

**Notes for a presentation on
International Policy and Law on Genetic Resources**

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When did genetic resources become a political issue? Why did the annoying lawyers and politicians decide that they had to intervene and propose new regulations that would interfere the classic way of doing things with genetic resources?

The best way to understand the current situation is to look back in history and see what events led us where we are now.

The first efforts to introduce biodiversity as a topic in the global policy agenda back to the 70s and, in particular, the International Conference on Human Environment, which took place in Stockholm in 1972. There, biodiversity conservation was identified as a priority in the world environmental agenda.

In the 50s, the experts had start to talk about the loss of biodiversity and the genetic erosion, especially in scientific bodies hosted by FAO, and during the 60s, the international *ex situ* collections are set up and the major expeditions to collect materials for international and national genebanks take place.

The shift from the scientific and technical approach to a more economic and political approach can be explained because of the rapid scientific and technological advances in the 60s and the 70s. The research of biological processes and their application to large scale industrial production of pharmaceutical products, the development of the first hybrid varieties of maize and, later, the advances in genetic engineering showed the intrinsic value of genetic resources and their economic potential for different production sectors.

There is when genetic resources start to attract the attention of people outside the scientific and technical spheres, including lawyers and politicians.

The concerns around genetic resources that were put on the table in those days could be summarized in two key questions:

1. Who is the owner of the material held in the genebanks? The country of provenance? The country where the collection is located? The humanity?
2. If new products are the result of applying technology to some genetic material, why aren't the rights of the providers of the material recognized in the final product?

These questions are still at the centre of political discussions around genetic resources.

In 1983, governments signed the first international agreement dealing with plant genetic resources, under the auspices of FAO. The International Undertaking on Plant Genetic Resources for Food and Agriculture affirms that:

- PGRFA are the heritage of the whole humanity, they belong to everyone.
- Governments must ensure the free exchange of material among all countries
- FAO will create a network of international genebanks available to everyone and specially developing countries.

The IU also established the Commission for Genetic Resources for Food and Agriculture, as an intergovernmental forum that would supervise the implementation of the international undertaking and would keep addressing policy issues related to genetic resources for food and agriculture. Nowadays, about 180 countries are members of the Commission.

The paradigm recognized in the International Undertaking didn't last long. In 1991, InBio, a public research institute in Costa Rica and the American pharmaceutical company Merck Sharp and Dome signed an agreement that is a milestone in the history of biodiversity law. In the agreement, InBio committed itself to send samples of life material to Merck Sharp and Dome instead of some monetary and non monetary benefits.

Implicit in this agreement is that Costa Rica understands that the country is the owner of biological resources within its territory and because of this, the government can establish conditions upon their use. Before this agreement, biological resources didn't have a clear legal status. The IU had affirmed that they were human heritage, but this was a pretty uncertain legal concept. Did it mean that they belonged to everybody? Did it mean that they belonged to no one? Did it mean that anyone could appropriate them?

The agreement between InBio and Merck put some things crystal clear:

1. Biological material can be a resource, meaning that they can be used to produce benefits and economic profit, such as water, minerals, oil...
2. Countries have rights over those resources and can regulate their utilization.
3. Countries can obtain benefits from the use of those resources by industry.

Costa Rica didn't invent anything new; they just put in practice the principles that were in many people's mind. These principles were finally consolidated and recognized internationally in the Convention on Biological Diversity in 1992.

Convention on Biological Diversity

The CBD was adopted in 1992, at the Earth Summit, held in Rio de Janeiro. Today, 196 countries are currently parties to the CBD.

The objectives of the CBD are:

- The Conservation of biological diversity
- The sustainable use of their components
- The equitable sharing of the benefits arising from the use of the genetic resources.

The CBD covers all the ecosystems, all the species and all genetic resources.

Members of the CBD recognize the countries sovereign rights over their genetic resources and their capacity to regulate the access to those resources and participate in the benefits that may arise from their use.

In some countries, the access and benefit-sharing legislation is very detailed, in others it is just one or two provisions in more general laws about biodiversity. The most common elements in access legislations are:

- The individual or institution seeking to collect or receive biological samples must get the prior informed consent from the national authority. In some cases, the authorization from indigenous or local communities holding traditional knowledge related to the resources is also required.

- The applicant and the national authority must negotiate the mutually agreed terms for the use of the material and the sharing of the benefits.

In most cases, access legislation has been very difficult to implement. Some of the reasons are:

- The actual nature of the biological resources, which make them easy to transport and difficult to control
- The lack of a systematic and rigorous legislation, clearly defining the steps and the actors involved in the process of providing access and sharing the benefits.
- The lack of economic and human resources in the national authorities.
- The fact that indigenous and local communities are not well informed about their rights and about their responsibilities.
- The principle of territoriality of national laws, which says that the laws of one country can't be enforced in other countries. When biological resources leave the country, it is difficult for the country of origin or provenance to claim the application of their access laws in front of a foreign court.

Due to the difficulties to implement and enforce access regulations and the fear to lose control over their resources, many rich biodiversity countries have adopted an extremely cautious attitude, over controlling the collection and use of genetic resources by foreign individuals and institutions.

Successful cases of access and benefit-sharing show that the key is not in limiting absolutely the access to the resources, but rather in promoting the dialogue between providers and users of the resources. These cases also show that the non monetary benefits are as or more important as monetary benefits. Provider should not focus exclusively on the monetary aspects of the ABS agreements, as there is a long range of non monetary benefits that may be realized from the very beginning:

- Joint research projects
- Technology, equipments, scientific knowledge
- Long term collaborative relationships
- Joint intellectual property rights
- A better knowledge of the national genetic pool
- Genetic resources with added value

TRIPS agreement

In parallel to the negotiations of the CBD, countries were negotiating the establishment of the World Trade Organization, which was adopted in Marrakech in 1994. This organization aims at the liberalization of trade around the world through the imposition of standards for the products to be treated equally in all countries. One of the aspects that were subject to standardization during the Uruguay Round was the intellectual property. The result of the negotiations was the agreement on Trade-Related aspects of Intellectual Property, or TRIPS. Basically, through the TRIPS agreements the members of the WTO commit to establish and enforce an intellectual property system that guarantees a minimum level of protection of intellectual property rights. Article 27.3. b, perhaps the most problematic one of the agreement, says that countries:

- Can allow the patentability of animals and plants
- Must allow the patentability of microorganisms
- Must allow the patentability of non biological or microbiological processes (like the process for isolating a gene, or an active principle)
- Must allow the protection of new plant varieties.

The implementation of this article by developing countries has been favored by bilateral agreements between them and USA, EU or Japan, since these agreements include the adoption of effective systems for the protection of intellectual property.

An special treatment for Plant Genetic Resources for Food and Agriculture: The Treaty and the FAO Comission on Genetic Resources

In mid 90s the rather restrictive exercise of countries' sovereign rights over their genetic resources and the intellectual property fever started to concern the experts in agriculture research.

Food security relies, to a great extent, on the development of new and better varieties of food crops and animal breeds. Since the Neolithic, farmers have been selecting crossing and testing crop varieties. More recently, breeders have continued this work using more modern techniques, but the main ingredients are always the same: the genetic resources. To be able to develop more adaptive and resistant varieties, farmers and breeders have to have access to a broad diversity of genetic resources. The access laws inspired by the CBD and the spread of intellectual property rights to living material forced the agricultural sector to react. They decided that PGRFA deserved a special treatment because of different reasons:

1. PGRFA are different from wild genetic resources

PGRFA	Wild PGR
Valued for intra-specific diversity	Inter-specific diversity is the focus
Are essentially products of human selection and depend upon farmers for their continued survival	Are products of natural selection and sustain themselves
PGRFA diversity concentrated around centres of origin and diversity of cultivated plants and their wild relatives	Distribution of wild PGR diversity largely independent of human activities (though limited and displaced by human activities)
Extensive 'movement' and breeding of crop diversity due to farmers exchanging seed and cross breeding with exotic material to maintain/increase productivity	Evolution of wild PGR is dependent on natural forces of selection
Global access is required for the continued agricultural development	Global access is an issue for wild relatives of crops and species of potential economic use, including potential pharmaceutical use

2. For the most important crops, it is impossible to identify the country of origin: International Exchange of plants over centuries makes it difficult, if not impossible,

to identify the place of origin of the most important crops. Current varieties of these crops are the result of thousands of crosses between varieties coming from different countries and world regions. For this reason, bilateral systems inspired by the CBD are not effective when dealing with plant genetic resources for food and agriculture.

3. All countries are dependant on PGRFA of other countries, no country is self sufficient in PGRFA. As a result of plant exchanges and crosses, all countries depend on plant genetic resources coming from other countries. No country can rely its entire agricultural production on the genetic resources from their own territory only. For this reason, all countries benefit from an open access system where everyone can share the genetic resources.

The concerns of the agriculture sector were addressed by the FAO Commission on Genetic Resources which decided to negotiate a binding international agreement based on the International Undertaking but in harmony with the principles of the CBD. The result is the International Treaty on Plant Genetic Resources for Food and Agriculture.

The Treaty was adopted in 2001, after 8 years of tough negotiations. It entered into force in 2004.

The Treaty creates a multilateral system for access and benefit sharing that creates a common pool of PGRFA for research and breeding.

All the member countries have committed to put their PGRFA in this pool and all the member countries have access to the pool. Part of the monetary benefits that may arise from the commercialization of new PGRFA go to a common fund for the conservation of agro-biodiversity and the support to small farmers in developing countries.

The scope of the multilateral system extends to the crops and forages listed in the Annex 1 of the Treaty which are under the Management and Control of the Government and are in the public domain.

In order to make the multilateral system, the Treaty member countries agreed the text of a Standard Material Transfer Agreement to be used for all the transfers of PGRFA within the system. The SMTA is a contract between the provider and the user of the resources. It facilitates the access to the resources because there is no need to negotiate each single clause.

The SMTA specifies the terms and conditions for the use of the PGRFA coming from the multilateral system and the benefit-sharing obligations of the recipient. Once a PGRFA has been transferred under an SMTA, all further transfers have to be done subject to a SMTA too. In this way, the access and benefit-sharing principles and obligations of the multilateral system always accompany that PGRFA.

Countries are currently working on the implementation of the Treaty at the national level, and, in particular, its multilateral system of access and benefit-sharing. There are different measures governments need to adopt to advance the implementation.