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Biotechnology — Biobanking of parasites —

Part 1: Helminths

PROOF/ÉPREUVE

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Foreword

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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.

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].

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*

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

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

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

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

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

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

3.4
helminth
relatively large multicellular invertebrate *parasites* (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) or a *final host* (3.3)

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

3.7
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)

[SOURCE: ISO 21710:2020, 3.15, modified — Note 1 to entry was deleted; in the definition, "microbial material" was replaced by "biological material" and "an MRC" was replaced by "a biobank".]

3.8
parasite
organism that temporarily or permanently resides in the body of another organism and receives the necessary nutrients therefrom

3.9
parasite life cycle
life history stage of the parasite
chain of consecutive life stages, in which the growth of *parasites* (3.8) is divided into eggs, larvae and adults

3.10
recommended data set
RDS
collection of data that includes useful information for an improved description of the functions and properties of a biological material

Note 1 to entry: This includes optional data fields for use by the *biobank* (3.1) in the catalogue, when available.

[SOURCE: ISO 24088-1:2022, 3.17, modified — In the definition, “microbial material” was replaced by “biological material”; in the note, “microbial biobank” was changed to “biobank”.]

3.11
room temperature
temperature in the range of 18 °C to 25 °C

Note 1 to entry: The definition is given for the purposes of this document. Local or national regulations can have different definitions.

[SOURCE: ISO 20186-1:2019, 3.23]

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 can be used as additional reference for the implementation of ISO 20387.

Properly trained personnel shall carry out the sampling and identification of samples.

The biobank for helminths shall prepare, implement and document procedures for the preservation, identification, information provision, distribution, etc. of parasitic resources.

NOTE Annex A includes a visualization of the helminths management process within a biobank.

The biobank shall determine the optimal storage environment for its use, and ensure that sufficient equipment, facilities and funds should be secured to store parasitic samples until they are necessary.

The biobank shall establish an effective utilization plan for parasitic resources by defining the collection, pre-treatment, identification, preservation, storage and distribution of parasite resources and associated data.

The biobank shall define and document the scope of activities in accordance with this document. The biobank should insist on the suitability of this document only to the defined extent of banking activities.

4.2 Legal and ethical requirements

The collection of biological material from live animals shall comply with applicable animal welfare practice. The biobank shall be aware of and able to demonstrate compliance with applicable animal welfare requirements.

NOTE Additional guidance can be found in References [2] and [3].

National and international legislation can require the biobank to retain documented information. This can include:

— evidence of compliance with applicable health and safety requirements;

— parasite risk classification;

— quarantine requirements;

— intellectual property rights;

— international treaties;

— access and benefit-sharing including biological material and associated data access, exchange and transfer.

4.3 Health and safety

4.3.1 General

The biobank or the legal entity of which it is a part shall ensure that health and safety procedures are in accordance with ISO 20387:2018, 6.2.1.5. All procedures shall be performed according to the appropriate biosafety classification (see ISO 35001 and WHO 4th guideline[26]).

The helminth egg concentration index of irrigation water is closely related to human health protection, such as the risk of direct contact and the risk related to crop types. Since helminth eggs can adversely affect the human body through crops, irrigation water applied to crops is regulated by many countries. In this regard, sewage and wastewater from the laboratory handling parasites or biological material derived from them shall be treated appropriately for the water quality of irrigation water.

Since helminth eggs are different in shape and size, they can only be identified by properly trained personnel. The personnel shall be familiar with the work of the laboratory handling parasites or biological material derived from them.

Procedures for separating adults and larvae from the host's organs or separating them from the host's feces or sputum shall be established, implemented and documented. These procedures shall take all necessary safety procedures into account (e.g. ISO 15190).

When conducting an experiment to separate adults and larvae from the host's organs or to separate them from the host's feces or sputum, personnel shall wear appropriate personal protective equipment (gloves, gowns, eye protection, etc.) to prevent infection or transmission of infective forms and conduct personal hygiene.

The biobank shall prepare procedures to respond to incidents, exposures and accidents in accordance with the relevant parts of ISO 15190 and ISO 35001.

4.3.2 Chemical safety

The biobank shall be in accordance with ISO 15190 when handling chemicals.

The biobank shall establish, document and implement policies and procedures concerning the storage, handling, use and disposal of chemicals, taking into account the applicable regulations of each country or region in which the biobank operates.

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.

The biobank's laboratory, culture room, and sample room dealing with chemicals shall indicate physical and chemical hazards such as explosiveness, flammability, oxidation, etc. and health hazards shall be marked at the entrance.

4.3.3 Biosafety, biosafety levels and biorisk

The biobank should follow ISO 35001 or WHO 4th guideline[26] when handling biological material contaminated with pathogens.

The biobank shall ensure that risks to health are managed effectively, including consideration for preventive and protective measures. Personnel shall be medically examined periodically according to exposure and risk.

The requirements of the personnel health programme, including requirements for record management and confidentiality, shall be determined by a biosafety risk assessment.