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

Gene banks are essential for the long-term conservation of livestock genetic diversity, in particular for the preservation and breeding programs of endangered breeds. Although many countries have taken measures to establish gene bank collections for endangered breeds national animal health legislation often lack specific provisions or derogations for gene banks, which are essential for long-term in vitro conservation of endangered breeds.

To address this, ERFP and EURC-EAB have jointly developed the Guidelines for the Development of National Animal Health Regulations for Material Intended for Gene Banks. These guidelines aim to help national authorities adapt existing frameworks to support the unique needs of gene banks, with particular reference to the long-term conservation of endangered livestock breeds. They seek to better balance animal health protection with the conservation of genetic diversity, and to strengthen gene banks' capacity to meet regulatory requirements

Chapter 1 is dedicated to contextualizing the rest of the content of the guide, so we begin by describing **what gene banks are**, their main functions and the type of material that can be stored in them. When analysing this context, it is essential to highlight the **need for the constitution of gene banks within the breeding programmes** of livestock breeds, both for their conservation and for their improvement. Finally, we establish the link between gene banks and health regulations, which is determined by the fact that **stored products are susceptible to disseminate animal diseases** and, therefore, must meet a series of requirements that minimise this risk. However, some of **these requirements**, designed for the commercial breeds, **represent real bottlenecks that hinder the conservation of animal genetic resources**, as consequence the existence of specific regulations for gene banks is desirable, as we explain at the end of the chapter.

Chapter 2 is intended for the objectives of the guide, which for its simplicity we reproduce verbatim:

- *To draw further attention to the importance 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 the competent national 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 Animal Breeding, 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.*
- *To Contribute to the official recognition of gene banks at 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 the further development of EU animal breeding and EU animal health legislation that will facilitate the conservation and sustainable use of valuable animal genetic resource at both national and EU level.*

In **Chapter 3** we take a look at the **regulations** that would be applicable at international, European and national level within two different areas, Animal Health and Animal Breeding. This chapter describes how animal health regulations on germinal products derive from the WOAH Terrestrial Animal Code, applying similar EU requirements for intra-EU. However, the EU's own regulations already provide exceptions for the movement of germinal products between gene banks between different member states. In this section of the guide, it is also recalled that **each EU member state (or third party) is competent to regulate germinal products in its** territory and therefore the one that has the capacity **to adopt specific regulations for gene banks**. Likewise, the European regulations on animal breeding and their references to ex situ conservation are mentioned.

The last section of **Chapter 3** details the **difficulties faced by gene banks due to the current regulatory requirements for germinal products**, which were designed for commercial breeds. This section details how **certain EU countries have already established adapted regulations to facilitate the work of gene banks**.

Chapter 4, although not very long, is **key**, since the first step in establishing adapted regulations for gene banks is to **identify and officially recognize these facilities**. In this chapter we give a series of recommendations for officially recognising gene banks, based on zootechnical and health regulations.

Chapter 5 is the most relevant of the entire guide, as it establishes the recommendations for developing animal health regulations adapted to gene banks. It should be noted that a series of measures are included that are complementary to each other and that each competent authority can choose according to its needs or starting situation. In this sense, **the guide should be understood as a toolbox**, from the simplest to the most complex possible, from which to choose. Within the text of the chapter, only general aspects are included, while the technical detail is developed in several of the annexes of the guide.

A common point when applying this regulation is that it should only **cover animals registered in a herd book** according to the EU (or national) regulations on animal breeding, so that the activities are carried out under the umbrella of a **breeding programme**.

When developing animal health regulations adapted for genebanks, the recommendations have been divided according to the type of material. Thus, those intended for the constitution of **semen collections are located in Annex I, part A**. In turn, two different locations have been contemplated to carry out the constitution of these collections: specialized **sperm collection centers** or collection **on farm** where the donor is located, a situation in which the availability of donors is facilitated.

Annex I, Part B contains the provisions for the collection of **embryos and oocytes.**

In addition to these generic regulations for the routine constitution of genebank collections, it is necessary to take into account **specific situations** in which it may be necessary to collect or store reproductive products to conserve animal genetic resources. These specific situations are the application of **stamping-out measures** in the face of the appearance of communicable diseases or the **storage of old material** whose health status we do not know. To deal with these situations, it is recommended to establish specific authorisations as the material is considered relevant for the conservation of livestock biodiversity. The recommendations for authorising collections in the event of **stamping-out** are set out in Annex 1. Part C and for the preservation of old samples in **Annex 1. Part D**.

In this chapter 5 we also highlight the importance of an adequate **system of documentation** of the material and its collection and storage conditions. The recommendations for establishing such a documentation system are set out in detail in **Annex II**.

In support of all the previous sections, **Annex III contains a list of pathogens that can be detected directly in semen**.

The last section of Chapter 5 is dedicated to summarizing the **health requirements applicable to collections of genomic material**, which are derived from the **animal by-products regulations**.

The last chapter of the guide, **Chapter 6**, contains a series of recommendations when applying the exception contemplated in Articles 45, 46 and 47 of Commission Delegated Regulation (EU) 2020/686, to allow the movement of reproductive products between gene banks located in different member states. This has been a huge milestone in the regulations, as it demonstrates that a **regulation adapted to the needs of the conservation of animal genetic resources in gene banks is possible**. Annex IV contains the advanced notification form to carry out this movement.

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