TECHNICAL SPECIFICATION

ISO/TS 23105

First edition
2021-10

Biotechnology — Biobanking — Requirements for the biobanking of plant biological material for research and development

Biotechnologie — Biobanking — Exigences relatives au biobanking de matériels biologiques végétaux pour la recherche et le développement

Reference number
ISO/TS 23105:2021(E)

COPYRIGHT PROTECTED DOCUMENT

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

Published in Switzerland

Contents

Page

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 276, *Biotechnology*.

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

Biobanking of plant biological materials is fundamental for botanical and agro-ecosystem research, sustainable crop development and production, ensuring genetic diversity and conservation. Biobank biological material collection and accession management are strategic to optimizing plant genetic resources. A plant biobank obtains its accessions in different ways, e.g. from donors (principally researchers or breeders), by collecting the biological material from the field and by exchange with other plant biobanks. Biological collections encompass numerous biological material types, including frozen plant tissues, fluid preserved plant tissues or associated extracts or some or all of them. These collections often require specialized experts to curate and assemble the collection. Appropriate biological material processing and storage conditions are also needed to maintain high-quality collections and maximize the potential of positive outcomes. This document provides guidance on how to collect, process, store, track and distribute plant biological materials.

Standards are needed for the collection, preparation, preservation, transportation and storage of plant biological materials for academic institutions, non-profit organizations and commercial agronomic businesses. This document provides the specific requirements, guidelines and effective practices for biobanking plant biological materials based on the current and available technological and scientific knowledge.

Biotechnology — Biobanking — Requirements for the biobanking of plant biological material for research and development

1 Scope

This document specifies requirements for the collection, preparation, preservation, transportation, storage, distribution and disposal of plant biological materials and associated data.

This document is applicable only to biological material that can be used for further processing of biomolecules, e.g. nucleic acids, proteins and metabolites.

This document is applicable to all organizations performing plant biobanking for research and development.

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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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
associated data
any information affiliated with *biological material* (3.4) including but not limited to research, phenotypic, clinical, epidemiologic, phytosanitary certificate and procedural data

Note 1 to entry: Associated data can include metadata.

[SOURCE: ISO 20387:2018, 3.3, modified — "phytosanitary certificate" and Note 1 to entry have been added.]

3.2
biobank
legal entity or part of a legal entity that performs *biobanking* (3.3)

[SOURCE: ISO 20387:2018, 3.5]

3.3
biobanking
process of acquisitioning and storing, together with some or all of the activities related to collection, preparation, *preservation* (3.9), testing, analysing and distributing defined *biological material* (3.4) as well as related information and data

[SOURCE: ISO 20387:2018, 3.6]

3.4
biological material
<plant material biobanking> plant as a whole, or any substance derived or part obtained from the plant entity

3.5
dried spots card
card containing chemicals that lyse cells, denature proteins and protect nucleic acids from nucleases as well as from oxidative and ultraviolet damage; can be used to process plant *biological material* (3.4) homogenates

3.6
life cycle
consecutive and interlinked processes applied to *biological material* (3.4) and *associated data* (3.1) from collection, if applicable, acquisition or reception to distribution, disposal or destruction

Note 1 to entry: This term refers to the *biobanking* (3.3) life cycle only.

[SOURCE: ISO 20387:2018, 3.29]

3.7
plant genetic resource
genetic material of plant origin, containing functional units of heredity (e.g. DNA or RNA), or elements thereof (e.g. mRNA, mtDNA)

3.8
plant biobank

plant genetic resource bank
plant gene bank
plant BRC
legal entity or part of a legal entity that performs the process of acquisitioning and storing, as well as some or all of the following activities: collection, preparation, *preservation* (3.9), testing, analysing and distributing defined *plant genetic resource* (3.7) as well as related information and data

Note 1 to entry: “Plant BRC” stands for “Plant Biological Resource Center”.

3.9
preservation
act of preventing or retarding biological or physical deterioration of *biological material* (3.4)

[SOURCE: ISO 20387:2018, 3.34, modified — “act of preventing or retarding” has replaced “act to prevent or retard”.]

3.10
processing
performing any activity on *biological material* (3.4) and *associated data* (3.1) during all stages of the *life cycle* (3.6)

[SOURCE: ISO 20387:2018, 3.36]

3.11
rejuvenation
growth of a vegetative propagule

3.12
vegetative structures
whole or portion of a plant not including the seeds

Note 1 to entry: In the scope of this document, vegetative structures can include propagules.

4 General requirements

The biobank shall follow ISO 20387:2018, Clauses 4 to 7.

The biobank shall establish, implement and maintain a quality management system in accordance with ISO 20387:2018, Clause 8.

The biobank shall identify each biological material and associated data relevant to the application of this document.

The biobank shall have procedures addressing biobanking for each type of biological material (e.g. whole plant, seeds, tuber, bulbs, scion wood, leaf, root, DNA, RNA) and associated data. This includes processes such as collection, acquisition, reception, characterization/evaluation, storage, preparation, preservation, rejuvenation and distribution.

The biobank shall ensure the legitimate acquisition of biological material and its associated data, and the retention of any relevant documentation. If legitimate acquisition cannot be demonstrated, the biological material shall be discarded, according to documented procedures, and this shall be documented.

NOTE 1 Such documentation can relate to relevant documents such as international treaties and agreements, and a phytosanitary certificate or passport.

NOTE 2 Legitimate acquisition can refer to relevant regulation, permits or authorization.

The biobank shall ensure that biorisk management procedures (e.g. ISO 35001, WHO guidance[3]) for potential plant pests and pathogens are established, documented, implemented and maintained, as appropriate.

The biobank shall take measures to prevent cross contamination.

The biobank or the legal entity of which it is a part shall ensure that human health and safety requirements are established, documented, implemented and maintained. The level of safety training required shall be determined using a comprehensive risk assessment of the biological and chemical materials, processes and equipment that is handled (see ISO 20387:2018, 6.2.1.5).

5 Biological material collection

5.1 General

Where possible, the intended purpose or final use of the biological material and associated data shall be determined, either by the biobank alone, in response to end-user criteria or by the biobank in conjunction with the end user. If determined, the intended or potential purpose shall be documented.

5.2 Collection procedure

5.2.1 The biobank shall develop and implement documented biological material collection procedures appropriate for each type of biological material according to its biological nature and intended purpose, where known. The biobank shall define biological material acceptance criteria.

5.2.2 The collection procedure shall address requirements for authentication, minimum quantity, viability, stability and maintenance to satisfy the fitness for purpose, where known. The collection procedure shall also address the following aspects, including but not limited to:

a) biological material type;

b) fitness for purpose, where known;

c) total number and amount comprising each biological material per collection;

d) containers that are fit for purpose (e.g. closure integrity, composition);

e) equipment;

f) collection method;

g) quality criteria for each biological material (e.g. the quantity and quality of targeted analytes such as DNA, RNA or protein);

h) collection location(s) (e.g. by GPS), schedule, personnel and assignment;

i) stage of maturity of the biological material.

5.2.3 When developing collection procedures, the following information shall be evaluated for inclusion:

a) taxonomic information, vernacular names, morphological characters and habitat;

b) geographical distribution and known populations;

c) population size and identified number of propagules to be collected;

d) recognized identification system of propagules;

e) statistical demographics for collection;

f) physiological traits that are relevant for plant biological material sampling;

g) information on putative plant disease or associated pests;

h) historical collection information, the appropriate season and timing for collection, and environmental information such as climate and accessibility;

i) permits required for collection, transportation, export and import.

The evaluation result shall be documented.

5.2.4 The biobank shall identify risks associated with the collection procedure for each biological material and take appropriate feasible measure(s) to mitigate the risks according to the likelihood of occurrence and the possible impacts. It is up to the biobank or the legal entity of which it is a part, or both, to determine what measures are appropriate and feasible.

5.2.5 The biobank shall define and document information related to the biological material (see Annex B and ISO 20387:2018, 7.2.1.1, 7.2.1.2, A.2 and B.2).

5.3 Preparation of collection containers, tools, supplies, reagents and consumables

The tools for collection, such as instruments, consumables and personal protective equipment, should be prepared and checked prior to collection. Preparing a checklist before collection can help to ensure an uninterrupted and efficient procedure.