

STN	Mikrobiológia potravinárskeho reťazca Metóda validácie Časť 2: Postup validácie alternatívnych metód porovnaním s referenčnou metódou (ISO 16140-2: 2016/Amd 1: 2024) Zmena A1	STN EN ISO 16140-2/A1 56 0107
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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)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/24

Obsahuje: EN ISO 16140-2:2016/A1:2024, ISO 16140-2:2016/Amd 1:2024

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EUROPEAN STANDARD

EN ISO 16140-2:2016/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2024

ICS 07.100.30

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.

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

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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of an identical text or by endorsement, at the latest by March 2025, and conflicting national standards shall be withdrawn at the latest by March 2025.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.

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Endorsement notice

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.



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*

First edition
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AMENDMENT 1
2024-09

ISO 16140-2:2016/Amd.1:2024(en)**COPYRIGHT PROTECTED DOCUMENT**

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

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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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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.

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In general, two types of methods are distinguished: reference methods and alternative methods.

A reference method is defined in ISO 16140-1:2016, 2.59, as an “internationally recognized and widely accepted method”. The note to entry clarifies that “these are ISO standards and standards jointly published by ISO and CEN or other regional/national standards of equivalent standing”.

In the ISO 16140 series, reference methods include standardized reference (ISO and CEN) methods as defined in ISO 17468:2023, 3.7, as a “reference method described in a standard”.

An alternative method (method submitted for validation) is defined in ISO 16140-1:2016, 2.4, as a “method of analysis that detects or quantifies, for a given category of products, the same analyte as is detected or quantified using the corresponding reference method”. The note to entry clarifies that: “The method can be proprietary. The term ‘alternative’ is used to refer to the entire ‘test procedure and reaction system’. This term includes all ingredients, whether material or otherwise, required for implementing the method.”

ISO 16140-4 addresses validation within a single laboratory. The results are therefore only valid for the laboratory that conducted the study. In this case, verification (as described in ISO 16140-3) is not applicable. ISO 16140-5 describes protocols for non-proprietary methods where a more rapid validation is required or when the method to be validated is highly specialized and the number of participating laboratories required by this document cannot be reached. ISO 16140-4 and ISO 16140-5 can be used for validation against a reference method. ISO 16140-4 (regarding qualitative and quantitative methods) and ISO 16140-5 (regarding quantitative methods only) can also be used for validation without a reference method.

The flow chart in Figure 0.1 gives an overview of the links between the different parts mentioned above. It also guides the user in selecting the right part of the ISO 16140 series, taking into account the purpose of the study and the remarks given above.

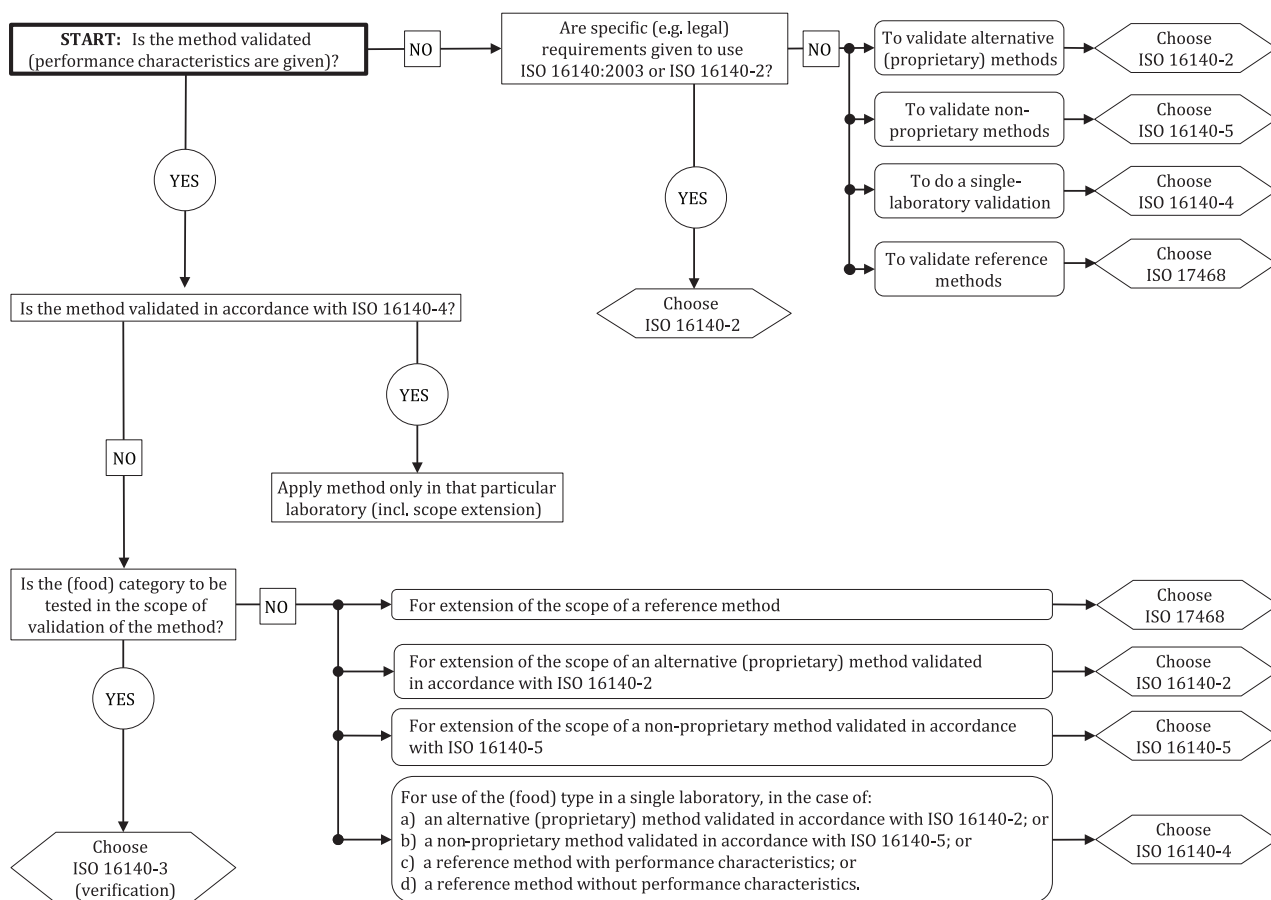


Figure 0.1 — Flow chart for application of the ISO 16140 series

koniec náhľadu – text ďalej pokračuje v platenej verzii STN