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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

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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).

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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.