
**Microbiology of the food chain —
Technical requirements and guidance
on the 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 document 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).

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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(s) optimization". In addition, a new annex providing guidance on method optimization studies is included, to compare two options during the development of a new standardized reference method or for its revision;
- the inclusion of the case of confirmation and 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 the 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 animals;
- environmental samples in the area of food and feed production and handling;
- samples from the primary production stage.

This document specifies 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 16140-2:2016/Amd.1:—¹, *Microbiology of the food chain — Method validation — Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method — Amendment 1: Revision of qualitative MCS data evaluation, RLOD calculations in the ILS, calculation and interpretation of the RT study, and inclusion of a commercial sterility testing protocol for specific products*

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.

1) Under preparation. Stage at time of publication ISO 16140-2:2016/DAmD.1:2023.

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* (3.7)

3.2

ILS organizer

organizing laboratory

laboratory with responsibility for managing all of the technical and statistical activities involved in the organization of the interlaboratory study

[SOURCE: ISO 16140-1:2016, 2.45, modified - “validation study, i.e. method comparison study and the interlaboratory study” has been replaced by “organization of the interlaboratory study” and the Note 1 to entry has been deleted.]

3.3

ILS participant

participating laboratory

individual laboratory technician, who works completely independently from other ILS participants, using different sets of blind samples or test portions

[SOURCE: ISO 16140-1:2016, 2.13, modified - “collaborator” has been replaced by “ILS participant”.]

3.4

interlaboratory study

study performed by multiple laboratories testing identical samples at the same time, the results of which are used to estimate performance characteristics of the candidate reference method

Note 1 to entry: The aim of an interlaboratory study is to determine the variability of the results obtained in different laboratories using identical samples.

[SOURCE: ISO 16140-1:2016, 2.33, modified - “alternative-method performance parameters” has been replaced by “performance characteristics of the candidate reference method”.]

3.5

pre-standardization stage

technical stage prior to the standardization stage and comprising the 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.

3.6

“real life” study

study of one or several methods, conducted in different laboratories, using their own routine samples and with preference given to naturally contaminated samples

3.7

standardized reference method

reference method described in a standard

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