

THE NAGOYA PROTOCOL



Genetic resources are that part of genetic diversity with actual or potential value. For many years, genetic resources were considered the "common heritage of mankind" and of "free access" to all of whom are interested in using them. However, well into the 1990s, the Convention on Biological Diversity (CBD), signed by more than 150 states at the United Nations Conference on Environment and Development (the Rio "Earth Summit"), and that entered into force on December 29, 1993, departed from those principles and recognized the states' sovereignty over their genetic resources. From then on, access to genetic resources was subject to domestic regulations, at the same time the concept of "benefit sharing" between providers and users of the resource was introduced.

The CBD was then the main International Agreement that thoroughly addressed biological diversity, based on its three main objectives:

1. The conservation of biological

diversity;

2. The sustainable use of its components, and

3. The fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

As regards the third objective, as of the 2002 United Nations World Summit on Sustainable Development held in Johannesburg and for eight years, a negotiation process took place within the framework of the CBD in order to adopt an international regime to promote and safeguard the fair and equitable sharing of the benefits arising out the utilization of genetic resources. Finally, on October 29, 2010, at the 10th meeting of the Conference of the Parties in Nagoya, Japan, the Nagoya Protocol was adopted under the following title: "The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity".

The Nagoya Protocol is an agreement between the signing Parties aimed at providing legal certainty and transparency both for providers and users of genetic resources. The Protocol introduced two novel concepts:

1. A series of specific obligations to be undertaken by each Party in order to ensure compliance of the users within their jurisdiction with the laws or the domestic regulatory requirements of the Party providing the genetic resources, and

2. The compromise of the Parties to comply with mutually agreed cooperation conditions.

By promoting the use of genetic resources and of the applicable traditional knowledge and strengthening the opportunities to fairly and equitably share the benefits arising out of their use, the Protocol intends to create incentives for the use of genetic resources, thus contributing to the conservation and sustainable use of biological diversity.

Countries in the region that have signed the Nagoya Protocol

Countries	Date
Mexico	05/16/2012
Panama	12/12/2012
Honduras	08/12/2013
Guatemala	06/16/2014
Peru	07/08/2014
Uruguay	07/14/2014

However, the Protocol is not the only international instrument that addresses the access and benefit sharing issues. The FAO International Treaty on Plant Genetic Resources for Food and Agriculture does this as well. This instrument entered into force on June 29, 2004 and, unlike the Nagoya Protocol that deals with genetic resources in general terms, the FAO Treaty focuses only on the plant genetic resources for food and agriculture.

Since the FAO Treaty became a specialized international instrument on access and benefit-sharing, it supersedes such provisions of the Protocol, as provided in Article 4(4) of the Nagoya Protocol. These interrelations are specifically mentioned in the preamble of the Protocol, in terms of recognizing both the fundamental role of the FAO Treaty and its multilateral system of access to genetic resources in harmony with the CBD.

How is it being applied in the region?

The Nagoya Protocol will enter into force 90 days after 50 countries ratify it. The 50th ratification was received last July 14, with Uruguay's ratification; therefore, the Nagoya Protocol will enter into force on October 12, 2014. As of that date, the Protocol will become a legally binding instrument and a supplementary agreement to the CBD.

In the Latin American region, the Protocol was ratified by Guatemala (June 16, 2014), Honduras (August 12, 2013), Mexico (May 16, 2012), Panama

(December 12, 2012), Peru (July 8, 2014), and Uruguay (July 14, 2014); as of the beginning of September 2014, there are 52 ratifications in total.

How is it related to cultivars' protection?

From the very beginning of the deliberations on the CBD and the Nagoya Protocol, there was great tension as regards the issue of access to genetic resources and its relationship with intellectual property and, more specifically, the regimes for the protection of plant varieties under the UPOV Convention and the patents on biotechnological components. However, throughout the years, this tension was limited to the issue of disclosing the origin of the genetic resources and/or traditional knowledge in the applications for plant variety property titles or patents. The purposes sought by the Protocol are to avoid two facts: on the one hand, the possibility of using the genetic resources not according to the rules and, on the other, facilitating their traceability.

The wording in the Protocol is quite clear: as regards other agreements, it is provided that the Protocol does not affect the rights and obligations arising out of other agreements, except where the exercise of those rights and obligations would cause a serious damage to biological diversity. The Protocol does not create a hierarchy between Agreements and does not prevent the development and implementation of other agreements, including other specialized benefit-sharing agreements, provided that they do not run counter to the objectives of the CBD and the Protocol.

Some experts believe that, as the FAO Treaty, the UPOV Convention is a specialized applicable instrument that prevails over the Protocol. In fact, the UPOV Convention is a *sui generis* system of the breeder's rights with certain exceptions and, in a way, is a specialized form of access and benefit-sharing of genetic resources. Every new plant variety created in the framework of the UPOV Convention is considered a new genetic

resource that is absolutely available for access and use in terms of the creation of new plant varieties.

How is the seed business affected?

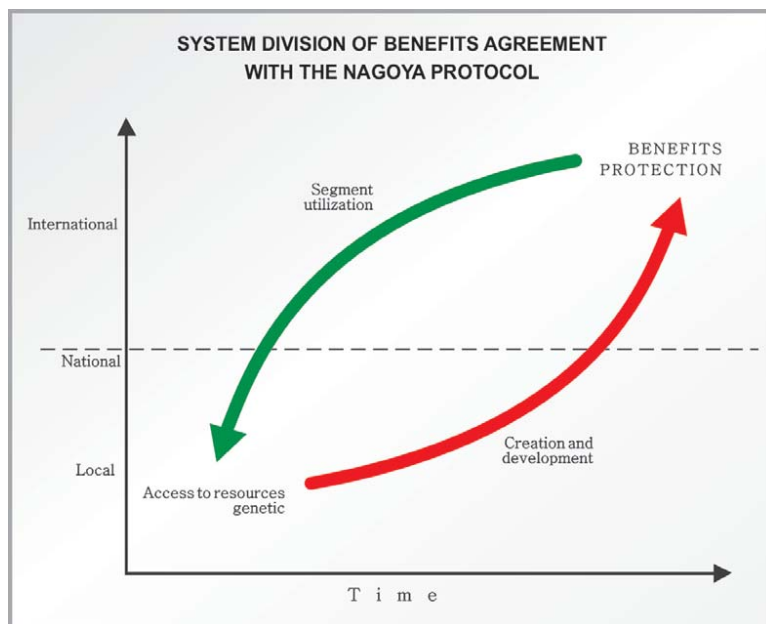
Several sources indicate that many of the Protocol's issues are ambiguous, which means that only when the Protocol is being implemented, the questions left unresolved will be cleared.

The experts on the Nagoya Protocol understand that, upon its ratification, it will be a long time before its results have been materialized. So far, it is difficult to predict how the entry into force of the Protocol and its interaction with the FAO Treaty may affect the seed business itself, although it is likely to have an impact on the genetic breeding plans of private companies and research institutions.

In fact, we observe the following:

- *The use of genetic resources collections in genebanks is declining;*
- *The collecting missions rarely taking place;*
- *The Protocol compliance rules probably will bring a lot of extra administrative burden;*
- *The application of the rules of access and benefit sharing has a great deal of legal uncertainty and ambiguity;*
- *The interface between the Nagoya Protocol and the FAO Treaty is not sorted out in practice.*

Another issue of importance is that the Protocol defines the conditions and how users of genetic resources and/or traditional knowledge associated with genetic resources (for example, researchers and commercial companies) may obtain access to such resources and knowledge. In providing for general obligations on sharing the benefits arising from the utilization of such resources and knowledge, the Protocol obliges the Parties to ensure that users under their jurisdiction respect the domestic access and benefit-sharing legislation and regulatory requirements of the Parties where the resources or knowledge have been acquired.



the participation of communities on their traditional knowledge, maintenance and conservation of biological diversity, reinforcement of the sovereignty of the States over their genetic resources and, in turn, a fair and equitable sharing of the benefits arising out of the commercial use of genetic resources.

However, to the exception of the UPOV Convention, which provides for a specific, clear, simple and unambiguous access to genetic resources and fair and shared benefits, the other international documents fail to do so.

On October 12, 2014, upon the entry into force of the Nagoya Protocol, the ratifying states will face the great challenge of implementing the Protocol's noble purposes, of facilitating its interaction with the FAO Treaty which, all in all, entails a significant legislative, institutional and administrative degree of organization. Specific legislation on access and fair and equitable sharing on the benefits, the terms of the PIC and the MAT, including monetary and non-monetary benefits in the latter, shall be introduced.

If this purpose is not achieved, not only will the intellectual effort be at a risk of not fulfilling its goals, but what is worse, the genetic resources will be at risk of not being used or being completely lost.

(I'd like to thank Anke van den Hurk, Chairman of the Sustainable Agricultural Committee of the International Seed Federation, for her comments, suggestions and corrections.)

As it stems from Article 15 of the CBD, the Protocol implements a system of access to genetic resources and fair and shared benefits based on two instruments:

- *The so-called Prior Informed Consent (or PIC); and*
- *The negotiation of Mutually Agreed Terms (or MAT).*

The PIC relies on the principle that each State has a sovereign power over access to its genetic resources, and that an official authorization from the country where the resource is obtained must be granted. The MAT is the agreement that evidences the relationship between the parties and that provides not only for the conditions of physical access to resources, but also as to how, when and in which

way the benefits will be shared, as well as any potential limitation or restriction to the use and/or transfer of those resources.

Indeed, the PIC and the MAT intend to balance the interests of provider States and users of genetic resources. Provider States must facilitate access to their genetic resources, whereas user States must promote the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, as defined in the MAT.

Conclusions

Together with the CBD and the FAO Treaty, the Nagoya Protocol supplements a series of international instruments that deal with access and use of genetic resources, focusing on

Agreements, treaties, and/or documents on genetic resources

Treated and / or documents	Summary
CBD - Convention on Biological Diversity	Organization within the United Nations
Nagoya Protocol	Organization within the CBD, contemplating fair and equitable sharing of genetic resources and traditional knowledge at international level
PIC - Prior Informed Consent	Document under the Nagoya Protocol, considering that every country has sovereign over its genetic resources
MAT - Mutual Agreed Terms	Document under the Nagoya Protocol, consisting in a contract between the provider and the consumer
FAO Treaty	Within the United Nations, addressing resources for to food and agriculture
UPOV Convention	Within the United Nations, addressing the plant breeder rights