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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

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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 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.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 of 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*

[1] Under preparation.

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/obphttps://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/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".

4 Technical procedure for standardizing a new reference method

4.1 General

The validation of a method in view of its standardization as a reference method includes six technical steps (see 4.2):

— step 1: method(s) selection (mandatory);

— step 2: method optimization (optional);

— step 3: method(s) evaluation study (recommended);

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

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

— step 6: interlaboratory study (mandatory).

The first five technical steps correspond to a pre-standardization stage and are usually performed before launching the standardization process. Step 6 (see 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, for example, 10- g or 25- g, when it is relevant and feasible. This will facilitate the use of the standardized reference 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.

Information on the studies conducted in step 1 to step 6 should not be shared publicly until their completion. Once these studies are completed, all relevant data as obtained in step 1 to step 6 should become publicly available, by reporting it either in a scientific publication or in a report. This report can be made available on the ISO Standards Maintenance Portal (~~https://standards.iso.org/iso/~~https://standards.iso.org/iso/) associated to each standardized

reference method and/or by including a link in the Bibliography of the standardized reference method to the publicly available report at another website.

NOTE Data, e.g. 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 reference 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 (mandatory)

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(s). Based on the information available, the working group in charge of developing the standard (referred to as 'the working group' from this point forward) shall select 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 (e.g. 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 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 (recommended)

4.2.3.1 General

An evaluation study of the candidate reference method(s) (see 4.2.1 and 4.2.2) should be 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 to reduce the number of candidate reference methods, ideally to one (step 5, also see 4.2.5).

The working group shall check that the candidate reference method(s) work(s) using culture media prepared in the laboratory from individual ingredients described in the candidate reference method(s).

4.2.3.2 Detection and quantification methods

When conducted, 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 to 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.

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