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Microbiology of the food chain — Specific requirements and guidance for proficiency testing by interlaboratory comparison

Microbiologie de la chaîne alimentaire — Exigences spécifiques et recommandations relatives aux essais d'aptitude par comparaison interlaboratoires

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

This first edition cancels and replaces ISO/TS 22117:2010, which has been technically revised. The following changes have been made:

— updates have been made to align the document with ISO 13528:2015.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 [12]. 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 for a provider (and associated collaborators) of PT schemes for microbiological examinations to meet and be recognized as competent. This applies particularly to the specific technical requirements necessary to deal with microorganisms, such as sample homogeneity and stability, as well as with the interpretation of detection tests which is not covered by an existing document.

PT 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:

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

— estimation of uncertainty of test results, in conjunction with routine results, for quantitative (enumeration) methods (see ISO/TS 19036) and levels of detection for qualitative (detection) methods;

— demonstration of staff competence to perform a specific microbiological examination;

— evaluation or validation of a given method by the study of trueness, precision and robustness;

— identification of variability in test results between individual laboratories;

— assignment of a “target” value for a microorganism in a material in order to establish a reference material (see ISO 17034).

However, these aspects are not specifically covered in this document.

PT schemes are therefore designed to meet certain criteria and the testing programme (frequency, number of samples, number of repeats, etc.) to meet the requirements of the type of method used and commodity tested, to achieve the level of control required by all parties.

Microbiology of the food chain — Specific requirements and guidance for proficiency testing by interlaboratory comparison

1 Scope

This document specifies requirements and gives guidelines for the organization of proficiency testing (PT) schemes for microbiological examinations of

a) foods and beverages,

b) feeding animals,

c) environmental samples from food and feed production and handling, and

d) primary production stages.

This document is also 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 document relates to the technical organization and implementation of PT schemes, as well as the statistical treatment of results of microbiological examinations.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 13528:2015, *Statistical methods for use in proficiency testing by interlaboratory comparison*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534-1, ISO 3534-2, ISO 5725-1, ISO 13528, ISO/IEC 17043 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/