TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN ISO/TS 22117

November 2010

ICS 07.100.30

English Version

Microbiology of food and animal feeding stuffs - Specific requirements and guidance for proficiency testing by interlaboratory comparison (ISO/TS 22117:2010)

Microbiologie des aliments - Exigences spécifiques et lignes directrices pour les essais d'aptitude par comparaison interlaboratoires (ISO/TS 22117:2010)

Mikrobiologie von Lebensmitteln und Futtermitteln - Spezielle Anforderungen an die Eignungsprüfung durch Ringversuche (ISO/TS 22117:2010)

This Technical Specification (CEN/TS) was approved by CEN on 9 August 2010 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of 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 United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. CEN ISO/TS 22117:2010: E

Foreword

This document (CEN ISO/TS 22117:2010) 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.

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 announce this Technical Specification: 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/TS 22117:2010 has been approved by CEN as a CEN ISO/TS 22117:2010 without any modification.

Contents

Page

Introduction

General requirements for organization of proficiency testing (PT) schemes of all types are given through ISO/CASCO (Committee on Conformity Assessment) in ISO/IEC 17043; additionally, general guidance is available from the International Union of Pure and Applied Chemistry (IUPAC, see Reference [9]) and the International Laboratory Accreditation Cooperation (ILAC, see Reference [8]). However, these recommendations may not be directly applicable to all cases and should be interpreted specifically for different laboratory sectors where PT schemes are organized. For this reason, a document is needed to establish the criteria which a provider (and associated collaborators) of PT schemes shall meet in order to be recognized as competent to provide PT schemes for microbiological analysis. This applies particularly to the specific technical requirements necessary to deal with living microorganisms, such as sample homogeneity and stability, as well as with the interpretation of presence/absence (detection) tests which is not covered by an existing document.

Proficiency testing schemes for microbiology laboratories are mainly used to evaluate performance, particularly trueness (bias) and in some cases precision, of food microbiological examinations in specific laboratories.

Additionally, data from such PT schemes can be used:

a) to provide information to the organizations responsible for laboratory acceptance within an official control framework and to allow continuous monitoring;

b) to aid laboratory accreditation in a general framework of quality management;

c) to inform those responsible for quality in the participating laboratories as part of the educative elements of external quality assessment of trueness (bias).

Information from PT schemes may also be used for:

1) identification of the possible sources of errors, particularly the bias component of uncertainty, to improve performance;

2) estimation of measurement uncertainty for enumeration methods (see ISO/TS 19036[6]) and limits of detection for presence/absence methods;

3) demonstration of staff competence to perform a specific microbiological examination;

4) evaluation or validation of a given method by the study of trueness and precision;

5) identification of variability between individual laboratories;

6) assignment of a “target” value for an analyte in a material in order to establish a reference material.

However, these aspects are not specifically covered in this Technical Specification.

Proficiency testing schemes are therefore organized to meet certain criteria and the testing programme (frequency, number of samples, number of repeats, etc.) shall meet the requirements of the type of method used and commodity analysed, to achieve the level of control desired by all parties involved.

Microbiology of food and animal feeding stuffs — Specific requirements and guidance for proficiency testing by interlaboratory comparison

1 Scope

This Technical Specification gives requirements and guidance for the organization of proficiency testing schemes for microbiological examinations of:

a) food and beverages;

b) animal feeding stuffs;

c) food production environments and food handling;

d) primary production stages.

This Technical Specification is also potentially applicable to the microbiological examination of water where water is either used in food production or is regarded as a food in national legislation.

This Technical Specification relates to the technical organization and the implementation of proficiency testing schemes, as well as the statistical treatment of the results of microbiological examinations.

This Technical Specification is designed for use with ISO/IEC 17043 and ISO 13528, and deals only with areas where specific or additional details are necessary for proficiency testing schemes dealing with microbiological analyses for the areas specified in the first paragraph.

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 3534-1, *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

ISO 3534-2, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

ISO 5725-5, *Accuracy (trueness and precision) of measurement methods and results — Part 5: Alternative methods for the determination of the precision of a standard measurement method*

ISO 7218, *Microbiology of food and animal feeding stuffs — General requirements and guidance for microbiological examinations*

ISO 13528, *Statistical methods for use in proficiency testing by interlaboratory comparisons*

ISO/IEC 17043:2010, *Conformity assessment — General requirements for proficiency testing*