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# Ad hoc action on specific measures for AnGR ex situ conservation in the framework of the animal health legislation. (Animal Health Legislation and Genebanks)

Kick-off meeting. 16<sup>th</sup> May 2023

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


 GOBIERNO DE ESPAÑA

 MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACIÓN

 AGENDA 2030

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## 1.1. OBJECTIVES OF THE MEETING.

- Knowing each other – team building.




- Presentation of the AHA.
- Brief situation in each country on the situation of the Animal Health Law and Genebanks.
- Plan the next activities.

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## 1.2 AGENDA.

1. Introduction and objectives of the meeting. Fernando Tejerina.
2. Round of introductions of members.
3. Presentation of the AHA: Background-Objectives-Schedule-Budget. Fernando Tejerina.
4. Brief presentation from countries on situation of the Animal Health Law and Genebanks.
5. Plan of further actions (all together).
6. AOBs

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## 2. ROUND OF INTRODUCTIONS OF MEMBERS.

EXPERT	COUNTRY/ORGANIZATION
Nikica Prvanovic	Croatia
Mario Ostovic	Croatia
Ewa Camara	EC
Ana Granados	EFFAB
Jaana Peippo	Finland
Isabelle Guerry	France
Laurence Guilbert	France
Delphine Duclos	France
Coralie Danchin*	France
Claudia Klein	Germany
Ewa Sosin	Poland
Danijela Bojkovski	Slovenia
Rosa Maria Diez	Spain
Fernando Tejerina*	Spain
Sipke Hiemstra*	The Netherlands
Annemieke Rattink	The Netherlands
Wim van der Poel	The Netherlands
Marcus Bates	UK

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### 3. PRESENTATION OF THE AHA. BACKGROUND.

- Germinal products, may represent a **risk of spread animal diseases**.
- To prevent the risk of the spread diseases, **regulations** provide that germinal products must be collected, produced, processed and stored at **specialized facilities** and be subject to special **animal health and hygiene regimes**.
- The animal health requirements can be a serious **burden** for the collection of germinal products for genebanks, especially in the case of endangered breeds (low biosecurity, not suitable animal health preventive programs, high costs).



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### 3. PRESENTATION OF THE AHA. BACKGROUND.

1. International level.
 


2. European level. European Animal Health Regulations.
 


3. National level: own Animal Health Regulations for national market

**Terrestrial Animal Health Code**



World Organisation for Animal Health  
Founded as OIE



INTERNATIONAL BIOMEDICAL TECHNOLOGY SOCIETY





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### 3. PRESENTATION OF THE AHA. BACKGROUND.

1. Only germinal products collected, processed or stored in centres or by teams **approved** by a State can be sent from its territory to the territory of other State (Member State in case UE:MMSS).
2. **Animal health requirements for the farm/territory of the origin of the donors** (“free” status of several “common” diseases).
3. **Rules for the admittance of donors** for germinal products collection: quarantine and tests.
4. **Animal health requirements of the donors in the centre.**
5. **Structure and performance requirements** for the centres/teams where the germinal products are collected/produced/stored.
6. **Traceability and certification** requirements.
7. **Conditions for the supervision of centres/teams by the authorities.**









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### 3. PRESENTATION OF THE AHA. BACKGROUND.

<u>MAIN ELEMENTS OF THE CURRENT REGULATION</u>	
1. Only germinal products collected, processed or stored in centres or by teams approved by a MMSS can be sent from its territory to the territory of other MMSS.	Donors (semen) of endangered breeds must be moved to approved centres.
2. Animal health requirements for the farm of the origin of the donors (“free” status of several “common” diseases).	Farms breeding endangered breed do not full fill the animal health requirements to send donors to centres: 1. Less professional farmers, 2. grazing farms: less biosecurity and less productivity 3. less investments in farm, 4 not suitable animal health preventive programs
3. Rules for the admittance of donors for germinal products collection: quarantine and tests.	Animal donors do not full fill the admittance rules or the quarantine and test are expensive for animals of low economical value and for produce “few” germinal products.



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### 3. PRESENTATION OF THE AHA. BACKGROUND.


<b>MAIN ELEMENTS OF THE CURRENT REGULATION</b>	
<p>5. Structure and performance requirements of the centres/teams where the germinal products are collected/produced/stored.</p>	<p>The collection needs a complex structure and procedures, the investment is focused in hold donors to produce big amounts of germinal products. Donors from endangered breeds = annoyance.</p>
<p>6. Traceability and certification requirements.</p>	<p>The procedures were developed focus in big amounts of germinal products.</p>
<p>7. Conditions for the supervision of centres/teams by the authorities.</p>	<p>Donors animals from endangered breeds are considered a risk for the status of the centres = annoyance</p>








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### 3. PRESENTATION OF THE AHA. BACKGROUND.


ANIMAL HEALTH REQUIREMENTS.




ANIMAL GENETICS RESOURCES CONSERVATION.

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### 3. PRESENTATION OF THE AHA. BACKGROUND. EUROPEAN 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** in accordance with Article 93, before they commence such activities...

**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.**




ALL GENE BANK IN EU  
CONTRIES MUST BE  
REGISTERED


GENEBANKS IN EU  
CONTRIES MOVING GPs TO  
OTHER MMSS MUST BE  
APPROVED

EACH COUNTRY CAN  
REGULATE GPs AT  
NATIONAL LEVEL.

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### 3. PRESENTATION OF THE AHA. BACKGROUND. EUROPEAN REGULATION.

Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 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 CONTRIES MOVING GPs TO OTHER MMSS  
MUST BE AUTHORISED OR RECOGNISED BY THE COMPETENT  
AUTHORITY AS A REPOSITORY OF ANIMAL GENETIC MATERIAL  
FOR EX SITU CONSERVATION.....

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### 3. PRESENTATION OF THE AHA. BACKGROUND. EUROPEAN REGULATION.

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


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).*

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### 3. PRESENTATION OF THE AHA. BACKGROUND. EUROPEAN REGULATION.

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


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 FOR THE  
MOVEMENT OF GERMINAL PRODUCTS  
ADAPTED TO THE NEEDS OF GENE BANKS



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EUROPEAN  
REFERENCE CENTRE FOR  
ENDANGERED  
ANIMAL BREEDS


3. PRESENTATION OF THE AHA. BACKGROUND. EUROPEAN REGULATION.

**EACH COUNTRY  
CAN REGULATE  
GPs AT NATIONAL  
LEVEL.**

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REFERENCE CENTRE FOR  
ENDANGERED  
ANIMAL BREEDS


3. PRESENTATION OF THE AHA. OBJECTIVES.

The main goal of the present Ad Hoc Action is: develop recommendations for competent authorities in countries on:


- The incorporation to the national animal health legal framework exceptions for the collection, transformation and storage of germinal products intended to be kept in a genebank.
- The suitable implementation of the derogation provided in Regulation (EU) 2020/686 on the movement of germinal products between genebanks located in different EU countries.

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### 3. PRESENTATION OF THE AHA. SCHEDULE.

<p>March – April 2023</p> <div style="text-align: center; margin-top: 5px;"></div>	<p>Make a team: EX Situ WG members and experts in animal health (priority from countries with specific animal health regulation for genebanks). Experts from the European Commission and ERC will be invited to participate in the AHA. The expected number of experts is around 10-12.</p>
<p>May 2023</p> <div style="text-align: center; margin-top: 5px;"></div>	<p>Organization of a Kick-off meeting by distance and translate to English of the specific animal health regulations for genebanks in force in different countries.</p>
<p>¿June – July 2023?</p> <div style="text-align: center; margin-top: 5px;"></div>	<p>Workshop (hybrid format) to collect the experiences in the countries on the animal health regulation for genebanks and discuss about current situation and future options.</p>
<p>October 2023 – April 2024</p> <div style="text-align: center; margin-top: 5px;"></div>	<p><b>Development of a guidelines with recommendations</b> for the suitable application of the derogation provide in Regulation 2020/686 and the incorporation to the national animal health legal framework exceptions for the collection, transformation and storage of germinal products intended to be kept in a genebank. These work will be developed by distance.</p>

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### 3. PRESENTATION OF THE AHA. BUDGET.

Estimated budget is 8.338 €. The distribution of the budget is as follows:

- Travel and accommodation for the workshop for 12 experts:
  - Travel – 500 EUR per person: 6.000 €
  - Accommodation – 100 EUR per person: 1.200 €
  - Meeting room + coffee breaks: 100 €
  - Dinner – 24 EUR per person: 288 €
- ¿Translation – 750 €?

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ERFP


EUROPEAN REFERENCE CENTRE FOR ENDANGERED ANIMAL BREEDS

### 3. PRESENTATION OF THE AHA. BACKGROUND.

ANIMAL HEALTH REQUIREMENTS.



ANIMAL GENETICS RESOURCES CONSERVATION.



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ERFP

EUROPEAN REFERENCE CENTRE FOR ENDANGERED ANIMAL BREEDS

### 5. PLAN OF FURTHER ACTIONS. (ALL TOGETHER)

1. Translation of regulation:
  - Slovenia. (no quarantine, ¿tests?, previous authorization for use)
  - Serbia. (no quarantine, no mandatory tests)
  - Spain. (Specific procedure for genebanks)
  - Germany (procedures: old material).
  - ¿?
2. Organization of the meeting:
  - Agenda: experience from countries / define the outline of the guidelines.
  - Speakers: ¿?
  - Place and time: ¿Madrid?¿July or October?

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