Water quality - Criteria for establishing equivalence between microbiological methods

Water quality - Criteria for establishing equivalence ds Ochological Control of the Contro between microbiological methods



EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 17994:2004 sisaldab Euroopa standardi EN ISO 17994:2004 ingliskeelset teksti.

Käesolev dokument on jõustatud
23.09.2004 ja selle kohta on avaldatud
teade Eesti standardiorganisatsiooni

Standard on kättesaadav Eesti standardiorganisatsioonist.

ametlikus väljaandes.

This Estonian standard EVS-EN ISO 17994:2004 consists of the English text of the European standard EN ISO 17994:2004.

This document is endorsed on 23.09.2004 with the notification being published in the official publication of the Estonian national standardisation organisation.

The standard is available from Estonian standardisation organisation.

Käsitlusala:

This International Standard defines an evaluation procedure for comparing two methods intended for the detection or quantification of the same target group or species of microorganisms. This International Standard provides the mathematical basis for the evaluation of the average relative performance of two methods against chosen criteria of equivalence.

Scope:

This International Standard defines an evaluation procedure for comparing two methods intended for the detection or quantification of the same target group or species of microorganisms. This International Standard provides the mathematical basis for the evaluation of the average relative performance of two methods against chosen criteria of equivalence. 31.

ICS 07.100.20, 13.060.70

Võtmesõnad:

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN ISO 17994

May 2004

100.20; 13.060.70

English version

Water quality

for establishing equivalence between microbiological methods (ISO 17994: 2004)

Qualité de l'eau - Critères pour établir l'équivalence entre les méthodes microbiologiques (ISO 17994 : 2004) Wasserbeschaffenheit - Kriterien für die Feststellung der Gleichwertigkeit von mikrobiologischen Verfahren (ISO 17994: 2004)

This European Standard was approved by CEN on 2004-04-09.

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.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

The European Standards exist 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

European Committee for Standardization Comité Européen de Normalisation Europäisches Komitee für Normung

Management Centre: rue de Stassart 36, B-1050 Brussels

Page 2 EN ISO 17994 : 2004

Foreword

International Standard

ISO 17994 : 2004 Water quality – Criteria for establishing equivalence between microbiological methods, which was prepared by ISO/TC 147 'Water quality' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 230 'Water analysis', the Secretariat of which is held by DIN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by November 2004 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 17994 : 2004 was approved by CEN as a European Standard without any modification.

Contents		Page
Foreword	TO	2
Introduction	<u>O</u>	2
1 Scope		3
2 Normative	ve references	
3 Terms, d	definitions and symbols	3
4 Principle	е	6
5 Basic re	equirements for an equivalence experiment	6
6 Calculati	tions	10
8 Test rep	onort	14
Annex A (information)	ative) Flowchart	
Annex B (informa	ative) Collaborative equivalence trials	16
	ative) Example	
Bibliography		20

Introduction

This International Standard presents the criteria and procedures for assessing the average quantitative equivalence of the results obtained by two microbiological analytical methods one of which may but need not be a standard or reference method.

The methods considered are based on counts of colonies or of positive and negative liquid enrichment tubes (MPN and presence/absence methods).

NOTE It is possible that a method that is not quantitatively equivalent with a reference method would be accepted, especially if it appears "better" than the reference either quantitatively or otherwise.

WARNING — Persons using this International Standard should be familiar with normal laboratory practice. This International Standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices and to ensure compliance with any national regulatory conditions.

1 Scope

This International Standard defines an evaluation procedure for comparing two methods intended for the detection or quantification of the same target group or species of microorganisms.

This International Standard provides the mathematical basis for the evaluation of the average relative performance of two methods against chosen criteria of equivalence.

Any two enumeration methods based on counts (of colonies or positive tubes) or any two detection methods [presence/absence (P/A) methods] intended for the same purpose can be compared.

This International Standard provides no solution to directly compare a quantitative method (colony count or MPN) with a detection method (P/A).

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/TR 13843:2000, Water quality — Guidance on validation of microbiological methods

3 Terms, definitions and symbols

3.1 Terms and definitions

For purposes of this document, the following terms and definitions apply.

3.1.1 General terms

3.1.1.1

reference method

prescribed analytical method to analyse a given group or species of microorganisms

NOTE As a rule, the reference method is a standard or a commonly used method.

3.1.1.2

trial method

any method which is to be tested for equivalence with a reference method