

European Regional Focal Point for Animal Genetic Resources 

EUROPEAN REFERENCE CENTRE FOR ENDANGERED ANIMAL BREEDS 

Genebanks in European Union Animal Health Regulation.

WORKSHOP.
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Fernando Tejerina Ampudia, PhD. Chair of the WG Ex Situ Conservation.

 GOBIERNO DE ESPAÑA  MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACION 

1

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EUROPEAN REFERENCE CENTRE FOR ENDANGERED ANIMAL BREEDS 

1. REGULATIONS/RECOMMENDATIONS ON MOVEMENTS OF GERMINAL PRODUCTS AT INTERNATIONAL, EUROPEAN AND NATIONAL LEVELS.

 **Oie** Terrestrial Animal Health Code 

 **IETS**
INTERNATIONAL EMBRYO TECHNOLOGY SOCIETY

European level. European Animal Health Regulations 

National level: own Animal Health Regulations for national market



2



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2. WHAT IS A GENE BANK?.

Article 2.10. Delegated Regulation (EU) 2020/686
'gene bank' means a repository of animal genetic material for ex situ conservation and sustainable use of genetic resources of kept terrestrial animals, held by a host institution authorised or recognised by the competent authority to fulfil these tasks;
EUGENA Terms of Reference.
Genebank: A genebank for AnGR is a repository for ex situ conservation and sustainable use of AnGR held by a host institution authorized and/or recognized by a national authority to fulfil these tasks. A genebank may be constituted by one or more repositories (in vitro or in vivo) collaborating as a network.




GENEBANKS ARE REPOSITORIES (STORAGE FACILITIES) OF ANIMAL GENETIC MATERIAL (INTER ALIA GERMINAL PRODUCTS)


GENEBANKS SHOULD BE AUTHORIZED OR RECOGNISED BY COMPETENT AUTHORITIES TO DEVELOP THE EX SITU CONSERVATION AND SUSTAINABLE USE ACTIVITIES.



3



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3. GENE BANKS IN EUROPEAN UNION REGULATION.

Regulation (EU) 2016/429, of 9 March 2016, on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')

Article 2. Scope
1.b. Germinal products


Article 4. Definitions.
(28) 'germinal products' means:
(a) semen, oocytes and embryos intended for artificial reproduction;
(46) 'germinal product establishment' means:
(a) in relation to semen, an establishment where semen is collected, produced, processed or stored;
(b) in relation to oocytes and embryos, a group of professionals or structure supervised by a team veterinarian competent to perform the collection, production, processing and storage of oocytes and embryos;




G.P (the most frequent material in genebanks) ARE UNDER THE SCOPE OF EU ANIMAL HEALTH REGULATION

GENEBANKS ARE GERMINAL PRODUCT ESTABLISHMENTS, SO THEY HAVE TO FULFIL THE REQUIREMENT FOR THAT TYPE OF ESTABLISHMENTS.

4



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3. GENE BANKS IN EUROPEAN UNION REGULATION.

Regulation (EU) 2016/429, of 9 March 2016, on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')


Article 84. Obligation of operators to register establishments

1. Operators of establishments keeping terrestrial animals or collecting, producing, processing or storing germinal products shall, in order for their establishments to **be registered**...

Article 94 Approval of certain establishments and delegated acts.

b) germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals are moved to another Member State;

Article 269 Additional or more stringent measures by Member States.




GENEBANKS, AT LEAST, STORE GERMINAL PRODUCTS, SO THEY SHOULD BE REGISTERED


G.P. ESTABLISHMENT IN EU COUNTRIES MOVING GPs TO OTHER MEMBER STATES MUST BE APPROVED, BUT NOT IN CASE OF GENE BANKS...

EACH COUNTRY CAN REGULATE GPs AT NATIONAL LEVEL.

5



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3. GENE BANKS IN EUROPEAN UNION REGULATION.

Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals.


Article 2. Definitions.

(10) 'gene bank' means a repository of animal genetic material for ex situ conservation and sustainable use of genetic resources of kept terrestrial animals, held by a host institution authorised or recognised by the competent authority to fulfil these tasks;




GENEBANKS IN EU COUNTRIES MOVING GPs TO OTHER MEMBER STATES MUST BE AUTHORISED OR RECOGNISED BY THE COMPETENT AUTHORITY AS A REPOSITORY OF ANIMAL GENETIC MATERIAL FOR EX SITU CONSERVATION.....

6



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3. GENE BANKS IN EUROPEAN UNION REGULATION.

Commission Delegated Regulation (EU) 2020/686.

Article 45. Additional rules for the granting of derogations by competent authorities for GP moved to gene banks in another MS.


1. The competent authorities of the MS of origin may grant derogations for movements to gene banks in another MS of GP, provided that the operator of the establishment of dispatch has obtained the **prior written consent** of the competent authority of the MS of destination to accept the consignment of GPs, of:

- **Endangered breeds** which do not fulfil the animal health requirements (Chapter 1).
- **Terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments** which do not fulfil the animal health requirements (Article 37).




THE EU REGULATION IS AWARE OF THE NEEDS OF
ENDANGERED BREEDS AND ZOOS.

7



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3. GENE BANKS IN EUROPEAN UNION REGULATION.



Commission Delegated Regulation (EU) 2020/686.

Article 45. Additional rules for the granting of derogations by competent authorities for GP moved to gene banks in another MS


2. The competent authority of the MS of destination shall only consent to accept the consignment of GP referred to in paragraph 1, provided that:

The operator of the gene bank intended to receive those GP ensures that the GP are only used for the *ex situ* conservation and sustainable use of genetic resources of kept terrestrial animals for which the receiving gene bank was established.

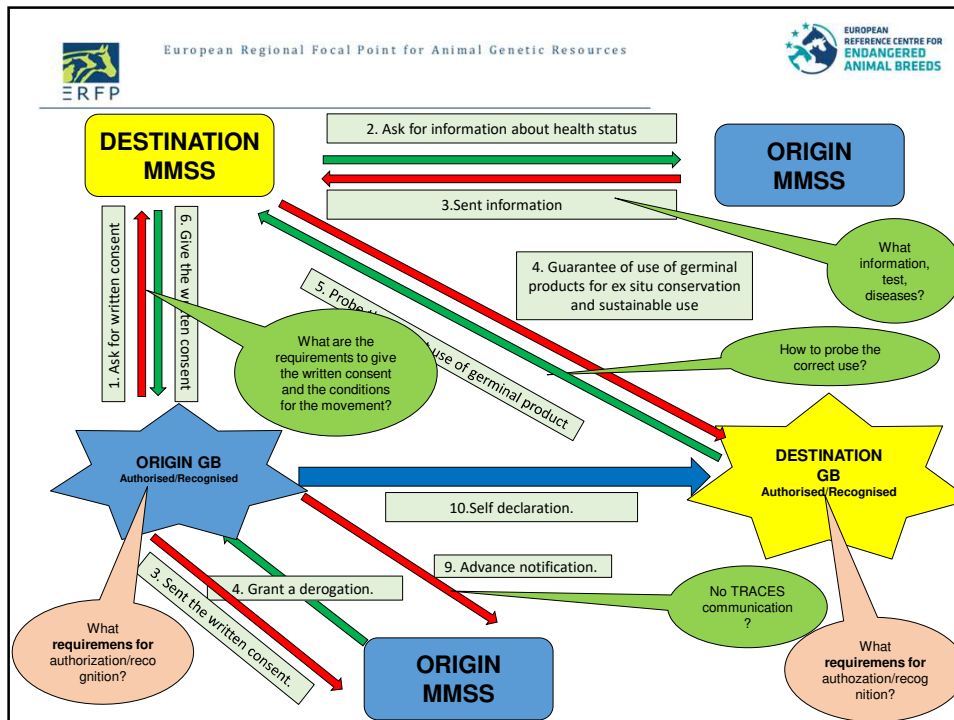
It has sufficient information, including information provided by the competent authority of the MS of origin or results of testing, or carries out treatment of the GP enabling it to prevent the spread of foot-and-mouth disease, infection with rinderpest virus and other listed diseases.

THE EU REGULATION SET DOWN AN
SPECIFIC PROCEDURE (BILATERAL
AGREEMENT) FOR THE MOVEMENT OF
GERMINAL PRODUCTS ADAPTED TO THE
NEEDS OF GENE BANKS




8




9

To take advantage of the derogation, **each member state should** develop and establish **specific derogations in their national animal health regulation** to allow the collections and storage of germinal products in genebanks.

10



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3. GENE BANKS IN EUROPEAN UNION REGULATION.

[Regulation \(EC\) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies](#)

ANNEX VII, CHAPTER C Minimum requirements for a breeding programme for resistance to TSEs in ovine animals

*6. The competent authority of the Member State may assist breed societies, to establish **genetic banks** consisting of semen, ova and embryos representative of prion protein genotypes which are likely to become rare as a result of the breeding programme.*



THE EU ANIMAL HEALTH REGULATION RECOGNISE THE VALUE OF GENE BANKS FOR THE CONSERVATION OF ANIMAL GENETICS RESOURCES BIODIVERSITY.

11



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3. GENE BANKS IN EUROPEAN UNION REGULATION.


[Commission Delegated Regulation \(EU\) 2022/126 of 7 December 2021 supplementing Regulation \(EU\) 2021/2115 of the European Parliament and of the Council with additional requirements for certain types of intervention specified by Member States in their CAP Strategic Plans for the period 2023 to 2027 under that Regulation as well as rules on the ratio for the good agricultural and environmental condition \(GAEC\) standard](#)

Article 45 Conservation, sustainable use and development of genetic resources in agriculture and in forestry.


6. Member States shall ensure that operations for the conservation, the sustainable use and development of genetic resources in agriculture and in forestry,[...], include the following:

*targeted actions promoting in situ and ex situ conservation, characterisation, collection and utilisation of genetic resources in agriculture and forestry, including web-based inventories of genetic resources currently conserved in situ, including on-farm or on-forest holding conservation, **and ex situ collections and databases**;*

12



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3. GENE BANKS IN EUROPEAN UNION REGULATION.

[COMMISSION REGULATION \(EU\) 2022/2472 of 14 December 2022 declaring certain categories of aid in the agricultural and forestry sectors and in rural areas compatible with the internal market in application of Articles 107 and 108 of the Treaty on the Functioning of the European Union.](#)

Article 30 Aid for conservation of genetic resources in agriculture.

7. The aid shall cover the costs for the following operations:

(a) targeted actions: actions promoting the *in situ* and *ex situ* conservation, characterisation, collection and utilisation of genetic resources in agriculture, including web-based inventories of genetic resources currently conserved *in situ*, **and of *ex situ* collections and databases**;



FUNDING INSTRUMENT OF CAP AND AT NATIONAL LEVEL ALLOW AND HIGHLIGHT THE SUPPORT FOR GENE BANKS FOR CONSERVATION OF ANIMAL GENETIC RESOURCES.

13



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3. GENE BANKS IN EUROPEAN UNION REGULATION.

[REGULATION \(EU\) 2016/1012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products \[...\] \('Animal Breeding Regulation'\)](#)

Not any reference to genebanks or gene banks.

*Preamble (23) If the aim of the breeding programme is to preserve the breed, the requirements of the breeding programme could be complemented by **ex situ** and *in situ* conservation measures or any other tools for monitoring the status of the breed that would ensure a long term, sustainable conservation of that breed. It should be possible for those measures to be laid down in the breeding programme.*


ANNEX IV EUROPEAN UNION REFERENCE CENTRES REFERRED TO IN ARTICLE 29

3. c.(i). develop or harmonise methods used for the *in situ* and **ex situ** conservation of endangered breeds or the preservation of the genetic diversity within those breeds or provide assistance in such development or harmonisation;




THE EU ANIMAL BREEDING REGULATION IS NOT HIGHLIGHTING THE ROLE OF GENE BANKS IN BREEDING PROGRAMMES. THE EUROPEAN REFERENCE CENTER COULD SET RECOMMENDATIONS FOR THE DEVELOPMENT OF GENE BANKS.

14



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3. GENE BANKS IN EUROPEAN UNION REGULATION.


[Regulation \(EC\) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation \(EC\) No 1774/2002 \(Animal by-products Regulation\)](#)

Article 17 Research and other specific purposes

1. The competent authority may, by way of derogation from Articles 12, 13 and 14, authorise the use of animal by-products and derived products for exhibitions, artistic activities, and for diagnostic, educational or research purposes under conditions which ensure the control of risks to public and animal health.

Such conditions shall include:

- (a) the prohibition of any subsequent use of the animal by-products or derived products for other purposes; and
- (b) the obligation to dispose of the animal by-products or derived products safely, or to re-dispatch them to their place of origin, if appropriate.



GENOMIC COLLECTIONS (NON REPRODUCTIVE MATERIAL) SHOULD ASK FOR AN AUTHORIZATION TO COMPETENT AUTHORITIES AND FOLLOW CONDITIONS FROM ARTICLE 17, REGULATION 1069/2009.

15



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4. CONCLUSIONS.

1. THE EUROPEAN UNION ANIMAL HEALTH REGULATION SET A BALANCE LEGAL FRAMEWORK FOR GENE BANKS INVOLVE IN MOVEMENTS OF GERMINAL PRODUCTS WITHIN MEMBER STATES.
2. THE DEVELOPMENT OF SPECIFIC DEROGATIONS TO ALLOW THE COLLECTION, PROCESSING, STORAGE, TRANSPORT AND USE OF GERMINAL PRODUCTS INTENDED TO BE KEPT IN GENE BANKS IS A COMPETENCE OF EACH NATIONAL GOVERNMENT.
3. OTHER EUROPEAN REGULATIONS RECOGNISED AND HIGHLIGHT THE ROLE OF GENE BANKS IN THE CONSERVATION AND SUSTAINABLE USE OF ANIMAL GENETIC RESOURCES.
4. THE ANIMAL BREEDING REGULATION SHOULD RECOGNISED GENE BANKS AS AN ESSENTIAL TOOL FOR THE BREEDING PROGRAMMES (CONSERVATION PROGRAMMES) OF ENDANGERED BREEDS.

16