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Transboundary breeds: The new regulation on movements within the Union/imports of germinal products, and their impact in the gene banking.

Madrid, Spain.

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1. Current situation: a regulation for the mainstream breeds.
2. Commission Delegated Regulation as regards approval of germinal product establishments, traceability and animal health requirements for the movements within the Union of germinal products of certain kept terrestrial animals: an opportunity for gene banking.
3. How implement the new derogations about gene banks: the role of ERFP (also at the national level).
4. and what about the zootechnical regulation?

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1. CURRENT SITUATION: A REGULATION FOR MAINSTREAM BREEDS.

- **Bovine – frozen semen:** Council Directive 88/407/EEC.
- **Bovine – frozen ova & embryos:** Council Directive 89/556/EEC.
- **Porcine – fresh semen:** Council Directive 90/429/EEC (intra Union trade).
- **Porcine – fresh and frozen ova & embryos; Ovine & Caprine – fresh and frozen semen, ova, embryos** Equine – **fresh and frozen semen, ova, embryos:** Council Directive 92/65/EEC. Commission Regulation (EU) No 176/2010
- **Other species - fresh and frozen semen, ova, embryos:** National measures according to the general principles of Council Directive 92/65/EEC.



Terrestrial Animal Health Code



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1. CURRENT SITUATION: A REGULATION FOR MAINSTREAM BREEDS. Main elements.

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.
2. Animal health requirements for the farm 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 of 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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EUGENA

1. CURRENT SITUATION: A REGULATION FOR MAINSTREAM BREEDS. What obstacles have the gene banking of transboundary endangered breeds:

MAIN ELEMENTS OF THE CURRENT REGULATION	
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 (team) of endangered breeds must be moved to approved centres.
2. Animal health requirements for the farm of the origin of the donor (less status of several "common" diseases).	Farms breeding endangered breed do not full fill the animal health requirements to send donors to centres: Less professional farmers, grazing farms: less biosecurity, less productivity, less investments in farm: poor health programs on farm.
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.
4. Animal health requirements of the donors in the centres.	Expensive for produce "few" germinal products
5. Structure and performance requirements of the centres/teams where the germinal products are collected/produced/stored.	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.
6. Traceability and certification requirements.	The procedures were developed focus in big amounts of germinal products.
7. Conditions for the supervision of centres/teams by the authorities.	Donors animals from endangered breeds are considered a risk for the status of the centres = annoyance



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EUGENA

1. CURRENT SITUATION: A REGULATION FOR MAINSTREAM BREEDS. What happens at national level?

- No regulation for the national trade of germinal products. ✗
- National regulation without especific derogations for gene banking. ✗
- National regulation with especific derogations for gene banking. ✓
- National regulation = regulation for intra community trade ✗



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Diapositive 5

TAF1 Tejerina Ampudia, Fernando; 09/05/2019

Diapositive 6

TAF1 Tejerina Ampudia, Fernando; 09/05/2019



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2. COMMISSION DELEGATED REGULATION AS REGARDS APPROVAL OF GERMINAL PRODUCT ESTABLISHMENTS, TRACEABILITY AND ANIMAL HEALTH REQUIREMENTS FOR THE MOVEMENTS WITHIN THE UNION OF GERMINAL PRODUCTS OF CERTAIN KEPT TERRESTRIAL ANIMALS: AN OPPORTUNITY FOR GENE BANKING. Main elements

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.
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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 of 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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2. COMMISSION DELEGATED REGULATION AS REGARDS APPROVAL OF GERMINAL PRODUCT ESTABLISHMENTS, TRACEABILITY AND ANIMAL HEALTH REQUIREMENTS FOR THE MOVEMENTS WITHIN THE UNION OF GERMINAL PRODUCTS OF CERTAIN KEPT TERRESTRIAL ANIMALS: AN OPPORTUNITY FOR GENE BANKING. Derogations for gene banks.

(35) A national gene bank plays an important role in storing the genetic material of animal populations that are particular to that Member State. **The objective of such national gene banks is *ex situ* conservation and sustainable use of kept animal genetic resources. Germinal products stored at the national gene banks are often of unknown animal health status or were collected, produced, processed and stored in accordance with a different animal health regime than is currently applicable in Union and national legislation.** As such germinal products have a particular value, as they are often genetic material of endangered breeds as defined in point (24) of Article 2 of Regulation (EU) 2016/1012 of the European Parliament and of the Council, and Member States have expressed their interest in exchanging such germinal products amongst themselves, **special conditions for granting derogations by the competent authorities for the movement of germinal products stored in national gene banks to other Member States should be laid down in this Regulation.** As a general rule, this Regulation should lay down the conditions for movements of those germinal products between national gene banks of different Member States, while rules for national distribution of germinal products from national gene banks to operators should be left to the competent authorities of Member States. **Special attention should also be paid to the animal health conditions for such movements, where testing for particular diseases may be required.**



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Article 1
Subject matter and scope

8. Chapter 4 of Part III lays down rules for the granting of derogations by competent authorities for movements between Member States of germinal products for scientific purposes and germinal products stored at gene banks.

Article 2
Definitions

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



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Article 45
Additional rules for the granting of derogations by competent authorities for germinal products moved to gene banks in another Member State

1. The competent authorities of the Member States of origin may grant derogations for movements to gene banks in another Member State of germinal products of endangered breeds which do not fulfil the animal health requirements provided for in Chapter 1, provided that the operator of the establishment of dispatch has obtained the prior written consent of the competent authority of the Member State of destination to accept the consignment of germinal products.
2. The Competent authority of the Member State of destination shall only consent to accept the consignment of germinal products referred to in paragraph 1, provided that:
 - (a) the operator of the gene bank intended to receive those germinal products ensures that the germinal products are only used for the *ex situ* conservation and sustainable use of kept animal genetic resources for which the receiving gene bank was established;
 - (b) they have sufficient information, including information provided by the competent authority of the Member State of origin or results of testing, or carry out treatment of the germinal products enabling them to prevent the spread of foot-and-mouth disease, infection with rinderpest virus and other listed diseases.



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Article 46
Rules on and information to be contained in the self-declaration document for germinal products intended for scientific purposes or to be moved to gene banks in another Member State

1. Where germinal products intended for scientific purposes or for storage at gene banks are to be moved to another Member State, the operator of the establishment of dispatch shall ensure that **a self-declaration document accompanies the germinal products** during the transport to the place of destination.
2. The operator of the establishment of dispatch shall ensure that the self-declaration document provided for in paragraph 1 includes at least the following information:
 - (a) the name and address of the consignor and the consignee;
 - (b) the name and address of the place of dispatch and the place of destination;
 - (c) where the germinal products were moved to and from a germinal product processing establishment, the dates of those movements;
 - (d) the type of the germinal products and the species of donor animals;
 - (e) the number of straws or other packages in the consignment to be dispatched;
 - (f) the following information allowing the identification of germinal products:
 - (i) the marking applied on the straws or other packages;
 - (ii) the place and date of their collection or production;
 - (g) **available results of the tests referred to in Article 45(2)(b).**



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Article 47
Advance notification by operators of movements of germinal products intended for scientific purposes or to gene banks between Member States

Where germinal products intended for scientific purposes or for storage at gene banks are moved to another Member State, **the operator of the establishment of dispatch shall notify the competent authority in the Member State of origin of the consignment in advance of the intended movement of those germinal products and provide the information listed in Article 46(2)(a) to (g).**



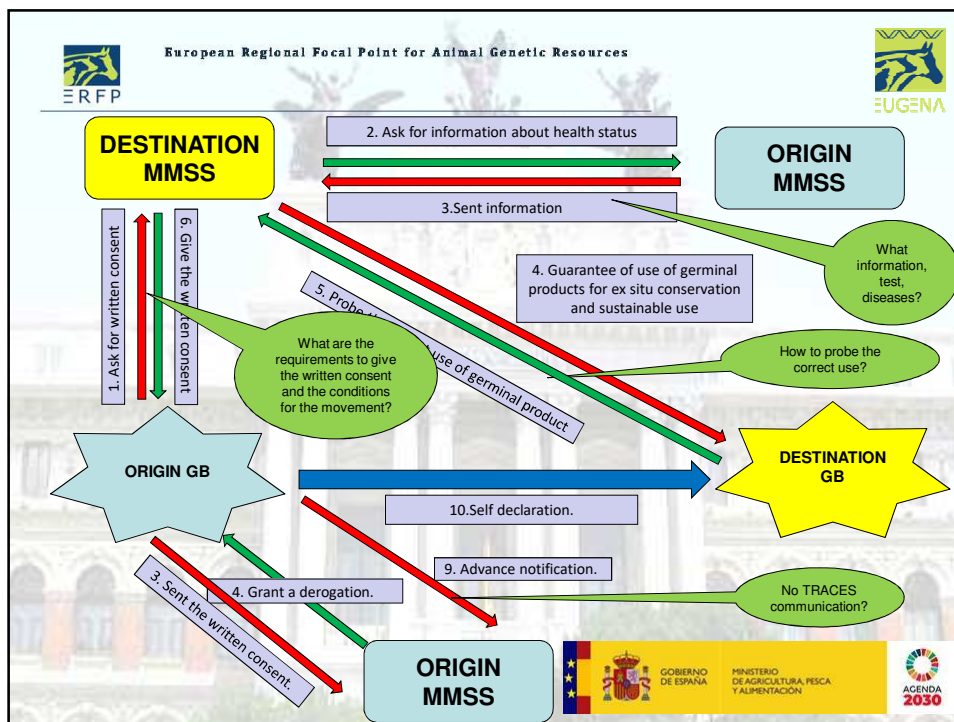
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3. HOW IMPLEMENT THE NEW DEROGATIONS ABOUT GENE BANKS: THE ROLE OF ERFP (ALSO FOR THE NATIONAL LEVEL).

The new regulation is very positive for endangered transboundary breeds gene banking....**BUT:**

- Different elements must be developed at national level, other need cooperation and mutual information between MMSS, and the procedure is not well defined.
- At the moment (and before) of implementing the regulation (april 2021), the national authorities use to pay attention to adapt their registers and operations to the main elements of the regulation, **the gene banking is not a priority.**
- In case of applications for a germinal product movement from a genebank in a MMSS to other genebank of other MMSS the officials could be extremely "prudent" with the analysis and authorisation of a new a no well defined procedure.

Logos: ERFP, EUGENA, GOBIERNO DE ESPAÑA, MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACIÓN, AGENDA 2030



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3. HOW IMPLEMENT THE NEW DEROGATIONS ABOUT GENE BANKS: THE ROLE OF ERFP (ALSO FOR THE NATIONAL LEVEL).

Article 2
Definitions
'gene bank' means a repository of animal genetic material for *ex situ* conservation and sustainable use of kept animal genetic resources of kept terrestrial animals, held by a host institution **authorised or recognised** by the competent authority to fulfil these tasks;

OPTIONS:

- Development of procedures/regulation at national level to authorise or recognise gene banks to move germinal products to others MMSS.

Proposal: ERFP (WG Ex situ): design recommendations/guidelines to develop the procedures/regulation to authorise or recognise gene banks for germinal products movement to gene banks in another Member State?? If the country have signed the EUGENA MoU, the authorisation/recognition could be use as LoA to enrol de bank in EUGENA.??


 Gene Banks joined EUGENA have been authorised or recognised yet.

Proposal: ERFP (WG Ex situ): Inform to MMSS and EU Commission gene Banks in EUGENA could move germinal products to others MMSS gene Banks without ulterior authorisation or recognition??




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DESTINATION


2. Ask for information about health status

3. HOW TO IMPLEMENT THE NEW DEROGATIONS ABOUT GENE BANKS: the role of ERFP (also at (for) the national level).


- A coherence between the written consent of the destination-MMSS, the derogations of origin-MMSS and the information required by the destination-MMSS (and the information of the self-declaration) must be established. The start point should be that the destination-MMSS establish the requirements for the movement in the written consent.

PROPOSAL: ERFP (Ex situ WG) may design recommendations/guidelines to help MMSS in the procedures for the movement of germinal products between genebanks.??


- A clear identification of the aims (ex situ conservation and sustainable use) of the destination genebanks should be necessary = authorisation and/recognition of gene Banks (as previous slide). PROMOTE EUGENA AS A REFERENCE IN THE INFORMATION ABOUT GENE BANKS IN EUROPE.



ORIGIN MMSS



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3. HOW TO IMPLEMENT THE NEW DEROGATIONS ABOUT GENE BANKS: THE ROLE OF ERFP (ALSO AT THE NATIONAL LEVEL).

The genebanking of germinal products at national level will be regulated by each MMSS = current situation.

Proposal: ERFP (Ex situ WG) may develop recommendations/guidelines for the development of national regulation about animal health requirements to the collection of germinal products whose destination is a gene bank.??



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4. AND WHAT ABOUT THE ZOOTECHNICAL REGULATION?

(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 longterm, 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. Tasks referred to in Article 29(4)(b)(ii) for European Union reference centres designated in accordance with Article 29(2).

(c) at the request of the Commission:

(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;

BUT....we don't have a reference centre to endangered breed and coordination between breeders societies of endangered transboundary breed is highly recommended.

PROPOSE: *ERFP (Ex situ WG + in situ WG) develop recommendations/guidelines for the development of Breeding Programmes by Breeders Associations of endangered transboundary breeds?*



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EUGENA

CONCLUSIONS AND PROPOSALS FOR THE WG IN RELATION WITH TRANSBOUNDARY BREEDS AND GENE BANKING AT NATIONAL LEVEL.


- *For first time the UE regulation establishes an specific derogation for the movement of germinal products between MMSS.*
- *The new regulation allows a better coordination of the ex situ conservation of AnGR.*
- *However the procedure is not defined in detail, different elements must be developed at national level, other aspects need the cooperation and mutual information between MMSS.*
- *At national level, as nowadays, the regulation on animal health issues of the gene banking is a competence of each MMSS.*
- *The Animal Breeding Regulation establishes general derogations about ex situ conservation, and in the case of transboundary breeds a coordination/cooperation between breeders associations must be a priority in the development of their Breeding programmes.*
- *What can the ERFP do (Ex situ WG)?*




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CONCLUSIONS AND PROPOSALS FOR THE WG IN RELATION WITH TRANSBOUNDARY BREEDS AND GENE BANKING AT NATIONAL LEVEL.

1. *Design recommendations/guidelines to develop the procedures/regulation to authorised or recognised gene banks for germinal products moved to gene banks in another Member State.?? If the country have signed the EUGENA MoU, the authorisation/recognition could be use as LoA to enrol the bank in EUGENA.??*
2. *Inform MMSS and EU Commission about gene Banks in EUGENA could move germinal products to others MMSS gene banks without ulterior authorisation or recognition??*
3. *Promote the use of EUGENA as the reference data base for the authorities in the MMSS of EU??*
4. *Design recommendations/guidelines to help MMSS in the procedures for the movement of germinal products between gene banks.??*
5. *Develop recommendations/guidelines for the development of national regulation about animal health requirements for the collection of germinal products whose destination is a gene bank.??*
6. *Develop recommendations/guidelines for the development of Breeding Programmes by Breeders Associations of endangered transboundary breeds?(Collaboration with In-situ WG)??*



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