



**International
Standard**

ISO 16677-1

**Biobanking — Germplasm —
Part 1:
Agricultural animal species**

Biobanques — Germoplasme —

Partie 1: Espèces animales agricoles

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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*

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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.]

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]

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. [ISO 16677-1:2025](https://standards.iso.org/iso/16677-1:2025)

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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.

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.

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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]).