INTERNATIONAL STANDARD

ISO 21710

First edition
2020-11

Biotechnology — Specification on data management and publication in microbial resource centers

Biotechnologie — Spécifications relatives à la gestion et à la publication des données au sein des centres de ressources microbiennes

Reference number
ISO 21710:2020(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

The application of varied data forms in different microbial resource centres (MRCs) for in-house data management and publication is a major problem, which severely impedes efficient data exchange globally. It can also hinder depositors/users and potential users of MRCs from accessing their holdings and related information, and therefore impedes exploitation of microbial material and associated data in academia and bio-industries in the long run.

This document provides a set of data fields for data publication, aiming to improve data exchange of online catalogues among MRCs, by applying unique identifiers and a uniform data form. It also helps to facilitate subsequent access and benefit sharing based on microbial material and associated data.

This document also specifies requirements for data management and internal data quality control to improve the overall accuracy and reliability of data and information documented in MRCs, which is the basis of efficient data sharing and exchange.

Biotechnology — Specification on data management and publication in microbial resource centers

1 Scope

This document specifies requirements for data management and publication in microbial resource centres (MRCs) to enable consistent formatting, and a quality control workflow to improve the overall quality of data. It also provides recommendations for MRCs to improve data sharing and integration of microbial material and associated data.

This document is intended to facilitate procedures such as accessioning, acquisition, authentication, preservation, storage, and distribution, and can be used by MRCs, regulatory authorities, organizations, and schemes using peer-assessment to confirm or recognize the competence of MRCs in data management and publication

NOTE International, national and/or regional regulations or requirements 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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

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

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

3.1
accessioning
documenting the addition of a new *microbial material* (3.17) and/or associated data to an *MRC* (3.18)

[SOURCE: ISO 20387:2018, 3.1, modified — Replaced “biological” by “microbial”; “a biobank” was replaced by “an MRC”.]

3.2
acquisition
act of obtaining possession and/or custody of *microbial material* (3.17) and/or associated data

[SOURCE: ISO 20387:2018, 3.2, modified — Replaced “biological” by “microbial”.]

3.3
associated data
any information affiliated with *microbial material* (3.17) including but not limited to collection, taxonomic, deposit history and provider data

[SOURCE: ISO 20387:2018, 3.3, modified — Replaced “biological” by “microbial”, the coverage in the inclusion was modified to data management related categories.]

3.4
authentication
process by which *microbial material* (3.17) is characterized to a defined level of specification using appropriate technology/documentation to establish a conclusive basis for accepting the material as genuine

[SOURCE: ISO 20387:2018, 3.4, modified — Replaced “biological” by “microbial”.]

3.5
catalogue
systematically arranged list or record often including descriptive information

[SOURCE: ISO 20387:2018, 3.10]

Note 1 to entry: It can include printed and online catalogues.

3.6
deposit
act of transferring possession and/or custody of *microbial material* (3.17) and/or associated data from *depositor* (3.7) to *MRC* (3.18)

3.7
depositor
provider
person or entity from whom/which the *microbial materials* (3.17) and/or associated data is received or acquired

[SOURCE: ISO 20387:2018, 3.41, modified — Replaced “biological” by “microbial” and deleted “for biobanking” at the end.]

3.8
distribution
process of providing selected *microbial material* (3.17) and/or associated data to *recipient(s)* (3.24)

[SOURCE: ISO 20387:2018, 3.20, modified — Replaced “biological” by “microbial”; “/user(s)” was deleted.]

3.9
interoperability
capability to communicate, execute programs, or transfer data among various functional units in a manner that requires the user to have little or no knowledge of the unique characteristics of those units

[SOURCE: ISO/IEC 20944-1:2013, 3.6.1.24]

3.10
IRCC
international recognized certificate of compliance
permit or equivalent document issued at the time of access as the evidence that the *microbial material* (3.17) and associated data has been accessed in accordance with the decision to grant *PIC* (3.22), and that *MTAs* (3.19) have been established for the user and the utilization

Note 1 to entry: When available on the ABS Clearing-House of the Nagoya Protocol, an IRCC number can be attributed, which can be used as a reference number.

Note 2 to entry: This term is based on the Nagoya Protocol.

3.11
legacy microbial material and associated data
microbial material (3.17) and associated data acquired or received by the *MRC* (3.18) before the MRC has implemented this document

3.12
life cycle of data
all stages in the process of data usage from initial establishment to its discontinuation

3.13
MAA
material accession agreement
material acquisition agreement
contractual document between a *depositor* (3.7) and an *MRC* (3.18) in a material transfer process

Note 1 to entry: It documents basic data such as place and date of sampling in a standardized form, and specifies the role, rights, and duties of the depositor and MRC.

Note 2 to entry: MAA is synonymous to material deposit agreement (MDA). It is normally put in place by an MRC.

3.14
MAT
mutually agreed terms
contractual arrangements between a *provider* (3.7) of *microbial material* (3.17) and/or associated data, and a *recipient* (3.24)

Note 1 to entry: It sets out specific conditions for the fair and equitable sharing of benefits arising from the utilization of microbial materials and/or associated data, and that can also include further conditions and terms for such utilization as well as subsequent applications and commercialization.

3.15
MDS
minimum dataset
collection of technical and scientific data digitized in specific fields of a database, which is necessary to distinguish unambiguously a particular *microbial material* (3.17) and provides a minimum amount of information available for each accession in an *MRC* (3.18)

Note 1 to entry: Microbial materials, except for legacy microbial materials, cannot be inserted into the catalogue, if this information is not available.

3.16
metadata
data that defines and describes other data

[SOURCE: ISO/IEC 11179-1:2015, 3.2.16]

3.17
microbial material
any substance(s) derived or part obtained from a microorganism, and any complexes or association between microorganisms

Note 1 to entry: It comprises all prokaryotes (archaea and bacteria), some eukaryotic organisms (fungi, yeasts, algae, protozoa), any association between the latter (e.g. lichens), non-cellular entities (e.g. viruses), their replicable parts and other derived materials (e.g. genomes, plasmids, cDNA). It also includes some viable but not yet culturable microorganisms.

3.18
MRC
microbial resource centre
microbial biobank
microbial BRC
legal entity or part of a legal entity that performs biobanking of *microbial material* (3.17) and associated data

3.19
MTA
material transfer agreement
contractual documents between an *MRC* (3.18) and a *recipient* (3.24) in a material transfer process

Note 1 to entry: All the documents can be designated as MTA as long as they contain information about the *in situ* origin or the source of the microbial material and associated data, information about the provider and recipient, and information that defines the limits of the use of the microbial material and associated data

Note 2 to entry: An MTA can also be associated with a microbial 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).

3.20
patent deposit
service of MRCs for long-term preservation of *microbial materials* (3.17) for the purposes of patent procedure

Note 1 to entry: It is a special service of an MRC recognized as the International Depositary Authority (IDA) by the World Intellectual Property Organization (WIPO) for the purposes of patent procedures under the Budapest Treaty.

3.21
persistent identifier
unique identifier (3.27) that ensures permanent access for a digital object by providing access to it independently of its physical location or current ownership

EXAMPLE https://doi.org/10.1016/S0140-6736(20)30251-8 is an example of a persistent identifier.

Note 1 to entry: It is used in the context of digital objects that are accessible over the Internet. Typically, such an identifier is not only persistent but also actionable (e.g. URI).

[SOURCE: ISO 24619:2011, 3.2.4, modified — note 1 to entry was entirely replaced to describe the usage of this term.]

3.22
PIC
prior informed consent
permission of the country of origin to a user to access *microbial materials* (3.17) and/or associated traditional knowledge

Note 1 to entry: This term is based on the Nagoya Protocol.

3.23
preservation
act or activity to prevent or retard microbial or physical deterioration of *microbial material* (3.17)

[SOURCE: ISO 20387:2018, 3.34, modified — Replaced “biological” by “microbial”.]

3.24
recipient
user
person or entity to whom/which the *microbial material* (3.17) and/or associated data is distributed

[SOURCE: ISO 20387:2018, 3.44, modified — Replaced “biological” by “microbial”.]

3.25
safe deposit
service of MRCs for long-term preservation of *microbial materials* (3.17) with distribution restrictions at the discretion of the *depositor* (3.7)

Note 1 to entry: All information concerning the *deposit* (3.6) and the nature of the microbial materials are treated in the strictest confidence. Access to this type of microbial material is permitted only by documented request of the depositor.

3.26
storage
maintenance of *microbial material* (3.17) under specified conditions for future use

[SOURCE: ISO 20387:2018, 3.47, modified — Replaced “biological” by “microbial”.]

3.27
unique identifier
code that is associated with a single entity within a given system

Note 1 to entry: Such an identifier can establish an unambiguous relationship between each microbial material and its associated data.

[SOURCE: ISO 20387:2018, 3.50]

Note 2 to entry: It can include accession number and other local identifiers (local IDs) in the web-based context.

3.28
URI
Uniform Resource Identifier
compact sequence of characters that uniquely identify an abstract or physical resource

EXAMPLE http://gcm.wdcm.org/Strain_numberToInfoServlet?strain_number=LMG%2026135 is an example of an URI in the Global Catalogue of Microorganisms database hosted by WDCM.

Note 1 to entry: URI is a kind of *unique identifier* (3.17). It is used in the field of computer science.

[SOURCE: IETF RFC 3986[14]]

4 Data publication in MRCs

4.1 General requirements and recommendations for data publication

4.1.1 The MRC shall develop, make available and frequently update online catalogues to keep pace with the in-house database and display modifications of information in a timely manner.

4.1.2 The MRC shall disclose data associated with the microbial material in the catalogue in accordance with the agreed terms and conditions presented in the applicable documents (e.g. MTA, MAA) or other contracts, if any. It is presupposed that these documents are in accordance with applicable statutory and regulatory requirements.

4.1.3 The MRC shall not disclose sensitive and other restricted information regarding safe deposit and patent deposit in any form as specified by relevant contracts, if any.

4.1.4 When the depositor requests a delay in the publication of the associated data, the MRC shall enforce an agreed timeframe and conditions, and may release the data into the catalogue after it is expired.

4.1.5 The catalogues of MRCs shall contain indispensable service information including ordering, shipping information, and basic template documents such as forms and agreements to comply with

requirements associated with the handling and shipping of microbial materials, which should enable the efficient use and be user-friendly.

4.1.6 Public data of microbial materials documented in the catalogue of MRCs should be shared to public databases such as GenBank https://www.ncbi.nlm.nih.gov/genbank/, Global Biodiversity Information Facility (GBIF) http://www.gbif.org/, Catalogue of Global Genome Biodiversity Network (GGBN) http://www.ggbn.org/ggbn_portal/, WFCC Global Catalogue of Microorganisms (GCM) http://gcm.wdcm.org/, if appropriate.

4.1.7 The online catalogue of MRCs should facilitate search capacity across community databases to support extensive searches for multiple characteristics of microbial materials and improve diversity of information.

4.2 Data fields of catalogue

4.2.1 The MRC shall properly arrange an accession form for online submission to deposit a microbial material and associated data efficiently, and it should apply a machine-readable tabular format, if applicable.

4.2.2 The MRC should ensure the availability of an MDS, and the MDS should include all the following data fields given in A.2.1: a) accession number, c) organism type, d) status, e) biosafety and biosecurity, f) other restrictions, and A.2.2: c) history of deposit. The MRC should select all or part of the optional data fields according to specific circumstances as specified in Annex A.

4.2.3 The MRC should maintain a high quality and cross-referenced online catalogue to link the data to publicly available controlled vocabularies specified in Annex A and the authorized databases in accordance with 4.1.6 and 4.1.7.

4.2.3.1 The MRC should link each name of microbial material with publicly available nomenclature databases to facilitate data retrieval and accessing. The MRC shall indicate the changes of nomenclature in the printed catalogues.

4.2.3.2 The MRC should link each sequence (e.g. genomic, metagenome, cDNA, RNA and protein sequences) to publicly available databases.

4.2.3.3 The MRC should link bibliographic information including digitized literature and patent to publicly available databases and document the DOI numbers, if applicable.

5 Data management and data quality control

5.1 General

The data management of MRC shall be in accordance with ISO20387:2018, 7.10.

5.2 Requirements for in-house data management

5.2.1 The MRC shall establish, implement and maintain a data management system to ensure that the essential information is available in the database, e.g. the storage period and location of microbial materials, frequency of data update and backup, and review and inspection actions for the different categories of data.

5.2.2 The MRC shall establish and maintain a security system and implement a procedure for the management of data and related documentation to prevent access by unauthorized users, ensuring

