International Standard

ISO 16677-1

First edition
2025-01

Biobanking — Germplasm —

Part 1: Agricultural animal species

Biobanques — Germoplasme —

Partie 1: Espèces animales agricoles

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Reference number
ISO 16677-1:2025(en)

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Published in Switzerland

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 16, *Horizontal methods for molecular biomarker analysis*, in collaboration with Technical Committee ISO/TC 276, *Biotechnology*.

A list of all parts in the ISO 16677 series can be found on the ISO website.

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Introduction

The protection of the genetic biodiversity of all living species is globally important. Although there is considerable social, economic and scientific guidance at the national and international levels, including protocols and treaties regulating the movement and development of species, these do not provide practical documents for individuals and organizations to ensure the stability of the future of genetic resource management. Biobanking germplasm is a major component of conserving animal genetic resources.[1] Effectively constructing such biobanks requires the ability to conserve various germplasms through cryopreservation, a robust information technology infrastructure and an understanding of how to evaluate genetic resources to facilitate use of the collection.[2]

A variety of animal genetic resource collections exist worldwide, as can be seen in the Domestic Animal Diversity Information System (DAD-IS) from the Food and Agriculture Organization (FAO) of the United Nations, performing a wide range of biobank activities for the short- and long-term needs of research communities and industry.[3] Animal biobanking is a comprehensive and dynamic process that can span decades of continued sample curation and evaluation of the collection, while projecting future needs[4]. The goal of a germplasm biobank is to provide society with a broad range of genetic options for different types of future use. Within the agricultural sector, the maintenance of sufficient genetic diversity of animal germplasm for future use faces challenges (e.g. low number of national and regional biobanks, animal health restrictions, lack of technology for wild species).[5][6] Therefore, stakeholder engagement can help to determine the scope of biobank activities and associated strategies to support food security.[7]

This document provides guidance for animal germplasm biobanks that can be used for the conservation of animal genetic resources for food and agriculture, and harmonization of strategy to capture the existing genetic diversity for future use.[6][8]

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Biobanking — Germplasm —

Part 1: Agricultural animal species

1 Scope

This document specifies requirements for the biobanking of animal germplasm, e.g. semen, embryos, oocytes, gonads and related tissue, including reception, preparation, quality control, storage and distribution.

This document is applicable to animal species for food and agriculture.

This document is applicable to all organizations performing biobanking of animal biological material and associated data, such as public or private gene banks and germplasm livestock collections centres.

NOTE International, national or regional regulations or requirements, or combinations of them, can also apply to specific topics covered in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 20387:2018, *Biotechnology — Biobanking — General requirements for biobanking*

ISO/TS 20388:2021, *Biotechnology — Biobanking — Requirements for animal biological material*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20387 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
agricultural animal species
all animal populations used for food and agricultural production

3.2
associated data
any information affiliated with *biological material* (3.6) including but not limited to research, phenotypic, clinical, epidemiologic, genetic, taxonomic, systematic, geographic location and procedural data

Note 1 to entry: Associated data can include metadata.

[SOURCE: ISO 20387:2018, 3.3, modified — “genetic, taxonomic, systematic, geographic location” and Note 1 to entry added.]

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3.3
biobank
legal entity or part of a legal entity that performs *biobanking* (3.4)

3.4
biobanking
set of activities, including acquisition, *storage* (3.15) and retrieval of defined *biological material* (3.6) and *associated data* (3.2), with the potential inclusion of one or more of the following: collection, *processing* (3.13), preservation, testing, analysis, distribution, destruction and disposal

3.5
biodiversity
variability among living organisms on the earth, including the variability within and between species, and within and between ecosystems

3.6
biological material
any substance derived or part obtained from an organic entity such as a human, animal, plant, microorganism(s) or multicellular organism(s) that is(are) neither animal or plant (e.g. brown seaweed, fungi)

Note 1 to entry: For this document, biological material applies only to animals and derivatives thereof.

Note 2 to entry: For this document, biological material can refer to the whole animal.

[SOURCE: ISO 20387:2018, 3.7, modified — Notes 1 and 2 to entry added.]

3.7
biosafety
practices and controls that reduce the risk of unintentional exposure or release of *biological materials* (3.6)

[SOURCE: ISO 35001:2019[9], 3.22]

3.8
cryopreservation
act to prevent or retard biological or physical deterioration of *biological material* (3.6)

[SOURCE: ISO 20387:2018, 3.34, modified — "cryopreservation" replaced "preservation".]

3.9
donor
organic entity, such as a human, animal, plant, etc., from which the *biological material* (3.6) and/or *associated data* (3.2) is collected for *biobanking* (3.4)

3.10
genetic resources
genetic material containing functional units of heredity (e.g. DNA or RNA), or elements thereof (e.g. mRNA, mtDNA), that can be used for propagation and reproduction

3.11
germplasm
biological material (3.6) derived from germ cells, somatic cells or stem cells used in sexual reproduction or assisted reproductive technologies

[SOURCE: ISO/TS 20388:2021, 3.10]

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3.12
material transfer agreement
MTA
documented agreement governing the transfer of *biological material* (3.6) and *associated data* (3.2) between a *biobank* (3.3) and a recipient

Note 1 to entry: An MTA document contains information about the *in situ* origin or the source of the biological material and associated data, information about the provider and recipient, and information that defines the limits of the use of the biological material and associated data.

Note 2 to entry: An MTA can also be associated with a biological material being deposited to meet the need of its depositor country/country of origin, particularly those that are the parties of the Convention of Biological Diversity (CBD) and Nagoya Protocol (NP).

3.13
processing
performing any activity on *biological material* (3.6) and *associated data* (3.2) during all stages of the life cycle

3.14
sample
small portion or quantity, taken from a population or lot that is ideally a representative selection of the whole

Note 1 to entry: A sample can be made up of one or more sampling units.

Note 2 to entry: A sample can be the whole in its entirety.

[SOURCE: ISO 16577:2022[10], 3.3.72, modified — Note 2 to entry added.]

3.15
storage
maintenance of *biological material* (3.6) under specified conditions for future use

3.16
owner
individual, legal entity or organization holding the legal title to the *germplasm* (3.11) or related tissue, or both

Note 1 to entry: The owner can also be the provider.

4 General requirements

4.1 General

The biobank shall meet the requirements described in ISO 20387, in addition to those in this document. ISO/TR 22758[11] can be used as additional reference for the implementation of ISO 20387.

The conservation of animal genetic resources for food and agriculture shall be undertaken to:

— maintain domestic animal biodiversity;

— ensure maintenance of breeds;

— anticipate environmental changes;

— facilitate research and training.

In situ conservation, *ex situ* conservation, *ex situ-in vivo* conservation and cryopreservation are appropriate strategies for biobanking with a goal of genetic conservation. The biobank shall develop an action plan involving one or more of these strategies to ensure diverse representation free of induced genetic drift.

The biobank shall prepare, implement and document procedures for the reception, preparation, cryopreservation, storage and distribution of animal germplasm. Personnel performing activities encompassing these procedures shall receive appropriate and relevant training.

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4.2 Legal and ethical

4.2.1 General

International regulations and agreements, national, regional and local laws, and regulations affecting animal germplasm, its transport, storage and distribution should be consulted and understood prior to beginning animal germplasm biobank activities to prevent potential interference or interruption.[12]

The biobank shall have animal germplasm resource policies that are consistent with international, national, regional and local practice that is accepted or regulated, or both.

The biobank shall retain documented information that is relevant to compliance with national and international legislation. This can include evidence of:

— approval by an ethics committee when needed;

— compliance with health and safety requirements;

— compliance with quarantine requirements;

— compliance with intellectual property rights;

— agreement or legally binding documents outlining the conditions for data access, exchange and distribution of conserved biological material.

Annex A provides examples of information that can be considered as evidence of compliance.

4.2.2 Animal welfare

The collection of biological material from live animals shall comply with recognized animal welfare practice. The biobank shall be aware of and able to demonstrate compliance with applicable animal welfare requirements. The World Organization for Animal Health (WOAH, formerly OIE) has developed an international terrestrial code that includes provisions for animal health, animal welfare and trade practices associated with animals and animal production, see Reference [13].

NOTE ISO/TS 34700[14] provides guidance for developing an animal welfare management plan.

4.3 Health and safety

4.3.1 General

Germplasm samples shall be handled properly and classified with their health status to prevent them from becoming a source of disease for animals and humans. The health status of germplasm samples is determined based upon the certifications required by exporting countries and the endemic conditions of the donor and recipient nations. Health status can be classified either with the presence or absence of notifiable diseases endemic to the sample origin or actual disease testing.

The biobank or the legal entity of which it is a part shall ensure that health and safety procedures conform to ISO 20387:2018, 6.2.1.5.

The biobank shall define the appropriate biorisk management for its collections.

NOTE Additional guidance on risk management can be found in ISO 35001[9] and the WHO Biosafety Manual Version 4[15].

The biobank shall ensure that risks to human health are managed effectively for preventive and protective measures. The biobank shall ensure that all personal protective equipment (PPE) is functioning properly and free of contamination before use. The biobank shall provide required PPE and ensure that it is easily accessible (see ISO 45001[16]).

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4.3.2 Personnel safety

A personnel health surveillance policy, according to anticipated zoonotic exposure and risk, shall be established and implemented.

PPE required to mitigate biorisk according to the organization's biorisk management system shall be available to personnel. It shall be used when collecting, transporting, processing and storing samples of animal origin. Personnel shall be medically examined periodically according to exposure and risk (see ISO 45001[16]).

4.3.3 Chemical safety

The biobank shall establish, document and implement policies and procedures concerning the storage, handling, use and disposal of chemicals, taking into account the relevant regulations of each country or region in which the biobank operates. Special attention should be given to facilities and securing devices for safely handling, storing and using liquid nitrogen.

Handling chemicals related to biobank activities can include, but is not limited to, extraction, synthesis, industrial production, transportation, use and disposal.

The safety data sheet (SDS) for all chemicals used by the biobank shall be prominently displayed or readily available.

5 Reception

5.1 When the biobank is responsible for the germplasm collection, ISO/TS 20388:2021, 5.1, 5.2.1, 5.2.2 and 5.2.9, shall be followed.

5.2 For the reception of biological material and associated data, the applicable requirements of ISO 20387:2018, 7.3.2, shall be followed.

5.3 The biobank shall retain records of shipment including, but not limited to, provenance information such as sender, provider, owner of the material, date of receipt, material description and quantity, etc. The biobank shall define the provenance information required for submission with biological material and associated data and share this data with providers.

5.4 The biobank shall define the acceptance criteria of biological material and associated data considering the fitness for purpose. It shall verify them upon receipt, which shall include at least the container integrity and the volume of liquid nitrogen inside the container, when applicable, in accordance with ISO 20387:2018, Annexes A and B.

5.5 The biobank shall establish procedure(s) and agreement(s) for receiving biological material and associated data in compliance with regulatory and ethical requirements, e.g. MTA, Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

5.6 The biobank should have a secure, designated transition area to hold incoming samples until legal, ethical documentation, biorisk and quality compliance of the biological material and associated data have been assessed and managed.

6 Preparation and cryopreservation

6.1 For the preparation and cryopreservation of received germplasm, the applicable requirements of ISO 20387:2018, 7.6 and 7.8, shall be followed.

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6.2 The biobank shall define and document the preparation or cryopreservation methods, or both. The methods shall be validated or verified, or both, where possible, in accordance with ISO 20387:2018, 7.9. The preparation or cryopreservation procedures, or both, shall consider at least the following:

— germplasm type (semen, embryos, oocytes and somatic cells);

— temperature of processing and cryopreservation, and storage, including cooling rates;

— protective diluents, including cryoprotective agents when applicable;

— definition of the parameters for the samples to be stored (e.g. number of aliquots or subdivisions, container type, volume, number of containers per animal).

6.3 Critical parameters, such as timing, method of harvest and cell characteristics, shall be defined and documented to select samples for the preparation and cryopreservation process (see Annex B).

6.4 The biobank shall have quality control (QC) procedures in place to verify the critical parameters during the germplasm life cycle within the biobank, including QC approaches from acquisition to distribution or disposal (see Annex C).

7 Storage

7.1 For the storage of cryopreserved germplasm, the applicable requirements of ISO 20387:2018, 7.5, 7.7, shall be followed.

7.2 The biobank shall have storage facilities considering relevant biosecurity and biosafety requirements in accordance with the germplasm stored.

7.3 The biobank shall identify, document, monitor, record and control environmental conditions and access to the storage room (e.g. ventilation, oxygen levels, liquid nitrogen supply) without adversely affecting fitness for the intended purpose. For more information, see ISO 20387:2018, 6.3 and 6.5.

7.4 The biobank should implement a procedure for verifying the germplasm inventory at planned intervals, considering the germplasm type and critical parameters defined (see 6.4).

NOTE The uniqueness of the germplasm can determine the feasibility of performing an inventory verification procedure. For example, it is not feasible to thaw cryopreserved embryos due to the amount and cost to collect them or thaw cryopreserved semen from a rare breed with a very small quantity of aliquots.

8 Distribution

8.1 For germplasm distribution, the applicable requirements of ISO 20387:2018, 7.3.3 and Clause A.7, shall be followed.

8.2 The biobank shall have a procedure in place for distribution of germplasm and retain records related to each distribution. This procedure shall define the information needed in the distribution requests for the decision-making process on the release of the germplasm, including but not limited to:

— affiliation of the applicant (e.g. legal entity, organization);

— type and quantity of germplasm requested;

— purpose for which the germplasm and associated data will be used (e.g. research, breeding);

— regulatory consideration (e.g. the import permit, CITES requirement, Nagoya Protocol requirement, if the recipient country regulates entry of that germplasm).

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NOTE The decision-making process considers criteria for distribution, critical analysis of the request based on those criteria, validation of the information provided and ensuring that the biobank has enough germplasm in the collection to satisfy the request.

8.3 In all cases of germplasm exportation, the veterinary and sanitary requirements in the recipient country apply (e.g. quarantine rules and diagnostic testing).

NOTE Legal requirements can vary from country to country.

8.4 The biobank shall agree the details of the transport with the recipient, including storage conditions (e.g. temperature) for the continued maintenance of germplasm integrity and responsibilities within the chain of custody for all germplasm from point of dispatch to point of receipt.

8.5 The biobank shall provide pertinent germplasm-associated data to the recipient (e.g. electronic data in an accessible database).

9 Management of information and data

9.1 For the management of germplasm information and data, the applicable requirements of ISO 20387:2018, 7.10, shall be followed.

9.2 The biobank shall develop and document a data management plan (DMP). It shall describe the data and metadata to be collected and managed and shall outline the ruleset for data and metadata collection, entry, storage and sharing. The DMP shall include data integrity, security controls and backup system to prevent loss or corruption of data. The plan shall be reviewed periodically and should adhere to the FAIR principle (Findability, Accessibility, Interoperability, Reuse of digital assets).[17]

9.3 The biobank shall have an information system in place that supports the management, interoperability and traceability of germplasm and tissue samples information.

NOTE Germplasm and tissue samples information can include data from collection, if applicable, acquisition or reception to distribution, disposal or destruction.

9.4 The biobank shall assign a unique identifier, an unambiguous identity and location to the stored germplasm, and a minimum set of data and descriptors, i.e. the metadata matching the data and metadata ruleset.[18]

9.5 When addressing data security, the biobank shall consider both the physical risk of destruction of data (e.g. equipment failure, loss of electricity, fire) and the risks from hacking or from unintentional corruption of data through human error. Sensitive data and any personal information of the provider should be stored securely to protect them from loss or theft.

Sensitive data in germplasm biobanks are usually related to ownership rights and personal information such as the breeder's home or business address and other contact information. However, commercially sensitive data or confidential business information can also be associated with sample and animal data, especially when genomic information is stored, and should be accounted for in a data protection statement at the time of reception.

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Annex A
(informative)

Examples of evidence of compliance

NOTE Adapted from Reference [6].

Examples of information that can be considered as evidence of compliance include:

- document type:
  - memorandum of understanding;
  - mechanisms for enforcement;
- document validity (in general, a maximum of five years is recommended);
- information accompanying a sample:
  - animal identification (ID), breed, type of germplasm, country of origin;
  - phenotypic information, genotypic information;
  - number of samples per animal and per breed;
- health tests and the results:
  - animal ID, tests performed and results;
  - verification of health status;
  - if tissue has been collected and stored for future tests;
- germplasm viability:
  - post-thaw viability and quality scores at collection and receipt of materials in the host country and upon repatriation;
- expected storage and handling cost and who is responsible for paying the expenses;
- availability of any or all data to groups that are either party to or not party to the relevant agreement;
- physical conditions for storing samples (e.g. liquid versus vapour phase of liquid nitrogen);
- safety with respect to infrastructure and physical security of the stored germplasm;
- frequency or extent of monitoring samples by host and country of origin representatives and the reporting process;
- mechanisms for repatriating samples to the country of origin (e.g. shipping via commercial carrier or government vehicles).

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Annex B
(informative)

Potential elements to consider for storage processes

Table B.1 provides complementary information for criteria to select samples for the storage process based on critical parameters. The values are just examples used for main livestock species, and they can vary according to machines, e.g. computer-assisted sperm analysis, species and the thresholds values shall be defined by each Biobank.

Table B.1 — Potential elements to consider for developing storage processes

Germplasm type	Reference parameters	Critical parameters
Semen	Sperm motility with up to 30 %; velocity on average path (VAP) with up to 60 mm/s; normal morphology sperm with up to 70 %	Sperm motility with up to 5 %; VAP with up to 30 mm/s; normal morphology sperm with up to 50 %
Embryos	Morula and blastocyst with up to 50 % cellular material composing the embryonic mass	Morula and blastocyst with up to 25 % cellular material composing the embryonic mass
Oocytes	Oocyte with a homogeneous granulated cytoplasm and at least three layers of compact cumulus cells	Oocyte with a relative homogeneous granulated cytoplasm and at least one layer of compact cumulus cells
Gonads and tissues (skin)	Gonads and tissues without deterioration/damage marks	Gonads and tissues with deterioration/damage marks

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Annex C
(informative)

Germplasm quality control

Table C.1 provides examples of quality control for germplasm.

Table C.1 — Germplasm quality control

Germplasm type	Quality control	When
Semen	Sperm kinetics and morphology	At reception and after thawing the sample[a]
Embryos	Development stage and quality grade according to IETS[19]	Before cryopreservation
Oocytes	Oocyte morphology	Before cryopreservation
Gonads and tissues (skin)	Visual inspection	At reception or preparation

[a] Exceptions can be applied for rare samples or those with low semen quantity.

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