



SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 22117:2011
01-marec-2011

Mikrobiologija živil in krme - Posebne zahteve in napotki za preskušanje strokovnosti z medlaboratorijsko primerjavo (ISO/TS 22117:2010)

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

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

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

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Ta slovenski standard je istoveten z: CEN ISO/TS 22117:2010

ICS:

07.100.30 Mikrobiologija živil Food microbiology

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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)

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

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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.

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TECHNICAL
SPECIFICATION

ISO/TS
22117

First edition
2010-11-01

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

*Microbiologie des aliments — Exigences spécifiques et lignes
directrices pour les essais d'aptitude par comparaison interlaboratoires*

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Reference number
ISO/TS 22117:2010(E)

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Published in Switzerland

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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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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/TS 22117 was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*.

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.

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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*