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

PREFACE.

These guidelines were developed jointly by the European Regional Focal Point for Animal Genetic Resources (ERFP) and the European Union Reference Centre for Endangered Animal Breeds (EURC-EAB). ERFP is the regional platform to support the in situ and ex situ conservation and sustainable utilization of animal genetic resources (AnGR) and to facilitate the implementation of the FAO Global Plan of Action for AnGR (GPA). EURC-EAB is responsible for the scientific and technical contribution to the definition and harmonization of methods for the conservation of endangered breeds, and for the conservation of the genetic diversity within those breeds, in accordance with Article 29(2) of Regulation (EU) 2016/1012.

The aim of the guidelines is to support the competent animal health authorities to align the national animal health protection frameworks for collection, storage and use of germinal products to the objectives of long-term in-vitro conservation (gene banks) of animal genetic resources, especially in the case of endangered breeds. The guidelines try to balance the animal health authorities' duty to safeguard animal health with the special requirements for gene banks for farm animal breeds. These guidelines also aim to promote gene banks awareness and organization to build capacities to answer the requirements of animal health protection rules.

In 2021, the ERFP developed the first European Strategy for Animal Genetic Resources, a result of the European Union funded H2020 project GenResBridge, which aims to strengthen the conservation and sustainable use of plant, forest and animal genetic resources in the European region.

The European Strategy for Animal Genetic Resources (Strategy) aims to facilitate the implementation of the FAO Global Plan of Action for Animal Genetic Resources (GPA) in the countries of the European region. The Strategy is in line with the priorities of the GPA and the European policy framework and contains a number of key recommendations for the work on conservation and sustainable use of AnGR throughout the whole of Europe.

An important activity in the management of AnGR is *ex situ* conservation, which means that animals or genetic material are not kept under normal management conditions ("*in situ*"). The most common *ex situ* conservation activities are carried out under cryogenic conditions ("*in vitro*"). Cryopreservation includes processing and storage of embryos, semen, oocytes, somatic cells or other tissues with the potential to reconstruct future living animals, but also non-reproductive material (DNA, tissue) can be conserved for research and breeding purposes.

The European Strategy for Animal Genetic Resources has identified a need related to the lack of specific derogations in national animal health legislation for gene banks, which allows a balance between the protection of animal health and the conservation of AnGR. Therefore, one of the key recommendations of the European Strategy is to "*promote specific derogations in national animal health legislation for material to be stored in gene banks, as well as for its distribution and use*".

This guide is intended to assist national competent authorities in complying with the key recommendation of the Strategy. To this end, it highlights the role of gene banks in the conservation of AnGR, and the need to explicitly define and recognize gene banks in relevant animal health policies and regulations. It also provides an in-depth analysis of international and EU regulations in this area. Most importantly, a number of recommendations are included, based on experiences of countries that already have specific regulations for gene banks, which make animal health protection compatible with the conservation of AnGR.

We hope that the content of this document will be useful and contribute to preserving the rich livestock heritage that we have inherited from our ancestors and that we must make available to our descendants.

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1.BACKGROUND.

1.1 What is a gene bank?.

An Animal Genetic Resources (AnGR) gene bank is an institution or organization that stores and manages germplasm and other types of genetic material (hereinafter referred to as "genetic material") from various livestock species. The main purpose of these gene banks is to preserve genetic diversity between and within domesticated animal populations for various purposes, including breeding, research, and conservation. The conservation of genetic material in a gene bank is also known as *ex situ in vitro* conservation. Different types of materials are cryopreserved in the gene bank to be used for breeding or regeneration of animals in the future. Depending on the type of preserved material, the collections are usually stored in tanks with liquid nitrogen or in other types of cold storage.

Depending on the structure and organization of the gene bank, the functions of the gene bank may include the collection of genetic material, processing (cryopreservation), storage, characterization, documentation and distribution of the material.

The management and operation of AnGR gene banks varies from country to country and can be carried out by government agencies, research institutions, non-governmental organizations, private organizations or a consortium of relevant stakeholders.

1.2 Why are gene banks relevant?

Gene banks are established to ensure the preservation and accessibility of genetic resources for present and future generations through cryopreservation, which allows genetic resources to remain viable over prolonged periods of time, even centuries. The main objectives of gene banks are the following:

1. **Conservation of genetic diversity:** One of the main objectives of animal gene banks is to maintain the genetic diversity within and between animal breeds for the species concerned, to prevent the loss of breeds, to maximize or optimize the amount of total genetic variation within and between breeds, and to ensure the conservation of important phenotypes and genotypes. Maintaining genetic diversity is crucial for the long-term adaptability, resilience, and sustainability of livestock populations.
2. **Breeding and genetic improvement:** Gene banks are a valuable resource for animal breeders and researchers working on breeding programmes. Access to diverse genetic material enables the development of new breeds or the improvement of

existing breeds, leading to increased productivity, disease resistance, and other desirable traits.

3. **Research:** Animal gene banks can provide researchers with access to genetic resources for numerous studies in the fields of genetics, genomics, epigenetics and animal biology.
4. **Emergency preparedness:** Gene banks play a role in emergency preparedness by securing genetic material that may be needed to restore or rebuild animal populations in the event of disasters, disease outbreaks, or other emergencies.
5. **International cooperation:** In the European region, countries and organizations collaborate internationally notably through the ERFP *ex situ* Working Group and the European Genebank Network for Animal Genetic Resources (EUGENA)[1], to share expertise on the management of animal gene banks. This helps to promote global efforts to conserve and do research on animal genetic resources.

1.3 Types of germinal products stored in gene banks.

Reproductive material includes semen, embryos, oocytes, primordial germ cells (PGCs), gonadal tissues and somatic tissue samples that can be reused by cloning. In practice, most gene bank collections consist mainly of semen, which is the cheapest and easiest reproductive material to collect for most species.

1.4 Other genetic material stored in gene banks (genomic material).

Collections of material other than reproductive material, such as blood or DNA, are often referred to as genomic collections or biobank collections. These gene banks are usually used for research and purposes other than conservation and breeding programmes, e.g. to characterise a population. Often, both types of material (reproductive and genomic material) are stored in the same gene bank. It is highly positive linking the results of genomic analyses with the correct management of the reproductive material of particular animal.

For example, genomic gene banks allow DNA analyses to be carried out without the need to use a semen straw. For some species, the number of samples per donor is extremely limited or expensive (e.g. poultry and equid), so it makes more sense to use other types of genetic material for characterization. The type of genomic material used in a biobank depends on the type of studies required:

[1] https://www.eugena-erfp.net/en/

1. **Blood and serum samples:** Blood samples can provide genetic information through DNA analyses, as well as information on blood-related parameters, such as blood chemistry, hormones, and immune responses. Serum samples can be used to analyse antibodies and immune responses and serve as an indicator of the sanitary status of the reproductive material stored in the gene bank.
2. **Hair and feather samples:** These samples may contain DNA that can be used for genetic analyses. They are particularly useful for non-invasive genetic studies.
3. **Bone, teeth and scale samples:** Genetic material can also be extracted from ancient or fossilised remains. This can provide insights into the genetics and evolutionary history of species. They can also be collected without harming the animal and provide valuable genetic data.
4. **Cell lines:** They can be used to study cell biology, genetics, and disease susceptibility.
5. **Organ and tissue samples:** In addition to reproductive tissues, various organs and tissues can be preserved and used for genetic analyses or biomedical research.
6. **DNA extracts:** Genetic material can be extracted from a variety of preserved specimens, including museum specimens, fossils, and archaeological remains, to study the genetics and evolution of species over time.

These diverse types of genomic material provide researchers with a wealth of information for understanding the genetics, behaviour, health, and evolutionary history of animals, as well as for conservation and breeding efforts.

1.5 Gene banks in the context of breeding programmes and long-term conservation goals

Ex situ conservation – the collection, storage and use of cryopreserved genetic material – is an important complementary tool in breeding programmes and for the long-term conservation of genetic diversity within and between different breeds. Animal gene banks play a crucial role in supporting breeding programmes and long-term conservation goals for farm animal breeds. In this context, it is important to note that both the European Union and all its Member States (an also all ERFP member countries) have signed the Convention on Biological Diversity and countries committed themselves to the implementation of the FAO Global Plan of Action for Animal Genetic Resources, and we are therefore committed to the conservation of biodiversity, including animal genetic resources. In this context, the following should be said about animal gene banks:

1. **Breeding programme support:** Animal breeders can access genetic material from gene banks to increase the genetic diversity within the herd or to improve and

maintain desired traits. This genetic diversity can be used to improve traits such as meat quality, milk production, disease resistance, and reproductive performance and is useful for emerging traits such as methane production or heat resistance.

2. **Conservation of rare breeds and genetic diversity within these breeds.** By preserving the genetic material of these breeds, gene banks can be uses to prevent the loss of genetic diversity, to minimize the degree of inbreeding, or (re)introduce genetic diversity.
3. **Research and development:** The animal genetic resources stored in gene banks are valuable for scientific research. Researchers can analyse the genetics of the stored material to gain insights into traits, diseases, and genetic diversity. This knowledge can be used in breeding programmes and research to improve animal health and productivity.
4. **Global collaboration:** Many animal gene banks are part of international networks and agreements to conserve farm animal genetic diversity globally. The gene bank network facilitates the exchange of knowledge and the sharing of genetic resources between countries and institutions. This co-operation helps to ensure that genetic diversity is preserved, documented and made accessible at a global level.

Gene banks contribute to adaptation to changing conditions and to livelihood and food security. They provide a source of genetic diversity that can be used to develop animal breeds that are better adapted to changing environmental conditions or more resistant to emerging diseases. They also contribute to food security by helping to develop and maintain productive and resilient livestock breeds.

The importance of gene banks is recognised by the FAO Commission on Genetic Resources and is linked to Sustainable Development Goal 2. SDG indicator 2.5.1b is defined as the number of breeds whose material is conserved in gene banks. This indicator is part of the monitoring of *target 2.5: maintain the genetic diversity of seeds, cultivated plants and farmed and domesticated animals and their related wild species.*

In Europe, the key role of gene banks can be observed thanks to the information stored in European Gene bank Network for Animal Genetic Resources (EUGENA), the largest network in Europe dedicated to *ex situ in vitro* conservation. EUGENA was founded by the European Regional Focal Point for Animal Genetic Resources and is a network of gene banks in European countries. The aim of EUGENA is to support the *ex situ* conservation and sustainable use of animal genetic resources and to facilitate the implementation of the FAO Global Plan of Action for AnGR resources and the Nagoya Protocol for Access and Benefit Sharing in Europe.

Almost five million samples of 456 different livestock breeds from fifteen species are stored in the 26 EUGENA gene banks (from fifteen countries) (July 2025).

For the purpose of these guidelines, a relevant reference to gene banks in EU legislation framework can be found in the Animal Breeding Regulation (EU) 2016/1012 of the European Parliament and of the Council. Preamble (recital 23) of which states: *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 long term, sustainable conservation of that breed. It should be possible for those measures to be laid down in the breeding programme.*

This recital assumes that gene banks should be considered as one of the actors involved in the activities of the breeding programmes for livestock breeds.

There are also references for *ex situ* conservation collections in the Common Agricultural Policy regulation (CAP, Article 45.6 Commission Delegated Regulation (EU) 2022/126), or in the State Aid (Article 30.7 Commission Regulation (EU) 2022/2472), which define ex situ gene banks as possible eligible activities for funding for their relationship with the conservation, sustainable use and development of genetic resources in agriculture.

In summary, animal gene banks are a valuable tool and actors for both breeding programmes and for the long-term conservation objectives for farm animal genetic resources. They help safeguarding animal genetic diversity and endangered breeds for the future, genetic improvement and our livestock adaptation to changing environmental conditions.

1.6 Relevance of sanitary standards for gene banks.

Genetic material stored in gene banks, especially germinal products, such as semen, oocytes and embryos, can be a source of risk for the transmission of infectious animal diseases, including zoonosis, which must be avoided. Germinal products are collected or produced from a limited number of donors but can be transferred to many recipients in various locations within the general animal population, which may spread pathogens at scale if not controlled for. The risk of disease shedding through germinal product use is thus controlled by animal health regulations defining biosecurity requirements for germinal products, donors and material processing.

Animal health regulations are of significant importance for animal gene banks for several important reasons:

1. **Prevention of disease spread:** Sanitary standards are essential to prevent the introduction and spread of disease when using stored material. Ensuring that animals are free from infectious diseases and pathogens is also critical to maintaining the sanitary integrity of stored genetic resources.

2. **Public and stakeholder confidence:** Strict adherence to sanitary standards enhances public and stakeholder confidence in the integrity and reliability of animal gene banks. This trust is crucial for securing funding, support, and participation in gene bank initiatives.

The protocols of gene banks therefore require appropriate health protection measures to ensure safety and proper use of their products in the future. However, certain requirements of health regulations can be an obstacle to the development of gene banks, especially when working with endangered breeds. It is strongly recommended that sanitary regulations take into account the specificities of gene bank and strike a balance between the conservation of livestock biodiversity and the protection of human and animal health, it means that the level of safeguarding for germinal products stored in gene banks must be similar to those for the commercial purposes, although the technical measures to reach this level could be different for the collection, storage and use of germinal products of any valuable animal genetic resources at the national level. A coordinated implementation and further development of animal health and zootechnical regulations is desirable to achieve their respective objectives.

The necessary coordination between animal breeding and animal health legislation requires a smooth communication between the competent authorities in these two areas. Only if such co-operation exists can regulations be established at national level that meet animal health protection requirements and allow the balanced development of gene banks for the conservation and sustainable use of animal genetic resources (in particular for endangered breeds). Finally, the institutions responsible for gene banks should be informed and involved in national implementation and further development of regulations on animal health with possible implications for *ex situ in vitro* conservation activities.

2. OBJECTIVES OF THE GUIDELINES.

Ex situ conservation is an important complementary tool in breeding programmes. EU animal breeding legislation (Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016) is the relevant legal framework for the recognition of breeding associations and the approval of breeding programmes. At the same time, both breeding programmes and gene banks must comply with EU animal health legislation (Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016) in the event of the exchange of breeding animals or germinal products within the Member States, between Member States within EU, or with other ERFP members.

In view of the specific challenges related to the development of gene banks and the conservation and sustainable use of endangered livestock breeds, both EU animal breeding and EU animal health legislation provide possibilities to implement specific measures at national level for breeding programmes for endangered breeds and for gene bank operations. The EU animal health legislation refers to gene banks and specifically mentions the possibility of bilateral exchange of genetic material, stored in gene banks, between EU Member States.

The objectives of these guidelines are:

- 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.

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

To control the risk of the spreading of animal infectious diseases, regulations at international, EU or national level stipulate that germinal products must be collected, produced, processed and stored in specialised facilities and that they are subject to specific animal health and hygiene rules. In order for animals to be admitted to these facilities and classified as donors of germinal products, they must fulfil specific and higher animal health standards than those applicable to the general population, including testing and quarantine before entering to the facility.

Other common elements of these regulations are the requirements for the storage of the germinal products and the rules for traceability of their movements, which include the labelling of straws or other storage containers and the requirement that any exchange of the material must be accompanied by an animal health certificate. In addition, there are also rules for the animal by-products that can be stored in gene banks.

Although not the purpose of this guide, gene banks will also be subject to other national or European Union regulations in the context of their activities, such as animal welfare, veterinary medicines, environmental protection, etc.

3.1 International Animal Health regulations.

The regulation of the international exchange of germinal products from the most relevant mammalian livestock species (no international recommendations exist for poultry and other species) is laid down in section 4 of the Terrestrial Animal Health Code (OIE, 2019) of the World Organisation for Animal Health (WOAH). The Terrestrial Code contains standards that should be used by veterinary authorities to take measures for the early detection, reporting and control of pathogens, including zoonoses, and to prevent their spread through international trade in animals and animal products, while avoiding unjustified sanitary barriers to trade. On the basis of these standards, countries may enter into bilateral agreements to allow international trade of germinal products.

In connection with the conservation and sustainable use of animal genetic resources, the Food and Agriculture Organisation of the United Nations (FAO) has also drawn up relevant reference documents for the establishment of gene banks. The FAO guidelines on:

« *Innovations in cryoconservation of animal genetic resources* [2] », Chapter 7 contains recommendations on animal health aspects in connection with gene banks. This document recognises that the WOAH Terrestrial Animal Health Code (https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/) is the gold standard for the movement of reproductive products at international level, but that these requirements can be an obstacle when establishing gene banks at national level, especially for endangered breeds. To facilitate the development of collections and the use of gene bank material from these breeds, the guide describes a set of valid recommendations for each state to develop its own regulations, where appropriate, which have also served as the basis for the development of this document. The objective of these recommendations is to achieve a level of protection for the animal health similar to that obtained with the WOAH standards.

3.2 European Union Animal Health Regulation.

The European Union has adopted its own regulations for the movement of germinal products within and between its Member States. However, these EU regulations have used the WOAH Terrestrial Animal Health Code as a reference, so the EU Animal Health regulations include remarkably similar requirements. The main regulation relating to germinal products in the EU is *Regulation (EU) 2016/429 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law').* In recital 133, the Animal Health Law, emphasises that: *"Germinal products can represent a similar risk of spreading transmissible animal diseases to live animals. In addition, there are specificities in their production which are related to high health demands for breeding animals and which call for stricter or particular animal health requirements concerning the donor animals."*

In article 1.1.d of Regulation (EU) 2016/429 is stated that one of the aims of the rule is: *(d) the registration and approval of establishments and transporters, movements and traceability of animals, germinal products and products of animal origin within the Union* and in Article 2, it is set down that the scope of that regulation, inter-alia is: *1.b Germinal products* and *1.d animal-by products.*

Regarding the definitions (Article 3), three are relevant to the objectives of these guidelines:

(28) 'germinal products' means:

[2] Boes, J., Boettcher, P. & Honkatukia, M., eds. 2023. Innovations in cryoconservation of animal genetic resources – Practical guide. FAO Animal Production and Health Guidelines, No. 33. Rome. https://doi.org/10.4060/cc3078en

(a) semen, oocytes and embryos intended for artificial reproduction;

(b) hatching eggs;

(30) 'animal by–products' means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, excluding germinal products;

(46)'germinal product establishment' means:

(a)in relation to semen, an establishment where semen is collected, produced, processed or stored;

(b)in relation to oocytes and embryos, a group of professionals or structure supervised by a team veterinarian competent to perform the collection, production, processing and storage of oocytes and embryos;

From the above definitions we can conclude, that gene banks that collect, produce, process, store and/or distribute semen, embryos, and oocytes, are germinal product establishments and must therefore fulfil the requirements laid down in the European Animal Health Regulation for this type of establishments. Genomic gene banks that collect other types of cells or tissues (genomic material) fall within the scope of the animal by-products regulation.

The main requirement for reproductive gene banks in Regulation (EU) 2016/429 is laid down in Article 84, which requires the registration of the establishment, collecting, producing, processing or storing germinal products, by the competent national authorities. Therefore, gene banks, storing germinal products, must always be registered at national level.

In addition to the previous requirement, Article 94.1.b, specify that: *germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals are moved to another Member State* shall be approved by the competent authorities.

The last article of Regulation (EU) 2016/429 relevant for the purposes of this guidelines is Article 269 which refers to additional or more stringent measures to be taken by Member States and allows Member States to adopt national measures on their territory that go beyond the measures laid down in animal health legislation, including for germinal products.

The general considerations set out in Regulation 2016/429 have been further developed by delegated regulations. Regarding germinal products, *Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the approval of germinal product establishments and traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals* is the most important. This Regulation lays down the detailed requirements for the movement of germinal products between Member States for the five main livestock animal species (bovine, ovine, caprine, porcine and equine).

Firstly, the Regulation lays down the conditions that germinal product establishments must fulfil to be authorized for movements to other Member States. It also distinguishes these authorised establishments from those registered only at national level, in accordance with Article 94.1.b, Regulation 2016/429.

The Regulation describes in more detail the traceability system for germinal products, based on the records to be kept by the establishments and the labelling of straws or other packaging containing germinal products.

The Regulation sets out the general requirements to be met by germinal product establishments and donors to participate in trade within the EU. It then details the specific animal health requirements that apply to the following areas:

- The origin establishment of the donors.
- Quarantine (except for equines) for semen donors.
- Laboratory testing of donors before quarantine, during quarantine and routinely in the case of semen collection centres.
- Collection of embryos or oocytes.

The Regulation contains several articles and annexes describing the conditions for the collection, production, processing, storage and transport of germinal products and, finally, the animal health certification of consignments of germinal products by official veterinarians.

In addition to the requirements for trade in germinal products of five large livestock species, Commission Delegated Regulation 2020/686 which also contains the rules for the exchange of germinal products derived from dogs, cats and animals of the Cervidae and Camelidae families. It also contains provisions for the movement of germinal products from animals kept in confined establishments.

However, the most important innovation in relation to gene banks is the establishment of a specific procedure for the movement of germinal products, which do not need to comply with all general rules, between gene banks in different Member States. The requirements for such movements are defined in Article 45 and require firstly, that the semen must originate from an endangered breed and, secondly, that prior written authorisation (a kind of *bilateral agreement)* is given by the competent authority in the Member state of destination. The conditions of the agreement cover the use of the germinal products (*ex situ* conservation and sustainable use of AnGR) and information on the animal health status of the material, with particular attention to foot-and-mouth disease and rinderpest virus. A procedure for implementing this exception is described in detail in Chapter 8.

To allow proper implementation of this derogation, a definition of the term «*gene bank*» has been laid down in the European Animal Health Regulation. The above-mentioned Delegated Regulation defines gene banks in Article 2.10 as "*a repository of animal genetic material for ex situ conservation and sustainable use of genetic resources of kept terrestrial animals, held by a host institution authorised or recognised by the competent authority to fulfil these tasks*."

The legal definition of the term «*gene bank*» could be especially useful for the development of further regulations at national level for the organisations that establish collections for the conservation and sustainable use of animal genetic resources.

A similar procedure of exemption from the general rules may be applied to germinal product to be moved for research purposes or from/to confined establishments.

In the case of gene banks containing genomic material fall within the scope of Regulation (EC) 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules concerning animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002. Article 17 of this Regulation provides that the competent authority may, by way of derogation from Articles 12, 13 and 14 of Regulation (EC) No 1069/2009, authorise the use of animal by-products and derived products for exhibitions, artistic activities, and for diagnostic, educational and research purposes under conditions ensuring the control of risks to public and animal health. Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules concerning animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and objects exempted from veterinary checks at the border under that Directive, supplements the rules for samples used in research and diagnostic and allows their storage as reference samples.

In addition to above-mentioned regulation there are further references in the EU regulation to gene banks or *ex situ* conservation activities. For example, the Animal Health Regulation states that germplasm banks are one of the activities to be developed in the framework of breeding programmes for TSE resistance in ovine animals (Annex VII, Chapter C, Regulation (EC) No 999/2001).

3.3. European Union Animal Breeding Regulation.

Regulation (EU) 2016/1012, the Animal Breeding Regulation, defines requirements for approval of breeding programmes regarding the bovines, equines, porcine, ovine and caprine species.

The preamble (recital 23) of (EU) 2016/1012 states that breeding programme which objective is the preservation of a breed, could complete the requirement of such programme with ex situ and in situ conservation measures.

Article 21 from this regulation defines "*the acceptance of purebred breeding animals and their germinal products for breeding*". Paragraph 5 from this article requires that germinal products used for breeding within an approved breeding programme "*shall be collected, produced, processed and stored at a semen collection or storage centre, or by an embryo*

transfer team, approved for intra-Union trade in these commodities according to the Animal Health Low." [e.g. approval according to Article 97 from Animal Health Law].

Acceptance of those breeding products into an approved breeding programme allows to enter or register breeding animals resulting from these germinal products into the main section of breeding books (Animal Breeding Regulation: Article 18, paragraph 1).

However, "*A Member State may authorize*" according to paragraph 6 from the Animal Breeding Regulation Article 21, by derogation from paragraph 5 from this article [*i.e. for the purpose of breeding within an approved breeding programme*], to use germinal products of purebred breeding animals from collection/storage centres, embryo transfer teams "*approved in accordance with the legislation of that Member State*".

The Animal Breeding Regulation thus recognizes the use in breeding programmes of germinal products not approved for movements between Member States but approved by national legislation for use on the national territories only. This provision can be mobilized to the benefit of sustainable use of *in vitro* animal genetic resources conserved by gene banks.

3.4 National animal health regulations.

The regulation of germinal products intended to be placed only on the market in the individual Member States and not exchanged within EU, depends on the provisions national governments have adopted in this respect. Some Member States (e.g. France or Germany) apply the same requirements of Commission Delegated Regulation 2020/686 to all their germinal product establishments, which in turn are derived from the WOAH Terrestrial Animal Health Code.

However, other EU countries, also depending on the species, only apply the requirements of EU legislation to establishments involved in trade with other Member States and third countries. National trade in germinal products is then subject to its own rules, which may include less strict requirements for specific types of establishments or specific derogations for all gene banks (in the case of Spain), a specific establishment for the national gene bank (in the case of The Netherlands) or for old material (in the case of Poland).

Other countries not members of the European Union have also developed legislation on germinal products to regulate their trade at the national level, without following the recommendations of the WOAH Terrestrial Animal Health Code. This is the case of the UK, where there are specific regulations that set the rules for the collection, storage and distribution of porcine and bovine semen at a national level, with more flexible requirements than those established by the WOAH.

3.5 Issues in the implementation of animal health regulation regarding gene banks.

3.5.1 Sustainability and operational costs.

The WOAH recommendations have been developed to ensure the highest level of biosecurity to prevent the spread of animal diseases in the trade of germinal products of mainstream breeds. If these recommendations are to be adhered to, large investments must be made in any establishment dealing with germinal products, which are likely to be compensated for by the benefits resulting from the trade in safe germinal products.

On the other hand, the requirements imposed by regulations at national or European level (both derived from the WOAH recommendations) can be a serious burden for the collection of germinal products of a sufficient number of breeding animals, especially in the case of endangered breeds. These breeds are often bred in less intensive production systems with fewer biosecurity measures and less stringent animal health programmes. Moreover, due to their high sanitary standards and commercial interests based, germplasm collection centres are often not interested in providing services for breeding programs of endangered breeds. Farms of interest that keep breeding animals of an endangered breed may not meet legal health requirements for sending donors to such centres. In addition, the quarantine period, testing and facility requirements can result in prohibitive costs for collecting a small number of samples with little commercial value.

Conversely, the collection, storage and use of germinal products for the efficient conservation of animal genetic resources, in particular to support national breeding programmes of endangered breeds, does not require the same scale of diffusion, or the same speed in delivering semen from the latest and youngest top-indexed males as in commercial operations. In the case of gene banks, a limited number of donors or samples, extended periods between collection and use, can bring additional epidemiological or analytical health status information to guarantee the health safety of gene banks germinal products.

3.5.2 Access to donors from endangered breeds.

The number of animal donors available is obviously limited for endangered breeds. In addition, at-risk breeds are often found in only a few locations, leaving little opportunity for selection of donor farms based on sanitary conditions. Finally, on many occasions breeders are reluctant to hand over their animals to specialized centres to carry out the procedures for collecting germinal products.

3.5.3 Storage and use of old samples.

Frequently, the gene bank or breed societies have developed collections of germinal products for years, and part of the material (mainly semen) collected in the past could not be in line with the current animal health regulations. Most often, this material was collected on the basis of sanitary and veterinary regulations in force in the past what means that often the donor health status or the condition of collection, production, processing, and storage were in accordance with a different animal health regime than it is currently applicable. For endangered and vulnerable breeds defined in point (24) of Article 2 of Regulation (EU) 2016/1012 of the European Parliament and of the Council (12), but also for populations subjected to intense selection, this material can however be of excellent value.

3.5.4 Emergency collections.

Disease outbreaks may also present a specific use case: health containment emergency measures may include stamping out eradication procedures of all animals from sensitive species in reported infected areas.

If all breeding animals from a specific endangered breed are located in declared infected areas, this situation may lead to immediate loss of this breed. In this case, and when the current extent of *in vitro* collections of germinal products stored for this breed cannot guarantee reconstruction of the breed from these samples, emergency collection of germinal products or genomic material from animals in the affected area could be the only option left to prevent the final loss of this breed. However, without specific measures and guarantees, germinal products collected under those circumstances would pose significant and specific health and sanitation risks for the gene bank.

To allow collection from local breeds of relevant material in case of an outbreak, it is highly recommended to organize entry points in the national animal health laws to grant specific authorization for collecting this type of samples, under appropriate conditions safeguarding specific storage and controlled use without increasing risks for the national animal health status.

3.5.5 National health legislation adapted to gene banks.

To adapt local health regulation of germinal products collected, stored and used by gene banks to the constraints identified above, it is strongly recommended that specific provisions for gene banking in these particular situations are laid down in the national animal health legislation, in particular for the collection of semen outside an authorised centre. Such customised, tailor-made arrangements for gene banks are possible under Community legislation, which allows for the development of additional requirements by Member States (see Article 269, Regulation (EU) 2016/429), and some examples have

already been developed. Such national provisions for the routine work and adaptation needs of gene banks, generally have the focus on the needs of (endangered) local breeds.

In the case of Spain, an exception has been included in the national animal health regulation on germinal products to allow the collection of reproductive material intended for storage in gene banks without complying with the general national regulations for marketing commercial germinal products, provided that these activities do not pose a risk to human or animal health. In order to apply this derogation, a number of procedures have been developed to regulate the collection of reproductive material in the field for the different livestock species (the procedures can be downloaded from: https://www.mapa.gob.es/es/ganaderia/temas/zootecnia/razas-ganaderas/establecimientos-reproduccion/Excepciones/).

In the case of Netherlands, the national gene bank for native cattle breeds has been granted a special exemption in the national animal health law.

In both Spain and the Netherlands, the requirements for material to be stored in gene banks are quite similar to the intra-Community trade regulations, although collection on the donors'farms is permitted, and quarantine is not required. However, health tests are required for donor animals analogous to those in Commission Delegated Regulation 2020/686 and also on the collected material.

In the case of Poland, the National Bank of Biological Material is allowed to store and place germplasm on the market, only on the territory of the Republic of Poland, semen collected before 1 May 2004 if it is stored in a separate facility and will be used exclusively for artificial insemination within an official approved breeding programme.

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

The first step in establishing specific requirements in the animal health regulations for gene banks is to clearly define which establishments are eligible. This will avoid the risk that other germinal product establishments that do not carry out activities for the purpose of conservation and sustainable use of animal genetic resources incorrectly benefit from the derogations for gene banks. To this end, it is essential to legally define at national level what a gene bank is.

A good reference to build up the definition is Article 2.10 of Commission Delegated Regulation (EU) 2020/686 to define the scope of the derogation allowing the movement of germinal products within gene banks in different Member States, which indicates that:

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

The definition contains three elements that are important for the further development of national animal health requirements for gene banks:

- Set a material scope: the repositories (collections) of animal genetic material.
- Set the objectives of the scope: *ex situ* conservation and sustainable use of genetic resources of kept terrestrial animals.
- Set the procedure to enable the operation of the facility: the institution should be authorised or recognised by the competent authorities for the objectives of *ex situ* conservation and sustainable use of genetic resources.

When developing national regulations for the recognition/authorisation of a gene bank, each competent authority shall follow the specific procedures laid down in its national legal framework and it is advisable to consider the following requirements for the recognition/authorisation of the establishments hosting gene banks:

- The EU and national animal health legislation:
    - In the case of germinal products gene banks, the establishment hosting the collection must be registered in accordance with Article 84 of Regulation (EU) 2016/429.
    - In the case of gene banks for non-germinal products, the establishment hosting the collection must fulfil the requirements of Regulation (EU) 1069/2009 on animal by-products.

    - Comply with all requirements of national animal health regulation, that Member States may develop in accordance with Article 269 of Regulation (EU) 2016/429.
- The EU and national animal breeding legislation:
    - The main objective of gene banks is the *ex situ* conservation and sustainable use of Animal Genetic Resources. These activities should be included in breeding programmes regulated by Regulation (EU) 2016/1012, as for their approval/recognition gene banks must participate in the development of an approved breeding programme carried out by a breeding society or breeding operation authorised by a competent authority. Such breeding programmes could specify the description of the conservation activities and the involvement of the gene bank, as set out in recital 23 of Regulation (EU) 2016/1012. If gene banks are outsourced by the breed society or the breeding operator, they are third parties to the breeding programme and must comply with the requirements laid down in Article 8.4 of Regulation (EU) 2016/1012.

It is strongly recommended that the competent authorities maintain, update and publish a list of recognised/authorised gene banks and make the list publicly available. See the example from Spain, in:
https://servicio.mapa.gob.es/arca/flujos.html?_flowId=buscadorBancoGermoPlasma-flow

The collection and storage of the information on the animal health situation of donors and farms of origin is key to allow a safe use of the material kept in gene banks. We strongly recommend linking the formal recognition of gene banks and the enforcement of health status documentation of germinal products by gene banks, according to a reference documentation standard on animal health status of donors and farms of origin, which could be defined at national level. Recommendations to develop these national standards can be found in Annex II of the present guidelines.

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

5.1 Common considerations.

In the previous two sections, we have analysed the relevant animal health and breeding regulations and the specific issues related to gene banks in this context. In this section, we will suggest recommendations to update the national animal health frameworks and improve gene banks organisation that would allow the constitution of gene banks in a more efficient way, while guaranteeing adequate conditions of use of the material in their collections and improving the documentation of the health status of germinal products stored by gene banks.

A common element in all cases is that such national rules would be settled down within the legal framework of each member state only, as we have indicated above.

Another common element would be that these measures would have to be adapted over time to the epidemiological context of each country concerned in relation to each of the diseases that could be transmitted using the material stored in the gene banks.

5.2 Animal health requirements for germinal products collection, storage and use on national territory by gene banks.

The EU Animal Health Legislation defines requirements for the movement of germinal products between member states. Additional national measures (AHL article 269) may define specific requirements only for the collection, storage and use of germinal products on their national territory, i.e. not moved across borders (excepted under derogation set in article 45 Regulation (EU) 2020/686).

Defining national-level health requirements for germinal products used on the national territory will not make a derogation to EU Animal Health requirements for the movements of germinal products between member states.

National-level requirements, restricted to germinal products used on the national territory, may be restricted to gene banks, based on the formal recognition step suggested before, or specific use cases, or applied to all national operators not moving germinal products between member states, if appropriate.

Restricting the application of national level-requirements to gene banks would limit the scope of application of this national-standard, easing the enforcement of these national

requirements by national competent authorities for animal health, besides the enforcement of EU animal health requirements for germinal products moved between member states.

A specific regulation for gene banks could be further restricted to breeding animals participating in an approved breeding programme carried out by a recognized breed society according to the Animal Breeding Regulation (EU 2016/1012). For the collected material to be useful for the conservation or sustainable use of a breed, a set of genealogical, productive and/or genomic records is required, which is only organized for animals entered or registered in the breeding books.

Health requirements for germinal products collection, storage and use, may be defined at national level and adapted to gene banks, building on:

- Epidemiological information (e.g. retrospective analysis of origin farm health status and current analyses of the farm health status after the collection).
- Analytic information on donors.
- Analytic information on germinal products batches.

This additional information can support granting, when this additional documentation is proven and conclusive, a national level authorisation to collect, store and use germinal products without enforcing all of EU level health requirements (e.g. relaxing constraints on quarantine isolation prior to collection in approved centres, the collection on farms or new schemes of test for the donors and germinal products).

These recommendations will be structured according to the species and type of material managed by the gene bank. In this way, we proposed the next recommendations:

- Technical recommendations for national-level adapted health requirements for **semen** collection, storage and use by gene banks, detailed in Annex I.A.
- Technical recommendations for national-level adapted health requirements for **embryo or oocytes** collection, storage and use by gene banks, detailed in Annex I.B.

5.3 Specific authorizations for collection and storage of germinal products qualified as *relevant animal genetic resources*.

In addition to the definition of an alternative national level standard of health requirements for germinal products only collected and used on the national territory restricted to gene banks, we would also recommend considering alternative national procedures or national frameworks to answer the specific concerns highlighted in section 3.4.3 (storage of old samples) or section 3.4.4 (emergency collections):

- Grant specific authorizations for the conserved collection and/or storage of specific germinal products (*relevant animal genetic resources*) not matching EU or national level health requirements but not including the use of these samples. To grant these authorizations, the competent authorities would take into consideration:

- how to organize, request and promote additional health status documentation of these germinal products by gene banks.
- how to deliver specific authorizations to allow the emergency collection of valuable (but potentially unsafe) samples.
- how to set *ad hoc* authorizations for collection and storage of germinal products, with specific requirements for storage facilities, labelling and registration of these samples.
- how to define a specific framework to allow the extended storage of old samples not matching the current EU or national level requirements.

Indeed, a specific authorization granting system may prove extremely useful, when national level requirements cannot be met (for example in case of an outbreak which seriously endangered a breed with a small population) and when donor animals on which the procedure is to be carried out have a special genetic relevance. Genetic relevance can be certified by the EU recognized breed society that manages the breeding programme of interest. Donor animals of specific genetic relevance may be used for conserved collections and storage, subject to a prior risk assessment by the competent authority, which may demand additional health requirements or establish specific rules for the use of the collected material to avoid the spread of any of the listed diseases in the EU.

- Technical recommendations for granting specific authorizations for emergency collection and storage of germinal products national heath requirements (last animals from endangered breed in case of diseases outbreaks) are detailed in Annex I.C.
- Technical recommendations for granting specific authorizations for extended storage of old samples from germinal products not matching national heath requirements are detailed in Annex I.D.

5.4 National-level authorizations for *in-vivo* use of germinal products qualified as *animal genetic resources* on national territory.

The last phase of the application of the specific authorizations that we have seen in the previous section, would be to regulate the possible use, of the germinal product considered as a relevant genetic resource stored.

When granting specific (and mostly case by case) authorizations for the *in vivo* use of germinal products stored without matching EU or national level health requirements, the competent authority would take in consideration:

- *ad hoc* risk analysis built from epidemiological context in the time and collection and samples documentation review.
- how authorizations could be restricted to specific use conditions (time frame, samples qualification, monitoring, recipients' confinement where required).

- how authorizations could be restricted to use in the breeding programme operations to conserve or reconstitute a breed highly endangered.
- techniques to reduce the risk of transmission of the possible biological risk by the germinal product.

5.5 Genomic material.

In the case of non reproductive material, storage is more focused towards the later performance of various analytical tests that can support the development of breeding programmes. Thus, the risk of disease transmission to a living population using this stored material should be extremely low.

However, the requirements for the establishment of these types of collections should be defined in such way that all donor health information is collected and stored in the gene bank on a long-term basis (See Annex II). It is also recommended to fulfil requirements in line to those set out in Article 16 (with the exception of 16.d.IV and 16.f) of Commission Delegated Regulation 2020/686, with the necessary exceptions in the case of animals of high genetic importance.

As animal by-products are involved, the samples taken must comply with the provisions of Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 (Animal by-products Regulation). In view of the purpose of the collections of non-reproductive material, they may benefit from the provisions of Article 17 of the above-mentioned Regulation, so that their operation requires an authorisation from the competent authority and they must comply with at least the following requirements:

- the prohibition of any subsequent use of animal by-products or derived products for other purposes; and
- the obligation to dispose the animal by-products or derived products safely or, where appropriate, to return them to their place of origin.

In addition, Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 specifies in Article 11 how these samples for diagnosis are to be handled and supplements the Regulation with Annex VI, which explicitly states that:

Users who handle research and diagnostic samples shall take all necessary measures to avoid the spread of diseases communicable to humans or animals during the handling of the materials under their control, in particular by way of the application of good laboratory practice.

Furthermore, Annex VI of the forementioned regulation, stipulates that research and diagnostic samples may be kept as reference samples (point 4). Therefore, collections of genomic material have a direct legal basis in the Community Regulations on animal by-products, which allow their establishment and development.

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

Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council 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, establishes a procedure allowing, for the first time, the exchange of germinal products between gene banks (or confined establishments) in different Member States, with specific and more flexible rules than for exchanges between authorised germinal product establishments.

The conditions for authorising the movement are laid down in Articles 45, 46 and 47 of Commission Delegated Regulation (EU) 2020/686, and the definition of "*gene bank*" in Article 2.10 of this Regulation, are also particularly important.

<u>The main elements to be considered in the development of this exception are:</u>

1. Both, the establishments of origin and destination of the germinal products, must be gene banks authorised or recognised by the competent authorities for the development of *ex situ* conservation activities or the sustainable use of animal genetic resources.

2. The material must originate from endangered breeds and must not fulfil the requirements for the intra- Union exchange of germinal products between approved establishments, either in whole or in part.

3. The competent authority of destination must have previously authorised the consignment, specifying the health requirements to be complied with to prevent at least the spread of foot-and-mouth disease and infection with rinderpest virus.

4. The competent authority at the place of origin shall authorise the movement of the germinal products if the requirements of the three points above are met and shall issue a specific authorization for this purpose

5. The operator of the gene bank in the country of origin shall attach a self-declaration to the consignment and notify the competent authority at the place of destination in advance via TRACES.

Recommended procedure for applying the derogation to the movement of germinal products between two gene banks.

1. To apply this derogation, gene banks involved in the movement must first prove that they are authorised or recognised as gene banks:

- They are authorised or recognised as gene banks, as specified in Article 2.10 of Regulation (EU) 2020/686. Recommendations for the procedure to carry out such authorisation or recognition, can be found in Chapter 4.

- The material must come from an endangered breed, for which they should consult the list of endangered breeds drawn up by each Member State in accordance with Article 2. 24 of *Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding*.

In addition, both gene banks shall be registered as operators in the TRACES system under the chapter *'Germinal products*', the section *'Other establishment related with certain germinal products*' and the activity *'Gene bank in accordance with CDR (EU) 2020/686*'.

2. Once the above requirements are met, the gene bank in the Member State of origin should contact the competent authority in the Member State of destination (the competent authorities are registered in TRACES) to request prior authorisation for the movement of the germinal products. In is recommended to attach the following information to this application:

- Type and quantity of germinal products intended to be moved.

- Species and breeds of donor animals.

- Current location of the germinal products.

- Date of collection of the germinal products.

- Location of the donor animals of the germinal products at the time of collection.

- All available health information on the donor animals available to the gene bank.

- Identification system of the germinal products and information on marking of straws and other packages.

- Destination gene bank of the germinal products.

3. The competent authority of the Member State of destination shall request all information it deems appropriate to ensure that the germinal products do not present a risk for the spread of foot-and-mouth disease and rinderpest virus infection. To this end, it is

recommended to consult the information available on the WOAH website on these diseases in the country of origin or to request information from the competent authority in the country of origin to exclude the presence of these two diseases during the period of collection of the germinal products. If these two diseases were present in the country of origin during one of the collection dates and the health information provided by the gene bank of the country did not allow to conclude that the movement does not pose a risk, tests for the detection of pathogens may be requested on a sample of the stored doses to be moved (provided that the material to be moved is semen doses).

In addition to the two diseases listed above, the competent authority of destination may request information on as many listed diseases relevant to the species of donor animals of the germinal products as it deems appropriate. It makes sense that the same diseases that are considered in the regulations on intra-Community trade in relation to the establishments of origin of the donor animals pre- and post-collection quarantine and routine testing at semen collection centres (list of diseases in Annex I). For each of these diseases, the epidemiological situation in the Member State of origin at the time of collection of the germinal products must be considered when applying for additional requirements. Such additional requirements could include, in addition to the information from the tests on the donor animals themselves, if available, the testing of a sample of the doses to be moved for pathogens.

4. Once all health-related information has been collected and analysed, the competent authority of the place of destination should ensure that the establishment of destination is an approved/recognised gene bank and that the germinal products are used for *ex situ* conservation or sustainable use of an endangered breed in its territory. For this purpose, it would be advisable that the gene bank of destination prepares a report indicating the destination of the germinal products to be received and that it participates in the breeding programme of the endangered breed, approved in accordance with Regulation (EU) 2016/1012.

5. If the competent authority of destination considers that the requirements of Commission Delegated Regulation (EU) 2020/686 are met, it shall, on the basis of all above information, issue a written authorisation allowing the movement of the germinal products from the gene bank at the place of origin and containing the list of those germinal products.

6. With this authorisation, the gene bank at the place of origin shall request the derogation from the competent authority at the place of origin and attach the written consent of the competent authority at the place of destination.

7. Upon receipt of the derogation, the pre-notification (model in Annex IV) shall be made via TRACES by the gene bank in the Member State of origin. The consignment must be accompanied by a self-declaration of the gene bank operator containing the information referred to in Article 46, CDR (EU) 2020/686.

8. Finally, it would be advisable that the competent authority of destination supervises the germinal products received and verifies that they are used in accordance with the report submitted by the gene bank of destination.

In the case of gene banks with genomic material, the rules for exchange between Member States is laid down in Article 11 of Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009, which states that:

3. Operators may dispatch research and diagnostic samples which consist of the following animal by-products and derived products to another Member State without informing the competent authority of the Member State of origin in accordance with Article 48(1) of Regulation (EC) No 1069/2009 and without the competent authority of the Member State of destination being informed by means of the TRACES system and agreeing to accept the consignment in accordance with Article 48(1) and (3) of that Regulation.

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

PART A. Semen collections.

In the various studies that have been carried out, and thanks to the EUGENA database, it appears that semen collections are the most common material in gene bank, and so it is these that we will devote the most attention. The reasons why it is the most used material are due to the fact that it is easy to obtain and that there is a great technological development for its processing and storage, thanks to the fact that artificial insemination is widely used in many livestock species.

A.1 Semen collection centres.

As explained in Chapter 4, semen for intra-Community trade, and in many cases also for national trade, must be collected in pre-approved specialised establishments that meet strict requirements in terms of facilities, donor origin, quarantine, health testing, processing and storage of semen. Collection in these facilities and according to these general rules would be the ideal method, but as outline in Chapter 4, meeting these requirements would hinder the development of gene banks for a large number of livestock breeds, especially endangered breeds.

An alternative to establishments authorised for intra-Community or national trade would be the establishment of semen collection centres for the creation of gene banks with lower requirements for certain aspects of biosecurity, allowing the authorisation of semen donors for short periods of time, but sufficient to carry out collections that allow the creation of collections of reproductive material for the conservation of livestock breeds.

Those types of semen collection centres for the establishment of gene banks should comply with the same requirements for facilities as set out in Part 1, Annex I to Commission Delegated Regulation (EU) 2020/686.

The general requirements to be fulfilled by donors should be in line with those laid down in Article 16 of Commission Delegated Regulation (EU) 2020/686, including the requirements laid down in Commission Delegated Regulation (EU) 2020/688 for various diseases, which are described in the next section devoted to the collection of semen on farm. In addition, specific disease requirements per species should be laid down for the five main species, which could correspond to those laid down in Article 20(1)(a) for bovine; 21(1)(a) for porcine, 22(a) and (b) for ovine and caprine and 23(1)(a) and (b) for equine, all of which refer to Commission Delegated Regulation (EU) 2020/686.

It would be advisable for donor animals to fulfil requirements similar to those laid down in Article 16 of Regulation (EU) 2020/686:

a) they were born and have remained since birth in the Union, or have entered the Union in accordance with the requirements for entry into the Union;
b) they come from establishments in a country or zone thereof, or from establishments under the official control of the competent authorities of a zone thereof and which fulfil the animal health requirements laid down in Delegated Regulation (EU) 2020/688;
c) they have been identified in the accordance with requirements of Regulation (EU) 2019/2035;
d) for a period of at least 30 days prior to the date of the first collection of the material and during the collection period:
    I. they have been kept in establishments which are not situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for those animals;
    II. they have been kept in establishments where no category D diseases relevant for those animals have been reported;
    III. they have not been in contact with animals from establishments situated in a restricted zone referred to in point or from establishments which do not meet the conditions referred to in point b;
    IV. they have not been used for natural breeding (not in the case of genomic material);
e) they showed neither symptoms nor clinical signs of any of the category D diseases referred to in point d).II. or of the emerging diseases on the day of collection of the material;

In this case, semen collection centres for the constitution of gene banks, it would not make sense to establish any kind of derogation in case the holding of the origin of the donor does not meet the above requirements, as the movement of donor animals to the centre poses a risk that could be avoided by collecting the material on the holding's own premises.

It would also be advisable for donor animals to be subjected, prior to entry in the centre, to the established analytical tests prior to entry into quarantine in accordance with Article 24.a of the Commission Delegated Regulation (EU) 2020/686.

To facilitate the development of the gene bank, these animals should be exempted from the compulsory quarantine period and the tests to be carried out during quarantine. To ensure a proper health status of the collected material, the competent authority should also require that the donor is analysed at the time of semen collection (or at the beginning and or end of the collection period) and/or that the collected material is tested for the diseases described in the next section, if possible (see Annex III for a list of the available tests for ruminants and porcine semen).

A.2 On-farm semen collection.

On-farm semen collection has a number of advantages that make it the ideal for the efficient establishment of gene banks for breeds that are not commercially relevant. There is no need to transport the animal to a specialised centre and associated risks are avoided. There are also lower costs of feeding and housing. In also makes it easier for farmers to dispose of donor animals, as they do not have to part with them. Finally, enough material can be collected in one or few collection processes to contribute to the conservation of the breed.

For a holding to be used for the semen collection, it must fulfil health requirements regarding the presence or absence of certain diseases. Delegated Regulation (EU) 2020/688 can be used as a reference when defining these requirements. However, each Member State determines the requirements for farms, depending on its epidemiological situation. Below you will find a list of diseases that could be considered in such requirements:

1. Bovine:
   - Brucella abortus, B. melitensis and B. suis.
   - Mycobacterium tuberculosis complex.
   - Infection with rabies virus.
   - Epizootic haemorrhagic disease virus.
   - Anthrax.
   - Surra (Trypanosoma evansi).
   - Bluetongue virus (serotype 1-24).
   - Enzootic bovine leukosis.
   - Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis.
   - Bovine viral diarrhoea.

2. Ovine and caprine:
   - Brucella abortus, B. melitensis and B. suis.
   - Mycobacterium tuberculosis complex.
   - Infection with rabies virus.
   - Epizootic haemorrhagic disease virus.
   - Anthrax.
   - Surra (Trypanosoma evansi).
   - Bluetongue virus (serotype 1-24).
   - Ovine epididymitis (Brucella ovis).

3. Porcine:
   - Rabies virus.
   - Aujeszky's disease virus.
   - Anthrax.
   - Brucella abortus, B. melitensis and B. suis.
   - African Swine Fewer.

4. Equine:
   - Surra (Trypanosoma evansi).
   - Venezuelan equine encephalomyelitis.
   - Rabies virus.
   - Dourine.
   - Equine infectious anaemia.
   - Infection with equine arteritis virus.
   - Contagious equine metritis.

5. All Poultry species:
   - Salmonella Pullorum, S. Gallinarum and S. arizonae.
   - Mycoplasma gallisepticum and M. meleagridis.
   - Highly pathogenic avian influenza.
   - Newcastle disease virus.

6. Domestic chicken :
   - Avian Encephalomyelitis (AE).
   - Egg drop syndrome (EDS).
   - Infectious bronchitis.
   - Mycoplasma sp.
   - Avian influenza.

7. Domestic turkey
   - Avian Encephalomyelitis (AE).
   - Mycoplasma sp.
   - Avian influenza.

8. Domestic goose
   - Goose parvovirus (GPV, Derzsy disease)
   - Mycoplasma sp.
   - Avian influenza.
   - Domestic duck.
   - Mycoplasma sp.
   - Avian influenza.

   It is also worth paying attention to Escherichia coli and Staphylococcus species. These bacteria can not only cause infections but also impair sperm quality, potentially affecting the success of storage.

9. Rabbits:
   - Mixomatosis.
   - Rabbit Hemorrhagic Disease.

In addition, specific disease requirements per species should be laid down for the five major livestock species, which could be correspond to those laid down in Article 20(1)(a) for bovine; 21(1)(a) for porcine, 22(a) and (b) for ovine and caprine and 23(1)(a) and (b) for equine, all of which refer to Commission Delegated Regulation (EU) 2020/686.

However, if the above requirements are not met and the animal on which the procedure is to be carried out has a special genetic relevance, certified by the breeders' association managing the breeding programme for which it is registered, it may be used as a donor animal, subject to a prior risk assessment by the competent authority, which may impose additional health requirements or lay down specific rules for the use of the collected material in order to avoid the spread of any of the listed diseases.

It is desirable that the donor animal has not been in direct contact with other animals on the holding during the last 30 days to better ensure that the donor animal has not been used for mating.

If the competent authority considers that further information on the health status of the donors is necessary, depending on the epidemiological situation in the area where the donors are located, each donor animal could be required to undergo serological or pathogenic testing. When defining the tests series, it would be advisable to focus on the pathogens that are present in the area where the donor is located, where there is a risk of transmission through semen and which are already covered by Community legislation, e.g.:

1. Bovine:

- Infection with Mycobacterium tuberculosis complex (M. bovis, M. caprae and M. tuberculosis).
- Infection with Brucella abortus, Brucella melitensis and Brucella suis.
- Enzootic bovine leucosis.
- IBR/IPV.
- Bovine viral diarrhea (BVD).
- Bovine genital campylobacteriosis
- Trichomonosis.
- Epizootic haemorrhagic disease virus
- Blue Tongue Virus

2. Porcine:

- Infection with Brucella abortus, Brucella melitensis and Brucella suis.
- Aujeszky's disease.
- Classical swine fever (CSF).
- Porcine Reproductive and Respiratory Syndrome virus.

3. Ovine and caprine:

- Infection with Brucella abortus, Brucella melitensis and Brucella suis.
- Brucella ovis.
- Epizootic haemorrhagic disease virus
- Blue Tongue Virus

4. Equine:

- Equine Infection Anaemia
- Equine viral arteritis
- Contagious equine metritis

Since the donors have not undergone a quarantine period, an additional guarantee could be achieved by requiring an analysis directly on a sample of each collected ejaculate. The pathogens that can be detected in ruminant and porcine semen by PCR testing are listed in the Annex III (recommendation of the Laboratoire National de Contrôle des Reproducteurs, WOAH Collaborating Centre for Infectious Reproduction Diseases in Europe) and it is recommended that each competent authority specifies the test series for the pathogens of concern in its territory.

The requirements that apply to farms of origin or the collection of semen or the analytical tests on donors or their reproductive products can be adapted to the post-mortem collection of epididymal semen. This technique offers a last opportunity to obtain material from animals with high genetic relevance after death. In this case, the place of collection could even be a slaughterhouse, which must fulfil the requirements previously mentioned for farms.

The collected material can be processed both in stationary laboratories to which the ejaculates are sent after initial dilution, and in mobile laboratories. It is recommended that the processing fulfils the requirements set out in Annex III Part I of Regulation 2020/686. Such processing could even take place in semen collection centres authorised for intra-Community trade in accordance with the provisions of Annex I, Part I point 1.b) of Regulation 2020/686. According to this provision, semen collection centres may, under certain conditions, process ejaculates that do not meet the requirements for intra-Community trade.

If a mobile laboratory is used, it must have a specially equipped part of the vehicle consisting of two separate sections: one section for the examination and preparation of semen, which must be the clean section and another section for the accommodation of equipment and materials used in contact with the donor animals.

The collected semen should be temporarily in a dedicated cryogenic container, without coming into contact with other germinal products of different origin until all test results of the donor animal or the collected material, required by the competent authority of the country concerned have been obtained. As soon as the test results are available and satisfactory, the material can be stored for long-term conservation. It is recommended that

only germinal products with the same health status are stored in the same container, regardless of the species origin or nature of the material in question, to rationalise the use of storage containers and the cost of the liquid nitrogen used in them.

An additional safety guarantee would be given if the material is kept in isolation for a longer period of time (e.g. 6 months), with the farm of origin of the material being monitored to detect if any of the diseases that could be transmitted through the use of the collected germinal products occur during this period.

If any of the above tests are positive, the collected material is hygienically destroyed and the cryogenic container is disinfected in accordance with Animal By-products Regulation. Notwithstanding this, it is recommended that if the officially recognised breeders' association certifies that the donor animal is of high genetic relevance, the competent authority may authorize its long-term storage, for which the following requirements may be imposed:

1. Special attention must be taken to ensure that the positive test results are accurately reflected in the records and gene bank data base (see Annex II).

2. Storage must be carried out in such a way that it does not come into contact with other material whose health tests fulfil the specified health requirements.

3. The stored material may only be used in an extreme emergency, e.g. to restore an extinct breed or to reverse serious losses of genetic variability in the population maintained *in-situ*.

4. The use of this material shall be carried out using techniques that prevent the transmission of diseases detected in semen and always with the prior authorisation of the competent health authority.

PART B. Embryos and oocytes.

Although embryo and oocyte collection is less common, due to its greater complexity and cost, it is a technique that allows the complete conservation of the entire genome of a breed (including the X chromosome in mammals), as successive backcrossing in several generations are not required to recover a breed.

For this material, the animal health rules governing intra-Community trade or the national rules inspired by them, do not provide for as many barriers as in the case of semen thus providing for the collection of embryos and oocytes take place outside specialized establishments, so that collection on farms or slaughterhouses by embryo production and/or embryo collection team is possible.

As in the case of semen collection, the health situation of the farms /slaughterhouses where the collection takes place should be first determined. To this end, the epidemiological situation of the area in which the farm is located must be analysed to establish which diseases should not be present. When establishing these requirements, the diseases already described in the previous section should be considered and, as with semen collection, some

exceptions to these requirements should be allowed if the genetic value of the animal is high and is recognized by the approved breeder's association.

As regards the requirements for donor animals on farms, they must have been clinically examined by the veterinarian team or a team member and certified to be free of symptoms or signs of any of the category D diseases relevant to the animals on the day of embryo/oocyte collection.

If the holding of origin is free from any of the above diseases, the rules for embryo/oocyte donors as laid down in Delegated Regulation (EU) 2020/686 may be followed. Therefore, it would only be necessary to perform analytical tests on donor animals of the following species:

1. Porcine: Female donor pigs for embryos collected in vivo should be serologically tested twice at least 21 days apart with negative results for infection with porcine reproductive and respiratory syndrome virus, the second test being carried out within 15 days prior to embryo collection.
2. Equine: The donor mare of embryos/oocytes should:
   - be subjected with negative results, to an agar-gel immuno-diffusion test (Coggins test) or an ELISA test for equine infectious anaemia carried out on a blood sample taken not earlier than 14 days after the beginning of the period of at least 30 days referred to in point (a) and not later than 90 days before the collection of oocytes or embryos.
   - be subjected to a pathogen identification test for contagious equine metritis (Taylorella equigenitalis), which is carried out with negative results on at least two samples (swabs) taken from the donor animal, which must in no case be earlier than 7 days (systemic treatment) or 21 days (local treatment) after any possible antimicrobial treatment of the donor animal.

If the farm is not free from any of the above diseases, the competent authority may require the donor animal to be tested for those disease, and the washing fluids resulting from the processing of the embryos/oocytes may also be tested.

In the case of collections in slaughterhouses, these establishments should fulfil the requirements set out in Part 3 of Annex III to Regulation (EU) 2020/686.

When processing oocytes and embryos, the requirements in Parts 2, 4 and 5 of Annex III to Regulation (EU) 2020/686 should be fulfilled. The embryos and/or oocytes should be temporarily stored until the analysis of the donor animals and/or washing fluids is received (if applicable). The same rules apply for authorisation for long-term storage for semen.

The requirements that apply to the farms of origin or collection and the analytical testing of donors can be applied to the post-mortem collection of oocytes, ovaries or other tissues for embryo production.

PART C. Technical recommendations for granting specific authorizations for emergency collection and storage of germinal products not matching EU or national health requirements.

Stamping out strategies, e.g. culling of infected animals and all likely contaminated livestock is a proven and effective tool for the control of animal infectious diseases, besides vaccination and alternative mitigation strategies. However, the speed and the scope of stamping out actions applied to all animals from a given species in reported infected areas, may result in lawful prescription of culling of most or all live animals from a given endangered breed.

C.1. Alert system and evaluation of needs.

We recommend national competent authorities to set up a formal or informal (e.g. persons in charge) official alert system to add to the management of stamping out actions a systematic evaluation of the impact of stamping out actions onto breeding programmes, with a specific focus on endangered breeds. This impact analysis may be organized alongside regular impact analysis of stamping out policies on livestock production. National (or international) breeding animals census and geographical distribution figures (including FAO mapping tools for animal genetic resources, or national census data) may help in the quick identification of endangered breeds effectively threatened by stamping out policies under consideration.

Given the specific health risks that granting an emergency collection and storage authorization would entail, the first element to be analysed is whether the risk of extinction is real and whether there are no other possible alternatives for the conservation of the breed. To carry out this assessment, the recognized breeders society that carries out an approved breeding programme for the breed under threat, must be consulted in order to assess whether the outbreak of the disease corresponds to the breed's distribution area. Likewise, it must be assessed if the existence of a collection of safe material previously stored in a gene bank before outbreak would allow the recovery of the breed. After both analyses and considering the costs of managing specific risks attached to contaminated samples, if there is a viable alternative, the collection of material from contaminated areas may not be considered as a case for derogation allowing emergency collection of relevant genetic resources.

C.2. Optimized emergency collection authorization and biosecurity measures.

Once it has been established that the collection and storage of the material is essential for the conservation of the breed, it must be the recognized breeders society that determines which animals are the most valuable from a genetic point of view. If their health situation allows it, the collection must focus on these animals, so that the number of collections is the minimum necessary to conserve the greatest genetic diversity. An animal health and breeding expert may be involved to optimize an appropriate donor sampling and collection strategy, minimizing the risks of germinal products contamination (incl. farm localization,

donor age and vaccination status for the target pathogen) while maximizing the breeding value of emergency collection (donor genetic diversity, number of germinal products collected).

Emergency collection must be organized enforcing biosecurity measures, taken to the extreme so that the collection procedure does not pose a risk of disease transmission to other farms or to the personnel in charge of them, in case of zoonoses. Authorization granting would usefully set emergency collection actions to the enforcement of these biosecurity requirements.

In addition to taking samples to analyse the presence of the pathogen causing the outbreak in the donor or in the germinal products, samples must be taken to analyse the presence of any other disease of relevance to the species in question from those described in section A.2 of this Annex I.

Storage of reproductive and non-reproductive samples from emergency collection actions must be carried out in such a way that it does not come into contact with other material whose health tests fulfil the regular national or EU specified health requirements. Sealed containers, as High Security Straws can be a recommended storage option, when we know the existence of proven sanitary risks.

Special attention must be taken to ensure that the test results are accurately reflected in the records and gene bank data base, including the origin of the material in a farm affected by an outbreak.

C.3. Specific framework of authorization for the use of emergency collection reproductive material

The stored reproductive material from emergency collection may only be used in the case of a demonstrated sustained need after outbreak, and in the absence of alternatives, e.g. to restore an extinct breed or to reverse serious losses of genetic variability in the population maintained in-situ. The use of such reproductive material would be always further subjected to the prior authorisation of the competent health authority, and conditioned to:

- donor reproductive and non-reproductive sample test results at collection time.
- other animals test results at collection time.
- the use of techniques that can prevent or decrease the transmission of diseases detected in semen.
- germinal product recipient confinement and testing, and complementary quantitative and time limitations of use, whatever deemed necessary to control shedding of pathogens of concern.

PART D. Technical recommendations for granting specific authorizations for extended storage of old samples of germinal products not matching EU or national health requirements.

In view of the presumed utility of this historical material, and the need to limit the risk of spreading disease, the possibilities and conditions for the storage, release and use of such material should be officially laid down in regulations by the competent authorities.

It is recommended that the following elements should be considered when establishing regulations for ancient material to maximise the safety of the use of these germinal products in living populations:

- collection of all available information on the sanitary status of the collected material and the health status of the donors (epidemiological information in the country in the year of collection, origin of the material (farm or AI centre), applicable regulations, test on the donors).

- optional testing of the stored material for certain diseases in accordance with the regulations in force for the species and country concerned and the epidemiological situation at the time of collection. The available tests for pathogens in ruminants and porcine are listed in Annex III.

- it is recommended that a risk assessment should be carried out on the basis of information collected by the competent authorities. The storage of that material should also be clearly defined in the regulations, in this sense the following requirements are recommended:

1. Storage must be carried out in such a way that it does not come into contact with other material that fulfils the applicable animal health regulation.

2. Particular attention must be paid to proper labelling – first for the old material, then of the storage location and in databases (gene bank records).

3. It is recommended that only germinal products with the same health status are stored in the same container, regardless of the species of origin or type of material concerned, in order to rationalise the use of storage tanks and the cost of the liquid nitrogen used in them.

If the historical material test is positive, the collected material will be hygienically destroyed in accordance with the animal by-products Regulation, and the cryogenic container will be disinfected. Notwithstanding the above, it is recommended that if the officially recognised breeders' association recognises the genetic relevance of the donor animal, the competent authority may authorise its long-term storage, for which the following requirements may be imposed:

1. Special attention must be taken to ensure that the positive results of the test are accurately reflected in the gene bank records.

2. Storage must be carried out in such a way that it does not come into contact with other material whose health tests meet the specified health requirements.

3. The stored material may only be used in an extreme emergency, e.g. to restore an extinct breed or to reverse serious losses of genetic variability in the population conserved in-situ.

4. The use of said material shall be carried out using techniques that prevent the transmission of diseases detected in semen and always with the prior authorisation of the competent health authority.

The stored material complying with their specific regulations, may only be used for the conservation and sustainable use of breed that are under the control of the breeders' association that manages the breeding programme of the breed. Prior authorisation from the competent authority could be obtained before using the historical material, including an analysis of the impact of use of the material on the population.

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

Gene banks, in case of collecting germinal products on farm or storing old material, may have to manage a larger set of animal health requirements or conditions than regular commercial germinal products storage centres. An extensive animal health data collection system is highly recommended, beyond regulatory compliance, to support and extend the safe use of gene bank samples.

Part A. Objectives of Animal Health Documentation System recommended for gene banks.

A.1. Identify animal health qualification levels.

Gene banks, with reference to collection, processing, storage conditions, and use of samples may need to manage one or more of the following germinal products health guarantee levels:

- EU exchange level (EU Animal Health Law-approved Centres for germinal products exchanges), all the samples can comply with Commission Delegated Regulation (EU) 2020/686.
- National legislation approved germinal product collection stored, including the provision for Article 45 Commission Delegated Regulation (EU) 2020/686, when a national level health standard is enforced by the national legislation, and when all the gene bank samples comply with this national standard.
- Samples not matching either EU/national standards, when part of health information is missing (e.g. old samples not matching health standards in force).
- Samples not matching either EU/national standards, when some health conditions are not satisfied: samples collected as emergency backup during outbreaks from contaminated areas, old samples from known contaminated donors regarding newly tested diseases.

In the case of germinal products, it is important that the marking of material obtained under any national regulation for gene banks is clearly differentiated from that which can be marketed for intra-Community trade.

Gene bank samples animal health documentation:

- is required to demonstrate compliance to EU or national level health standards for samples collected, stored and distributed under either EU or national regulations.
- may support specific *ad hoc* collection, storage and use authorization for samples not matching either EU or national animal health regulations. The extension and the quality of documentation of such samples will condition if and how such samples can be safely used, and if and how a specific authorization of storage or use of specific samples may be delivered.
- in all cases, considering the long-term value of gene banks collections, and the regular updates of health regulations, a proactive investment of gene banks in health data documentation(including systematic animal health documentation of farms when on farm collection is used), will maximize opportunities for safely using genetic valuable samples in the future.

A. 2. Support EU or national legislation compliance.

The development of national regulations for gene banks requires that gene banks can reliably ensure compliance with the requirements set out therein. The basis for achieving this objective is that they have an information and documentation management system that provides the data necessary to correctly categorize and assess the risk of the collected material and this is equivalent to the products obtained through EU regulations or other national regulations.

The actual minimum animal health documentation content to support regulation compliance is therefore explicitly defined by EU or national regulation requirements. However, to allow for future regulatory framework revisions, this system must collect as much relevant information as possible on the donor animals and their health status, as well as the analyses carried out on the donors or, where appropriate, on the material collected, including but not limited to the following:

- Place of collection.
- Date of collection.
- Farm of origin of the donor and its animal health status and records (vaccines, test results) in the 12 months previous and after the collection, if applicable.
- Diseases known to be present or absent in the region of origin in the 12 months previous and after the collection.
- Identification of the donor animal(s).
- Quantity of straws or other packaging produced.
- Where appropriate, antibiotics added to the germinal product.
- Description of the semen/oocyte/embryo treatment process, if applicable.
- When available, in addition, and recommended as following Annex I.A and I.B: analytical results of donor health test before/during/after collection time. e.g. analytical tests carried out on the donor animal in the 12 months previous and after the collection.

- Where appropriate, results of analytical tests on the collected material.
- when available, in addition, and recommended as a provision to match future health standards revision: access to donor material sampled before/during/after collection for health testing (donor reproductive - e.g. semen - or non-reproductive - e.g. serum - material).

A. 3. Prospective documentation of epidemiological context of gene bank germinal product samples

Any specific authorization of collection, storage as referred to in section 5.3 of these guidelines, or specific authorization of use of such samples as referred to in section 5.4, may only be granted on the basis of a risk assessment, that takes into account epidemiological information, traceability and analytical records, demonstrating an appropriate level of safety for the intended storage or use of this specific material.

The long-term storage of samples before use, which is a typical use case for gene bank samples (heading at long term conservation of genetic variability over space and time), demands a good collection of information, as it allows for **a retrospective assessment of the epidemiological context** of a given geographical area, and a given donor herd at the collection time. As an example, the loss of information from not testing donors when using on farm collection, may be balanced with the long-term retrospective qualification of donor herd, which could be known with a high certainty *a posteriori* under usual circumstances (sufficient density of species, regular monitoring of herds over extended time).

The health documentation of Gene bank will thus aim at **connecting a given germinal product sample with generally known and accepted health status qualification** of a given area, wherever possible assessed from official national and international monitoring (WOAH). Samples collected from donors located in farms, areas, officially qualified as free of a given pathogen **at collection time** (including an appropriate before and after that time) may be safely expected to be indeed free of this pathogen and safely used as regards this pathogen.

To ensure an efficient link between a given germinal product sample and the retrospective assessment of epidemiological status of a given premise/herd/donor, the key determinants of connections will be:

- the accurate recording and tracking of **collection time** and **collection location**, that information must be moved to sample identification and sample labelling.
- the accurate recording and tracking of donor identification.
- the exhaustive recording of any relevant event in relation with animal health status of the collection premises (including farm when collection is performed on farms) over collection time.

Part B. General recommendations for health data documentation by gene banks.

All information should be recorded by the gene bank and stored digitally on a long-term basis in order to be available at the time of use of the material. Gene bank samples health documentation will more efficiently support regulatory compliance, will more efficiently support *ad hoc* specific authorization delivery of collection, storage or use for non-standard samples:

- when sample traceability and health information is collected according to a quality management system, ensuring consistence, accountability and long-term persistence of this information.
- when using a relational database format to allow the comprehensive extraction and display of all linked and relevant information for each sample.
- when this information can be reviewed easily by animal health competent authorities, using any appropriate and proportionate system.
- when the format of this information (herd/farm identification) can be efficiently merged with corresponding terrestrial animal heath monitoring of epizootic infectious animals' diseases, national or WOAH based, and when critical time and location data can safely refer to a publicly documented epidemiological context.

Part C. Recommended health data to be collected by gene banks.

C.1. Germinal product sample (e.g. semen or embryo straw) documentation

Univocal identification and systematic recording of:

- donor identification, in accordance with Union animal health law on the identification and registration of animals of the species concerned. This information must be marked in the straw.
- collection time (day timestamp): as regards animal health documentation, collection time is a critical information which must be secured. Gene bank should be able to demonstrate and certify perfect tracking of collection time for all samples stored. Different batches collected at separate times from the same donor may come indeed with different health guarantees. This information must be marked in the straw.
- collection location (herd/premises official identification): collection location, especially when "on farm" collection is considered, must be precisely defined, wherever possible in accordance with official EU or national herds/farm register identification. Gene bank should be able to demonstrate and certify perfect tracking of accurate collection place for all samples stored. The identification of the location must be marked in the straw.

- sample reference marking and identification.
- processing and storage information (e.g. extender batch, open/closed format storage, storage tanks).
- sample health standard qualification, in accordance with the levels defined in part A.1 of this annex. This information must prevent the cross contamination with germinal product with lower standards health samples (for example: sample from emergency collection during outbreaks are processed and stored without allowing any contact with regular samples).

C.2. Donor documentation

- donor identification.
- exhaustive list of reproductive samples collected and stored from this donor over time, with identification of collection and location time, and reference to stock availability in gene bank or alternative storage (if possible).
- If available, exhaustive list of non-reproductive (blood, serum, faces, tissues) samples collected and stored over time, with identification of collection and location time, and reference to stock availability in gene bank or alternative storage system.
- exhaustive list of donor life history health test results and corresponding donor sampling times, either performed by breeders or gene banks 12 months before/12 months after collection.
- Donor birth herd or last herd of donor before movement of donor animal to collection premises.

C.3 Collection premises documentation, when on farm collection is used.

- official herd location identification set in animal health legislation.
- animal housing conditions on collection premises (indoor/outdoor, including animal movements over pastures).
- biosecurity and isolation barriers from same species animals on collection premises (if any).
- Official health status of origin herds (e.g. when could be qualified as “free of”) as regards pathogens of interest 12 months before/12 months after collection.
- Register of vaccinations and any available health test results for pathogens of interest from any donor or non-donor on collection premises in the 12 months before the first collection/12 months after the last collection.

ANNEX III. AVAILABLE TESTS FOR THE DIRECT DETECTION OF PATHOGENS ON SEMEN

As compiled by Laboratoire National de Contrôle des Reproducteurs, WOAH collaborating centre for infectious reproduction diseases in Europe.

1. RUMINANTS

- Bovine Viral Diarrhea
- Border Disease
- Bovine Herpesvirus 1
- Blue Tongue Virus
- Smallenberg Virus
- Brucella
- Leptospira
- Coxiella burnetii
- Campylobacter fetus venerealis
- Tritrichomonas fetus
- Mycobacterium bovis
- Mycobacterium paratuberculosis
- Neospora caninum
- Listeria
- Mycoplasma bovis
- Epizootic Haemorrhagic Disease.

2. SWINE

- Porcine reproductive and respiratory syndrome virus.
- Aujeszky
- Classical Swine Fever
- African Swine Fever
- Brucella
- Parvovirus
- Porcine Circovirus 2
- Porcine epidemic diarrea virus.
- Leptospira
- Influenza
- Bordetella
- Haemophilus parasuis
- Salmonella
- Actinobacillus
- Mycoplasma hyopneumoniae
- Pasteurella Multocida T
- Coronavirus (GET/CVRP)
- Delta Coronavirus

ANNEX IV. MODEL OF ADVANCE NOTIFICATION.

EUROPEAN UNION **INTRA**

Part I: Description of consignment

I.1. Consignor
Name
Address
Country ISO Code

I.2. IMSOC reference

I.2.a. Local reference

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Country ISO Code

I.6. Operator conducting assembly operations independently of an establishment
Name
Address
Approval Number
Country ISO Code

I.7. Country of origin ISO Code

I.8. Region of origin Code

I.9. Country of destination ISO Code

I.10. Region of destination Code

I.11. Place of dispatch
Name
Address
Approval Number
Country ISO Code

I.12. Place of destination
Name
Address
Approval Number
Country ISO Code

I.13. Place of loading
Name
Address
Approval Number
Country ISO Code

I.14. Date and time of departure

I.15. Means of Transport

Mode	International transport document	Identification

I.16. Transporter
Name
Address
Approval Number
Country ISO Code

I.17. Accompanying documents
Commercial document reference
Date of issue
Country
Place of issue

I.18. Transport conditions
Frozen ☐ Ambient ☐ Chilled ☐

I.19. Container No / Seal No

I.20. Certified as
Germinal products ☐

I.21. For transit through a third country ☐
Third country ISO Code
Exit point BCP code
Entry point BCP code

I.22. For transit through Member State(s) ☐
Member State ISO Code

I.23. For export ☐
Third country ISO Code
Exit point BCP code

I.25. Journey Log

I.26. Total number of packages

I.27. Total quantity

I.28. Total gross weight

I.30. Description of consignment

Commodity	Species	Identification Number	Quantity	Nature of commodity

Identification Mark	Package count	Date of collection / production	Plant / Establishment / Centre

en / es 1 / 6

EUROPEAN UNION — Notification CERTAIN GERMINAL PRODUCTS

II. Health information

Part II: Certification

I, the undersigned hereby notify the movement of a consignment of germinal products described in Part I in accordance with Article 163(2) of Regulation (EU) 2016/429 of the European Parliament and of the Council and with Article 33, Article 34(b) or with Article 47 of Commission Delegated Regulation (EU) 2020/686 and confirm, based on the information from the operator, that:

II.1. the consignment consist of

(1) ☐ [germinal products to be moved for processing to a germinal product processing establishment and the consignment fulfils the animal health requirements laid down in Chapter 1 of Part III of Delegated Regulation (EU) 2020/686;]

(1) ☐ [germinal products to be moved after processing from a germinal product processing establishment and the consignment fulfils the animal health requirements laid down in Chapter 1 of Part III of Delegated Regulation (EU) 2020/686;]

(1) ☐ [germinal products intended for scientific purposes and the consignment fulfils the animal health requirements laid down in Article 44 of Delegated Regulation (EU) 2020/686. ;]

(1) ☐ [germinal products intended for storage at a gene bank and the consignment fulfils the animal health requirements laid down in Article 45 of Delegated Regulation (EU) 2020/686.;]

(1)(2)II.2. according to information from the operator, the germinal products described in Part I

(1) ☐ II.2.1. were tested for the following diseases on the date set out below with negative results:

Disease	Test	Date (dd.mm.yyyy)

(1) ☐ II.2.2. have been subjected to the following treatment _____ on the following date (dd.mm.yyyy) _____ ;II

EUROPEAN UNION — Notification CERTAIN GERMINAL PRODUCTS

II. Health information

Part II: Certification

Part I:

Box reference I.11: Indicate place of dispatch

Box reference I.12: Indicate place of destination

Box reference I.14: Indicate date of dispatch

Box reference I.19: Indicate the number of the seal applied to the transport container

Box reference I.30: Indicate the following information:

- Species of donor animals
- "Type" of germinal products - semen, oocytes or embryos
- "Quantity" - number of straws or other packages with the same marking
- "Identification mark" - marking applied on the straws or other packages
- Date of collection or production of germinal products
- "Approval or registration number of plant/establishment/centre" - place of collection or production of germinal products

Part II:

(1) Delete if not applicable.

(2) Applicable to germinal products for storage at gene banks. Complete if testing or treatment was carried out.

Certifying Officer/Official veterinarian

Name (in capital letters) — Qualification and title

Date of signature — Signature

Stamp