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

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National foreword

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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)

This European Standard was approved by CEN on 20 June 2015.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by January 2017, and conflicting national standards shall be withdrawn at the latest by January 2017.

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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.

Contents

Page

Foreword

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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.

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 International Standard, five 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(s) evaluation study;

— step 3: "real life"/multilaboratory study;

— step 4: selection of the proposed reference method for further validation;

— step 5: interlaboratory study.

Except for step 5 in certain cases (see 4.2.5), these five technical steps correspond to a prestandardization stage (see 3.3), being performed before launching the standardization process.

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

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 made available for the choice of a candidate reference method (see 3.1). Based on the information available, the group in charge of developing the standard selects one or several candidate reference methods.

4.2.2 Step 2: Method(s) evaluation study

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

The evaluation of the candidate reference method/each candidate reference method aims at assessing the scope of the method applicability to the range of food categories or environmental sample type to which the method applies. If the method is to be applied to a broad range of foods (general case for standardized reference methods), then at least five categories of food shall be studied (see details in ISO 16140-2:2016, 5.1.3.1). For each food category/sample type, at least one food type and one suitable strain shall be selected. This evaluation study should be conducted in artificial contamination conditions, in order that step 2 and step 3 (see 4.2.3) are complementary to assessing the scope of the method.

This evaluation study should also enable estimation of performance parameters and fulfil the requirements of the method comparison study, as stated in ISO 16140-2:

— for qualitative methods: sensitivity and specificity, level of detection, inclusivity and exclusivity (in accordance with ISO 16140-2:2016, 5.1);

— for quantitative methods: relative trueness (see next paragraph), accuracy profile, inclusivity and exclusivity, and optionally, limit of quantification (in accordance with ISO 16140-2:2016, 6.1).

ISO 16140-2:2016, 5.1 and 6.1 describe a method validation study, comparing an alternative method to a reference method. The methodology described in these subclauses may be used to compare the different candidate reference methods. If one candidate reference method has been selected (see 4.2.1), these subclauses need to be adapted to the case of validating a method alone, without comparison to another method. In particular, reference materials or artificially contaminated samples may be used instead of the reference method to assess the sensitivity and specificity/trueness of the candidate reference method.

NOTE For further details on the procedure for preparing samples, see of ISO 16140-2:2016, Annex C.

If several candidate reference methods have been evaluated at this step, the outcome of this evaluation study should enable the relevant group in charge of developing the standard to reduce the number of candidate reference methods.

4.2.3 Step 3: "Real life"/multilaboratory study

The "real life" study (see 3.4) shall be conducted on the candidate reference method(s) (see 4.2.1), using a wide range of samples with preference given to naturally contaminated samples. This study is a multilaboratory study (see 3.2) conducted in different laboratories, preferably located in different countries/different parts 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 reagents and culture media to reflect their diversity.

If the outcome of this study is not satisfactory, the relevant group in charge of developing the standard shall reconsider the choice of the candidate reference method(s) and come back to step 1.

This "real life" study may be conducted in parallel with step 2 (see 4.2.2).

4.2.4 Step 4: Selection of method for further validation

Based on the information and data gained in the steps 1 to 3 (see 4.2.1 to 4.2.3), the relevant group in charge of developing the standard shall select one method for further validation (see step 5, 4.2.5).

4.2.5 Step 5: Interlaboratory study

An interlaboratory study shall be conducted to adopt a new method selected at step 4 (see 4.2.4). The interlaboratory study is required in particular when it concerns the analysis of a pathogenic microorganism. In exceptional cases, a method may be adopted without an interlaboratory study where it is not possible to conduct one; this decision shall be taken on a case-by-case basis.

The aim of the interlaboratory study is to determine the trueness and precision (repeatability and the reproducibility for quantitative methods) of the selected method implemented in different laboratories using identical samples and to confirm that the method meets the established criteria of performance. Whenever possible, the study conditions should reflect the normal variation between laboratories.

The interlaboratory study should be conducted in accordance with ISO 16140-2:2016, 5.2 for qualitative methods or ISO 16140-2:2016, 6.2 for quantitative methods. The interlaboratory study should include one matrix per food category studied in step 2 (see 4.2.2).

The interlaboratory study may be organized before the beginning of the standardization process, but it is recommended to conduct it after having launched the standardization process (for example, just before the enquiry stage) in order to ensure a greater consensus on the candidate reference method.

5 Technical procedure for revising a standardized reference method

5.1 General

The group in charge of developing the standard shall agree on the changes to be made to the existing standardized reference method and shall assess whether these changes are of a major or minor nature. A major change induces a different result obtained with the method, whereas a minor change does not affect the result obtained with the method.

EXAMPLE 1 Minor changes include editorial changes to the text of the method.

EXAMPLE 2 Major changes include a change in the method detection/quantification technology or significant modification of the enrichment procedure (e.g. nature of the enrichment broth, incubation time, and temperature).

If the group in charge of developing the standard determines that further validation of the modified method is required, start the process at step 4 (see 4.2.4).

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

5.2 Impact of reference method revision on the existing validation of alternative methods

When adopting a revision of an existing standardized reference method, a decision shall be taken regarding the potential impact of such a revision on the validation of alternative methods, which have been previously validated against that existing standardized reference method. The group in charge of revising the standardized reference method (see 5.1) shall assess whether the revision of the reference method is major or minor.

If the assessment of the group in charge of revising the standardized reference method is that the change is minor, no further action is needed and no additional validation is required for any alternative method previously validated against that standardized reference method.

If the revision of the standardized reference method is considered potentially major, the group in charge of revising the standardized reference method shall evaluate the data presented in support of the revision of the standardized reference method. If these data show that both the previous and revised reference method produce equivalent performance data, the change is determined to have no impact on previously validated alternative methods.

If, however, the data show that the revision of the standardized reference method has produced a statistically significant improvement in the performance of the reference method compared to the former version of the said method, then the group in charge of revising the standardized reference method shall reconsider the need to revalidate existing alternative methods against the revised reference method.

If the group in charge of revising the standardized reference method concludes that the existing validation of alternative methods should be revisited, this group may recommend that an additional method comparison study of each alternative method be performed against the new reference method (in accordance with ISO 16140-2:2016, 5.1 or ISO 16140-2:2016, 6.1). An interlaboratory study might be required and may be carried out.

In case of certification of alternative (proprietary) methods, this matter should then be referred to the certification bodies, which have validated the alternative methods.

Annex A
(normative)

Flow chart on technical steps for the establishment or revision of a standardized reference method

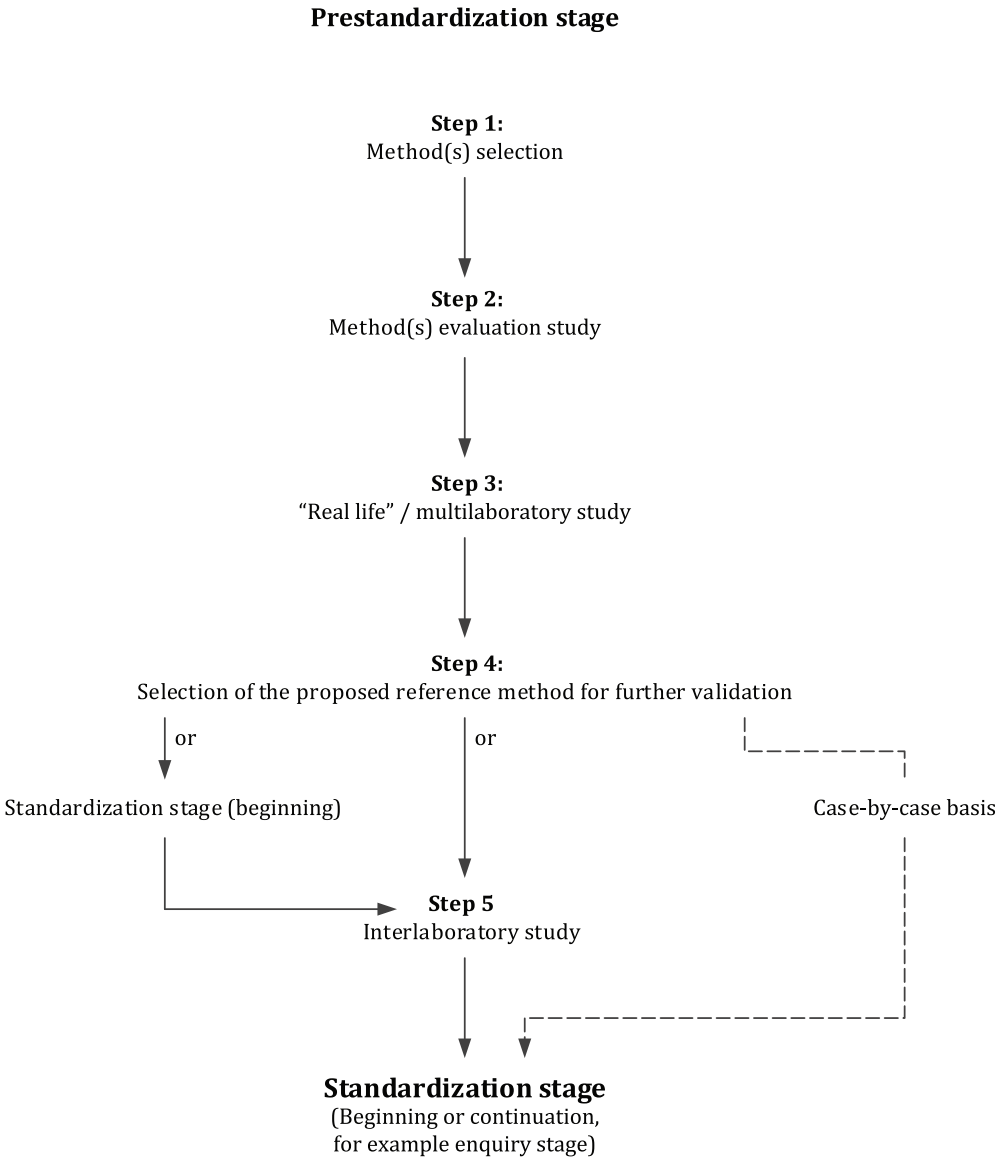

Figure A.1 — Flow chart of prestandardization stage

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