricultural trade among Member States and supporting cooperation and technical assistance among countries.

All Central American countries have specific sanitary and phytosanitary legislation in place.

Regional networks on genetic resources

Various regional and sub-regional networks on genetic resources have been created over the past years. Some are technical-scientific networks, whereas others address more policy, legal and social issues related to genetic resources. These networks include the following.

The Consortium for the Ecoregional Development of the Andean Region (CONDESAN), formed by public- and private-sector partners, seeks to support the development of policy initiatives in agrobiodiversity as a means of contributing to sustainable rural development in the Andes.

In the area of direct use and management of plant genetic resources, PROCITROPICOS (1992) is formed by the seven national institutes for agriculture research of the Amazon basin countries. It seeks to support sustainable agricultural, forest and farming practices within the framework of the Amazon Cooperation Treaty. Its members include EMBRAPA (Brazil), MAGDR (Bolivia), CORPOICA (Colombia), INIAP (Ecuador), INIA (Peru), MAAHF (Suriname) and FONAIP (Venezuela).

PROCISUR is a sub-regional program for research in plant genetic resources for Argentina, Brazil, Bolivia, Chile, Paraguay and Uruguay.

The Andean Network on Plant Genetic Resources (REDARFIT) (1992) seeks to integrate strategies for conservation, sustainable use and valuation of plant genetic resources in the region by supporting the scientific and technological capacity of countries. PROCITROPICOS and PROCITUR are also part of a network that operates under the aegis of the Inter-American Institute of Cooperation in Agriculture (IICA) and is supported by IPGRI.

The Network on Technical Cooperation for Plant Biotechnology in Latin America and the Caribbean (REDBIO) was sponsored by FAO. The FAO Regional Office (in Chile) operates as the Technical Secretariat of this network. The network's objective is to streamline adaptation, generation, transfer and application of plant biotechnology in Latin America and the Caribbean.

In the case of Central America, the Mesoamerican Network for Genetic Resources (REMERFI) is a well-established cooperation mechanism that serves a wide range of research institutions in the region, including CIMMYT, CATIE and others. PROFRIJOL and PRECODEPA are more crop-specific networks, serving beans and potatoes, respectively. Other more specific and crop-oriented or thematic programs and networks include the Latin America Fund for Rice Production (FLAR), Regional Project for Beans in the Andean Region (PROFRIZA) and the Regional Network on Forest Information for Latin America and the Caribbean.

Food crops		
Crop	Genus	Observations
Breadfruit Asparagus Oat Beet	Artocarpus Asparagus Avena Beta	Breadfruit only.
Brassica complex	<i>Brassica</i> et al.	Genera included are: <i>Brassica, Armoracia, Barbarea,</i> <i>Camelina, Crambe, Diplotaxis, Eruca, Isatis,</i> <i>Lepidium, Raphanobrassica, Raphanus, Rorippa</i> and <i>Sinapis</i> . This comprises oilseed and vegetable crops

LIST OF CROPS COVERED UNDER THE MULTILATERAL SYSTEM

		such as cabbage, rapeseed, mustard, cress, rocket, radish and turnip. The species <i>Lepidium meyenii</i> (maca) is excluded.
Pigeon Pea	Cajanus	
Chickpea	Cicer	
Citrus	Citrus	Genera <i>Poncirus</i> and <i>Fortunella</i> are included as rootstock.
Coconut	Cocos	
Major aroids	Colocasia, Xanthosoma	Major aroids include taro, cocoyam, dasheen and tannia.
Carrot	Daucus	
Yams	Dioscorea	
Finger Millet	Eleusine	
Strawberry	Fragaria	
Sunflower	Helianthus	
Barley	Hordeum	
Sweet Potato	Ipomoea	
Grass pea	Lathyrus	
Lentil	Lens	
Apple	Malus	
Cassava	Manihot	Manihot esculenta only.
Banana/Plantain	Musa	Except Musa textilis.
Rice	Oryza	
Pearl Millet	Pennisetum	
Beans	Phaseolus	Except Phaseolus polyanthus.
Pea	Pisum	
Rye	Secale	
Potato	Solanum	Section tuberosa included, except Solanum phureja.
Eggplant	Solanum	Section melongena included.
Sorghum	Sorghum	
Triticale	Triticosecale	
Wheat	<i>Triticum</i> et al.	Including Agropyron, Elymus and Secale.
Faba Bean/Vetch	Vicia	
Cowpea et al.	Vigna	
Maize	Zea	Excluding Zea perennis, Zea diploperennis and Zea luxurians

Forages

Genera Species

LEGUME FORAGES

Astragalus	chinensis, cicer, arenarius
Canavalia	Ensiformis
Coronilla	Varia
Hedysarum	Coronarium
Lathyrus	cicera, ciliolatus, hirsutus, ochrus, odoratus, sativus
Lespedeza	cuneata, striata, stipulacea
Lotus	corniculatus, subbiflorus, uliginosus
Lupinus	albus, angustifolius, luteus
Medicago	arborea, falcata, sativa, scutellata, rigidula, truncatula
Melilotus	albus, officinalis
Onobrychis	Viciifolia

Ornithopus	Sativus
Prosopis	affinis, alba, chilensis, nigra, pallida
Pueraria	Phaseoloides
Trifolium	alexandrinum, alpestre, ambiguum, angustifolium, arvense, agrocicerum, hybridum, incarnatum, pratense, repens, resupinatum, rueppellianum, semipilosum, subterraneum, vesiculosum

GRASS FORAGES

Andropogon	Gayanus
Agropyron	cristatum, desertorum
Agrostis	stolonifera, tenuis
Alopecurus	Pratensis
Arrhenatherum	Elatius
Dactylis	Glomerata
Festuca	arundinacea, gigantea, heterophylla, ovina, pratensis, rubra
Lolium	hybridum, multiflorum, perenne, rigidum, temulentum
Phalaris	aquatica, arundinacea
Phleum	Pratense
Poa	alpina, annua, pratensis
Tripsacum	Laxum

OTHER FORAGES

Atriplex	halimus, nummularia
Salsola	Vermiculata