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# Biotechnology — Biobanking of parasites —

# Part 1: Helminths



PROOF

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Field Code Changed

This document was prepared by Technical Committee ISO/TC- 276, *Biotechnology*.

A list of all parts in the ISO- 18209 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~~www.iso.org/members.html.

## Introduction

The biological industry has been using helminths to treat diseases such as Crohn's disease, ulcerative colitis, auto-immune disease like allergic asthma, and even incurable disease like cancer. The industry is also developing anthelmintic drugs and rapid infection diagnosis methods.

A biobank that can fulfil the role as a platform for collecting, storing~~,~~ and distributing parasitic resources is of urgent need.

This document supports processes that maintain animal welfare, as it is anchored in the principle of the three Rs: to "Replace, Reduce and Refine the use of animals~~"[20].~~"[20].

This document deals with the management and operation of the biobank: Helminth, which can safely manage and supply uncontaminated parasitic resources for the biological industry to develop treatment of autoimmune diseases, parasite infection diagnostic tests, and anthelmintics.

In this document, the following verbal forms are used:

— ~~"~~"shall" indicates a requirement;

— ~~"~~"should" indicates a recommendation;

— ~~"~~"may" indicates a permission;

— ~~"~~"can" indicates a possibility or a capability.

# Biotechnology — Biobanking of parasites — —

# Part 1: Helminths

## 1 Scope

This document provides requirements for the biobanking of helminths as parasitic resources including the collection, safeguarding, classification, proliferation, preservation, storage, and distribution of helminths.

This document sets requirements for the quality of helminths and their associated data, the data collection, and safety management when handling the helminths as a source of human disease infection.

This document is applicable to all organizations performing biobanking with helminths used for research and development.

NOTE International, national or regional regulations or requirements, or multiple 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 15190:2020, *Medical laboratories — Requirements for safety*

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

ISO 21710:2020, *Biotechnology — Specification on data management and publication in microbial resource centers*

ISO 24088-1, *Biotechnology — Biobanking of microorganisms — Part 1: Bacteria and archaea*

ISO 35001, *Biorisk management for laboratories and other related organisations*

ISO 45001:2018, *Occupational health and safety management systems — Requirements with guidance for use*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements*

World Health Organization (WHO). (2020) *Laboratory Biosafety Manual* (4th ed.)

Meechan, P. K., & Potts, J. (2020) *Biosafety in Microbiological and Biomedical Laboratories* (6th ed.), Centers for Disease Control and Prevention (CDC)

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20387, and ISO 24088-1, 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~~https://www.iso.org/obp

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

**3.1**
**biobank**
**parasite resource bank**
legal entity or part of a legal entity that performs biobanking of *parasites* ~~(3.9)~~(3.8)

[SOURCE: ISO 20387:2018, 3.5, modified — The ~~additional~~accepted term "parasite resource bank" was added and the words "of parasites" were added to the definition.]

**3.2**
**cyst**
form~~,~~ in which *parasites* ~~(3.9)~~(3.8) are surrounded by resistant covers or membranes

**3.3**
**final host**
organism that nourishes a *parasite* ~~(3.9),~~(3.8), which undergoes a stage of reproduction from the final adult stage

**3.4**
**helminth**
relatively large multicellular invertebrate *parasites* ~~(3.9)~~(3.8)

Note 1 to entry: Helminth can be found in the gastrointestinal tract and other parts of the stomach as well as in other organs and parts of the body.

Note 2 to entry: Typical helminth include acanthocephalan, nematode and platyhelminth (monogenean, trematode, cestode).

**3.5**
**host**
organism that nourishes a *parasite* (3.8) and is either an *intermediate host* ~~(3.6)~~(3.6) or a *final host* ~~(3.3)~~(3.3)

**3.6**
**intermediate host**
organism that nourishes a *parasite* ~~(3.9)~~(3.8) during the larva stage

**3.7**
~~**legally controlled biological resources**~~
~~biological resources, which are managed by the relevant Central Administrative Organization, Act on the Prevention and Management of Infectious Diseases, Act on Bioethics and Safety, Act on Plant Protection, Act on the Prevention of Domestic Animal Infectious Diseases, Act on Foreign Trade, etc.~~

~~**3.8**~~
**minimum dataset**
**MDS**
collection of technical and scientific data digitized in specific fields of a database, which is necessary to distinguish unambiguously a particular biological material and provides a minimum amount of information available for each accession in a *biobank* (3.1)