Institutional and legal framework for ex situ conservation at national level

Country information – CZECH REPUBLIC

- Historical overview of gene bank development (1/15 pg)

Until 1990, there was the only State Breeding Enterprise carrying on several specified insemination stations for all kinds of mammal farm animals and operating a commercial Central gene bank facility.

After getting private in 1991 and open to foreign stock, and even more with wholesale inflow of foreign breeds, stored material have been losing on value and stepwise dissolved. In 2000, we were unfortunately not able to find relics of that material anymore.

With opening the National Program (NP) for conservation genetic resources in 1996 we started again gather and collect semen doses from local endangered breeds (as the NP supports and deals with these breeds only), later on we were able to produce and deposit also embryos.

Since 2000 for research reasons some academy and research institutes cooperating with the NP started collecting tissues and/or DNA samples. Now the NP operates 3 semen (embryo) banks and 2 tissue/DNA deposits. Tissue deposit conserve mostly somatic and stem cells, the DNA deposit contains about 12000 samples of mammals and fowls.

So far, only the state supported NP take place, there are no NGO and/or foundation neither private activities developed.

- Objective(s) of national cryopreservation programme/policy (2/15)

  - Collection goals

- deposit of material for (non-commercial) breeding management of local endangered breeds and/or regeneration of that populations in emergency
- conserving genes in instantaneous status for future (scientific) utilisation

  - Collection categories

- sacred deposit (duplicated)
- handling deposit (for periodic checks and viability testing)
- operating deposit (for utilization in targeted mating program, breed revitalization etc.)

  - Achievements until today

Size of collection as of 1.11.2012

Breed	Embryo	Semen doses		Breed	Semen doses	
		sires	doses		sires	doses
FARM ANIMALS (MAMMALS)				FRESWATER FISH IN AQUACULTURES		
Cattle: Czech Red	125	7	10 200	Carp (11 local breeds)	148	2060
Czech Red Pied (old type)	1070	22	12 900	Tench (7 local lines)	290	660
Horse : Old Kladruber	0	31	1400	Catfish (3 local lines)	13	130
Hutsul	0	5	290	Beluga	2	80
Silesan Noriker	0	7	440	Sturgeon	51	510
Bohemio-Moravian Belgier	0	8	435	Trout (3 breeds)	88	910
Pig : Prestice Black Pied	0	110	2500			
Czech Extra-fleshy	0	8	225			
White goat	0	17	300			
Brown goat	0	11	230			
Shumavska sheep	0	60	1080			
Valachian sheep	0	20	315			

- Future plans

to schedule quality check and testing for material prepared by old technologies
to develop conservation methods for small animals and fowl
to develop alternative conservation methods to be used in advanced biotechnologies

- Participation of stakeholders: responsibilities/roles by stakeholder/actor (3/15)

  - Laws, regulations or arrangements between stakeholders

According to the Breeding Act (344/2006 Coll.) The NP participant is obliged upon request provide the determined person (*i.e. National Coordinating centre*) with a sample of genetic material (semen dosed, embryos, ova etc.) and data related to that material free of charge (*it means that no money are asked to allow for taking the samples, but all the direct costs are covered by the State through the determined person*). Data which may constitute a trade secret are excluded from that obligation.
The access and rights of disposal to in this way stored material are the subject of Agreements on providing and transfer (see attachment) to that time when mandatory international agreements shall be worked out and implemented, these agreements shall secure by appropriate mode the protection of rights of intellectual property to this material and fair benefit sharing issuing from its future utilisation.
The maintenance costs of gene bank are covered by the State.

  - Transboundary issues/arrangements

Not yet prepared, recommended to wait for relevant EU arrangements

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- Decision making process (1/15)
    - Type of material
    - Collection targets (populations, individuals)

With a rather short range of respective populations and with the expectation of future rapid progress in genomics, we assume as feasible to collect any accessible material. The only limitation is the capacity of licensed collecting and processing stations and legal requirements (transport of animals for a long distance and keeping them there for a rather long time of quarantine, etc.).
We are operating a mobile lab for on-farm for collecting+freezing pig, ram and buck semen, with an exemption for separate storage such material in a standard gene bank. However, such material can not be placed on the market.
In **semen doses** we preferably select sires of highly endangered parental lines (horses), in other species with regard to kinship (sheep, goats). In boars we collect representants of parental lines within 3-5 year periodicity.
In cattle **embryos** we try to produce as much as possible descendants of mothers with the highest share of old authentic genes mated to least related sires.
In **somatic tissues/cells and DNA** we collect any available material, mostly from animals included into various research projects, across the entire breeder's community. Within our research projects (as a by-product) we are going about cultivating and conserving also stem cells.

- Storage and documentation (2/15)
    - Storage facilities and rules
    - Data management and documentation
    - Gene bank security

There is a Central gene bank, operated by the commercial gene bank of the Czech Breeders Association which conserves (in separated duplicates) all the collected material of cattle, horses, pig, sheep and goats since 1996, i.e. also material not compatible to the EU rules (see below).
The second gene bank is an „operational deposit" of the Institute of Animal Science (IAS) in Kostelec which conserve semen of boars, rams and bucks intended for lines renewal and breed reconstruction projects. Besides, it contains a deposit of somatic cells.
The third gene bank is a deposit of the IAS in Prague – Uhrineves which contains a deposit of DNA samples and stem cells.
Specific requirements for cryoconservation fish sperm and its storage are assured in a gene bank of the Research Institute of Fishery and Hydrobiology at the University of South Bohemia in České Budejovice.
Stallion and bull semen is collected in EU licensed commercial insemination stations; boar semen is collected in a licensed station at the IAS in Kostelec.
Exempted ram and buck semen doses (see above) are collected on farm by a specialized mobile team of the IAS Kostelec.

Security rules in all these facilities conform to general security rules for gene banks included the flameproofness, blackout back-up and alert, labour place safety, etc.
For any material acquisition and release there is a protocol and MAA/MTA agreement.
Every gene bank keeps its own documentation with an annual stocking. Data on materials are (except primary papers) filled into in an e-database.

- Sanitary arrangements/regulations (1/15)

Every 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. However, there is an exemption for material collected before we join the EU (2004) – it is possible to keep it but without an access to the EU market.
When collecting „exempted materials" on-farm we insist on the same sanitary requirements both for donor animals and for breeding facility as by the „regular materials" so that the only difference is that the former are not collected on the licensed collecting place.

- Legal issues (related to genetic material and data) (5/15)
    - Ownership and IP
    - Collecting new material: Articles and conditions in Material Acquisition Agreements [translated agreement]
    - Access to gene bank: Articles and conditions in Material Transfer Agreements [translated agreement]

Provided material originates from animals financially supported by the State. These subsidies are paid just to compensate breeders their extra duties by reason of their involvement in the NP. After placing into the gene bank, this material becomes a sample without market value under the state administration.

Material is provided at no cost, with a fee to reimburse the donor for preparation animals, health examination cost, assistance by collecting etc. Issues related to the IP see in attached MAA/MTA.

ANNEX:

Material Acquisition Agreement

Preamble

This is a document, which expresses a prior informed consent (PIC) with the provision of genetic material to the Gene bank of the National Program for conservation and utilisation farm animal genetic resources and governing conditions for the further use of this genetic material, hereinafter referred to as the "material".

A. Parties to this agreement:

The supplier…….. (Address)…….., hereinafter referred to as the "donor"

Name of donor	
Address	
Participant Number of the National Program	

The recipient party: Gene bank (Address) ……. hereinafter referred to as the „recipient"

Name of the Gene bank	
Address	
Corporation Identification Number	

B. Material Information

Nature and amount of the material provided (semen dose, embryo)
Minimum identification data (species, breed/line, identification of the donor's animal(s), date of acquisition from in situ conditions) – in an attached list

The donor grants material and related information to the recipient under the terms and conditions of this agreement. The material being provided is identified in the attached list, which forms part of this agreement. The donor asks that the recipient agree to the following before the recipient receives the material:

1) The above material is the property of the donor and is made available as a service to the National program of conservation and utilization of farm animal genetic resources (Decree of the Ministry of Agriculture No. 206553/2011-MZE-17253) hereinafter referred to as the "National Program", only.
2) Donor warrants that he/she is legally free to provide the material.

3) The recipient will hold the material in trust in a gene bank, periodically check it, and provide long-term conservation in compliance with all applicable statutes and regulations.
4) After placing into the gene bank, this material becomes a sample without market value.
5) 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.
6) Any delivery of the material for purposes mentioned in the paragraph 5) will be transferred under a separate Material Transfer Agreement having terms consistent with the terms of this Agreement, and will be referred to the donor.
7) Unless prohibited by law, recipient 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, to the extent permitted by law, the donor shall be liable to the recipient when the damage is caused by the gross negligence or wilful misconduct of the donor.
8) The material is provided at no cost - with a transmittal fee* solely to reimburse the donor for its preparation and distribution costs.

(If a fee is requested, the amount will be indicated here: […… insert fee].

*) not accordant text be crossed out

The recipient must sign both copies of this Agreement and return one signed copy to the donor. The donor will then supply the material.

Recipient: ……

Address: ……
Name of Authorized Official: …….

Signature of Authorized Official: ……Date: ……

Donor: ……

Address: ……

Name of Authorized Official: …….

Signature of Authorized Official: ……Date: ……

N.B.
This Agreement is applied for genetic material supplied by participants in the National Program who, pursuant to the §14 of the Breeding Act No. 344/2006 Coll., provide these samples on request of the authorized person coordinating the program.

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Material Transfer Agreement

Preamble

This Agreement is governing conditions for the transfer of genetic material, hereinafter referred to as the "material," and any information relating thereto, hereinafter referred to as the "information," from the gene bank to the requesting party. The material received under this Material Transfer Agreement (MTA) was acquainted with the Prior Informed Consent (PIC) and will be used in a bona fide and sustainable way, in full respect of the principles laid down in the Convention on Biological Diversity (CBD).

A. Parties to this agreement:

The provider: Gene bank…….. (Address), hereinafter referred to as the "provider"

The requesting party hereinafter referred to as the "recipient."

Name of recipient	
Address	
Identification Number	
End User	

B. Material (to be filled by the provider)

Amount and nature of the material provided (semen, embryo, tissue type, DNA etc., and form – lyophilized, deep frozen etc.,)
Minimum identification data (species, breed, sex of the donor animal, accession number of the gene bank,)
Description (origin, place and date of acquisition from in situ conditions,)
PIC (copy of, or a reference to)

C. Objectives of use of genetic resources provided under this agreement

The material and related information is intended only for use in characterization, testing and/or evaluation, education, non-profit research, or in the breed reconstruction project.
The recipient will use the material for …….. (specified by the recipient)

On completion of these activities any remaining quantities of the material and all the eventual derivates will be treated as follows :……(specified by the provider)
Breed Reconstruction Project (Annex to the Agreement)*

D. Conditions of transfer of the material

The material and information are provided on the following conditions:

1) The recipient agrees neither to claim ownership over the material nor to seek intellectual property rights over them or information passed along.

2) The recipient will not sell, distribute or otherwise made available the material and/or information to any other party for any purpose or use this material and/or information in any way for the commercial purposes.

3) The recipient will use the material and the information exclusively for the purpose described under Section C above.

4) The recipient will ensure that the material will at all times be used and handled in compliance with all relevant laws, rules and regulations applicable, and for the purposes of testing will follow the protocols of standard test and reference procedure.

5) The recipient agrees to furnish relevant performance data arising from the evaluation of the material to the provider. Upon request of provider or recipient these data will only be made publicly available after an embargo period of……years.

6) Any other information and/or research results obtained using the material, will be considered proprietary to the recipient. Prior to publication of such results, the recipient will provide the provider with a copy of such intended publication. All such intended publications will contain an acknowledgement of the provider.

7) The recipient is free to file patent application(s) claiming inventions made by the recipient through the use of the material but agrees to inform the provider prior to applying for any intellectual property rights related to the use of any received material and notify the provider upon filing a patent application claiming method(s) of manufacture or use(s) of the material.

8) 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 (Annex to the Agreement).

9) The recipient agrees to collaborate in the conservation program by future provision of genetic material of similar type and amount originated from the progeny born in the breed reconstruction project and by provision of scientific information relevant to conservation and sustainable utilization of the respective genetic resource.

10) The material is provided at no cost, the recipient will – will not* undertake to reimburse the provider for costs associated with distribution of the material to the recipient.

11) Except to the extent prohibited by law, the recipient assumes all liability for damages, which may arise from the use, storage or disposal of the material. The provider will not be liable to the recipient for any loss, claim, damage, illness, or injury to person or property whatever the cause may be arising out of or pertaining to recipient's use of the materials, except to the extent permitted by law when caused by the gross negligence or wilful misconduct of the provider.

12) This agreement abides by the law of the Czech Republic. For any dispute resolution relating to the interpretation of application of this Agreement will, unless amicably settled, solely competent is the relevant Czech court.

13) This agreement shall only be capable of change by written amendment executed by duly authorized officers of the parties.

14) The relevant signatories must sign each of three copies of this Agreement, one of which retained by the National Coordinating Centre for Farm Animal Genetic Resources, one retained by the recipient and one by the provider.

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*) not accordant text be crossed out

Approval by the NCC:

I hereby warrant that I, as an Authorized Official of the NCC hereby certify my approval of the transfer of the material to the recipient.

Name of Authorized Official (NC): _____

_____ _____

Signature of Authorized Official Date

Provider (the gene bank from whom the material will be released)

Name: _____

Address: _____

_____ _____

Signature of Authorized Official of the gene bank Date

Recipient

Name: _____

Address: _____

I hereby certify that I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the material. I hereby warrant that I have the full authority to execute this Agreement and to thereby bind the recipient.

_____ _____

Signature l Date