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MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACIÓN


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Examples of specific animal health derogations to support genebanks:

Animal Health Regulation on genebanking in Spain

**MINISTRY OF AGRICULTURE, FISHERIES AND FOOD OF SPAIN.**  
GENERAL DEPUTY DIRECTORATE OF LIVESTOCK PRODUCTION MEANS.  
**Dra Rosa Díez Sastre**

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**Law 8/2003** («Spanish Animal Health Law»).

**Royal Decree 429/2022:** standards for the movement of GPs of livestock species at the national level and measures for the application of European regulations applicable to movements within the EU.

**Royal Decree 45/2019:** zootechnical standards applicable to purebred breeding animals, hybrid breeding pigs and their reproductive material, updates the National Program for the conservation, improvement and promotion of breeds livestock

**Genebank:** collection of genetic material (semen, oocytes, embryos, somatic cells or DNA) officially recognized within the framework of the breeding program, whose purpose is the *ex situ* conservation or sustainable use of pure breeds of livestock.

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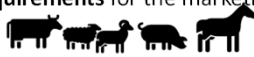




# Estructure


17 articles


Royal Decree 429/2022

**CHAPTER I.** General layouts: Subject matter, scope and definitions

**CHAPTER II. Zootechnical, health and traceability requirements** for the marketing of GPs of bovine, ovine, caprine, porcine and equine animals **within member states.** 

**CHAPTER III. Zootechnical, health and traceability requirements** for the marketing of GPs in Spain

**Article 10. Derogations from the requirements for marketing of GPs in Spain.** 







**CHAPTER IV.** Distributors

**CHAPTER V.** General Registry of establishments and distributors of GPs and National Registry of GeneBanks

**CHAPTER VI.** Regime of offenses and penalties

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## Derogations applied in GPs intended to be stored in genebanks

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health requirements

laboratory tests

conditions applied in collection, production, processing, storage and transportation of GPs.

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## CHAPTER III.

Royal Decree 429/2022

### Article 10. Derogations from the requirements for marketing of GPs in Spain.

**Cases:**

- a) GPs intended for genebanks
- b) Collection of GPs in case of difficult difficult to handle breeds
- c) support conservation programs for endangered breeds
- d) GPs from equines participating in officially recognized selection or sports tests and registered in official stud books.
  - Teaching centers

Prior and express authorization from the Competent authority

According Procedures approved by the National Zootechnical Commission.

Establishments with granted exceptions will not be able to participate in the movement of reproductive products to other Member States, except in the cases contemplated in articles 44 and 45 of Delegated Regulation (EU) 2020/686.

They must be reflected in the General Registry of Establishments and distributors of GPs.

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## CHAPTER V

Royal Decree 429/2022

### Article 13. General Registry of establishments and distributors of GPs.




**Buscador de establecimientos de reproducción autorizados para comercio nacional**

Denominación:	<input type="text"/>
CCAA:	<input type="text" value="v"/>
Especie:	<input type="text" value="v"/>
Ámbito de comercialización	<input type="text" value="v"/>
Tipo de establecimiento	<input type="text" value="v"/>
Banco de Germoplasma	<input type="text" value="Si"/>
Excepciones concedidas	<input type="text" value="Si"/>
Expedición de certificados zootécnicos	<input type="text" value="v"/>
Estado	<input type="text" value="v"/>

**Buscar**

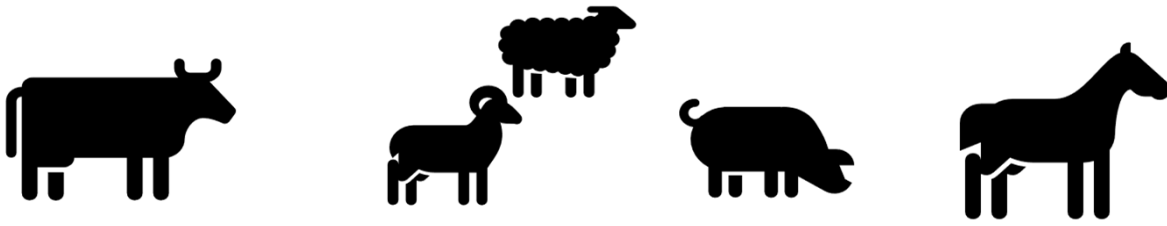
<https://servicio.mapa.gob.es/es/ganaderia/temas/zootecnia/razas-ganaderas/establecimientos-reproduccion/>

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## Derogations applied in GPs intended to be stored in genebanks

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## Derogations applied in GPs intended to be stored in genebanks

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- General requirements
- Farm requirements
- Health requirements
- Destination of the collected material, storage and transport

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**Derogations applied in GPs intended to be stored in genebanks**


### General requirements





Official Catalogue of Cattle Breeds of Spain\_**Breeding society certificate**

Born and remained since birth in the Union or have entered the Union in accordance with the conditions for entry into the Union\_**Owner of the animal certificates using model Annex I**

Establishments located in a Member State complying with animal health requirements\_**official vet certificate**

Identified in accordance with EU legislation\_**verification by the vet of the centre.**

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**Derogations applied in GPs intended to be stored in genebanks**


### General requirements

At least 30 days prior to the date of first collection of GPs and during the collection period\_**official vet certificate** :

- Kept in establishments not located in a restricted zone due to the occurrence in the donor species of a category A disease.
- kept in establishments where no category D disease has been notified.
- not been in contact with animals of lower health status.

Not used for natural reproduction\_**Owner of the animal certificates using model Annex I**

No symptoms/clinical signs of category D diseases, or emerging diseases on the day of semen collection\_**verification by the vet of the centre**

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### Derogations applied in GPs intended to be stored in genebanks

#### Farm requirements

*Mycobacterium tuberculosis*

Category A/emerging disease

FREE

*Brucella abortus, melitensis and suis*

official vet certificate

enzootic bovine leukosis

Minimum requirements for handling and facilities in slaughterhouses or bullrings where post-mortem semen will be obtained

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### Derogations applied in GPs intended to be stored in genebanks

#### Farm requirements

*Brucella abortus, melitensis and suis*

FREE

Category A/emerging disease

official vet certificate

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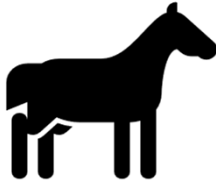
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## Derogations applied in GPs intended to be stored in genebanks

### Farm requirements

No clinical signs of <b>infectious/contagious disease</b> on the day of collection of the semen	No clinical signs of <b>EVA</b> or <b>CEM</b> within <b>30 days</b> prior to semen collection.
No cases of <b>EIA</b> in the previous <b>90 days</b>	No cases of <b>surra</b> in the previous <b>30 days</b>
No cases of <b>dourine</b> in the previous <b>6 months</b>	Not located in a restricted zone due to the <b>outbreak of a Category A disease</b>

**official vet certificate**



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## Derogations applied in GPs intended to be stored in genebanks

### Farm requirements

**Aujeszky's disease**


**Category A/emerging disease**

**FREE**

**Brucella abortus, melitensis and suis**

**PRRS** not detected for at least **30 days** prior collection

**official vet certificate**



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## Derogations applied in GPs intended to be stored in genebanks

### Health requirements

- Brucella abortus, B. melitensis and B. suis*
  - serological test on a blood sample (CDR (EU) 2020/688)
- enzootic bovine leucosis
  - serological test on a blood sample
- Campylobacter fetus ssp. Venerealis*
  - test performed on a washout sample of the artificial vagina or foreskin.
- Trichomonas foetus*:
  - test performed on a foreskin sample.

**semen collected post-mortem**

Aetiological analysis of:

- Brucella abortus, B. melitensis and B. suis.*
- Mycobacterium tuberculosis complex.
- IBR.
- BVD.

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## Derogations applied in GPs intended to be stored in genebanks

### Health requirements

- Brucella abortus, B. melitensis and B. suis*
  - serological test on a blood sample
- ovine epididymitis (*B. ovis*)
  - serological test

**Caprine may be exempt**

Aetiological analysis of:

- Brucella abortus, B. melitensis and B. suis* (ejaculates collected from holdings classified as M4 are exempt from this analysis)
- B. ovis*

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## Derogations applied in GPs intended to be stored in genebanks

### Health requirements

HEALTH TESTING PROGRAMME at least once a year

EAV every 30 days maximum

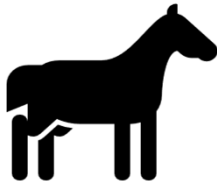
- seroneutralization test
- Or test to isolate the virus or detect its genome by PCR

CEM every 60 days maximum

- PCR

EIA every 90 days maximum

- ELISA or agar gel immunodiffusion test (Coggins test), negative



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## Derogations applied in GPs intended to be stored in genebanks

### Health requirements

Aujeszky detection:

- 2 serological tests for gE glycoprotein separated at least 21 days

Swine brucellosis:



- buffered brucella antigen test
- or a competition ELISA test
- or an indirect ELISA test

PRRS:

- RT-PCR

Aetiological analysis of:

- *Brucella abortus*, *B. melitensis* and *B. suis*.

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## Derogations applied in GPs intended to be stored in genebanks

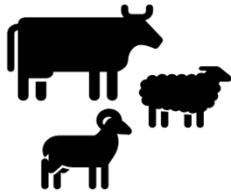
Health requirements: **Bluetongue and epizootic haemorrhagic disease**

a) for the last **60 days** before the collection of semen **outside the restricted area** or, **official vet certificate**

b) for the last **60 days** before semen collection **in a seasonally free area** or,


c) **etiological analysis** in blood to rule out the presence of Bluetongue and EHE viruses. If this analysis is positive, it may be performed on frozen semen in order to rule out the presence of Bluetongue and EHD viruses in the final doses or

d) In the case of donor animals present during the last 60 days in a restricted zone by bluetongue, they have been **vaccinated and revaccinated**.



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## Derogations applied in GPs intended to be stored in genebanks

Destination of the collected material, storage and transport

Exclusive cryogenic containers until negative results

**Positive result** unless the genetic centre certifies the genetic relevance of the donor animal

Hygienically disposal (R 1069/2011)



1. GP may be stored without contact with other material

2. may only be used in the event of reconstitution of an extinct breed or to reverse serious losses of genetic variability in the population conserved *in situ*.

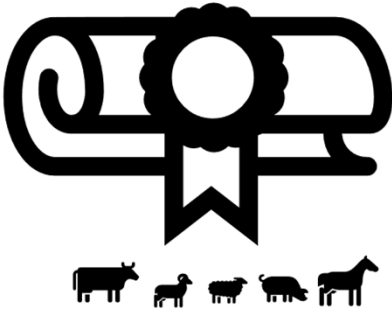
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## Derogations applied in GPs intended to be stored in genebanks

### Destination of the collected material, storage and transport



certificate of the genetic relevance of the donor animal



- positive results must be recorded in the genebank database.
- The use of this material will be carried out:
  - ✓ using techniques that prevent the transmission
  - ✓ under prior authorization from the competent authority.

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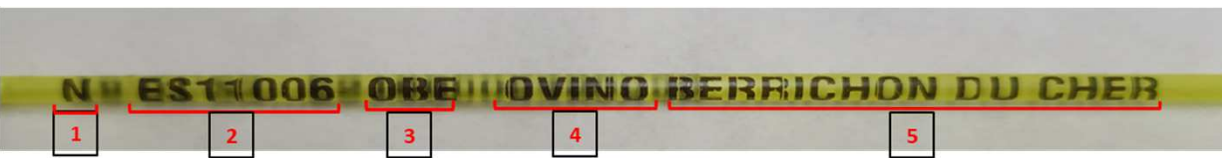
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## Derogations applied in GPs intended to be stored in genebanks


### Destination of the collected material, storage and transport

Example straw\_side 1:





- "N" means germinal products has been collected under a Spanish derogation and it's not suitable for intracomunitary movement (except derogation of article 44 of CDR 2020/686)
- Unique approval number or unique registration number of the establishment (see point 3)
- Breed code (established in Annex II of Royal Decree 429/2022)
- Name of specie
- Name of breed


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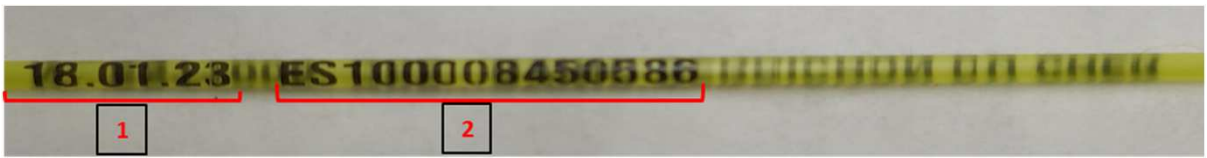




## Derogations applied in GPs intended to be stored in genebanks

**Destination of the collected material, storage and transport**

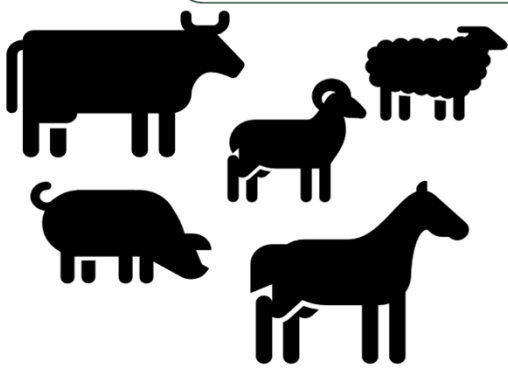
**Example straw\_side 2:**

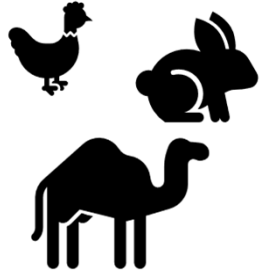


1. Date of collection, following the format dd.mm.yy
2. Animal identification

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**Royal Decree 45/2019: zootechnical standards applicable to purebred breeding animals, hybrid breeding pigs and their reproductive material, updates the National Program for the conservation, improvement and promotion of breeds livestock**





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Recapitulation

**Procedures to carry out derogations in GPs intended for genebanks.**

**Procedures for each species: BIG FIVE**

**Each procedure lays down:**

- General requirements
- Farm requirements
- Health requirements
- Destination of the collected material, storage and transport

**Participants:**

- Owner
- Vet of the centre
- Official Vet
- Breeding society

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Recapitulation

**Non compliance-Health Requirements**

+

**special genetic relevance certified by the genetic center**

+

**a risk assessment by the competent authority**

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