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## Do national access regimes promote the use of genetic resources and benefit sharing?

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**Abstract:** This paper examines the implementation of national regimes on access to genetic resources in a number of developing countries, particularly in the members of the Andean Community. It discusses the principles of the Convention on Biological Diversity that inspired such regimes, the main aspects of the adopted legislation, the expectations that countries had while introducing it and the problems faced by regulatory authorities in dealing with access applications. The paper also analyses the implications of such regimes on research and the extent to which the objectives with regard to benefit sharing have been reached. The problems created by the application of uniform rules to all kinds of genetic resources is also addressed, in connection with the treatment of plant genetic resources for food and agriculture (PGRFA). The paper suggests the need to review the access regimes in order to consider the special case of PGRFA, and to solve the difficulties found in their application.

**Keywords:** access regimes; genetic resources; Andean community; convention on biological diversity.

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### 1 Introduction

The Convention on Biological Diversity (CBD), adopted in 1992, introduced, for the first time in an international binding agreement, provisions on access to genetic resources and

the sharing of benefits derived from their exploitation. One of the objectives of the Convention is “the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources” (article 1). Generally considered by developing countries as supportive of their interests, the CBD affirms the sovereign rights of States to exploit their resources “pursuant to their own environmental policies” (article 3). Access, where granted, shall be on mutually agreed terms and subject to the prior informed consent of the Contracting Party providing the genetic resources (articles 15, 4 and 5). In addition, each Contracting Party shall take legislative, administrative or policy measures 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 utilisation of genetic resources with the supplying Contracting Party.

The objectives of the CBD are the conservation of biodiversity, the sustainable use of its components and benefit sharing. The principles of prior informed consent, access under mutually agreed terms and benefit sharing are intimately linked to the Convention’s conservationist objectives. If applied to discharge the responsibility of States to conserve biodiversity, those principles should ensure that access does not affect the future availability of genetic resources, and that the costs incurred by States to conserve them are borne by those who benefit from their use.

The CBD has attempted to establish a balance between the exercise of sovereign rights over genetic resources and the global interest in having access to and utilise the world’s biological diversity. As it provides a general framework, without precise definitions on many aspects (such as the determination of benefit sharing), the Convention leaves considerable leeway to design national laws and policies. However, it also requires a sophisticated institutional capacity to negotiate access agreements, anticipate possible benefits and enforce the deals made.

Many countries have developed biodiversity conservation strategies and plans to implement the CBD. Only a few, though, have effectively adopted the Convention’s access mechanisms. While many countries have drafted legislation, putting in place access regulations has proven to be more difficult than expected. Moreover, as illustrated by the experiences reviewed in this study, applying such regulations has been problematic. In fact, criticism is mounting from different quarters about the impact of legislation inspired by the Convention, especially on scientific research (Ochave, 1999; Barber et al., 2002, p.409).

One problem with the way in which the CBD has been implemented in some countries relates to the treatment of plant genetic resources for food and agriculture (PGRFA). Although the CBD was conceived as an instrument for the conservation of all sectors of biodiversity, at the Nairobi Conference (1992) the need for a special treatment for plant genetic resources for food and agriculture (PGRFA) was recognised.<sup>1</sup> However, national legislation developed during this period under the Convention did not differentiate between PGRFA and other resources, thereby ignoring the various features that make PGRFA unique.<sup>2</sup> It took almost ten years for the international community to develop rules specifically applicable to PGRFA, as contained in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).<sup>3</sup>

This study examines the legislation and, where available, information on the application of regimes relating to the access to genetic resources in a number developing countries, particularly in the members of the Andean Community. It also discusses

the implications of such regimes on access to genetic resources and research, and the economic benefits derived from their application.

## **2 The Andean access regime**

Decision 391 of the Andean Community (composed of Bolivia, Colombia, Ecuador, Peru and Venezuela), adopted in 1996, regulates access to genetic resources. With its elaboration and adoption the Andean Community pioneered – with Philippines<sup>4</sup> – the establishment of access legislation.

The underlying assumption at the time of the adoption of the Decision was that State intervention would permit to reap the benefits from the rich biodiversity existing in those countries, by establishing well-negotiated contracts for bio-prospecting, and by curbing, at the same time, the misappropriation of genetic resources for commercial purpose—an issue of special concern for the Andean countries (Brock and Xepadeas, 2003).<sup>5</sup>

A significant part of the world's biodiversity originates from the Andean Community countries. Though no serious systematic assessment of the economic value of such biodiversity has been done (neither at the time Decision 391 was adopted nor later),<sup>6</sup> governments in the region had considerable expectations about the potential income that the exploitation of such biodiversity could generate (Caillaux and Ruiz Müller, 1999).<sup>7</sup> The Decision applies to the access to and transfer of such resources with commercial, scientific or conservationist purposes,<sup>8</sup> by natural or juridical persons, public or private, national or foreign. The only exception relates to local, indigenous or Afro-American communities, who can freely exchange and use covered resources, but only if for their own consumption and according to customary practices.

The genetic resources covered by Decision 391 are subject to the sovereign rights of the Andean States (article 3). Such resources are deemed 'goods or patrimony of the Nation or of the State' in each country. The rights over such resources are considered "inalienable and not subject to prescription or to seizure or similar measures; they are recognised without prejudice to property regimes of the biological resources that contain them, the land on which they are found, or the associated intangible component" (article 6). This distinction between 'genetic resources' and 'biological resources' has significant implications, as mentioned below, for the operation of the system.

Article 37 of Decision 391 specifically deals with materials held in ex-situ conservation centres (ESCCs). Entities carrying out activities 'implying access to genetic resources' are bound to enter into access contracts with the respective national competent authority (NCA). Breaching this obligation may entail administrative, civil or criminal sanctions.<sup>9</sup>

In sum, Decision 391 seems to essentially aim at creating an institutional base for the Andean countries to extract value from their genetic resources. Decision 391 does not certainly ignore the conservationist goal of the CBD, but both the history of negotiations<sup>10</sup> and the purposes stated in article 2 of the Decision suggest that the conservation of biological diversity and the sustainable use of the components were not conceived as its primary goals (Febres, 2002, p.16). The Decision provides a general framework to regulate access, leaving many significant issues to decision by member States. The practical way in which governments handled the quite complex issues associated to access to genetic resources is, therefore, of crucial importance.

The following section reviews the experience of the five countries of the Community, based on information supplied by government officials, experts and other stakeholders.<sup>11</sup>

### **3 National experiences**

#### *3.1 Bolivia*

The National Strategy for Biodiversity Conservation aims, *inter alia*, to attract investments in this area. A National Programme for Sustainable Bio-trade was also developed. Bolivia developed its access regime, based on Decision 391, through Decree 24,676. The process for granting access involves several institutions. The national competent authority is the Ministry of Sustainable Development. A technical council (Consejo de Asesoramiento Técnico-CAT) provides advice. The Ministry also relies for the evaluation of access applications on the cooperation of non-governmental organisations (NGOs).

Five applications were submitted to the national competent authority in Bolivia but only one contract has been signed. Two of those applications – not approved yet – relate to genetic resources for food and agriculture (wild peanut species and native potato varieties *solanum tuberosum sp andigenum*).

The first application was filed in 1997. It aimed at obtaining authorisation to export 1,200 live llamas and alpaca, to be sold (at US\$ 200/head) for consumption as meat. An NGO contacted to assist in this case did not provide the required advice, and the Technical University of Oruro was called to replace it. The authorisation established that, as benefit sharing, the local association of producers (ANAPACA) would be supported for the establishment of storage facilities and the improvement of breeding programmes.

A second application, relating to the access to plant and microbial resources, was filed in 2000 by the New York Botanical Garden. Bolivian authorities realised that this institution was filing this application to transfer samples of materials to a private company (Merck) for taxonomic and chemical studies in the context of a research project on asthma. The Universidad Autónoma de Santa Cruz acted as advisor to the national authority. The government requested, as benefit sharing, a one million US dollars investment involving the establishment of a laboratory in Bolivia. The application was abandoned.

A third case related to peanut varieties. It was filed by the University of Georgia (USA) but later abandoned.

Under a fourth application, access was requested by the Gent University and a company to conduct taxonomic, chemical and ethnobotanical studies of aromatic plants. The government requested benefit sharing consisting in the participation of local professionals in publications and US\$ 10/kilogram of supplied material. An accessory contract was entered into with the community of Apillapampa. A royalty of 2% was also negotiated, but divergences arose with regard to whether the beneficiary should be the community (government's position) or the university (applicants' position).

In a fifth case, access was requested by IPGRI and the Department of Agriculture of USA to wild relatives of peanut varieties. Benefit sharing would have been based on training and payment of a fee (US\$ 6,000). Alerted by RAFI and the Foro Boliviano para el Medio Ambiente, peasant communities strongly opposed it. The access contract was not signed.

Finally, an application was filed by MIGROS (the European food retailer) for access to ten in-vitro plants of five native potato varieties. The applicant's aim was to obtain seed for multiplication. A royalty was agreed upon, 50% of which would be paid to the communities that held such varieties and the remainder to the local entity that supported the project. It was estimated that royalty payments could reach from \$10,000 to \$1,00,000 Euros/year.

The Bolivian experience shows that farmer communities and some NGOs may become important actors in the process of access authorisation. In 2000, such communities requested the government to declare a moratorium on access until the issue was discussed with their participation. A bi-ministerial commission was established to examine the applicable legal framework (CBD, Decision 391 and WTO rules).

### 3.2 *Colombia*

The legal framework for the implementation of Decision 391 in Colombia includes Decree 370/97 (defining the competent national authority), Resolution 620/79 (establishing access procedures) and an opinion – which has no binding character – by the Consejo de Estado (State Council) of 1997 clarifying the scope of article 6 of Decision 391.<sup>12</sup> These instruments do not constitute, however, a complete regulation to implement Decision 391, since many procedural and substantive aspects remain unregulated. The Colombian government has not considered the implementation of Decision 391 a policy priority.<sup>13</sup> No reference to this matter has been made in ministers' reports. The competent national authority has lacked human resources with adequate technical and professional training.

The State is deemed to have exclusive authority to negotiate on and obtain benefits from genetic resources. Such benefits belong to the State and would only arise for indigenous communities and farmers if 'associated knowledge' were involved in the access application.

Under the adopted national framework, a neat distinction was made between 'genetic resources' and 'biological resources'. While the former were deemed by the competent authorities to belong to the State, the latter were deemed to belong to the holder of the resources. This distinction is deemed to have generated a perverse incentive, to the detriment of the Decision 391 regime, as access to biological resources could be obtained more easily than to genetic resources.<sup>14</sup> For instance, some oil companies that received permits for operation in Colombia, established laboratories where research on forest resources has been conducted.

Fifteen access applications have been filed in Colombia, only three out of which were evaluated. The majority of applications were made for doctoral research projects conducted by Colombian nationals. Though one application (for activities of academic nature) was accepted in 1998, negotiations to establish the contract did not start yet. Thirteen applications were abandoned before the termination of the evaluation phase, reportedly due to the complexity of the information requested and applicable procedures. The processing of applications lasted between one and four years, leading to high transaction costs and discouraging applicants. In the case of one application, for instance, the evaluation had not been initiated three years after its filing. Delays may be attributed to a large extent to the absence of well-defined rules about the information to be supplied by the applicant as well as the lack of criteria for the evaluation.

### 3.3 Ecuador

No implementing regulations of Decision 391 have been approved (though up to six versions of a draft were discussed and many institutions were consulted). The frequent change of authorities was one of the factors that prevented action from being taken. Three applications have been submitted, but no contract has apparently been signed so far.

### 3.4 Peru

Peru has adopted a National Strategy on Biological Diversity (Decreto Supremo No. 102-2001-PCM) and enacted various laws and regulations, *inter alia*, Law 27300 on Sustainable Development of Medicinal Plants (2000) and Law 27821 on the Promotion of Nutritional Supplements for Alternative Development (2002). Implementing regulations for Decision 391, however, have not been adopted in Peru.

Three institutions have had authority with regard to access issues, depending on the type of resources involved: Instituto del Mar del Peru (IMARPE)<sup>15</sup> for marine resources; Instituto Nacional de Recursos Naturales (INRENA) for any application involving wild species and wild relatives of domesticated species; and Instituto Nacional de Investigación Agrícola (INIA) for domesticated plant species. In November 1991, a Technical Group on Biodiversity was established to analyse the legal and political framework for the transfer of materials from ex-situ conservation centres. Among other tasks, the Group undertook the drafting of a Material Transfer Agreement for use by those centres.

Like in the other Andean countries, there have been few access applications in Peru. Eleven applications were received by INIA. Nine of them related to scientific research and were approved. The majority of the applications involved taxonomy and molecular biology studies, such as an application by a student from Washington University for collection and study of *licopersicom pimpinefolium*, and an application by a North Caroline University for collection of *phytophthora infestans*. No agreement has been formalised yet pursuant to these applications.

INIA received two applications relating to plant genetic resources involving native Andean crops, which have not been processed due to the lack of regulations to implement Decision 391. Recently, an inter-ministerial working group that included representatives from government, universities, NGOs and (in its initial phase) indigenous and farmer communities was established as a result of an initiative of the Comisión Nacional de Diversidad Biológica (CONADIB). Though the working group considered the option of implementing Decision 391 directly, without adopting an implementing regulation, this idea was rejected, particularly due to the need to define which department/s would act as NCA/s and what its or their functions would be (Perkoff and Ruiz Müller, 2000, p.98). A first draft regulation of Decision 391 was published in 1999; based on comments and suggestions received, a draft was elaborated and is currently under discussion.

The experience of the International Centre for Potato (CIP), which is subject to article 37 of Decision 391, dealing with materials held by ESCCs illustrates the impact of the Decision in the case of PGRFA. One of the main difficulties for CIP has stemmed from the lack of regulations to implement Decision 391 and the ensuing uncertainty not only about the applicable rules but also about the authorities that are competent to take decisions in the area of genetic resources in Peru. The problem faced has been not so

much the complex procedures to be complied with, but the risk of undertaking actions that, due to the absence of clear rules, could be deemed illegal.

While in the 1970s there was an intense activity of collection by CIP, such activity was substantially reduced during the 1980s and 1990s due to the threat posed by terrorism (Sendero Luminoso), the downsizing of collection programmes and, to some extent, the uncertainty about the legal applicable regime on access. For instance, the implementation of a 1997 agreement between CIP, INIA and USDA for collection of wild species was delayed, and finally suspended in 1999, due to lack of clarity about the authority that should grant the permission to collect. Moreover, the Centre's policy has been to receive materials for short-term treatment, but not for conservation, unless governmental permission has been given. This constraint has reportedly impeded the supply of services and the undertaking of research that could have benefited Peruvian farmers.

Materials have been distributed by CIP on the basis of the agreements with the providers for their long-term conservation and its policy of unrestricted availability.<sup>16</sup> Landrace material acquired prior to the CBD that remained to be designated for technical reasons (e.g., suspicion of genetic redundancies) can still be distributed according to the terms of the agreement with providers. CIP's policy, especially after the CBD entered into force, has been to reach an agreement with the provider of the material, if the intention was to include it into CIP's long-term holdings. If there were not such an agreement, no acquisition would take place. Material could be received, however, under special circumstances, only for research at headquarters, but it would not be subject to distribution. CIP also adopted specific policies when deemed necessary to comply with national regulations. Thus, after the Peruvian government prohibited the export of non-processed *maca*, and until the prohibition was repealed, CIP suspended all transfer of *maca* samples.

Microorganisms (such as bacteria and fungi) and insects are not received or transferred by CIP independently of the date of acquisition, in the absence of a specific governmental authorisation. A controversial case has arisen, for instance, with regard to the transfer to Costa Rica of samples of 'baculo' viruses. In view of INRENA, permission to distribute these materials was required, despite the fact that they were commercially available from various sources (in this case, the Centre finally denied the request and suggested the Costa Rican entity to acquire commercially available samples).

However, after nearly three years of discussions, INRENA has developed an MTA for the transfer by CIP of about 30 samples of microorganisms (six of which were found in Peruvian territory).

### 3.5 Venezuela

The Constitution of 1999 declares the sovereign rights of the Venezuelan State over its territory and the resources found therein, including the genetic resources, their derived products and intangible components (article 97). In addition, it guarantees and recognises the collective intellectual property of indigenous peoples' knowledge, technologies and innovations (article 124). The patenting of natural resources found in indigenous habitats and the associated knowledge is prohibited. The Constitution further mandates the State to protect the biological and genetic diversity (article 127).

The Biological Diversity Law (2000) confirms sovereign rights over biological resources and declares them inalienable, imprescriptible and immune to any seizure

measure. It also confirms the collective rights of local and indigenous communities with regard to traditional knowledge related to the biological diversity, and includes a criminal sanction (including prison, fine and suspension in office) for government officials that recognise intellectual property rights over modified samples or parts thereof where they were illegally acquired (article 120).

The competent authority for the implementation of the access regime is the Ministry of the Environment and National Resources (MARN). Its National Office of Biological Diversity adopted a resolution about the access procedures, which usually last for more than one year (though they have been speeded up recently). In addition to access legislation, applicants must comply with other regulations, such as permits to enter protected areas and for collection of materials. The Ministry of Science and Technology also intervenes when the research project requires its prior approval.

In Venezuela, 30 applications have been submitted, all of them by individual researchers or research institutions. No application has been filed by a private company. Forty three percent of the total number of applications related to plant genetic resources (7% held *ex situ*, 93% *in situ*). Sixty five percent of applications on such resources were submitted by national applicants. Only 35% of the applications resulted in contracts finally signed. The first 'framework' agreement was entered into with the Instituto Venezolano de Investigaciones Científicas (IVIC). Particular projects may be incorporated as annexes to the agreement. The applications for access were distributed, per area of study, as follows:

- agriculture 20%
- conservation 52%
- medicine 28%.

An access contract has not been required in cases where applications only concern basic research (generally PhD studies on ethnobotany) rather than the search for chemical compounds for commercial purpose.

The following access contracts were concluded:

- 1 Fundación para el Desarrollo de las Ciencias (1999), with a duration of three years. The project was suspended due to difficulties with the indigenous communities (which required a moratorium).
- 2 Universidad Central de Venezuela (currently being executed).
- 3 US Department of Agriculture (abandoned).
- 4 Instituto Nacional de Investigaciones Agrícolas (currently being executed).
- 5 Instituto Nacional de Investigaciones Agrícolas (to be subscribed).

The problems in obtaining the consent of indigenous communities for the use of the 'intangible' component (associated knowledge) reportedly were the cause of some of the applications to be abandoned. In the case of one application by IVIC, for instance, the subscription of an access contract was prevented by opposition from peasant communities. They refused to grant prior informed consent, allegedly due to problems of organisation and limitations in understanding the procedures and even reading and interpreting the required documents.



Despite that the number of applications and contracts found in Venezuela is larger than in other Andean Community countries, the implementation of Decision 391 did not fulfil its objectives either. The main problems included:

- Lack of transparent (documented) criteria to adopt decisions, leading to casuistic application of the regime. No regulations or guidelines have been made publicly available.
- Limited institutional capacity, and lack of training of staff in charge of processing applications.
- Legal uncertainty for applicants, even after a contract is subscribed.
- Lack of coordination among institutions responsible for processing applications.

Another problem found in Venezuela,<sup>17</sup> as well as in other Andean countries, in the application of Decision 391, has been the absence of differential treatment for PGRFA.

### 3.6 *Costa Rica*<sup>18</sup>

Costa Rica adopted, in 1998, an access regime for genetic, biochemical resources and the traditional associated knowledge, as a component of the Biodiversity Law (No. 7788). The law is in force since its publication (April, 1998). However, a legal action filed by the General Attorney's Office – alleging the unconstitutionality of powers granted to the Comisión Nacional para la Gestión de la Biodiversidad (CONAGEBIO) (National Commission for the Management of the Biodiversity) – has in practice impeded the full application of the Law.

Costa Rica's regime covers all kinds of genetic materials, including for food and agriculture.<sup>19</sup> The law allows, however, developing special procedures for the access to materials in ex-situ collections (if duly registered). The relevant regulations have not been adopted yet and there is no official record of the ex-situ collections in the country.

Parties interested in obtaining access must file a request before the Technical Office (TO) and negotiate with the Conservation Area, Indigenous Territory, landowner or holder of ex-situ collections, as appropriate. Agreements so developed must include conditions for a fair and equitable distribution of benefits, and be endorsed by the TO. Particular requirements are established for permissions for basic research or bio-prospecting, and for access aimed at commercial use. An environmental impact assessment can also be requested from the TO.

Due to the lack of staff and of determination of the procedures to apply the law, no access has been granted under the described regime as yet. A number of applications were reportedly submitted (but not processed). They included applications by:

- University of Madison-Wisconsin for collecting samples of wild potato varieties in a protected area
- a research institute from Firenze, Italia, relating to bacterial biodiversity
- National University of Costa Rica to collect wild material of *Sechium* ('chayote' and 'tacacos') in protected areas and from an ex-situ collection.

In contrast, more than twenty applications were submitted and approved under the agreement between INBio<sup>20</sup> and the Ministry of the Environment and Energy (MINAE),

based on the Law of Wild Life Conservation No. 7317 of 21st October, 1992 and its regulation No. 26435-MEE of 3rd December, 1997. Permissions are granted by the National System of Conservation Areas (NASYCA) upon the submission of an administrative form and consultation with the Conservation Area where the collection will take place. This procedure is relatively simple and takes approximately one month.

The conditions for the approval of applications under the INBio-MINAE agreement include:

- up-front payments for conservation (a minimum of 10% of the research budget is transferred to MINAE for conservation purposes)
- benefit sharing mechanisms:
- milestone payments for the discovery and development phases of a potential product, to be shared 50:50 with MINAE
- a percentage of royalties on net sales of the final product (covering also derivatives from the original natural scaffold and/or any technology derived thereof), also to be shared 50:50 with MINAE
- IPR should include participation of INBio's scientists if applicable (Joint patents and publications)
- technology transfer to and training of local scientists should be significant and should include state-of-the-art technologies
- the discovery and development of a product must engage non-destructive uses of natural resources and be consistent with the national legislation regarding access to genetic resources and development thereof.

Some of the agreements with INBIO have generated outputs such as two compounds with significant anti-bacterial activity, 52 bacterial strains with nematocidal activity, one compound with significant anti-malarial activity and two phytopharmaceuticals (Cabrera, 2003).

### *3.7 Brazil*

Brazil regulated access to genetic resources by means of Provisional Measure No. 2.186-16, of 23rd August, 2001.<sup>21</sup> This Measure was adopted by the Federal government to address a perceived legal vacuum in the regulations on the use of genetic resources. It was triggered by a contract between Novartis Pharma (Switzerland) and Bioamazonia, an organisation created by the government in association with scientific and business institutions to promote the sustainable use of Amazonia's biodiversity. The contract provided for an investment by the pharmaceutical company of around four million dollars over three years for the study of up to 10,000 microorganisms to develop pharmaceutical products. Bioamazonia would share in the benefits of the commercial exploitation of products obtained.

The Provisional Measure established an inter-ministerial Council with the power to issue permits for the use of genetic resources on land inhabited by indigenous communities, whenever it deems that the use of such resources would be of 'outstanding public interest'. The Council was exclusively integrated with representatives from

the executive branch. However, it regularly includes, as invitees to its meetings, representatives from the scientific community, civil society and indigenous communities.

Under Brazilian law, the collection of materials, including for research purposes, is subject to prior authorisation by the Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis (IBAMA). The access regime, as adopted under the Provisional Measure only applies to:

- already collected material
- the use of materials at the molecular or genetic level, or for further reproduction, whether for commercial purposes or not.

If a commercial purpose is involved, an access contract must be entered into between the interested party and the government. Seven applications for access have been made under the Provisional Measure, out of which only three are from private companies. No application has been approved so far.

A new access legislation has been submitted to Congress. It includes the protection of collective intellectual property rights as original rights recognised by the law. Those rights are inalienable and perpetual; registration is declaratory. Criminal sanctions, including prison, are proposed for violation of the law.

### 3.8 *Philippines*

The government of Philippines enacted, in 1995, the Executive Order (EO) No. 247 “Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes”. It establishes a framework to regulate biodiversity prospecting on the basis of a system of Research Agreements between collectors and the government containing terms concerning provision of information and samples, technology cooperation and benefit sharing. The order requires the intervention of several institutions in approval procedures. It created an Inter-Agency Committee on Biological and Genetic Resources (IACBGR) to approve and monitor compliance with Research Agreements, as well as to coordinate other matters.

The prospecting of biological and genetic resources shall be allowed when the person, entity or corporation, foreign or domestic, undertaking such activities, on recommendation of the Inter-Agency Committee on Biological and Genetic Resources, has entered into a research agreement with the Philippine government.

If the research and collection of biological and genetic resources are intended directly or indirectly for commercial purposes, the agreement to be entered into is a Commercial Research Agreement (CRA). All research agreements with private persons and corporations, including all agreements with foreign or international entities, must conform to the minimum requirements of a Commercial Research Agreement. If the prospecting of biological and genetic materials is intended primarily for academic purposes, the agreement shall be an Academic Research Agreement (ARA). The Order distinguishes the conditions applicable to commercial and academic agreements.

The rights of indigenous and local communities must be protected, especially with regard to informed consent procedures. In the case of local communities, prospecting of biological and genetic resources shall be allowed if prior informed consent is given. In the case of indigenous communities, the Order specifies that prospecting shall be

allowed “within the ancestral lands and domains of indigenous cultural communities only with the prior informed consent of such communities; obtained in accordance with the customary laws of the concerned community”.

A comprehensive report on the application of the Executive Order was conducted by the German Development Institute (GDI). As of April 2002, 15 CRAs and 20 ARAs had been applied for under the Executive Order 247, but only six were approved by the IACBGR. Five applications were abandoned, with the applicants complaining about the complexity of procedures. The main problems identified included:

- broad coverage of the Executive Order, including all activities related to research, collection and utilisation of biological and genetic resources, whether for scientific or commercial purposes<sup>22</sup>
- low information level of applicants
- long processing time of the applications, in some cases more than three years
- weak institutional capacity
- difficulty in operating an inter-agency approach.<sup>23</sup>

A more careful look at the role of different players in the application process showed that

- Many applications were incomplete, with either documents missing or their content being unsatisfactory, even in cases of applicants who were supposed to be well informed and staffed. Applicants were not fully aware of the Order’s requirements, despite the fact that the government launched an awareness programme including workshops in a number of provinces and letters to more than one hundred academic institutions to explain the regulation and procedures. Moreover, information material was made available for scientists.
- Some agencies in charge of handling applications were relatively slow in processing them. The agencies were not provided additional funds or staff to undertake these tasks. Though the multi-stakeholder approach pursued by the IACBGR<sup>24</sup> has been deemed a positive element, as far as it ensured participatory and transparent decision-making, common criticisms are irregular meetings, low attendance rates, lack of commitment by IACBGR members and slow decision-making procedures. IACBGR lacks institutional capacity and is unable to get funds to cover its activities (Liebig et al., 2002, p.39).
- Foreign industry has not been sympathetic to the access regime. A statement by a major pharmaceutical company indicated, for instance, that “it will not pursue natural products research in those countries that impose requirements similar to those contained in the Philippine Executive Order 247 ... Government initiatives that place onerous restrictions on those seeking access to genetic resources or do not afford appropriate protection to intellectual property rights will result in fewer efforts to survey natural resources for pharmaceuticals and that will ultimately work to the detriment of environmental protection ...”<sup>25</sup>
- The need to obtain prior informed consent of communities in whose territories research will be conducted<sup>26</sup> has also been criticised by scientists due to the time required and expenditures to be incurred (generally not covered by research grants) to comply with them.

Most of the stakeholders interviewed by GDI thought that the regulation was not 'working well, that the application process takes too much time and is too complicated' (Liebig et al., 2002, pp.36–38). For some analysts, the perceived complexity and bureaucracy of the EO 247 system have acted as a disincentive for commercial bio-prospecting activities in the country (Barber et al., 2002, pp.408–410).

Moreover, in accordance with one commentator, "the PIC procedure laid down in the Implementing Rules of EO 247 is administratively cumbersome and prone to abuse. It effectively discourages local researchers, especially those in government institutions, from conducting any academic research. More significantly EO 247 fails to address the possibility of holdouts and rent-seekers among the source communities – a possibility that is not far-fetched given the political culture in the Philippines. The bio-prospector, especially the academic collector, could effectively be held hostage by the source communities. The situation is made worse by the fact that in the Philippines one has to contend with powerful single-issue groups, who, for ideological or political reasons, are opposed to any form of bio-prospecting, even for drug development purposes. Given the dismal state of research infrastructure in the Philippines and the fact that many of the Philippino research scientists obtain their degrees through collaborative research with foreign scientists, the aforesaid provision of EO 247 could only result in scientific isolation and backwardness. This is especially true with respect to drug discovery where the possibility of finding a commercially viable product from the collected materials is not at all assured" (Ochave, 1999, quoted in Heath and Weidlich, 2003, pp.94, 95).

### 3.9 *India*

India is one of the 12 mega-biodiversity countries of the world. In 2000, India adopted, after a long debate, the Biological Diversity Bill. Its objectives are to conserve, encourage the sustainable use of and regulate access to biological resources with the purpose of securing equitable share in benefits arising out of their utilisation as well as of the associated knowledge.

The Bill applies to all activities affecting the biodiversity. Some matters affecting biodiversity are also governed by the Protection of Plant Varieties and Farmers' Rights Act, 2001 (Plant Varieties Act) and the Seed Act. Both the Plant Varieties Act and the Bill include benefit-sharing rules, but they set up mechanisms that are distinct and unrelated. The procedures for granting benefit sharing are set out in more detail in the Plant Variety Act than in the Bill.

In line with the CBD, the Bill asserts the sovereign right of the government over the use and exploitation of genetic resources (Preamble, para 4). It provides that access to biodiversity by foreign persons and Indian citizens is subject to PIC through the National Biodiversity Authority (Sections 3 and 19), and prior information to the State Biodiversity Board, respectively (Sections 7 and 24). However, research by Indian citizens and local people and communities is exempted from the Bill's requirements.

The Bill provides for benefit sharing. The Authority has to ensure that the terms and conditions, subject to which approval is granted, secure equitable sharing of benefits arising out of the use of accessed biological resources and the associated knowledge. This should be in accordance with mutually agreed terms between the applicant, local bodies concerned and the benefit claimers (Sections 21 and 41). Joint ownership of IPRs with the Authority, or to the actual contributors if they can be identified, is provided for (Section 21). Other forms of benefit sharing include financial compensation and

development schemes for the local people such as technology transfers, setting up a venture capital fund and payment of monetary compensation (Sections 27 and 32).

Finally, the Bill contains a number of provisions aimed at addressing the problem of misappropriation of genetic resources. Consent by the Authority is required to apply for intellectual property rights (IPRs) in or outside India for any invention based on research or information on Indian biological resources (Section 6). Though the Authority can certainly not prevent such rights being granted in a foreign country, it may oppose the grant of such IPRs in any country (Section 19(4)).<sup>27</sup>

## **4 Implications of access regimes**

### *4.1 Impact on research*

Due to limited human resources and funding, and to the influence of foreign science, most research undertaken in developing countries concentrates on issues of interest to developed countries. In addition, science made in developing countries generally makes a marginal contribution to the global scientific output. Scarce efforts are devoted to investigate and exploit the potential of domestic biological resources and the associated TK (Arunachalam, 1995). Some elements of access regimes aimed at controlling access to genetic resources may further constrain that type of research: “if even domestic university researchers need to undergo complicated procedures to obtain permission of access, this might seriously hamper research in a field that should be considered a country’s natural *forte*. In other words, if a country’s competitive strength lies in its genetic resources, requirements of access permission should serve the purpose of preventing undue exploitation rather than preventing research” (Heath and Weidlich, 2003, p.83).

There is some evidence suggesting, in fact, that the way in which access regimes have been implemented has had a negative impact on research. For instance, under the Decision 391, ‘associated knowledge’ may include TK as well as scientific knowledge produced by research centres. Thus, there is no clear distinction between taxonomic studies and bio-prospecting for materials of commercial value. In Venezuela, the collection of biological materials by individual researchers and scientific institutions is subject, as noted above, to the same procedures of authorisation as those made by entities with commercial purposes. This is likely to have impeded or discouraged academic research (Febres, 2002, p.114). Decision 391 is also reported to have imposed barriers rather than promoted research in Bolivia, particularly undermining the capacity of local researchers to cooperate with centres in developed countries.<sup>28</sup> In the case of Colombia, it has been found<sup>29</sup> that Decision 391 did not promote but created obstacles to local R&D on genetic resources. It did not encourage local companies to invest and exploit the potential of genetic resources, discouraged foreign companies and institutions to undertake research in the region and to cooperate with local entities and generated a perverse system of incentives as it promoted the use of other indirect mechanisms of access to genetic resources.

Similar observations have been made in other countries. Scientists in Brazil have urged the government to modify the laws introduced to curb biopiracy that are stifling their research on Brazilian biodiversity.<sup>30</sup> Although in Philippines the local scientific community initially supported and promoted the development of an access and benefit

sharing regime, it has become one of the strongest critics of EO 247, 'complaining that the whole process is too tedious, too costly, too time consuming and' too broad, encompassing activities that do not have commercial prospects and thus frustrating efforts to better understand and conserve the country's biodiversity, and with considerable negative impact on scientific research activities' (Barber et al., 2002, p.410).

#### 4.2 Economic benefits

Although inspired by the CBD, national access regimes seem to have made a substantial shift in their focus from conservationist to mainly benefit-sharing objectives. This shift was probably grounded on over-expectations on the capacity to extract value from domestic genetic resources, especially from bio-prospecting for new industrial products, such as pharmaceuticals. These activities are unlikely to generate significant funds.<sup>31</sup> One reason for this is that a considerable percentage of the added value in bio-prospecting projects accrues outside the country where it takes place (Cabrera, 2003, pp.246, 247).

In addition, the assumption that private companies were prepared to subject themselves to stringent conditions and complex procedures to get access to genetic resources and associated knowledge has proven wrong. Companies are apparently unwilling to incur significant up-front costs in bio-prospecting, especially if samples of the same resources are available in other countries without or with less stringent regulations. The experience of the Andean countries may indicate that either the companies obtain anyway the genetic resources they are interested in (without complying with the access procedures), or that substitutes are found in other biodiversity-rich countries or by using other technologies.

Companies seem particularly troubled by what they perceive as a growing divergence between access measures introduced by policy makers and their practical implementation. Several companies are also reported to have said that the costs involved in following the access procedures – in terms of benefit-sharing commitments, travel, communications and staff time – made working in these countries uncompetitive (Ten Kate and Laird, 1999, p.298).

A major problem faced by national authorities in charge of access regimes is that they lack precise guidance on the content of 'mutually agreed' terms, and on the ways to determine the level and modalities of benefit sharing in each particular case. This requires comprehensive information, negotiating capacity and some prediction about possible outcomes of a transaction. Authorities need a good understanding of the operation and evolution of the biodiversity demand and to be aware of the technical and scientific changes that affect it, as well as of a number of technical and legal issues.<sup>32</sup> Their task is particularly difficult, as there is no true market for genetic resources; it is *created* through access contracts.

While benefits may not rapidly arise (especially due to long periods of product development), the implementation of an access regime also implies costs (salaries, training, studies, travel, etc). The potential value of genetic resources justifies States' investments, but a cost-benefit analysis is required to determine how to optimise the use of strained States' budgetary resources in implementing access regimes.

### *4.3 Making access regimes compatible with the ITPGRFA*

The ITPGRFA establishes a Multilateral System (MS) of Access and Benefit sharing for PGRFA of an agreed list of 35 food crops, and 29 forage genera. Under the MS, PGRFA<sup>33</sup> can be accessed and exchanged free of charge if they are to be solely used for research, breeding or training purposes. Benefits under the MS are not attributed directly to the country supplying PGRFA on a bilateral basis, but they are shared on a multilateral basis among all Contracting Parties.<sup>34</sup>

Access regimes operate on the basis of bilateral transactions, formalised through various agreements with the State and other stakeholders. As they do not differentiate between sectors of biodiversity, access to PGRFA is subject to the same substantive conditions and procedures as access to any other resources. The ITPGRFA stipulates facilitated access for crops listed in its Annex I. It will be necessary, hence, to reconcile the access regimes with the facilitated access provided for under the Treaty. While for some experts, there would be no contradiction between the two systems and a clarification<sup>35</sup> or amendment of procedures<sup>36</sup> would be sufficient, a revision of such regimes may be required to carve out an exception and effectively facilitate the flow of PGRFA in the MS.

## **5 Conclusions**

The CBD relies on a contractual model to grant access to genetic resources and ensure benefit sharing in case of commercial exploitation thereof. It is the State's prerogative to negotiate and agree on the terms of access, and its burden to monitor and enforce the contract's provisions. National policy makers also need to determine criteria for ensuring benefits sharing.<sup>37</sup>

The authorities in charge of access procedures may act as facilitators<sup>38</sup> for the exchange of genetic resources, if they proactively seek for and promote access operations, help to set up partnerships and draft mutually acceptable contracts, or as gatekeepers, if they only act upon demand from interested parties and limit access to cases where certain conditions are met. Access may, in fact, be regarded as an opportunity or as a threat. The latter approach seems to have prevailed so far in the development and implementation of national access regimes.<sup>39</sup>

National authorities in charge of the application of access regimes need to possess a sophisticated technical competence to calculate costs and benefits of possible access transactions (such as the risk of erosion emerging from access activities), and ensure the convergence of different stakeholders' interests. This complex task requires competent and trained staff, and an adequate budget. None of this seems to have been available so far.

National access regimes were adopted in a context of concerns – which are still valid – about the misappropriation of genetic resources and the lack of compensation for the benefits their commercial exploitation could generate. As a result, such regimes have been essentially defensive, aimed at controlling rather than promoting the use of genetic resources for research and commercial purpose.

Those regimes have had a number of positive effects; namely, they have created awareness in various circles about the importance and potential value of genetic resources, and about the need to define and implement policies on the matter. A number



of unintended consequences have arisen, however. Although there is no conclusive evidence indicating that access regimes have impeded access to and research on genetic resources, it is quite clear that they have not promoted the collection of, research on and commercial exploitation of such resources. Clearly, if genetic resources are not accessed and used, no benefits are generated.

There seems to be an emerging consensus among experts and government officials that the original expectations that underpinned the establishment of the access regimes have not been achieved. In fact, it is unlikely that bio-prospecting could generate significant income flows to preserve biodiversity. The interest of commercial companies exists but it is probably not as high as predicted when the CBD was adopted. The relative bargaining power of the parties may also make it difficult to obtain significant benefits from access contracts (Ragavan, 2002).

It can be argued that the failure to achieve the objectives of access regimes is mainly due to poor implementation of the rules that are otherwise adequate. Although the existence of implementation problems is quite evident, notably in the Andean area, several substantive and procedural aspects may have also contributed, decisively, to the identified problems. While an access regime should be comprehensive enough and allow authorities to evaluate the circumstances of each case, it should also be predictable, realistic in terms of implementation and enforcement capacities and not affect the flow of genetic resources in key areas such as PGRFA. The grounds on which access can be permitted or denied should be transparent, so as to assist applicants in decision making, especially with regard to cost evaluation.

PGRFA, the access to which is essential for a sustainable agriculture and food security, were subject under the CBD and national access regimes to the same rules applicable to other sectors of biodiversity. The adoption of the ITPGRFA will probably require carving out in the access regimes an exception for PGRFA in the MS. Adopting such an exception may also provide an occasion for reviewing the experience obtained with those regimes and to rectify, as necessary, the aspects that have frustrated the expectations that their establishment had created. Developing countries still have a great opportunity to promote the sustainable use of their biodiversity and increase the benefits obtainable from their exploitation, while participating in the global exchange and conservation efforts of genetic resources.

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## Notes

<sup>1</sup>Resolution 3 of the Nairobi Conference.

<sup>2</sup>See COP Decision 2/15 (1995) (available at <http://www.biodiv.org>).

<sup>3</sup>Available at <http://www.fao.org>.

<sup>4</sup>See an analysis of the Philippines' access regime below.

<sup>5</sup>The case of the *quinoa* (US patent No. 5.304.718) variety and several patents relating to *maca* (*Lepidium meyenii*) and its use are telling examples. Access regulations were regarded by Andean governments as one of the mechanisms of defence against misappropriation of genetic resources by foreign companies.

<sup>6</sup>Valuing biodiversity is not a simple task. For a method to obtain an economic welfare measure, see Brock and Xepadeas (2003, p.1597).

<sup>7</sup>See e.g., Caillaux and Ruiz Müller (1999, pp.8, 11).

<sup>8</sup>In the case of access by universities, research centres and researchers, framework contracts may be established under which several access transactions may be covered. These contracts seem to be subject to the same conditions than other access contracts (Febres, 2002, p.37).

<sup>9</sup>See article 47 of the Decision.

<sup>10</sup>See e.g., Caillaux and Ruiz Müller (1999), who note that two negotiating proposals were considered: one for a regime mainly aimed at conservation/protection, and another one, which finally prevailed, aimed at establishing a strict control over the flow of genetic resources and benefit from their potential value (p.11).

- <sup>11</sup>This information is substantially based on *Informe Final. Primera Reunión del Comité Andino sobre Recursos Genéticos*, 3rd November, 2000, SG/RC.RG/I/Informe Final, 16th February, 2001, interviews and discussions by the author with experts and government officials and presentations at the 'Seminario Regional: Acceso a los recursos fitogenéticos en la región Andina: el CBD, la Decisión 391, el Tratado de la FAO y otros avances políticos y normativos', SPDA-SAREC-CIP, Lima, 17–18 July, 2003.
- <sup>12</sup>Article 6 provides that 'genetic resources and their by-products which originated in the Member Countries are goods belonging to or the heritage of the Nation or of the State in each Member Country, as stipulated in their respective national legislation. These resources are inalienable, not subject to prescription and not subject to seizure or similar measures, without detriment to the property regimes applicable to the biological resources that contain those genetic resources, the land on which they are located or the associated intangible component'.
- <sup>13</sup>In 1999, a technical proposal to adopt a National Biodiversity Policy was prepared but never implemented effectively.
- <sup>14</sup>The distinction has been considered artificial, as a 'genetic resource' is, in the last instance, a form of utilisation of a biological resource (presentation by Torres, R. at the 'Seminario Regional: Acceso a los recursos fitogenéticos en la región Andina: el CBD, la Decisión 391, el Tratado de la FAO y otros avances políticos y normativos', SPDA-SAREC-CIP, Lima, 17–18 July, 2003).
- <sup>15</sup>According to the current draft regulation on access, the Ministry of Fishing will be responsible in the future for handling access applications related to aquatic and marine species.
- <sup>16</sup>The agreement between CIP and the Peruvian government giving CIP an international status provides in an annex that 'CIP has all the necessary rights, and can assume all the obligations deemed convenient to accomplish its objectives', and lists among the activities that CIP is supposed to carry out to 'recollect, maintain and distribute germplasm in such a way that it can be used within the host country or any other country in the world'.
- <sup>17</sup>Presentation by Febres at the 'Seminario Regional: Acceso a los recursos fitogenéticos en la región Andina: el CBD, la Decisión 391, el Tratado de la FAO y otros avances políticos y normativos', SPDA-SAREC-CIP, Lima, 17–18 July, 2003.
- <sup>18</sup>This section is substantially based on Cabrera, 2003.
- <sup>19</sup>The conservation and use of these resources are also subject to other regulations, such as the decree of creation of the National Commission of Plant Genetic Resources, No. 18661-MAG of 9th September, 1988, and the Law of Seeds No. 6289 of 4th December, 1978.
- <sup>20</sup>INBio has developed a proactive approach towards biodiversity prospecting. It operates a Business Development Office, with a highly qualified expert staff, which looks for the identification of potential partners (Cabrera, 2003).
- <sup>21</sup>A 'provisional measure' is a decree with immediate effects and the legal weight of a law, which can be renewed by the Executive Power until Congress enacts it as a law or votes it down.
- <sup>22</sup>The Executive Order applies to scientific and academic institutions, non-government organisations and local government entities involved in biodiversity inventory, conservation of traditional crop varieties and endangered and endemic wild fauna. However, its scope was narrowed down in practice: research and collection activities associated with pure conservation work, biodiversity inventory and taxonomic studies are only regulated under the research permit process in place before the Order came into force (Barber et al., 2002).
- <sup>23</sup>For instance, the IACBGR was supposed to meet once-per-quarter to review and make recommendations on applications for ARAs and CRAs. But in the period between the installation of a new national executive administration in mid-1998 and September 1999, for example, the IACBGR only met once.
- <sup>24</sup>The IACBGR has representatives from different government agencies, non-governmental organisations, peoples' organisations and research institutions.
- <sup>25</sup>Excerpt from letter by Bruce S. Manheim Jr., Fox, Bennett and Turner, on behalf of Bristol-Myers-Squibb, to the Hon. Timothy Wirth, Undersecretary for Global Affairs, Department of State, USA, 3rd November, 1995, quoted in Ten Kate and Laird (1999).

- <sup>26</sup>Prior informed consent of the local community is required in Philippines for outsiders' access to all types of natural resources under the 1997 Indigenous Peoples Rights Act.
- <sup>27</sup>In the Indian Patent (Second Amendment) Bill 1999, the grounds for rejection of the patent application, as well as revocation of the patent, include non-disclosure or wrongful disclosure of the source of origin of biological resource of knowledge in the patent application, and anticipation of knowledge, oral or otherwise. It has also been made incumbent upon patent applicants to disclose in their patent applications the source of origin of the biological material used in the invention.<sup>1</sup>
- <sup>28</sup>Carlos del Viso (Bolivia), at the 'Seminario Regional: Acceso a los recursos fitogenéticos en la región Andina: el CBD, la Decisión 391, el Tratado de la FAO y otros avances políticos y normativos', SPDA-SAREC-CIP, Lima, 17–18 July, 2003.
- <sup>29</sup>Ricardo Torres at the 'Seminario Regional: Acceso a los recursos fitogenéticos en la región Andina: el CBD, la Decisión 391, el Tratado de la FAO y otros avances políticos y normativos', SPDA-SAREC-CIP, Lima, 17–18 July, 2003.
- <sup>30</sup>See 'Brazil's Biopiracy Laws 'are stifling research'', *SciDevNet*, 21st July 2003. ([www.scidev.net](http://www.scidev.net)).
- <sup>31</sup>See, e.g., Sedjo and Simpson (1995).
- <sup>32</sup>Such as IPRs, contract drafting, determination of royalty rates, transfer of materials to third parties, definitions (products, extracts, etc), dispute resolution, etc., See Cabrera (2000, 2001).
- <sup>33</sup>The coverage of the MS is only PGRFA under the control of States and in the public domain, or held by all other holders of PGRFA listed in the Annex. who decide to include them in the MS. Collections held by the CGIAR Centres are subject to a specific regime (article 15 of the Treaty).
- <sup>34</sup>Benefit sharing is to be provided through information exchange, technology transfer, capacity building and the mandatory sharing of the monetary benefits of the commercialisation of products incorporating material accessed from the Multilateral System when further access to such resources is restricted. The primary focus of benefit sharing is on farmers in the developing world, who conserve and sustainably utilise PGRFA.
- <sup>35</sup>Presentation by Monica Rosell at the 'Seminario Regional: Acceso a los recursos fitogenéticos en la región Andina: el CBD, la Decisión 391, el Tratado de la FAO y otros avances políticos y normativos', SPDA-SAREC-CIP, Lima, 17–18 July, 2003.
- <sup>36</sup>A proposal of this kind was made in the technical report prepared for the CAN by SPDA and CAD-IUCN in 1994. See Caillaux and Ruiz Müller (1999, p.18).
- <sup>37</sup>The Bonn guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilisation (see COP Decisión VI/24) may provide guidance for this purpose.
- <sup>38</sup>This concept was elaborated by Krattiger and Lesser (1995).
- <sup>39</sup>See articles 50 and 51 of the Decision relating to the functions of the Competent National Authority and of the Andean Committee on Genetic Resources. The promotion of access activities, partnerships, etc., is not mentioned among their functions.