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Microbiology of the food chain — Estimation of measurement uncertainty for quantitative determinations

Microbiologie de la chaîne alimentaire — Estimation de l'incertitude de mesure pour les déterminations quantitatives

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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 19036:2006, which has been technically revised. It also incorporates the amendment ISO/TS 19036:2006/Amd.1:2009. The main changes compared with the previous edition are as follows:

— provision has been made for the estimation of technical uncertainty, and also for other relevant sources of uncertainty involved in quantitative microbiological tests, relating to:

  — the matrix uncertainty (i.e. the uncertainty due to dispersion of microbes within the actual test matrix);

  — the Poisson uncertainty that relates to colony count techniques;

  — the confirmation uncertainty associated with tests to confirm the identity of specific organisms following a count for presumptive organisms;

  — the uncertainty associated with most probable number (MPN) estimates;

— the experimental design for the estimation of intralaboratory reproducibility standard deviation described in this document in connection with the technical uncertainty is now the same as the design described in ISO 16140-3 for the verification of quantitative methods;

— worked examples have been added to illustrate ways in which uncertainty estimates should be generated and reported;

— annexes have been added to provide details of some of the important, or alternative, procedures and issues associated with uncertainty estimation.

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

The term "measurement uncertainty" (MU) is used to denote the lack of accuracy (trueness and precision) that can be associated with the results of an analysis. In the context of quantitative microbiology, it provides an indication of the degree of confidence that can be placed on laboratory estimates of microbial numbers in foods or other materials.

ISO/IEC Guide 98-3 (also known as the "GUM") is a widely adopted reference document. The principal approach of ISO/IEC Guide 98-3 is to construct a mathematical or computer measurement model that quantitatively describes the relationship between the quantity being measured (the measurand) and every quantity on which it depends (input quantities). That measurement model is then used to deduce the uncertainty in the measurand from the uncertainties in the input quantities.

ISO/IEC Guide 98-3 recognizes that it might not be feasible to establish a comprehensive mathematical relationship between the measurand and individual input quantities and that in such cases the effect of several input quantities can be evaluated as a group. ISO/IEC 17025 also recognizes that the nature of the test method can preclude rigorous calculation of measurement uncertainty.

In the case of the microbiological analysis of samples from the food chain, it is not feasible to build a comprehensive quantitative measurement model, since it is not possible to quantify accurately the contribution of each input quantity, where:

— the analyte is a living organism, whose physiological state can be largely variable;

— the analytical target includes different strains, different species or different genera;

— many input quantities are difficult, if not impossible, to quantify (e.g. physiological state);

— for many input quantities (e.g. temperature, water activity), their effect on the measurand cannot be described quantitatively with adequate precision.

For the reasons given above, this document mostly uses a top-down or global approach to MU, in which the contribution of most input quantities is estimated as a standard deviation of reproducibility of the final result of the measurement process, calculated from experimental results with replication of the same analyses, as part of the measurement process. These quantities reflect operational variability and result in technical uncertainty. In food chain quantitative microbiology, assigned values or reference quantity values are usually not available so bias (which quantitatively expresses the lack of trueness) cannot be reliably estimated and is not included in the uncertainty estimated by this document.

While reproducibility provides a general estimate of uncertainty associated with the measurement method, it might not reflect characteristics associated with matrix uncertainty, resulting from the distribution of microorganisms in the food matrix.

Also, microbiological measurements often depend on counting or detecting quite small numbers of organisms that are more or less randomly distributed leading to intrinsic variability between replicates and a corresponding distributional uncertainty. For colony-count techniques, the Poisson uncertainty is determined, to which may be added, in certain cases, an uncertainty linked to confirmation tests used to identify isolated organisms. An additional uncertainty component is also required for most probable number (MPN) determinations. Relevant distributional uncertainty components, estimated from statistical theory, are calculated from individual experimental data.

These three different kinds of uncertainty (technical, matrix and distributional uncertainties) are combined using the principles of ISO/IEC Guide 98-3. This approach is similar to that followed by ISO 29201 in the field of water microbiology.

Technical uncertainty is often the largest of these three kinds and is estimated from a reproducibility standard deviation, which inevitably includes some contributions from the other two kinds. The preferred estimate of technical uncertainty is based on intralaboratory reproducibility, in the same way as ISO 16140-3. If consistent with laboratory protocols and client requirements, a general value of uncertainty may be reported as based only on a reproducibility standard deviation.

Microbiology of the food chain — Estimation of measurement uncertainty for quantitative determinations

1 Scope

This document specifies requirements and gives guidance for the estimation and expression of measurement uncertainty (MU) associated with quantitative results in microbiology of the food chain.

It is applicable to the quantitative analysis of:

— products intended for human consumption or the feeding of animals;

— environmental samples in the area of food production and food handling;

— samples at the stage of primary production.

The quantitative analysis is typically carried out by enumeration of microorganisms using a colony-count technique. This document is also generally applicable to other quantitative analyses, including:

— most probable number (MPN) techniques;

— instrumental methods, such as impediometry, adenosine triphosphate (ATP) and flow cytometry;

— molecular methods, such as methods based on quantitative polymerase chain reaction (qPCR).

The uncertainty estimated by this document does not include systematic effects (bias).

2 Normative references

There are no normative references in this document.

3 Terms, definitions and symbols

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions 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/

3.1.1
sample
<general> one or more items (or a proportion of material) selected in some manner from a population (or from a large quantity of material) intended to provide information representative of the population, and, possibly, to serve as a basis for a decision on the population or on the process which had produced it

[SOURCE: ISO/TS 17728:2015, 3.2.2, modified — Note 1 to entry has been deleted.]

3.1.2
laboratory sample
sample (3.1.1) prepared for sending to the laboratory and intended for inspection or testing

[SOURCE: ISO 6887-1:2017, 3.1]