

# LEGAL ASPECTS OF GENETIC MATERIAL AND GENETIC INFORMATION PROPERTY

## ASPECTOS LEGALES DE LA PROPIEDAD DEL MATERIAL GENÉTICO Y DE LA INFORMACIÓN GENÉTICA

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Biodiversity. Genetic resources. Intellectual property.

### PALABRAS CLAVE ADICIONALES

Biodiversidad. Recursos genéticos. Propiedad intelectual.

### SUMMARY

In this paper the the legal aspects related to the intellectual property represented by the genetic material (resources) and the genetic information is summarized. Its relevance to samples and date developed in biodiversity studies is discussed. Also the conclusions reached in international discussions about such regulations are presented as a point of reference to be taken into account in the relations among countries. A special mention is made regarding the regulation of the commercial transfer of genetic material.

### RESUMEN

En este trabajo se resume la situación actual con respecto a los aspectos legales relacionados con la propiedad intelectual del material genético y de la información genética. También se presentan las conclusiones alcanzadas en discusiones internacionales sobre estas regulaciones para ser tomadas como punto de referencia en las relaciones entre países. Se hace una mención especial a la regulación de la transferencia comercial del material genético.

### INTRODUCTION

Some of the issues presented here are a summary of the paper by Cardellino (2003). There are at least three levels of legal instruments that are relevant to ownership and use of genetic resources:

- International treaties and conventions which the country or countries involved have signed.
- National legislation covering genetic resources.
- Material transfer agreements (MTA) or commercial transactions between providers and users of genetic resources, regulated by law.

All these legal instruments must be in mutual agreement in order to achieve harmonious and practical procedures for regulating and protecting genetic resources and the rights of parties involved, and prevent the proliferation of bilateral litigation. It is desirable that the most fundamental issues and basic principles for genetic resources

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are covered by multilateral agreements so that bilateral negotiation is greatly simplified and all countries have equal opportunity. Most international legal instruments deal with plant genetic resources. For animal genetic resources the Convention on Biological Diversity (CBD) and the Bonn Guidelines of the CBD apply. There is no equivalent of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) for animal genetic resources. There is also no equivalent for animal genetic resources of the global system of gene banks that exists for plant genetic resources. Gene flow and commercialization issues for plant genetic resources have many and important differences to those for animal genetic resources.

The CBD requires parties to facilitate access and " ... *not to impose restrictions that run counter to the objectives of the Convention*". Access must be on "*mutually agreed terms*" and subject to "*prior informed consent*". The first requirement (mutually agreed terms) implies that both supplier and recipient of genetic material must agree on terms and conditions of the transfer. Here is an opportunity for the providing country to negotiate a share of the benefits arising from this cession and from the use of the specified genetic resources by the recipient. This is generally done through a contract in the form of a Material Transfer Agreement (MTA), a contractual arrangement executed bilaterally that sets the conditions and the agreed terms under which the genetic material is to be transferred. The MTA will specify which uses of the genetic resources provided are permitted and which are

prohibited. There may be provisions as to whether the resources or its derivatives are allowed be commercialized or not. There may also be specifications as to generation of rights over the genetic resources or any other resources derived from them. The sharing of benefits must also be specified. The second condition (prior informed consent) means that the authority of the providing country, as a result from a request from an applicant, can decide to grant or refuse access to the genetic resource. The applicant may be asked to provide information concerning the purposes for which the genetic resources are required and to describe the proposed arrangements for benefit sharing. During this procedure the granting authority may set up consultations with local communities and national stakeholders in order to protect their rights.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is part of the agreements of the World Trade Organization (WTO, 2003), and it requires all WTO Members to provide minimum standards of protection for a wide range of IPRs including copyright, patents, trademarks, industrial designs, geographical indications, and others. The full text is available on line ([www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf)). Among the issues raised by TRIPS that have provoked the most discussion is the extent to which patents should be allowed on inventions relating to living forms, for example microorganisms, and the requirement to provide IP protection for plants, raising compatibility questions with the CBD. Under

## LEGAL ASPECTS OF GENETIC PROPERTY

TRIPS, countries may exclude from patentability plants and animals and essentially biological processes for producing them, but not microorganisms. It does not mention whether or not genes should be patentable, whether derived from plants, humans or animals. It is not specified what constitutes an invention in relation to genetic material. For example, it may be argued that genetic material identified in nature is patentable on the grounds that isolating and purifying it makes it different from an unpatentable discovery. This is a matter left for national legislation. The only specific requirement, other than for microorganisms, is that plant varieties be protected.

The World Intellectual Property Organization (WIPO, 2003) has as its main objective to promote the protection of IP throughout the world and to harmonize national legislation in this field ([www.wipo.int](http://www.wipo.int)). Today its main function is to serve as a forum for negotiation of international IP treaties.

### MATERIAL TRANSFER AGREEMENTS (MTA) AND INTELLECTUAL PROPERTY PROTECTION (IPP)

#### EXAMPLE OF MTA AMONG MULTIPLE PARTNERS

The example presented is an agreement for the long-term conservation and use of genetic resources arising from a Pig Biodiversity Research Project sponsored by the EU. It included initially 13 contracting partners, including FAO. There was an initial agreement with the purpose

of protecting ownership and property rights of the blood and DNA samples transferred among participants to the project. It is stated that the material will remain the property of the individual providers. All parties to the agreement recognize that no other use of the material can be made without written permission from both the relevant individual provider and the country of origin.

The second agreement is a long term one, regarding conservation and use of genetic material. Its preamble refers to the objectives of the research: "... to demonstrate the benefits of an evaluation of genetic diversity in the European pig, taking into account both commercial populations and local breeds in order to enhance utilization and preservation for future generations..." and to "... the importance to humanity of protecting and conserving germplasm from animal genetic resources...". Note is taken of the provisions of the CBD, particularly those pertaining to affirmation of sovereign rights of nations over their biological resources and access and benefit sharing mechanisms. The importance of the project in FAO's strategic framework for animal genetic resources is also mentioned.

The contracting parties agree to a number of term definitions used throughout the MTA: project, project participants, owners, material providers, genetic material, management group, DNA repositories, typing laboratories, analytical laboratories, stored DNA, material providers DNA, project data, project raw data, project summary data, country of origin, database, and user.

The objectives of this agreement are (a) to facilitate the conservation of the genetic material collected under the project, to be used in future for international R&D; (b) to clarify property rights in all genetic material sampled in the project; (c) to establish a management structure which will decide on the management and use of the stored DNA and project data. It is stated that the agreement shall be applied in a manner consistent with the provisions of the CBD.

The governance of the agreement is done through a Management Group representing the interests of all parties. The Group will take decisions on control to access to the stored DNA and project data, taking into account the provisions of the CBD and of FAO's global strategy for the management of farm animal genetic resources. The basic principle covering access to the stored DNA and project data is that these will be used as new techniques and tools become available, which may give much greater insight into diversity within or between the breeds in the sample. The project data may be utilized in further analyses which are aimed at advancing understanding of animal genetic resources, and the results published openly in recognized technical journals. The Group will receive advice from and report to the material providers and the country of origin, and will seek advice and monitor and guide the operation of the DNA repositories, the data repository curator, the typing and analytical laboratories, and contracts to the original agreement. The Group will decide upon applications for the use of stored DNA and project data from the interested

parties to the original project, and other users wishing to utilize stored DNA and project data. Following this section, the duties of each of the project participants are described in detail.

Stored DNA will be maintained for each breed and animal using internationally accepted methods, taking all care without further responsibility, and with the guidance of the Management Group. The DNA repository will be maintained secure from all-comers and from power failures, with a record of all people permitted to access the repository and of their accessions, taking all care without further responsibility, under the guidance of the Management Group. Similar provisions are detailed regarding data maintenance, access, reporting and use for further analysis.

The original project participants retain their rights to: (a) all original data relating to all breeds included in the original project, to do further analyses of these data as they may desire and separately decide upon; (b) participate in decisions associated with the management and use of the stored DNA; (c) assist in building upon the data and results from the original project, in future research utilizing the project DNA.

All intellectual property rights (IPRs) residing in or arising from the genetic material belong to the original material providers. All genetic material provided to this project by the material providers is of one of two categories: (a) Stored DNA assigned to the DNA repositories. Control and access to this stored DNA for further research resides with the Management Group; (b) Material providers' DNA includes project DNA used in the

typing laboratories, or that still held by the material providers. This remains the property of the original material provider. Control and access to this material providers' DNA for further research and any other use resides with the original material provider. The project DNA which remains with the typing laboratories will be retained by the typing laboratory or returned to the materials provider, as determined by the materials provider. Such transfers of material provider DNA will use a simple MTA if this is required.

The term of the MTA is for a period of 10 years. It will be automatically renewed for further periods of 5 years unless notice of non-renewal is given before the expiration date. Any dispute between the Contracting Parties arising out of the interpretation or execution of this Agreement shall be settled by mutual agreement. If the Contracting Parties are unable to reach agreement on any question in dispute or on a mode of settlement other than arbitration, either party shall have the right to request arbitration in accordance with the Arbitration Rules of the United Nations Commission on International Trade Law (UNCITRAL), as at present in force. The Contracting Parties agree to be bound by any arbitration award rendered in accordance with the above, as the final adjudication of any such dispute. The present Agreement shall be governed by general principles of law, to the exclusion of any single national system of law. The Contracting Parties may propose that the Agreement be amended by giving notice thereof. In case of mutual agreement in this respect, the amendment shall enter into force on whatever date is set.

#### EXAMPLE OF PROTECTION OF IPR IN A CONTRACT

The following are proposed clauses in Intellectual Property (IP) Arrangements for a continuation of the research project used previously as example. The ownership of, and access to, the project material (biological samples and nucleic acids derived from them) is set out in the Material Transfer Agreement developed by the FAO as part of the first Pig Biodiversity Project. All biological samples will remain the property of the laboratory and country from which they originated. The partners have agreed that the interconnected nature of the project is such that all results will be jointly owned by the Parties, and a consortium agreement will be executed to this effect.

It is possible, although it is not a specific objective of the project, that protectable IP may be generated by the project. In the case of protectable IP, the partner(s) that obtain protectable IP should grant a free license to use the protected IP to the other Parties (consortium members). Partners will cooperate in the licensing of the IP, and income will be shared based on the contributions made to the costs of protection on a country by country basis. Those partners contributing to the costs of protection will be termed Participating Partners. Participating Partners may grant royalty-bearing licenses to third parties in their country of origin. This license will not include the right to sublicense. In addition, the consortium will seek to exploit the technology on a wider basis by granting royalty-bearing licenses. All license income will be shared equally between the Participating Partners.

## CARDELLINO

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