SLOVENSKI STANDARD
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Mikrobiologija v prehranski verigi - Ocena merilne negotovosti pri kvantitativnem določanju (ISO/DIS 19036:2018)

Microbiology of the food chain - Estimation of measurement uncertainty for quantitative determinations (ISO/DIS 19036:2018)

Mikrobiologie der Lebensmittelkette - Feststellung von Messunsicherheiten bei quantitativen Bestimmungen (ISO/DIS 19036:2018)

Microbiologie de la chaîne alimentaire - Estimation de l'incertitude de mesure pour les déterminations quantitatives (ISO/DIS 19036:2018)

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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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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 on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*.

This first edition cancels and replaces ISO/TS 19036:2006, which has been technically revised.

The main changes are as follows.

The standard now includes provision not only for estimation of technical uncertainty but also for other relevant sources of uncertainty that are involved in quantitative microbiological tests. These additional sources relate 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 in colony-count and other techniques to confirm identity of specific organisms following a count for presumptive organisms; and

— the uncertainty associated with Most Probable Number estimates.

Worked examples illustrate ways in which uncertainty estimates should be generated and reported. Annexes provide details of some of the important, or alternative, procedures and issues associated with uncertainty estimation.

Introduction

The term 'Measurement Uncertainty' (MU) is used to define 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.

The *Guide to the expression of uncertainty in measurement* (GUM) [1] is a widely adopted reference document. The principal approach of the GUM is to construct a mathematical or computer *measurement model* that quantitatively describes the relationship between the quantity being measured (the *measurand*, Y) and every quantity on which it depends (*input quantities*, X_i). That measurement model is then used to deduce the uncertainty in the measurand from the uncertainties in the input quantities.

The GUM recognises 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 17025 [2] also recognises that the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement.

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; and

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

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

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

For these reasons, trueness is not included in the assessment of measurement uncertainty.

For the reasons given above, this International Standard mostly uses a "top-down" or "global" approach to measurement uncertainty 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*.

Whilst the technical uncertainty provides a general estimate of uncertainty associated with the sample(s) tested, it may 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. Additional uncertainty estimate is also required for Most Probable Number 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 the GUM.[1] This approach is similar to that followed by ISO 29201 [3] in the field of water microbiology.

Technical uncertainty is usually the largest component and, if consistent with laboratory protocols and client requirements, a general value of uncertainty may be reported as limited to technical uncertainty.