

GUIDELINES FOR THE DEVELOPMENT OF THE MATERIAL TRANSFER AGREEMENT (MTA) FOR RESEARCH.

1. OBJECTIVE

The aim of this document is to help the Genebanks in the process to develop a MTA for Material intended to be employed for conservation and breeding. These guidelines provide a potential set of elements, which could be incorporated in a MTA. They could be considered as “tool box” to facilitate process of developing own MTA to be used by a given Genebank.

Each Genebank could consider developing their own MTA model in consultation with relevant stakeholders that are receiving Material from to the Genebank. The MTA model can be further amended for individual transfer of animal genetic resources.

2. POSSIBLE CONSIDERATIONS BEFORE DEVELOPING A MTA

- The Genebank policy and objectives, including on transfer.
- The national law and internal rules of the institution hosting the Genebank and organization employing the Material.
- ABS (Access and Benefit Sharing) legislation and regulatory measures, if relevant.
- Relevant national and international veterinary and animal breeding regulations.
- The regulation about general data protection.
- The ownership of the Material.

A review of the MTA by a legal expert is highly recommended

3. ELEMENTS FOR THE DEVELOPMENT OF A MTA

This chapter of the guidelines aims to summarize the elements, which could be used in the development of each MTA.

Part 1. IDENTIFICATION OF THE PARTIES.

Provider: Genebank

Provider data:

- Name:
- Represented by, if relevant:
- Address:
- Country"
- Power of signature:

Recipient: Any legal/private person(s) (from the same country or from abroad) that will employ animal biological material from the Genebank

Recipient data:

- Name:
- Represented by:
- Address:
- Country:
- Power of signature:

Part 2. PREAMBLE

Parties may want to agree on the objectives of the agreement and make references to:

- Relevant specific national laws, regulations or derogations for acquisition and use of Genebank Material;
- The national law and internal rules of the institution hosting the Genebank and organization providing the Material ;
- The Genebank policy and objectives, including the relevant use following criteria implemented by the Genebank for using Material for conservation of animal genetic resources and/or for animal breeding, research and development;
- The Convention on Biological Diversity (CBD);
- The FAO Global Plan of Action (GPA) for Animal Genetic Resources;
- Relevant national and international veterinary and animal breeding regulations;
- The European Genebank Network EUGENA governed by the European Regional Focal Point on Animal Genetic Resources;

- The Nagoya Protocol, and in particular Article 8 (Special Considerations), Art.19 (Model Contractual Clauses) and Article 20 (Codes of Conduct, Guidelines and Best Practices and/or Standards);
- The aims of the Recipient in relation with the transfer of the Material from the Genebank (i.e. activity in which the Material is going to be used).

Part 3. DEFINITIONS

- **Material:** Any animal biological material that can be used for reproduction and research;
- **Genebank:** Repository for ex situ conservation, sustainable use, research and development of animal genetic resources held by a host institution.
- **Provider:** Genebank manager for physical access and/or authorized body to approve access;
- **Recipient:** Any legal entity or private person, either from the same country or from abroad, that would like to access animal genetic resources for research purposes;
- **Project:** set of research activities in where the material is going to be used.
- **Owner:** Any legal entity or private person(s) who have the ownership rights over the provided material.

Part 4. SPECIFIC OBJECTIVES OF THE MTA

This part should provide a specific description of the objectives of the MTA, which may include:

- To support research activities;
- Reference to services/price in return of the material provided by the recipient of the material to the Genebank, if relevant;
- Description of the research project (Annex II) and justification of the need for the Material.

Part 5. DESCRIPTION OF THE MATERIAL.

- Information about the type and amount of the Material transferred from the Genebank to the Recipient should be provided in Annex I;
- Information about the Material may include, inter alia:
 - ✓ Identification of the Material (sample/animal/breed),
 - ✓ Type of Material (semen, embryos, etc.),
 - ✓ Quantity and quality of Material,
 - ✓ ID of the donor animal, genealogical data, recordings or genetic/genomic values of donor animal,
 - ✓ Sanitary/health status/certificates of the Material and their donors in the moment of the collection,
 - ✓ Place and date of collection,
 - ✓ Technical recommendations for the use and storage of the Material,
 - ✓ Temperature of conservation,
 - ✓ Technical specifications on type of straw/vial etc.,
 - ✓ The owner of the Material before entering it into the Genebank.

Part 6. FINANCIAL ARRANGEMENTS AND OWNERSHIP

1. The recipient and the Genebank should establish financial arrangements on acquisition and delivery of the material.
2. Regarding financial arrangements, there are different possibilities:
 - The Genebank transfers the Material to the Recipient:
 - i. Free of charge,
 - ii. Covering some costs (i.e. delivery),
 - iii. Selling Material on commercial basis,
 - iv. In exchange of services provided by the Recipient,
 - The Recipient and the Genebank can establish restricted scope of uses of Material (i.e. in the Annex II on Description of the activities).
3. Regarding ownership of the Material, there are different options:
 - Full transfer of the ownership from Genebanks to the Recipient,
 - The ownership is transferred to the Recipient but the Genebank maintains rights to participate in the decision making process on the use of its Material,
 - The ownership remains with the Genebank and Recipient has rights to use the Material only as described in the Annex II.

Part 7. RIGHTS AND DUTIES OF THE GENE BANK

The rights and duties of the Genebank depends of the specific arrangements included in the MTA, and could contain the following elements:

- The Genebank provides samples of the Material under its ownership or in representation of the owner of the samples;
- The Genebank provides detailed information on type and quantities of biological Material (semen, embryos, tissue etc.,; number of samples etc., ...) as well as their sanitary status;
- The Genebank is responsible for accuracy of information on technical and legal aspects related to the provided biological Material included in the Annex to the MTA;
- The Genebank maintains all relevant documentation on the Material for X number of years since the date of transfer to Recipient from the Genebank (obligatory 20 years for EU MS);
- In case when the Material originates from a country regulating access to genetic resources the Genebank has to transfer relevant ABS documentation (PIC, MAT, IRCC) together with the Material to the Recipient;
- The Genebank must comply with national and, if it is the case, the European and international veterinary regulations on the movement of germinal products;

- the Genebank will provide the Recipient with the Material as specified in Annex I. Material will be made available by the Genebank (within a given period of time) after signing this Agreement;
- the Genebank will inform Recipient of liabilities and restrictions related to use of the Material (purpose of use, rights of disposal etc.) due to the national legislation or agreement with the original owner(s) of the Material, as indicated in the Material Acquisition Agreement (MAA) or will obtain permission for the use of the Material from the original owner(s), if relevant;
- The Genebank makes publicly available Genebank policies, rules and procedures related to acquisition and transfer of Material.

Part 8. RIGHTS AND DUTIES OF THE RECIPIENT

The rights and duties of the Recipient depends of the specific arrangements negotiated in each MTA, and could include the following elements:

- the Recipient will use the transferred Material for research purposes, according to the project, specified in Annex II;
- the Recipient shall not use the Material for any other purpose than the described in Annex II, without the prior written consent of the Genebank;
- The Recipient must comply with the access conditions settled by the Provider country, if relevant.
- the Recipient is not allowed to transfer the Material received from the Genebank to a third party;
- the Recipient will pay for the Material the total amount of € [...] (as a handling fee or other fee) according to the internal procedures as indicated by the Genebank;
- the Recipient will make available the offspring generated with the received Material to the Genebank for replenishing the Genebank collection, if relevant.
- the Recipient will implement the relevant technical specifications and protocol(s) on the use of the Material (Annex III);
- Any provided Material that remains unused will be
 - ✓ returned to the Genebank
 - ✓ kept in the storage
 - ✓ destroyed by the Recipient, if requested by the Genebank. In the event the unused Material was destroyed, a written declaration on the destruction would have to be signed by the Recipient and would have to be provided to the Genebank within X weeks from destruction;
- the Recipient alone will not apply for any intellectual property rights related to the provided Material;
- the Recipient will inform the Genebank of any problems, defects or difficulties related to the use of the Material;
- the Recipient will report to the Genebank on progress in implementation of the Project;
- The Recipient is allowed to publish the results of research and will acknowledge the Genebank in the publication. In case of substantial contribution to the manuscript, Genebank will also become co-author;
- The Recipient will make available the data generated in the Project to the Genebank, within X months after the signature date of the MTA;



- The Recipient is allowed to make data generated within the Project publicly available, respecting an embargo period of X years after the signature date of the MTA.

Part 9. TERMS OF TRANSFER OF RIGHTS, INVENTIONS AND PUBLICATION

- No right or license to biological/genetic Material is granted by the Genebank to the Recipient;
- If the research results in any invention(s), the Recipient of the Material shall disclose such inventions promptly to the Genebank;
- The Recipient and the Genebank shall then negotiate the ownership and licensing of such invention(s) and the apportionment of any commercial benefits arising from them;
- The Recipient cannot include the biological/genetic Material and/or associated information in a patent application or any other deed of intellectual property rights without the preliminary written agreement with the Genebank;
- The Provider and the Genebank shall agree on the publication of research results.

Part 10. MTA COMMITTEE

In the event that the ownership has not been totally transferred from the Genebank to the provider, it is recommended to establish a committee between both parties to analyze the possible uses of the material.

Part 11: WARRANTY

There is no warranty for the Material. The biological Material is understood to be experimental in nature and may have not stable properties.

Part 12. LIABILITY

- The Recipient will use the Material in compliance with all relevant national and international laws, applicable to the Material, the Recipient is obliged to be familiar with relevant laws, especially sanitary/veterinary laws and requirements.
- In no event the Genebank will be liable for any use of the Material made by the Recipient. The Recipient agrees that it shall not hold the Genebank responsible for, and shall ensure the Genebank harmless from consequences of any use of the Material by the Recipient.
- The liability during shipping from the Genebank to the Recipient lies with the carrier service provider.
- In the case of any further transportation of the Material by the Recipient, all risks rest with the Recipient



Part 13. GOVERNING LAW

- Specific/relevant laws and regulatory measures of the Provider's country.

Part 14. DISPUTE SETTLEMENT

- Dispute settlement will be conducted according to the domestic law of the Provider's country;
- This Agreement shall be interpreted, governed and enforced exclusively in accordance with the law of the Provider, unless it is decided otherwise;
- Parties hereto shall attempt to settle any dispute arising from or relating to this agreement in an amicable way. All disputes which arise under this Agreement shall be judged exclusively by the competent court [] in the country of the Provider.

Part 15. ARRANGEMENTS ABOUT GENE BANK DATA PROTECTION

The inclusion and use of personal data in the MTA, will be treated in accordance with the regulation of General Data Protection.

Part 16. EFFECTIVE DATE

- This Agreement will enter into effect on the date established by the national laws on contracts / MoU, and in case that there are no national laws addressing this issue, it will enter into force on the date when both Parties have signed this agreement;
- The validity of the MTA (in the event that the ownership has not been totally transferred) is for X numbers of years;
- Nothing in this agreement shall be construed as the granting of rights between the Parties, and neither Party hereto shall be obliged to enter into any further agreements.

SIGNATURE (for Agreement)

- Provider Date

- Recipient Date

ANNEX I. – Description of the Material

ANNEX II. – Research Project

ANNEX III. – Technical specifications and protocols on the use of the Material