



NSAI
Standards

Standard Recommendation
S.R. CEN 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)

S.R. CEN ISO/TS 22117:2010

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

SWIFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces:

This document is based on:
CEN ISO/TS 22117:2010

Published:
15 November, 2010

This document was published
under the authority of the NSAI
and comes into effect on:
15 November, 2010

ICS number:
07.100.30

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

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

Contents

Page

Foreword.....	3
----------------------	----------

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.

This page is intentionally left BLANK.

S.R. CEN ISO/TS 22117:2010

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*



Reference number
ISO/TS 22117:2010(E)

© ISO 2010

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2010

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction.....	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Scheme design and purpose	2
4.1 General	2
4.2 Scheme objectives	2
4.3 Laboratory requirements for schemes.....	3
4.4 Choice of test matrices	3
4.5 Information on test methods used by the PT provider.....	3
4.6 Statistical design	3
5 Technical requirements and guidance for sample design and content	4
5.1 Target organisms level	4
5.2 Sources, characterization and traceability of organisms	4
5.3 Background and competitive flora	5
5.4 Matrix selection and effects	5
6 Sample verification by the provider	5
6.1 General	5
6.2 Sample homogeneity testing — General considerations.....	5
6.3 Homogeneity testing for quantitative (enumeration) samples	6
6.4 Homogeneity testing for qualitative methods	7
6.5 Stability testing by the provider.....	7
7 Sample handling.....	8
7.1 General	8
7.2 Instructions to participants	8
8 Performance evaluations.....	9
8.1 General	9
8.2 Preliminary considerations	9
8.3 Quantitative methods.....	9
8.4 Assessment of qualitative methods	16
Annex A (informative) Example of details to be included in a PT scheme plan.....	19
Annex B (informative) Methods of testing for variation between portions of test materials	21
Annex C (informative) A practical method to assess long-term performance of participants in PT schemes using enumeration methods.....	24
Annex D (informative) Example of a safety data sheet	26
Bibliography.....	28

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.

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*

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- Looking for additional Standards? Visit Intertek Inform Infostore
 - Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation
-