SLOVENSKI STANDARD
oSIST prEN ISO 16140-2:2013

01-marec-2013

Mikrobiologija živil in krme - Metoda validacije - 2. del: Protokol za validacijo metod, alternativnih referenčni metodi (ISO/DIS 16140-2:2013)

Microbiology of food and animal feed - Method validation - Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method (ISO/DIS 16140-2:2013)

Mikrobiologie von Lebensmitteln und Futtermitteln - Verfahrensvalidierung - Teil 2: Arbeitsvorschrift für die Validierung von alternativen (urheberrechtlich geschützten) Verfahren anhand eines Referenzverfahrens (ISO/DIS 16140-2:2013)

Microbiologie des aliments - Validation des méthodes - Partie 2: Protocole pour la validation de méthodes alternatives (brevetées) par rapport à une méthode de référence (ISO/DIS 16140-2:2013)

Ta slovenski standard je istoveten z: **prEN ISO 16140-2 rev**

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EUROPEAN STANDARD

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English Version

Microbiology of food and animal feed - Method validation - Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method (ISO/DIS 16140-2:2013)

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This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 275.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (prEN ISO 16140-2:2013) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 16140:2003.

Endorsement notice

The text of ISO/DIS 16140-2:2013 has been approved by CEN as a prEN ISO 16140-2:2013 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 16140-2

ISO/TC **34**/SC **9** Secretariat: **AFNOR**

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Microbiology of food and animal feed — Method validation —

Part 2:
Protocol for the validation of alternative (proprietary) methods against a reference method

Microbiologie des aliments — Validation des méthodes —

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

[Revision of first edition (ISO 16140:2003)]

ICS 07.100.30

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 16140-2 was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology* in collaboration with Technical Committee CEN/TC 275, *Food analysis - Horizontal methods*, Working group 6, *Microbiology of the food chain*.

This second edition cancels and replaces the first edition (ISO 16140:2003), which has been technically revised.

ISO 16140 consists of the following parts, under the general title *Microbiology of food and animal feed — Method validation*:

— *Part 1: Vocabulary*

— *Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method*

Introduction

The need for the food industry to rapidly assess the microbiological quality of raw materials and finished products and the microbiological status of manufacturing procedures, has led to the development and refinement of alternative microbiological methods of analysis that are quicker and/or easier to perform than the corresponding reference method; some can also be automated.

The suppliers/producers of the alternative methods, the food and drink industry, the public health services and other authorities need a reliable common protocol for the validation of such alternative methods. The data generated can also be the basis for the certification of a method by an independent organization.

This part of the ISO 16140 is intended to provide a specific protocol and guidelines for the validation of proprietary methods intended to be used as a rapid and/or easier to perform method than the corresponding reference method. In addition, this part of the ISO 16140 can also be used for the validation of other, non-proprietary, methods that are used instead of the reference method. This part of ISO 16140 is intended as the successor of the validation protocol published in the first version of ISO 16140 (ISO 16140:2003).

The use of this standard involves expertise on relevant areas such as microbiology, statistical design and analysis as indicated in the respective sections. The statistical expertise encompasses overview of sampling theory and design of experiments, statistical analysis of microbiological data (from colony counts or presence/absence tests) and overview of statistical concepts on random sampling, sample heterogeneity, sample stability, design of experiments, variance components.

When this part of ISO 16140 is next reviewed, account will be taken of all information then available regarding the extent to which the guidelines have been followed and the reasons for deviation from them in the case of particular products.

The harmonization of validation methods cannot be immediate, and for certain groups of products International Standards and/or national standards may already exist that do not comply with this horizontal method. It is hoped that when such standards are reviewed they will be changed to comply with ISO 16140 so that eventually the only remaining departures from this horizontal method will be those necessary for well-established technical reasons. For example, ISO/DIS 16297, *Milk - Bacterial count - Protocol for the evaluation of alternative methods*, deals with a very specific validation for a specific subject (the hygienic status of raw milk samples) and will remain as a vertical standard besides the ISO 16140. In case such a validation is needed, the vertical standard is leading.

Microbiology of food and animal feed — Method validation — Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method

1 Scope

This part of ISO 16140 specifies the general principle and the technical protocol for the validation of alternative, mostly proprietary, methods in the field of microbiological analysis of food, animal feed, and environmental and primary production stage samples for the validation of alternative (proprietary) methods. Validation studies according to this standard are intended to be performed by organizations involved in method validation.

2 Normative references

The following referenced documents are indispensable for the application 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 16140-1:—[1)], *Microbiology of food and animal feed — Method validation — Part 1: Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 16140 1:—.

4 General principles for the validation of alternative methods

The validation protocol comprises two phases:

— a method comparison study of the alternative (proprietary) method against the reference method carried out in the organizing laboratory;

— an interlaboratory study of the alternative (proprietary) method against the reference method carried out in different laboratories.

The technical rules for performing the method comparison study and the interlaboratory study are given in clause 5 and 6, depending upon whether the alternative (proprietary) method is qualitative or quantitative in nature.

1) To be published. (Revision of ISO 16140:2003)

5 Qualitative methods – Technical protocol for validation

5.1 Method comparison study

5.1.1 General considerations

The method comparison study is the part of the validation process that is performed in the organizing laboratory. It consists of three parts:

— a comparative study of the results of the reference method to the results of the alternative method in (naturally and/or artificially) contaminated samples (so called relative accuracy study);

— a comparative study to determine the relative level of detection (RLOD) in artificially contaminated samples (so called RLOD study);

— an inclusivity/exclusivity study of the alternative method.

5.1.2 Paired or unpaired study

The reference and alternative methods shall be performed with, as far as possible, exactly the same sample (same test portion). However, a distinction is made between studies where the same test portion can be used for both the reference and the alternative method, due to both methods having exactly the same first step in the enrichment procedure and those where different test portions need to be used for the reference and the alternative method (e.g. due to different enrichment broths). In the case where the same test portion is used for both methods, the results from both methods are highly related to each other. For example, when the sample is not contaminated, both methods should find the result of that sample negative. Due to this relationship the data produced by the reference and the alternative method are named **paired** or matched. In this standard the wording, 'paired study' will be used for this type of study.

The opposite situation, where there is no common first enrichment step for both the reference and the alternative method, is also possible. In this case, different test portions, coming from the same batch or lot of (food) product, have to be used for each method and the resulting data are named **unpaired** or unmatched. In this standard, the word 'unpaired study' will be used for this type of study. The choice of having a **paired** study or an **unpaired** study depends on the protocols of the reference and alternative method. In case there is a common first step in the enrichment procedures, a **paired** study design is mandatory.

A positive result obtained with the alternative method shall, in general, be confirmed in order to determine whether the result is a true positive or false positive result. This confirmation is only needed for the accuracy study part. All positive results obtained with the alternative method in an **unpaire**d study shall be confirmed. In a **paired** study, only the positive results obtained with the alternative method, for which the corresponding result with the reference method was negative, shall be confirmed. The confirmation procedure should be such that an isolate of the target organism is obtained. In most cases, this will be based on the reference method procedure. However, this is not mandatory.

This section describes the method comparison study in case the reference and alternative method have a joint first step in the enrichment procedures (**paire**d study) and in case the reference and alternative method do not have a joint first enrichment step (**unpaired** study). Differences between both types of studies are indicated in the text where appropriate.

5.1.3 Sensitivity study

The sensitivity study is the ability to detect the analyte. This study is conducted using naturally and/or artificially contaminated samples. Different food categories and types will be tested for this.

5.1.3.1 Selection of food and other categories to be used

The selection of (food) categories and types used within the validation will depend on the type or group of microorganism and the scope of the validation.

