

# Legal and instrumental arrangements for genebanks in the Czech Republic

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# Legal and instrumental arrangements for genebanks in the Czech Republic



Legal and instrumental arrangements unwind from the purpose of conservation

- standard future use in breeding (marketing)
- use in management of endangered breed (breed reconstruction/revitalization projects)
- research and advanced biotechnologies (cloning, transgenosis)
- sacred preservation for any future needs

for 1) and 2) we have to meet all requirements of the consolidated EU legislation

- material to be collected and stored on approved stations
- donor animals must meet given genetic and veterinary requirements
- + ~tens of prescriptions for respective species

# Legal and instrumental arrangements for genebanks in the Czech Republic contd.



Every collecting and storage station (gene bank) possesses its **own service arrangements** and regulations that are compatible to the EU sanitary rules for acquisition, storage and placing on the market of respective material

2009/712/EC: Commission Decision implementing Council Directive 2008/73/EC as regards Internet-based information on establishments approved in accordance with Community veterinary and zootechnical legislation applied in **CZ Law Ordinance No.380/2003 Coll.**



**STÁTNÍ VETERINÁRNÍ SPRÁVA**  
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**State Veterinary Administration is a public administration body under the Ministry of Agriculture of the Czech Republic**



<http://www.svscr.cz>

Animal Welfare

BIP in the Czech Republic

BSE in CR

Lists of Establishments

List of transporters

List of warehouses

List of authorised  
aquaculture production  
businesses



Lists of Establishments in the CZ

Assembly centres

Dealers

Semen collection and storage centres

Embryo collection and production teams

Quarantine facilities or centres

**Bovine collecting centres 8**

**Bovine semen banks 13**

**Porcine collecting centres 20**

**Equine collecting centres 5**

**Bovine embryo producing teams 4**

**+ National Program Genebank**

**~ 8 cryobanks in research institutions (no legal regulations)**

# Legal and instrumental arrangements for genebanks in the Czech Republic: Bottlenecks



- 0 stations for ovine and caprine material
- problematic transport and placing private animals into approved stations (takes 2-3 months with pre- and post-collecting quarantine)
- material collected before we joined the EU (2004)

„**Exempted material**“ status – the National Program Genebank must warrant spatial, technical and operational separation from the regular (commercial) material

Exempted material, however, must meet the same veterinary and sanitary requirements as the „regular one“ (donor animals inspected for respective diseases, farm and locality must be of infectious-free status)

*Exempted ram and buck semen doses are collected on farm by a specialized mobile laboratory of the IAS Kostelec.*



# What is genetic material?

- Up to date Breeding Act No.344/2006 Coll.:  
collected reproduction material, namely sperm, ovarian cells, embryos, and other tissues enabling transfer and regeneration of the respective genetic resource when maintaining its genetic substance
- Possible future definition:  
any material containing transferable complete genetic information  
(=nucleotic DNA)
- CBD definion: any material...containing functional units of heredity

## Type of collected material

Semen doses, embryos, ovarian cells, somatic cells,  
blood, DNA isolates

*„Regular“ semen doses are collected on approved stations*

*Embryos are produced and collected onfarm by approved teams*

# Where and how we harvest the material



Provided material originates from animals supported by the State (National program, NP) to compensate breeders their extra duties

Breeding Act 344/2006 Coll.:

*NP participants are obliged upon request provide the National Coordinating centre with genetic material and data related to that material free of charge. Data which may constitute a trade secret are excluded from that obligation.*

Provider costs for preparation animals, health examination, assistance by collecting etc. are reimbursed by the State, as well all direct costs of collecting, processing and storage are covered by the State

# Ownership, access and dispositional rights



- After placing into the gene bank, this material becomes a sample without market value under the State administration.
- The maintenance costs of gene bank are covered by the State.
- The access and dispositional rights to the material are the subject of agreements on acquisition and transfer, that shall secure protection of rights of intellectual property to this material and fair benefit sharing issuing from its future utilisation
  - **Material Acquisition Agreement** expresses a prior informed consent (PIC) with the provision of genetic material and governs conditions for the further use of this material
  - **Material Transfer Agreement** governs conditions for the transfer of material and any information related from the gene bank to the requesting party



# Material Acquisition Agreement

- the material is the property of the donor and is made available as a service to the National program only
- the recipient (genebank) will hold the material in trust in and provide long-term conservation in compliance with all applicable statutes and regulations.
- the material will be used for characterization, testing and/or evaluation, education, non-profit research, or in the breed reconstruction project under the terms of the National Program, **only**
- **any delivery** of the material will be transferred under a separate Material Transfer Agreement and will be referred to the donor
- *genebank assumes all liability for claims for damages against it by third parties, which may arise from the use, storage or disposal of the material except that the donor shall be liable to the recipient when the damage is caused by the gross negligence or wilful misconduct of the donor*



# Material Transfer Agreement

- the recipient will use the material and the information **exclusively for the aforesaid purpose** and handle it in compliance with all relevant laws, rules regulations and procedures applicable
- the recipient will not sell, distribute or otherwise made available the material and/or information to any other party for any purpose or use it in any way for the commercial purposes
- progeny born with the use of the material in the breed reconstruction project becomes a property of recipient, the recipient agrees that the progeny will be handled according to the project
- the recipient agrees to collaborate in the conservation program by future provision of genetic material originated from the progeny born and by provision of all relevant information
- data arising from the evaluation of the material will be furnished to the provider. *Upon request of provider or recipient these data may be made publicly available after an embargo period.*



# Material Transfer Agreement contd.

- any information (research results) obtained using the material will be considered proprietary to the recipient. Prior to publication of such results the recipient will hand the provider a text of the publication
- the recipient is free to file **patent application claiming inventions** made through the use of the material but agrees **to inform prior to do so** the provider for any intellectual property rights related  
*(this implies consecutive obligation of genebank to inform the original donor who can negotiate over future benefits directly with the recipient)*
- the recipient assumes all liability for damages, which may arise from the use, storage or disposal of the material  
*(provider will not be liable for any loss, damage or whatever arising out of recipient's use of the materials, except when caused by the gross negligence or wilful misconduct of the provider)*
- this agreement abides by the law of the Czech Republic, for any dispute resolution, unless amicably settled, solely competent is the relevant Czech court