



SLOVENSKI STANDARD
SIST EN ISO 16140-2:2016/A1:2024

01-november-2024

Mikrobiologija v prehranski verigi - Validacija metode - 2. del: Protokol za validacijo alternativnih (lastniških) metod glede na referenčno metodo - Dopnilo A1 (ISO 16140-2:2016/Amd 1:2024)

Microbiology of the food chain - Method validation - Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method - Amendment 1 (ISO 16140-2:2016/Amd 1:2024)

Mikrobiologie der Lebensmittelkette - Verfahrensvalidierung - Teil 2: Arbeitsvorschrift für die Validierung von alternativen (urheberrechtlich geschützten) Verfahren anhand eines Referenzverfahrens (ISO 16140-2:2016/Amd 1:2024)

Microbiologie de la chaîne alimentaire - Validation des méthodes - Partie 2: Protocole pour la validation de méthodes alternatives (commerciales) par rapport à une méthode de référence - Amendement 1 (ISO 16140-2:2016/Amd 1:2024)

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ICS:

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English Version

Microbiology of the food chain - Method validation - Part 2:
Protocol for the validation of alternative (proprietary)
methods against a reference method - Amendment 1 (ISO
16140-2:2016/Amd 1:2024)

Microbiologie de la chaîne alimentaire - Validation des
méthodes - Partie 2: Protocole pour la validation de
méthodes alternatives (commerciales) par rapport à
une méthode de référence - Amendement 1 (ISO 16140
2:2016/Amd 1:2024)

Mikrobiologie der Lebensmittelkette -
Verfahrensvalidierung - Teil 2: Arbeitsvorschrift für die
Validierung von alternativen (urheberrechtlich
geschützten) Verfahren anhand eines
Referenzverfahrens - ÄNDERUNG 1 (ISO 16140
2:2016/Amd 1:2024)

This amendment A1 modifies the European Standard EN ISO 16140-2:2016; it was approved by CEN on 25 July 2024.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN ISO 16140-2:2016/A1:2024 (E)

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European foreword

This document (EN ISO 16140-2:2016/A1:2024) has been prepared by Technical Committee ISO/TC 34 "Food products" in collaboration with Technical Committee CEN/TC 463 "Microbiology of the food chain" the secretariat of which is held by AFNOR.

This Amendment to the European Standard EN ISO 16140-2:2016 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2025, and conflicting national standards shall be withdrawn at the latest by March 2025.

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

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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The text of ISO 16140-2:2016/Amd 1:2024 has been approved by CEN as EN ISO 16140-2:2016/A1:2024 without any modification.

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International Standard

ISO 16140-2

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 method comparison
study data evaluation, relative level
of detection calculations in the
interlaboratory study, calculation and
interpretation of the relative trueness
study, and inclusion of a commercial
sterility testing protocol for specific
products

*Microbiologie de la chaîne alimentaire — Validation des
méthodes —*

*Partie 2: Protocole pour la validation de méthodes alternatives
(commerciales) par rapport à une méthode de référence*

*AMENDEMENT 1: Révision de l'évaluation des données des études
de comparaison de méthodes qualitatives, des calculs du niveau
de détection de l'étude interlaboratoires et de l'interprétation
de l'étude de justesse relative, et ajout d'un protocole pour la
détermination de la stérilité commerciale pour des produits
spécifiques*

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AMENDMENT 1
2024-09

ISO 16140-2:2016/Amd.1:2024(en)

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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).

A list of all parts in the ISO 16140 series can be found on the ISO website.

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.

ISO 16140-2:2016/Amd.1:2024(en)

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 method comparison study data evaluation, relative level of detection calculations in the interlaboratory study, calculation and interpretation of the relative trueness study, and inclusion of a commercial sterility testing protocol for specific products

Introduction

Replace the text with the following:

Introduction**0.1 The ISO 16140 series**

The ISO 16140 series has been expanded in response to the need for various ways to validate or verify test methods. It is the successor to ISO 16140:2003. The ISO 16140 series consists of six parts with the general title, *Microbiology of the food chain — Method validation*:

- *Part 1: Vocabulary;*
- *Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method;*
- *Part 3: Protocol for the verification of reference methods and validated alternative methods in a single laboratory;*
- *Part 4: Protocol for method validation in a single laboratory;*
- *Part 5: Protocol for factorial interlaboratory validation for non-proprietary methods;*
- *Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures.*

ISO 17468 is a closely linked International Standard, which establishes technical rules for the development and validation of standardized methods.

In general, two stages are needed before a method can be used in a laboratory:

- The first stage is the validation of the method. Validation is conducted using a study in a single laboratory followed by an interlaboratory study (see this document, ISO 16140-5 and ISO 16140-6). In the case when a method is validated within one laboratory (see ISO 16140-4), no interlaboratory study is conducted.
- The second stage is method verification, where a laboratory demonstrates that it can satisfactorily perform a validated method. This is described in ISO 16140-3. Verification is only applicable to methods that have been validated using an interlaboratory study.