SLOVENSKI STANDARD
oSIST prEN ISO 17468:2022

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Mikrobiologija v prehranski verigi - Tehnične zahteve in navodila za vzpostavitev ali revizijo standardnih referenčnih metod (ISO/DIS 17468:2022)

Microbiology of the food chain - Technical requirements and guidance on establishment or revision of a standardized reference method (ISO/DIS 17468:2022)

Mikrobiologie der Lebensmittelkette - Technische Anforderungen und Leitfaden zur Einführung oder Überarbeitung von genormten Referenzverfahren (ISO/DIS 17468:2022)

Microbiologie de la chaîne alimentaire - Exigences et recommandations techniques pour le développement ou la révision d'une méthode de référence normalisée (ISO/DIS 17468:2022)

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Microbiology of the food chain — Technical requirements and guidance on establishment or revision of a standardized reference method

Microbiologie de la chaîne alimentaire — Exigences et recommandations techniques pour le développement ou la révision d'une méthode de référence normalisée

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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 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 34, *Food products*, Subcommittee SC 9, *Microbiology*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 463, *Microbiology of the food chain*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 17468:2016), which has been technically revised. The main changes are as follows:

— a cross-reference is made not only to ISO 16140-2, but also to ISO 16140-4 and ISO 16140-6;

— a new optional step has been added, method optimization, together with a new annex providing guidance on such optimization studies, to compare options in the development of a new standardized reference method or for its revision;

— the inclusion of the case of confirmation or typing methods;

— the assessment of the nature of a change (minor/major) during the revision of a standardized reference method.

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.

Microbiology of the food chain — Technical requirements and guidance on establishment or revision of a standardized reference method

1 Scope

This document gives technical requirements and guidance on the establishment or revision of standardized reference methods used for the analysis of microorganisms in:

— products intended for human consumption;

— products for feeding of animals;

— environmental samples in the area of food and feed production and handling;

— samples from the primary production stage.

This document defines the technical stages of the establishment of a new standardized reference method and of the revision of an existing standardized reference method. It includes, in particular, requirements and guidance on the validation of the selected method.

This document is intended to be implemented in particular by ISO/TC 34/SC 9 and its corresponding structure at CEN level, which is CEN/TC 463.

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 5725-2, *Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*

ISO 11133, *Microbiology of food, animal feed and water — Preparation, production, storage and performance testing of culture media*

ISO 16140-1:2016, *Microbiology of the food chain — Method validation — Part 1: Vocabulary*

ISO 16140-2:2016, *Microbiology of the food chain — Method validation — Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method*

ISO 16140-4:2020, *Microbiology of the food chain — Method validation — Part 4: Protocol for method validation in a single laboratory*

ISO 16140-6:2019, *Microbiology of the food chain — Method validation — Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 16140-1 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
candidate reference method
method selected and likely to become the *standardized reference method* (3.5)

3.2
multi-laboratory study
study of one or several methods conducted in different laboratories, using their own samples analysed in routine

3.3
pre-standardization stage
technical stage prior to the standardization stage and comprising different steps described in this document

Note 1 to entry: The standardization stage starts with the proposal stage which is the approval of a New Work Item Proposal (ISO/NP) for inclusion of the Work Item on the work programme of ISO/TC 34/SC 9.

3.4
"real life" study
study of one or several methods, using a wide range of samples and with preference given to naturally contaminated samples

3.5
standardized reference method
reference method described in a standard

Note 1 to entry: See ISO 16140-1 for the definition of "reference method".

4 Technical procedure for standardizing a new reference method

4.1 General

In the frame of this document, six technical steps (see 4.2) are required for the validation of a method in view of its standardization as a reference method:

— step 1: method(s) selection;

— step 2: method optimization;

— step 3: method(s) evaluation study;

— step 4: "real life"/multi-laboratory study (this step does not apply to confirmation and typing methods);

— step 5: selection of one candidate reference method for further validation;

— step 6: interlaboratory study (see ISO 16140-1:2016, 2.33).

The first five technical steps correspond to a pre-standardization stage (see 3.3) and are usually performed before launching the standardization process. Step 6 (4.2.6) is usually performed during the standardization process [preferably, after the committee stage (ISO/CD) and before the enquiry stage (ISO/DIS)].

A flow chart of the technical steps for the establishment of a new standardized reference method is given in Annex A.

The working group in charge of organizing the studies on a qualitative method shall consider the inclusion of a test portion size larger than e.g. 10 g or 25 g, when it is relevant and feasible. This will

facilitate the use of the standardized method without the need for further validation when a larger test portion size is routinely used.

EXAMPLE Detection of *Salmonella* in 375 g infant formula test portions.

All relevant data as obtained in step 1 to step 6 should be reported either in a scientific publication or in a report to be made available on the ISO Standards Maintenance Portal associated to each standardized method.

NOTE Data, for example regarding inclusivity and exclusivity, can be derived from earlier studies as long as the information is traceable to the originally published data or made available on the ISO Standards Maintenance Portal associated to the standardized method.

The performance characteristics obtained from the interlaboratory study (step 6, also see 4.2.6) shall be incorporated into the corresponding standardized reference method.

4.2 Technical steps

4.2.1 Step 1: Method(s) selection

Information from different sources (national/regional standardized methods, scientific papers on methods with evaluation data, evaluation/validation reports on methods, practicability of the method) shall be collated for the choice of a candidate reference method (see 3.1). Based on the information available, the working group in charge of developing the standard selects one or several candidate reference methods.

4.2.2 Step 2: Method optimization (optional)

If a candidate reference method comprises, after the step of method(s) selection (see 4.2.1), one factor with two options (examples: two options for a culture medium, for the time/temperature of incubation), a method optimization study can be conducted, comparing the two options.

Annex B provides guidance to working groups in charge of developing the standards on how to compare these two options and make a choice for the method to be standardized and to be further evaluated (see 4.2.3).

If the candidate reference method(s) does (do) not comprise(s) any factor with options, proceed directly to step 3 (see 4.2.3).

4.2.3 Step 3: Method(s) evaluation study

4.2.3.1 General

An evaluation study of the candidate reference method(s) (see 4.2.1 and 4.2.2) is conducted, normally by one laboratory, but more than one laboratory may also be involved.

If several candidate reference methods are evaluated at this step, the outcome of this evaluation study should enable the relevant working group in charge of developing the standard to reduce the number of candidate reference methods, ideally to one (also see step 5).

The working group in charge of developing the standard shall check that the candidate reference method(s) work(s) using culture media made up in the laboratory from individual ingredients described in the candidate reference method(s).

4.2.3.2 Detection and/or quantification methods

The method(s) evaluation study enables the estimation of performance characteristics listed below and aims at assessing them for a large variety of (food) types and (food) items, within the (food) categories studied, representative of the scope of the method. In accordance with ISO 16140-2:2016, 5.1.3.1: if

the method is to be applied for a broad range of food, at least five food categories shall be studied. If the method is to be validated for a restricted number of food categories, then only these categories need to be studied. In addition to the food categories, pet food and animal feed samples, environmental samples, and primary production stage samples can be included as additional categories.

NOTE The working group in charge of standardizing the method assesses, possibly through an inventory among users, whether it is sufficient to validate the method for a restricted number of (food) categories.

This study should fulfil the requirements of the single-laboratory method validation study without comparison to a reference method, as stated in ISO 16140-4:

— for qualitative methods:

  — factorial approach (in accordance with ISO 16140-4:2020, 5.1.2): sensitivity, level of detection (LOD_{50}), inclusivity/exclusivity; or

  — conventional approach (in accordance with ISO 16140-4:2020, 6.1.2): specificity, LOD_{50}, sensitivity, inclusivity/exclusivity.

— for quantitative methods:

  — factorial approach (in accordance with ISO 16140-4:2020, 5.2.2): relative trueness, accuracy profile, in-house precision study (repeatability and in-house reproducibility), inclusivity/exclusivity; or

  — conventional approach (in accordance with ISO 16140-4:2020, 6.2.2): relative trueness, accuracy profile, in-house precision study (repeatability and in-house reproducibility), inclusivity/exclusivity, and if applicable, limit of quantification.

4.2.3.3 Confirmation or typing methods

The method(s) evaluation study shall fulfil the requirements of the method comparison study for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures, as stated in ISO 16140-6:2019, Clause 6: inclusivity and exclusivity. As there is no comparison to a reference method, compare the inclusivity and exclusivity results directly to the identity of the strains (second interpretation in Table 2 and Table 4 of ISO 16140-6:2019, 6.5).

4.2.4 Step 4: “Real life”/multi-laboratory study

The “real life” study (see 3.4) shall be conducted on the candidate detection/quantification reference method(s) (see 4.2.1), using a wide range of samples with preference given to naturally contaminated samples. This study is a multi-laboratory study (see 3.2) conducted in different laboratories, located in different countries/different regions of the world to cover the largest diversity possible of:

a) matrices where the target microorganism can naturally be found;

b) strains of the target microorganism.

In particular, each laboratory shall use its own samples (see before), reagents and culture media to reflect their diversity. In particular, the different commercial media, if existing, should be used. For culture media and reagents, follow the requirements in ISO 11133 on quality control.

If the outcome of this study is not assessed as acceptable by the relevant working group in charge of developing the standard, this working group shall reconsider the choice of the candidate reference method(s) and go back to step 1.

This “real life” study may be conducted in parallel with step 1 (see 4.2.1) or step 3 (see 4.2.3).

NOTE The “real life” study is not applicable to confirmation or typing methods.