

National and Regional Gene Banks - Access and Benefit Sharing and IP Related Issues

Elżbieta Martyniuk

National Research Institute of Animal Production/ Warsaw University of Life Sciences

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, a new international agreement was adopted by the Tenth Conference of the Parties to the Convention on Biological Diversity (COP 10) in 2010. It aims at providing a legal framework to articulate the “*quid pro quo*” that underpins the Convention on Biological Diversity (CBD): access to genetic resources in exchange for benefit sharing arising from their utilisation. The Nagoya Protocol recognizes the importance of genetic resources for food and agriculture and their special role for food security (Article 8).

The Nagoya Protocol and TRIPS agreement

Adoption of the Nagoya Protocol has intensified discussions to address a contradiction between Article 27 (*Patentable Subject Matter*) of the WTO Trade Related Intellectual Property Rights Agreement (TRIPS) and the CBD; and has enforced the need to renegotiate certain TRIPS provisions.

Para 1 of the Article 27 of TRIPS does not provide an obligation to disclose the origin of a genetic resources (GR) involved in a patent claim, and para 3b of TRIPS, allows patents for both plants and animals. These two elements of TRIPS agreement are contradictory to the third objective of the CBD (fair and equitable sharing of benefits); and Article 3 of the CBD (Principle: States have the sovereign right to exploit their own resources); as well as Article 15 of the CBD (Access to Genetic Resources). Moreover, current agreement on patentable subject matter is against the general spirit and trust of the Nagoya Protocol.

Status of the NP discussion: global

With adoption of the Nagoya Protocol, Parties to the CBD, established at COP 10 a roadmap for the first meeting of the Conference of the Parties serving as the Meeting of the Parties (COP/MOP) of the Nagoya Protocol (decision UNEP/CBD/COP/DEC/X/1). Parties as well established an Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol (the Intergovernmental Committee), and decided that it shall undertake the preparations necessary for the first meeting of the Nagoya Protocol COP/MOP, at which time it will cease to exist. The first session of the Intergovernmental Committee took place in June 2011; the second is now scheduled for 2-6 July, 2012 (initially mid April 2012). The COP 10 endorsed the work plan for the Intergovernmental Committee and nominated its Co-Chairs: Mr. Fernando Casas (Colombia) and Mr. Timothy Hodges (Canada).

The COP 10 also established a Special Voluntary Trust Fund for Additional Voluntary Contributions to support ratification of the Nagoya Protocol. The Executive Secretary of the CBD was requested to provide technical assistance to Parties to assist early ratification and implementation of the Protocol.

As of 18 May 2012, 92 countries out of 193 Parties to the CBD, have signed the Nagoya Protocol and four have ratified it (Gabon, Jordan, Rwanda and Seychelles). The Nagoya Protocol will enter into force 90 days after the date of deposit of the fiftieth instrument of ratification.

Status of the NP discussion: the EU

The DG Environment of the European Commission in 2011 commissioned a legal and economic impact assessment study of the Nagoya Protocol. The study includes: comparison of core Nagoya Protocol provisions and existing EU policies and legislation; identification of options for implementation of the Nagoya Protocol obligations at the EU level and analysis of potential impacts of possible implementation options.

The European Commission also conducted a web-based public consultation to explore the possible effects of the Protocol and to gather concrete proposals on the practical challenges of implementation and organized meetings with relevant interested stakeholders. The impact assessment study should be finalized soon and draft proposals for community legislation available in the third quarter of 2012.

The animal genetic resources sector (AnGR) sector participated in the public consultation, mainly represented by the European Forum of Farm Animal Breeders. They expressed concern that animal breeding, being an international activity, may be hampered by additional regulations, which is not desirable. Additional regulations will likely also involve extra costs resulting in trade barriers for animal breeding organisations. They also underlined that international trade of seed stock is the single most important factor to increase efficiency and volume of animal production. Accordingly, any regulation that blocks trade will likely impose a severe limitation on progress in efforts to improve animal production. The European Forum of Farm Animal Breeders also expressed concern about possible misinterpretation of the Nagoya Protocol.

Related processes and initiatives: FAO CGRFA

The FAO Commission on Genetic Resources for Food and Agriculture (CGRFA) successfully negotiated the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). The Treaty was adopted by the FAO Conference in November 2001 (Resolution 3/2001), and came into force 29th June 2004.

The Multi Year Programme of Work of the CGRFA covers policy developments related to access and benefit sharing (ABS) in the area of agricultural biological diversity. The 13th session of the CGRFA in 2011 established an Ad Hoc Technical Working Group on Access and Benefit-sharing for Genetic Resources for Food and Agriculture to:

- identify relevant distinctive features of the different sectors and sub-sectors of genetic resources for food and agriculture requiring distinctive solutions;
- taking into account the relevant distinctive features identified, develop options to guide and assist countries, upon their request, in developing legislative, administrative and policy measures that accommodate these features; and
- analyze, as appropriate, possible modalities for addressing access and benefit-sharing for genetic resources for food and agriculture, taking into account the full range of options, including those presented in the Nagoya Protocol.

Taking into account provisions of Article 4 of the Nagoya Protocol, the CGRFA may decide to develop further legally binding ABS instruments for specific components of biodiversity for food and agriculture that will implement, in mutually supportive manner, the objective of the Nagoya Protocol, as is the case of PGR under the ITPGRFA.

National implementation of the NP

The Nagoya Protocol includes a number of obligations for contracting parties that would be both the users and the providers of genetic resources. Those include, among others:

- Designation of a national focal point and competent national authority/ies on ABS;
- Development and implementation of national legislation;
- Provision of any information required by a ABS Clearing-House for the Protocol;
- Facilitation of access to genetic resources and associated traditional knowledge;
- Implementation of measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with PIC and MAT;
- Implementation of measures to address situations of non-compliance;
- Establishment one or more checkpoints;
- Support for development, update and use of sectoral and cross-sectoral model contractual clauses for MAT.

Similarities/ differences between AnGR and PGR

The table below presents comparisons between plant and animal genetic resources taking into account a number of characteristics (adopted from Hiemstra et al., 2006).

Issues:	PGR	AnGR
Breeding	initial crossbreeding	selection within population
Inbreeding	used extensively	not desirable
Testing costs	relatively inexpensive	might be very expensive
Genetic modification	possible/efficient	difficult/not accepted
Gene flow	$S \rightarrow N$	$N \rightarrow N$ and $N \rightarrow S$
Centres of origin	well defined	multiple domestication
Ownership	public genebanks/seed sector	private
Value of individual	very low	high to very high
Trading	breeders'/farmers' rights	bilateral agreements
Patentability (TRIPS)	varieties	breeds not patentable

One of the most important differences between plant and animal genetic resources is gene flow. In the case of PGR, as the centres of domestication of majority of crop species are in the South, plant breeders from the North need access to varieties and wild relatives to continue successful plant breeding and development of new varieties. In case of AnGR, breeding is cumulative, based on genetic progress obtained over generations of within breed selection, which resulted in development of a number of highly productive breeds that

became a mainstream of intensive commercial production. The exchange of such material takes place mainly between developed countries (N → N) and increasingly between developed and developing countries (N → S). The latter is due to the so-called livestock revolution, which has seen rapid introduction of intensive systems and enhancement of overall livestock production in developing countries. The AnGR from North offer the potential for rapid increases in the genetic potential in the livestock sector in the South. So far, there are few examples of successful introgression of exotic genotypes to mainstream breeds (e.g. Meishan pig breed); and use of wild species is almost negligible.

It should be stressed that the current exchange of AnGR in livestock sector is beneficial for farmers and currently quite effective. Due to the private ownership of farm animals, the exchange is based on private-private transactions. Individual contracts cover a wide spectrum of approaches – from very simple to very complex and sophisticated. The price paid by a buyer reflects the genetic value of the breeding stock and the buyer owns AnGR after purchasing semen or live animals. The standards for transfer are set by zootechnical legislation (to provide buyer with all relevant and trustworthy information) and veterinary requirements.

While ABS regime in general, may provide for transparency and uniformity as well as measures against those circumventing national legislation, there are risks that the approach will become overly complicated with resulting expensive ambiguous regulations. Accordingly, there is need for a sectoral approach to address ABS for genetic resources for food and agriculture, taking into account differences among all sub-sectors that contribute genetic resources for food and agriculture, and in particular AnGR. A sectoral approach would be implemented at national level but could have international provisions.

The Nagoya Protocol and the operation of AnGR gene banks /PGR gene banks

In the case of PGR - crop species included in the Annex 1 of the ITPGRFA, and accessed from collections operating under the ITPGRFA (held by Contracting Parties, the International Agriculture Research Centres of the CGIAR, and also natural and legal persons) the Multilateral System of Access and Benefit-sharing regulates exchange of genetic resources.

The Governing Body of the ITPGRFA has established the Standard Material Transfer Agreement (STMA) which:

- It is a mandatory model for parties wishing to provide and receive material under the Multilateral System;
- Cannot be varied or abbreviated in any way;
- The STMA are private agreements between the particular providers and recipients;
- The Governing Body, through FAO as the Third Party Beneficiary, is recognized as having an interest in the agreements.

The Article 5 of the SMTA defines rights and obligations of the provider and Article 6 indicates the rights and obligations of the recipient of PGR. The material obtained from the gene banks shall be used or conserved only for the purposes of research, breeding and training for food and agriculture. It does not include chemical, pharmaceutical and/or other non-food/feed industrial uses. The benefit sharing arrangements depend on the way of commercialisation of a PGR Product that incorporates material obtained through the Multilateral System. If a PGR Product (e.g. new plant variety registered in UPOV) is not available without restriction, the Recipient shall pay a fixed percentage of the sales of the

commercialized Product. When a Product is available without restriction the Recipient is encouraged to make voluntary payments to the Multilateral System.

The PGR collections operating outside the ITPGRFA are implementing various arrangements for ABS, from free access (e.g. national gene banks in USA and Canada) to access on commercial basis (private providers of genetic resources).

The fundamental biological differences between plant and animal genetic material being stored in gene banks results in different technical requirements and management procedures that have to be implemented. Moreover, while the PGR gene banks are common, so far in case of AnGR, the number of operational national gene banks (in public domain) with the objective to conserve AnGR is rather limited, and they are mainly in developed countries. There is really no AnGR genebanks established under international organizations such as CGIAR, and bilateral /regional initiatives are rare. However, there is some growth in developing private bio-bank sector with commercial interests.

European gene banking strategy: Issues and Options

The Global Plan of Action for Animal Genetic Resources for Food and Agriculture adopted in 2007 in Interlaken, contains Strategic Priority 10 (Develop and implement regional and global long-term conservation strategies), with Action 3: “Establish regional and global networks of gene banks for animal genetic resources and harmonize approaches to conservation in gene banks and to facilitating exchange”. These provisions indicated clearly that governments and international community consider gene banking as an important element in the conservation of AnGR, and that there is a need for concerted and collaborative action at both the global and regional levels.

In the European region, the first step in this direction was taken with the establishment of the FABISnet, an integrated network of decentralized country biodiversity and gene bank databases. The common CryoWeb gene bank management software is available to the 17 partners that participated in this EC funded project, as well as other interested countries. At the global level, the FAO Guidelines for cryoconservation of AnGR will support development of common technical standards for operation of the animal gene banks.

What are the options for the European gene banking strategy?

When considering potential options for the European gene banking strategy, the most promising is: a virtual gene bank (Option I) that might operate as a network of already existing gene banks (such approach was already adopted at the national level in Italy).

In such a case, individual partners from participating countries would be responsible for collection, storage and overall management of their gene banks. The common part may include: technical requirements and standards, software and database, and also a set of ABS provisions (e.g. Material Transfer Agreement). The system would facilitate access to AnGR for members of the network. In lights of the Nagoya Protocol, such a development may require special provisions in national ABS legislation.

Taking into account a limited number of operating AnGR gene banks, high costs of their establishment and running, lack of technical expertise and resources, another option to consider would be a physical regional gene bank (Option II): – maybe not in Europe but in

other regions. Although Option II could be a viable approach to conserving AnGR, it is rather unlikely to happen, as this would require lengthy negotiations, and it may not be possible to reach agreement on sharing and use of conserved materials. It may be more practical to consider AnGR gene banks on a bilateral basis rather than a regional approach. In such a case, a similar modality as the STMA in case of PGR should be developed to facilitate access and benefit sharing.