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

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee AW/9, Microbiology.

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Mikrobiologie der Lebensmittelkette - Feststellung von Messunsicherheiten bei quantitativen Bestimmungen (ISO 19036:2019)

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European foreword

This document (EN ISO 19036:2019) has been prepared by Technical Committee ISO/TC 34 "Food products" in collaboration with Technical Committee CEN/TC 463 “Microbiology of the food chain” the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by May 2020.

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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).

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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 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.

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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.

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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]

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3.1.3
test sample
sample (3.1.1) prepared from the *laboratory sample* (3.1.2) according to the procedure specified in the method of test and from which *test portions* (3.1.4) are taken

Note 1 to entry: Preparation of the laboratory sample before the test portion is taken is infrequently used in microbiological examinations.

[SOURCE: ISO 6887-1:2017, 3.4]

3.1.4
test portion
measured (volume or mass) representative *sample* (3.1.1) taken from the *laboratory sample* (3.1.2) for use in the preparation of the initial suspension

Note 1 to entry: Sometimes preparation of the laboratory sample is required before the test portion is taken, but this is infrequently the case for microbiological examinations.

[SOURCE: ISO 6887-1:2017, 3.5]

3.1.5
measurand
particular quantity subject to measurement

[SOURCE: ISO/IEC Guide 98-3:2008, B.2.9 modified — The example and the Note 1 to entry have been deleted.]

3.1.6
trueness
measurement trueness
closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value

Note 1 to entry: Trueness is not a quantity and thus cannot be expressed numerically, but measures for closeness of agreement are given in ISO 5725 (all parts).

Note 2 to entry: Trueness is inversely related to systematic measurement error, but is not related to random measurement error.

Note 3 to entry: "Measurement accuracy" should not be used for "trueness" and vice versa.

[SOURCE: ISO/IEC Guide 99:2007, 2.14, modified — The preferred term has been changed from "measurement trueness" to "trueness".]

3.1.7
bias
measurement bias
estimate of a systematic measurement error

[SOURCE: ISO/IEC Guide 99:2007, 2.18, modified — The preferred term has been changed from "measurement bias" to "bias".]

3.1.8
intralaboratory reproducibility
intermediate precision
closeness of agreement between test results obtained with the same method on the same or similar test materials in the same laboratory with different operators using different equipment

[SOURCE: ISO 8199:2018, 3.6]

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3.1.9
measurement uncertainty
MU
parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the *measurand* (3.1.5)

Note 1 to entry: The parameter may be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence.

Note 2 to entry: Measurement uncertainty comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of a series of measurements and can be characterized by experimental standard deviations. The other components, which also can be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information.

Note 3 to entry: It is understood that the result of the measurement is the best estimate of the value of the measurand and that all components of uncertainty, including those arising from systematic effects, such as components associated with corrections and reference standards, contribute to the dispersion.

[SOURCE: ISO/IEC Guide 98-3:2008, 2.2.3, modified — The preferred term has been changed from "uncertainty of measurement" to "measurement uncertainty".]

3.1.10
standard uncertainty
u
uncertainty of the result of a measurement expressed as a standard deviation

[SOURCE: ISO/IEC Guide 98-3:2008, 2.3.1, modified — The symbol has been added.]

3.1.11
combined standard uncertainty
$u_c(y)$
standard uncertainty (3.1.10) of the result of a measurement when that result is obtained from the values of a number of other quantities, equal to the positive square root of a sum of terms, the terms being the variances or covariances of these other quantities weighted according to how the measurement result varies with changes in these quantities

[SOURCE: ISO/IEC Guide 98-3:2008, 2.3.4, modified — The symbol has been added.]

3.1.12
expanded uncertainty
U
quantity defining an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the *measurand* (3.1.5)

Note 1 to entry: The fraction may be regarded as the coverage probability or level of confidence of the interval.

Note 2 to entry: To associate a specific level of confidence with the interval defined by the expanded uncertainty requires explicit or implicit assumptions regarding the probability distribution characterized by the measurement result and its *combined standard uncertainty* (3.1.11). The level of confidence that may be attributed to this interval can be known only to the extent to which such assumptions may be justified.

Note 3 to entry: An expanded uncertainty U is calculated from a combined standard uncertainty $u_c(y)$ and a *coverage factor k* (3.1.13) using:

$$U = k \times u_c(\mathrm{y})$$

[SOURCE: ISO/IEC Guide 98-3:2008, 2.3.5, modified— The symbol has been added and Note 3 to entry has been replaced.]

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3.1.13
coverage factor
k
number larger than one by which a *combined standard uncertainty* (3.1.11) is multiplied to obtain an *expanded uncertainty* (3.1.12)

[SOURCE: ISO/IEC Guide 98-3:2008, 2.3.6, modified— The symbol has been added and the definition has been reworded.]

3.1.14
technical uncertainty
uncertainty resulting from operational variability associated with the technical steps of the analytical procedure

Note 1 to entry: Technical uncertainty includes the variability of the taking, mixing, and dilution of the *test portion* (3.1.4) taken from the *laboratory sample* (3.1.2) to prepare the initial suspension and subsequent dilutions. It also includes the effects of variability in incubation and media.

Note 2 to entry: Adapted from ISO 29201:2012, 3.4.2.

3.1.15
matrix uncertainty
uncertainty resulting from the extent to which the *test portion* (3.1.4) is not truly representative of the *laboratory sample* (3.1.2)

3.1.16
distributional uncertainty
uncertainty resulting from intrinsic variability associated with the distribution of microorganisms in the *sample* (3.1.1), the initial suspension and subsequent dilutions

Note 1 to entry: In microbiological suspensions, intrinsic variability is usually modelled by the Poisson distribution. When partial confirmation is practised or the MPN principle is used, the resulting distribution may differ from the Poisson distribution.

Note 2 to entry: Adapted from ISO 29201:2012, 3.4.3.

3.2 Symbols

For the purposes of this document, the following symbols apply.

ΣC	for colony-count methods, total number of counted colonies used to calculate the measurement results
n_p, n_c	for colony-count methods with partial confirmation, number of presumptive colonies tested, and number of confirmed colonies, respectively
s_R	reproducibility standard deviation
s_{IR}	intralaboratory reproducibility standard deviation
$s_{IR:\mathrm{corr}}$	intralaboratory reproducibility standard deviation, corrected by subtraction of matrix and distributional components
s_r	repeatability standard deviation
$s_{r:\mathrm{corr}}$	repeatability standard deviation, corrected by subtraction of distributional components
S_{unwanted}	sum of squares of unwanted components
u	standard uncertainty

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$u_{distrib}$	distributional standard uncertainty
u_{tech}	technical standard uncertainty
u_{conf}	confirmation standard uncertainty
u_{matrix}	matrix standard uncertainty
u_{MPN}	most probable number standard uncertainty
$u_{unwanted}$	standard uncertainty of the unwanted component
$u_{Poisson}$	Poisson standard uncertainty
$u_c(y)$	combined standard uncertainty (of output estimate)
k	coverage factor
U	expanded uncertainty (of output estimate) = $k \times u_c(y)$

4 General considerations

MU associated with any measurement value includes multiple components.

As indicated in the Scope (see Clause 1), the uncertainty estimated by this document does not include contributions from systematic effects (bias). In food chain quantitative microbiology, assigned values or reference quantity values are usually not available so bias cannot be reliably estimated.

This document considers three distinct types of uncertainty component:

— technical uncertainty;

— matrix uncertainty;

— distributional uncertainty.

Technical uncertainty arises from operational variability and is estimated, using a global approach, from a reproducibility standard deviation of the final result of the measurement process (see Clause 5). This global approach means that the technical uncertainty estimate comes from final test results rather than by calculation using estimates of uncertainty at every individual stage of the test.

Matrix uncertainty arises from imperfect mixing of the laboratory sample, resulting in poor reproducibility of microbial levels between test portions, which can be large for solid matrices, and especially for composite food products. Matrix uncertainty is estimated for each kind of matrix (see Clause 6).

Even for homogeneous materials, the random distribution of microorganisms leads to distributional uncertainty (see Clause 7), of which three potential kinds are considered in this document. The relevance of each depends on the method used:

— for colony-count techniques:

  — Poisson uncertainty (see 7.2);

  — confirmation uncertainty (see 7.3);

— for MPN techniques: MPN uncertainty (see 7.4).

The uncertainty for each distributional uncertainty source is estimated mathematically.

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This document presents two options for estimating the combined uncertainty for a reported measurement.

a) Technical, matrix and distributional uncertainty components for a reported value may be estimated separately from each other (see Clauses 5, 6 and 7), after which the three components are combined (see 8.1.2).

b) A general value of uncertainty may be reported as based only on a reproducibility standard deviation, if consistent with laboratory protocols and client requirements (see 8.1.3). Technical uncertainty is indeed often the largest of the three uncertainty components.

5 Technical uncertainty

5.1 Identification of main sources of uncertainty

5.1.1 General aspects

It can be helpful to consider the sources of technical uncertainty usually associated with the main stages in a microbiological method. Typical sources for colony-count or MPN techniques are:

— taking a test portion from the laboratory (or test) sample;

— preparation of the initial suspension;

— serial dilution;

— inoculation;

— incubation;

— counting of colonies in a colony count technique, and/or detection of growth (as in a MPN technique);

— confirmation (if appropriate).

Figure 1 shows the main sources of uncertainty in food chain microbiology considered in this document.

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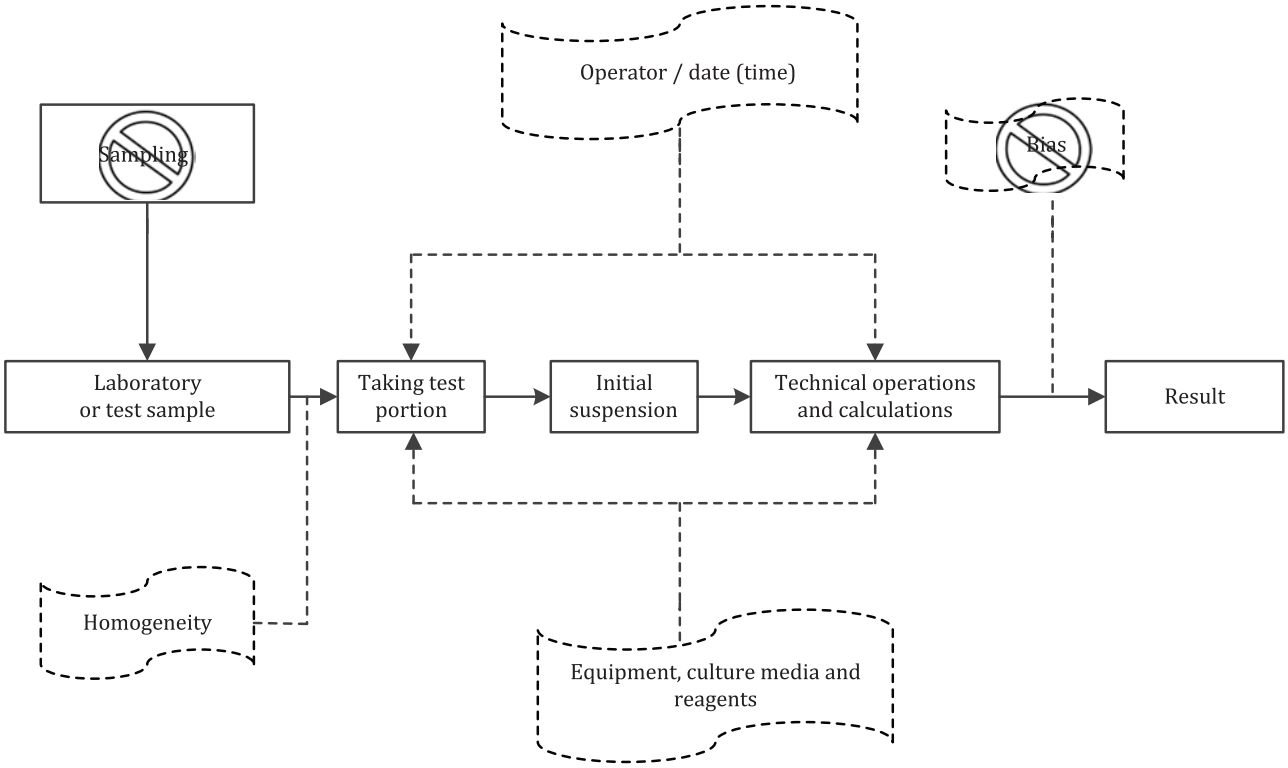

Key

———— the sequential procedures

- - - - - - - the factors that affect uncertainty estimation

⊘ these factors are not covered by this document

Figure 1 — Main sources of uncertainty in food chain microbiology covered in this document

5.1.2 Sampling uncertainty

Sampling uncertainty, i.e. error associated with the drawing of the laboratory sample from a lot under investigation, can contribute significantly to the overall error[18], but it is not part of the uncertainty linked to the measurement itself and is not covered by this document.

Matrix uncertainty that arises from the inability of the test portion to perfectly represent a heterogeneous laboratory sample or test sample is covered in Clause 6. The extent of such inability can depend on the size of the test portion taken for examination (see ISO 6887-1).

5.1.3 Bias

As indicated in Clauses 1 and 4, MU estimated by this document does not include contributions from systematic effects that is bias.

5.1.4 Critical factors

Examples of critical technical factors that can influence uncertainty and need to be controlled include: the source and type of culture media and/or other reagents (such as the ones used for confirmation), the dilution, inoculation and incubation procedures, the counting techniques (manual or automated), and changes to the operator or group of operators, etc.

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