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AD HOC ACTION ANIMAL HEALTH REGULATION AND GENEBANK:

GUIDELINES FOR THE DEVELOPMENT OF NATIONAL ANIMAL HEALTH REGULATIONS FOR MATERIAL INTENDED TO BE KEPT IN GENE BANKS.

26th August 2023.

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GOBIERNO DE ESPAÑA MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACIÓN AGENDA 2030

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1. AHA ANIMAL HEALTH REGULATION – GENEBANKS. OBJECTIVES.

The main goal of the 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 (other material) 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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1. AHA ANIMAL HEALTH REGULATION – GENEBANKS. SCHEDULE.

March – April 2023

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 were invited to participate in the AHA.

May 2023

Organization of a Kick-off meeting (16TH MAY) by distance and translate to English the specific animal health regulations for genebanks in force in different countries.

October 2023

Workshop (hybrid format, 9TH October), collected experiences in the countries on the animal health regulation for genebanks, discussed about current situation and proposed the outline of the guidelines.

October 2023 – April 2024

Development of a guidelines with recommendations for the suitable incorporation to the national animal health legal framework exceptions for the collection, transformation and storage of germinal products intended to be kept in genebank. These work are being developed by distance.

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1. AHA ANIMAL HEALTH REGULATION – GENEBANKS. EXPERTS TEAM.

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

18 EXPERTS FROM 9 COUNTRIES, EUROPEAN COMMISSION AND EFFAB

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2. WORKSHOP. 9TH OCTOBER. SINT MICHIELSGESTEL. THE NETHERLANDS.

WORKSHOP TOPICS:

- The relevance of genebanks in the breeding and conservation programmes
- Genebanks in European Union Animal Health Regulation.
- Examples of specific animal health derogations to support genebanks:
  - National genebank derogation fo cattle in The Netherlands and situation for other species.
  - Animal Health Regulation on genebanking in Spain.
  - National derogation for cattle in United Kingdom.
  - Regulation on the storage of old material in Poland.
  - Regulation on the storage of old material in Germany.
- How to control the health status of semen?
- Proposal of outline for the guidelines and plan the further steps.

PRESENTATIONS IN: https://www.animalgeneticresources.net/index.php/event/aha-animal-health-regulation-genebanks-physical-meeting/

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3. GUIDELINES FOR THE DEVELOPMENT OF NATIONAL ANIMAL HEALTH REGULATIONS FOR MATERIAL INTENDED TO BE KEPT IN GENE BANKS. FIRST DRAFT.

SOME GENERAL CONSIDERATIONS:

- THE NATIONAL REGULATION ON COLLECTION, PROCESSING, STORAGE AND USE OF GERMINAL PRODUCTS ARE OUT (EXCEPT ESTABLISHMENT REGISTRATION AND TRACEABILITY) OF THE SCOPE OF EUROPEAN UNION REGULATION ON ANIMAL HEALTH.
- THE GUIDELINES PROPOSE SOLUTIONS TO FACILITATE THE DEVELOPMENT OF **NATIONAL REGULATIONS**, BUT THE FINAL DECISION TO DEVELOP THAT REGULATION IS IN THE HANDS OF EACH NATIONAL GOVERNMENT.
- THE USERS OF THE GUIDELINES WILL BE ANIMAL HEALTH LAW-MAKERS, NO GENEBANK MANAGERS.
- THE GUIDELINES HAS NOT TECHNICAL RECOMMENDATIONS ON THE PROCESS OF COLLECTION, PROCESSING OR STORAGE OF THE MATERIAL, THAT IS NOT THE OBJECTIVE OF THE DOCUMENT.
- THE GUIDELINES DO NOT SET MANDATORY REQUIREMENTS, MAINLY PROPOSE OPTIONS AND NATIONAL AUTHORITIES MUST SELECT THE MOST SUITABLE FOR ITS SITUATION (EPIDEMIOLOGICAL OR IN RELATION WITH THE CONSERVATION OF AnGR). GUIDELINES = "TOOL BOX" 
- THE GUIDELINES TRY TO REACH A BALANCE BETWEEN THE CONSERVATION OF AnGR AND ANIMAL/PUBLIC HEALTH PROTECTION, BUT THESE LAST ARE THE FIRST PRIORITY.

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3. FIRST DRAFT GUIDELINES. DISCUSSION

0. **PREFACE.**
1. **INDEX.**
2. **BACKGROUND:**

- What is a gene bank?
- Why are gene banks relevant?
- Types of germinal products stored in gene banks.
- Other genetic material stored in gene banks (genomic material).
- Gene banks in context of breeding programs and long-ter s.
- Relevance of sanitary standards for gene banks.

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3. FIRST DRAFT GUIDELINES. DISCUSSION

3. OBJECTIVES OF THE GUIDELINES

•To draw further attention to the relevance of gene banks and gene bank collections in the context of breed specific conservation and breeding programmes and for the long-term conservation of farm animal genetic diversity, in particular among National Competent Authorities and breed societies.

•To inform National Competent Authorities, responsible for the implementation of EU Animal Breeding and/or the EU Animal Health legislation, about the importance of gene banks, and the need to set specific derogations for gene banks when implementing EU Animal Breeding legislation, EU Animal Health legislation and **national regulations** in those fields.

•To contribute to the official recognition of gene banks at the national level, and to advise national gene banks and National Competent Authorities about the implementation of necessary derogations in Animal Health Law at national level.

•To demonstrate the options of Commission Delegated Regulation (EU) 2020/6 ons for the movement of germinal products stored in gene banks between the framework of the EU Animal Health legislation.

•To advise the European Commission, the Standing Committee on Zootechnics, tee on Plants, Animals, Food and Feed on further development of EU Animal Bre alth legislation that will further facilitate the conservation and sustainable use of livestock.

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4. LEGAL FRAMEWORK, REGULATIONS, RECOMMENDATIONS AND GUIDELINES ON SANITARY ASPECTS OF STORAGE, USE AND TRADE OF GERMINAL PRODUCTS AND GENOMIC MATERIAL.

- International regulations:
  - Animal Health Code (OIE, 2019) of the World Organization for Animal Health.
  - FAO guide Innovations in cryoconservation of animal genetic resources
- European Union Regulations.
  - Regulation (EU) 2016/429 on transmissible animal diseases […] ('Animal Health Law').
  - Commission Delegated Regulation (EU) 2020/686 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.
  - Other: Animal-by products regulation, TSE regulation,.
- National regulations.
- Bottleneck in the animal health regulation for the development

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3. FIRST DRAFT GUIDELINES. DISCUSSION

5. FORMAL RECOGNITION OF GENE BANKS AT NATIONAL LEVEL AND REQUIREMENTS.

- Set a legal definition and requirements for the formal recognition of gene banks.
- For the recognition, take into consideration the regulations in:
  - Animal Health.
  - Animal by-products.
  - Animal breeding: the ex situ conservation activities developed by gene banks should be describe in the breeding programmes and in case of outsorcing the gene bank must fulfil conditions in article 8.4, Regulation 2016/1012.
  - Publicity of recognized gene banks at national level.

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3. FIRST DRAFT GUIDELINES. DISCUSSION

6. RECOMMENDED ANIMAL HEALTH REQUIREMENTS FOR THE COLLECTION, PROCESSING, STORAGE AND USE MATERIAL INTENDED TO BE KEPT IN AND MANAGED BY GENE BANKS.

- Common considerations:
  - The requirements must be set in the national regulation.
  - The requirements should focus in the disease present in the country at the time of collection.
  - Donors should fulfil a general requirements similars to those set in article 16, Regulation 2020/686.
  - Exception to the general requirements are desirable in case of donors with special genetic relevance.
  - Collection and kept of information on donors.
  - Traceability and marking of material.
  - Participation on breeding programmes.

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3. FIRST DRAFT GUIDELINES. DISCUSSION

6. RECOMMENDED ANIMAL HEALTH REQUIREMENTS FOR THE COLLECTION, PROCESSING, STORAGE AND USE MATERIAL INTENDED TO BE KEPT IN AND MANAGED BY GENE BANKS.

- Semen collections.
  - Specialized semen collection centres.
    - Same requirement than those for intracomunitary trade, with the exceptions of:
      - ✓ Quarentinne.
      - ✓ Test on quarentinne and routinary.
    - Option to carry out test on the donor at the time of collection or on the material collected.

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6. RECOMMENDED ANIMAL HEALTH REQUIREMENTS FOR THE COLLECTION, PROCESSING, STORAGE AND USE MATERIAL INTENDED TO BE KEPT IN AND MANAGED BY GENE BANKS.

- Semen collections.
  - On-farm semen collection.
    - Requirements for the establishment keeping the donor should be stated in accordance with the epidemiological situation of the country. Requirements set in the European Union Regulations for the origin stablishment of the donor could be use as reference.
    - Test on donor animals or material collected, in function of the epidemiological situation of the country.
    - Collection of epididimal semen post mortem.
    - Processing in fixed or mobiles labs, should follow the same requirements than those set for intracomuntary trade (or national)
    - Embargo period.
    - Storage conditions of the material.
    - Exceptions in case of material from genetic relevant dono

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- Embryos and oocytes.
  - Requirements of the European Union Regulation allow, actually, the collection on farm.
  - Exceptions in case of genetic relevant animal for the requirements for the establishment or testing.

- Genomic material.
  - Under the scope of the animal-by products regulation: authorization and implementation of good laboratory practice.
  - Donors should fulfil a general requirements similars to t 16, Regulation 2020/686, with exceptions in case of an relevance.

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3. FIRST DRAFT GUIDELINES. DISCUSSION

7. DEROGATIONS/CONDITIONS FOR THE USE OF OLD MATERIAL.

- Collecting all available information on the sanitary status of the collected material and health status of donors.
- Optional testing on the material storage for particular diseases according to the current regulations for the species and country and the epidemiological situation at the time of collection.
- Assessment of the risk based on collected information by the competent authorities is recommended.
- Storage conditions.
- Exceptions in case animals with genetic relevance.

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3. FIRST DRAFT GUIDELINES. DISCUSSION

8. IMPLEMENTATION OF THE DEROGATION FORESEEN IN THE ARTICLE 45, COMMISSION DELEGATED REGULATION (EU) 2020/686.

- The main elements to be considered to develop the derogation.
- Recommended procedure to apply the derogation to a shipment of germinal products between two gene banks.

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4. FURTHER STEPS IN THE DEVELOPMENT OF GUIDELINES.

- Collect comments and proposals from WG members and AHA team, by 10th May.
- AHA Team analyze the comments and proposals and "produce" a new version of the guidelines, which will be sent for a new round of comments.
- AHA Team analyze again the comments and produce the final version for the approval in ERFP General Assembly.
- Dissemination of the guidelines.

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THANK YOU

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