

**Toiduainete ja loomasööda mikrobioloogia.
Alternatiivsete meetodite valideerimise
protokoll.**

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 16140:2003 sisaldab Euroopa standardi EN ISO 16140:2003 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 14.08.2003 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 16140:2003 consists of the English text of the European standard EN ISO 16140:2003.</p> <p>This document is endorsed on 14.08.2003 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala: This EN ISO 16140 defines 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</p>	<p>Scope: This EN ISO 16140 defines 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</p>
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English version

Microbiology of food and animal feeding stuffs

Protocol for the validation of alternative methods

(ISO 16140 : 2003)

Microbiologie des aliments – Proto-
cole pour la validation des méthodes
alternatives (ISO 16140 : 2003)

Mikrobiologie von Lebensmitteln und
Futtermitteln – Arbeitsvorschrift für
die Validierung alternativer Verfahren
(ISO 16140 : 2003)

This European Standard was approved by CEN on 2002-07-06.

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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 document (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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