European Regional Focal Point for Animal Genetic Resources

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.

6th May 2025.

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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 an experts team.**
May 2023	**Organization of a Kick-off meeting.**
October 2023	**Workshop.**
October 2023 – April 2024	**Development of a guidelines with recommendations:**

- **First Draft:** Cyprus WG (April 2024)
- **First round of comments (WG members and experts team):** Karin Olsson, Claudia Klein, Nina Svartedal and Danijela Bojkovski.
- **Meeting of experts team (August) and second draft of the guidelines, presented in the ERFP GA.**
- **Second round of comments (WG members, experts team and NC):** Delphine Duclos, Claudia Klein, Krisztina Liptoi, **Marcus Bates, Danijela Bojkovski (team),** Nina Svartedal, Gustavo Gandini, Luca Butazzoni and **Pierre Cherel**.
- **Coordinators meeting (January 2025).**
- **New proposal of structure and text by Pierre Cherel (February 2025).**
- **Review of coordinators (March 2025) and new version (April 2025)**
- **Third round of comments, May 2025.**

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

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 AND 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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2. GUIDELINES. MAIN CHANGES IN THE LAST YEAR.

PREFACE.

- Introduction of institutions.
- Main objective.
- European Strategy for Animal Genetic Resources and Action Plan.
- Ex situ conservation.
- A Key recommendation on Animal Health Regulation.

1. 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-term conservation goals.
- Relevance of sanitary standards for gene banks.

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2. GUIDELINES. MAIN CHANGES IN THE LAST YEAR.

2. 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 promote awareness and capacity building to gene banks regarding the necessary protocols for collection, processing storage, documentation and use of germinal products to guarantee health status and safety.

•To inform National Competent Authorities, responsible for the implementation of EU Animal Breeding regulation about the importance of gene banks, and available options to allow the use of germinal products from gene banks in approved breeding programs.

•To inform National Competent Authorities, responsible for the implementation of Animal Health Law, about the importance of gene banks, and the need to set national health frameworks and protocols for gene banks, when appropriate.

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2. OBJECTIVES OF THE GUIDELINES

•To contribute to the official recognition of gene banks at the national level, in the context of Animal Breeding and Animal Health regulations. .

•To highlight the possibilities of Commission Delegated Regulation (EU) 2020/686 on the implementation of derogations for the movement of germinal products stored in gene banks between Member States under EU Animal Health legislation.

•To advise the European Commission, the Standing Committee on Zootechnics, and the Standing Committee on Plants, Animals, Food and Feed on further development of EU Animal Breeding and EU Animal Health legislation that will facilitate the conservation and sustainable use of valuable animal genetic resources both national and EU level.

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3. LEGAL FRAMEWORK ON SANITARY AND **ANIMAL BREEDING ASPECTS OF GERMINAL PRODUCTS.**

- International Animal Health regulations.
- European Union Animal Health Regulations.
- European Union Animal Breeding Regulation.
- National Animal Health regulations.
- Issues in the implementation of animal health regulation regarding gene banks.
  - Sustainability and operational costs.
  - Access to donors from endangered breeds.
  - Storage and use of old samples.
  - Emergency collections.
  - National health legislation adapted to gene banks.

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

5. RECOMMENDED ADAPTATION OF NATIONAL HEALTH LEGISLATION FRAMEWORKS AND GENE BANKS.

- Common considerations.
- Animal health requirements for germinal products collection, storage and use on national territory by gene banks. Annex I: A and B
- Specific authorizations for collection and storage of germinal products qualified as *relevant animal genetic resources.* Annex I: C and D. (Old material and emergency collections).
- National-level authorizations for *in-vivo* use of germinal products qualified as *animal genetic resources on national territory.*
- Genomic material.

6. EXCHANGE OF GENE BANK MATERIAL BETWEEN EU MEMBER STATES.

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2. GUIDELINES. MAIN CHANGES IN THE LAST YEAR.

ANNEX I. SUGGESTED NATIONAL-LEVEL HEALTH REQUIREMENTS FOR GERMINAL PRODUCTS ADAPTED TO GENE BANKS.

PART A. SEMEN COLLECTIONS.

- **Semen collection centres.**
- **On-farm semen collection.**

PART B. EMBRYOS AND OOCYTES.

PART C. TECHNICAL RECOMMENDATIONS FOR GRANTING SPECIFIC AUTHORIZATIONS FOR EMERGENCY COLLECTION AND STORAGE OF GERMINAL PRODUCTS NOT MATCHING EU OR NATIONAL HEALTH REQUIREMENTS.

- **Alert system and evaluation of needs.**
- **Optimized emergency collection authorization and biosecurity measures.**
- **Specific framework of authorization for the use of emergency collection reproductive material.**

PART D. TECHNICAL RECOMMENDATIONS FOR GRANTING SPECIFIC AUTHORIZATIONS FOR EXTENDED STORAGE OF OLD SAMPLES OF GERMINAL PRODUCTS NOT MATCHING EU OR NATIONAL HEALTH REQUIREMENTS

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ANNEX II. RECOMMENDED GENE BANKS DOCUMENTATION SYSTEM FOR ANIMAL HEALTH QUALIFICATION OF GERMINAL PRODUCTS STORED.

PART A. OBJECTIVES OF ANIMAL HEALTH DOCUMENTATION SYSTEM RECOMMENDED FOR GENE BANKS.

- **Identify animal health qualification levels.**
- **Support EU or national legislation compliance.**
- **Prospective documentation of epidemiological context of gene banks germinal product samples.**

PART B. GENERAL RECOMMENDATIONS FOR HEALTH DATA DOCUMENTATION BY GENE BANKS.

PART C. RECOMMENDED HEALTH DATA TO BE COLLECTD BY GENE BANKS.

- **Germinal product sample documentation.**
- **Donor documentation.**
- **Collection premises documentation, when on farm collection is used.**

ANNEX III. AVAILABLE TESTS FOR THE DIRECT DETECTION OF PATHOGENS ON SEMEN.
ANNEX IV. MODEL OF ADVANCE NOTIFICATION.

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3. FURTHER STEPS IN THE DEVELOPMENT OF GUIDELINES.

- Collect comments and proposals from WG members and AHA team, by 15th May.
- Coordinators analyze the comments and proposals and “produce” the final version of the guidelines.
- **Dissemination of the guidelines.**

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