

# SLOVENSKI STANDARD

## SIST EN ISO 16140-1:2016

01-oktober-2016

Nadomešča:

SIST EN ISO 16140:2003

SIST EN ISO 16140:2003/A1:2012

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**Mikrobiologija v prehranski verigi - Validacija metode - 1. del: Slovar (ISO 16140-1:2016)**

Microbiology of the food chain - Method validation - Part 1: Vocabulary (ISO 16140-1:2016)

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Mikrobiologie der Lebensmittelkette - Verfahrensvalidierung - Teil 1: Terminologie (ISO 16140-1:2016)

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Microbiologie de la chaîne alimentaire - Validation des méthodes - Partie 1: Vocabulaire (ISO 16140-1:2016)

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**Ta slovenski standard je istoveten z: EN ISO 16140-1:2016**

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**ICS:**

01.040.07	Naravoslovne in uporabne vede (Slovarji)	Natural and applied sciences (Vocabularies)
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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 16140-1**

July 2016

ICS 07.100.30

Supersedes EN ISO 16140:2003

English Version

## Microbiology of the food chain - Method validation - Part 1: Vocabulary (ISO 16140-1:2016)

Microbiologie de la chaîne alimentaire - Validation des  
méthodes - Partie 1: Vocabulaire (ISO 16140-1:2016)

Mikrobiologie der Lebensmittelkette -  
Verfahrensvalidierung - Teil 1: Terminologie (ISO  
16140-1:2016)

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**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

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## European foreword

This document (EN ISO 16140-1:2016) 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of an identical text or by endorsement, at the latest by January 2017, and conflicting national standards shall be withdrawn at the latest by January 2017.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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STANDARD

ISO  
16140-1

First edition  
2016-06-15

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**Microbiology of the food chain —  
Method validation —**

**Part 1:  
Vocabulary**

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

*Partie 1: Vocabulaire*  
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## ISO 16140-1:2016(E)

## 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](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*.

This first edition of ISO 16140-1, together with ISO 16140-2, cancels and replaces ISO 16140:2003, which has been technically revised. It also incorporates the Amendment ISO 16140:2003:Amd.1:2011.

ISO 16140 consists of the following parts, under 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*

The following parts are under preparation:

- *Part 3: Protocol for the verification of reference and validated alternative methods implemented in a single laboratory*
- *Part 4: Protocol for single-laboratory (in-house) method validation*
- *Part 5: Protocol for factorial interlaboratory validation of non-proprietary methods*
- *Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing*

## Introduction

The use of validated methods is an important requirement for obtaining reliable results with a specific method. It also facilitates the comparability of results obtained with the same method in different laboratories. Validation procedures covered by ISO 16140 (all parts) involve various aspects of validation, such as validation of alternative (proprietary) methods, single laboratory validation, validation of (alternative) methods using a limited number of laboratories, and verification of methods (demonstration of a laboratory to correctly apply a validated method). In addition, there is a close link to ISO 17468 describing the procedure for the validation of the standard methods themselves.

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