Irish Standard
I.S. EN ISO 16140:2003

Microbiology of food and animal feeding stuffs - Protocol for the validation of alternative methods (ISO 16140:2003)

I.S. EN ISO 16140:2003

Incorporating amendments/corrigenda/National Annexes issued since publication:
EN ISO 16140:2003/A1:2011

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English Version

Microbiology of food and animal feeding stuffs - Protocol for the validation of alternative methods - Amendment 1 (ISO 16140:2003/AMD 1:2011)

Microbiologie des aliments - Protocole pour la validation des méthodes alternatives - Amendement 1 (ISO 16140:2003/AMD 1:2011)

Mikrobiologie von Lebensmitteln und Futtermitteln - Arbeitsvorschrift für die Validierung alternativer Verfahren - Änderung 1 (ISO 16140:2003/AMD 1:2011)

This amendment A1 modifies the European Standard EN ISO 16140:2003; it was approved by CEN on 29 July 2011.

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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Foreword

This document (EN ISO 16140:2003/A1:2011) 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 Amendment to the European Standard EN ISO 16140:2003 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2012, and conflicting national standards shall be withdrawn at the latest by February 2012.

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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 16140:2003/AMD 1:2011 has been approved by CEN as a EN ISO 16140:2003/A1:2011 without any modification.

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Foreword

This document (EN ISO 16140:2003) has been prepared by Technical Committee CEN/TC 275 "Food analysis - Horizontal methods", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 34 "Agricultural food products".

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 November 2003, and conflicting national standards shall be withdrawn at the latest by November 2003.

The annexes A, C to K and M to T are normative. The annexes B, L and U are informative.

This document contains also a Bibliography.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

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.

Among these alternative methods, some can yield results that are equivalent to those provided by the reference method, while others can lead to results that differ appreciably.

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 organisation.

Because of the extent of the methods comparative study described in this standard for use by the organising laboratory, the procedure is sometimes not appropriate for use as an "in house" method for the validation of an alternative method by an individual laboratory.

1 Scope

This document establishes the general principle and the technical protocol for the validation of alternative methods in the field of microbiological analysis of food, animal feeding stuff and environmental and veterinary samples (see 5.1.1.2.1) for:

— the validation of alternative methods which can be used in particular in the framework of the official control;

— the international acceptance of the results obtained by the alternative method.

It also establishes the general principles of certification of these alternative methods, based on the validation protocol defined in this EN ISO 16140 (see 4.2).

Where an alternative method is used on a routine basis for internal laboratory use without the requirement to meet (higher) external criteria of quality assurance, a less stringent comparative validation of the alternative method than that set in this standard may be appropriate.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

ISO 3534-1, *Statistics – Vocabulary and symbols – Part 1: Probability and general statistical terms.*

ISO 5725, *Accuracy (trueness and precision) of measurement methods and results.*

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INTERNATIONAL STANDARD

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Microbiology of food and animal feeding stuffs — Protocol for the validation of alternative methods

Microbiologie des aliments — Protocole pour la validation des méthodes alternatives

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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.

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ISO 16140 was prepared by the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this document, read "...this European Standard..." to mean "...this International Standard...".

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