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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16140-1

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of an identical text or by endorsement, at the latest by January 2017, and conflicting national standards shall be withdrawn at the latest by January 2017.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

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

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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 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).

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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*.

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*

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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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Microbiology of the food chain — Method validation —

Part 1: Vocabulary

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1 Scope

This part of ISO 16140 defines general terms and definitions relating to method validation of microbiology in the food chain.

This part of ISO 16140 is applicable to the validation of methods for the analysis (detection or quantification) of microorganisms in

— products intended for human consumption,

— products intended for animal feeding,

— environmental samples in the area of food and feed production, handling, and

— samples from the primary production stage.

2 Terms and definitions

2.1
acceptability limit
AL
maximum positive or negative acceptable difference between the *reference value* (2.60) (or if not known, the accepted reference value) of a *sample* (2.69) and an individual result obtained when applying the operating procedure of an analytical method

Note 1 to entry: Because *accuracy* (2.2) is defined as 'the closeness of agreement between a measured quantity value and an assigned quantity value of a measurand', acceptability limits can be interpreted as the maximum measure of the lack of accuracy for *quantitative methods* (2.57).

2.2
accuracy
measurement accuracy
closeness of agreement between a measured quantity value and an assigned quantity value of a measurand

Note 1 to entry: The concept 'measurement accuracy' is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.

Note 2 to entry: The term 'measurement accuracy' should not be used for measurement *trueness* (2.77) and the term measurement *precision* (2.51) should not be used for 'measurement accuracy', which, however, is related to both these concepts.

Note 3 to entry: 'Measurement accuracy' is sometimes understood as closeness of agreement between measured quantity values that are being attributed to the measurand.

[SOURCE: JCGM, 2012, modified]

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