

Microbiology of the food chain - Technical requirements and guidance on establishment or revision of a standardized reference method (ISO 17468:2016)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 17468:2016 sisaldab Euroopa standardi EN ISO 17468:2016 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 17468:2016 consists of the English text of the European standard EN ISO 17468:2016.
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English Version

Microbiology of the food chain - Technical requirements and guidance on establishment or revision of a standardized reference method (ISO 17468:2016)

Microbiologie de la chaîne alimentaire - Exigences et recommandations techniques pour le développement ou la révision d'une méthode de référence normalisée (ISO 17468:2016)

Mikrobiologie der Lebensmittelkette - Technische Anforderungen und Leitfaden zur Einführung oder Überarbeitung von Standardverfahren (ISO 17468:2016)

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COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN ISO 17468:2016) has been prepared by Technical Committee ISO/TC 34 "Food products" in collaboration with Technical Committee CEN/TC 275 "Food analysis - Horizontal methods" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2017, and conflicting national standards shall be withdrawn at the latest by January 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 17468:2016 has been approved by CEN as EN ISO 17468:2016 without any modification.

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*.

Introduction

This International Standard has been developed in order to set common rules for the validation of reference methods standardized in the field of food microbiology by ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*, and its corresponding structure at CEN level (CEN/TC 275, *Food analysis — Horizontal methods*, Working Group 6, *Microbiology of the food chain*).

This International Standard refers to the complete process of method validation, including comparison of performance data to predetermined criteria/acceptability values. These values are not set in the present edition of this International Standard, due to the lack of available data.

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

1 Scope

This International Standard gives technical requirements and guidance on the establishment or revision of standardized reference methods for the analysis (detection or quantification) of microorganisms in

- products intended for human consumption and for the feeding of animals,
- environmental samples in the area of food/feed production and food/feed handling, and
- samples from the primary production stage.

This International Standard defines the technical stage (or early stage) of the establishment of a new standardized reference method or of the revision of an existing standardized reference method. It includes, in particular, requirements and guidance on the validation of the selected method.

This International Standard is intended to be implemented in particular by ISO/TC 34/SC 9 and its corresponding structure at CEN level, CEN/TC 275, *Food analysis — Horizontal methods*, Working Group 6, *Microbiology of the food chain*.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable to its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 16140-1, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 16140-1 and the following apply.

3.1

candidate reference method

method selected and likely to become the *standardized reference method* (3.5)

3.2

multilaboratory study

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

3.3

prestandardization stage

technical stage prior to standardization stage and comprising different steps described in this International Standard

Note 1 to entry: Standardization stage starts with voting on a New Work Item Proposal for inclusion of the Work Item in the work programme.