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Microbiology of food and animal feeding stuffs — Guidelines for the estimation of measurement uncertainty for quantitative determinations

Microbiologie des aliments — Lignes directrices pour l'estimation de l'incertitude de mesure pour les déterminations quantitatives

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Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Terms and definitions 1

3 Principles 3
3.1 Global approach for the estimation of measurement uncertainty (MU) 3
3.2 Consideration of bias 3

4 General aspects 4
4.1 Combined standard uncertainty 4
4.2 Standard deviation of reproducibility 4
4.3 Expanded uncertainty 4
4.4 General rules for the estimation of the reproducibility standard deviation 4

5 Intralaboratory standard deviation of reproducibility 5
5.1 General 5
5.2 Experimental protocol 5
5.3 Calculations 7

6 Reproducibility standard deviation of the method derived from an interlaboratory study 8
6.1 General 8
6.2 Use in food microbiology 9

7 Reproducibility standard deviation derived from an interlaboratory proficiency trial 10

8 Expression of measurement uncertainty in the test reports 10

Annex A (informative) **Results of trials on the uncertainty component linked to the sub-sampling of test portion and to the preparation of the initial suspension** 11

Bibliography 16

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

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An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 19036 was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*.

Laboratories operating under ISO/IEC 17025 accreditation and related systems are required to evaluate measurement uncertainty (MU) for the analyses they conduct, and to report it when relevant. The MU estimation gives a measure of the confidence that can be put on the analytical results, not on the laboratory competency.

Given this need, ISO/TC 34/SC 9 considered that it was necessary to define a general approach to the estimation of measurement uncertainty in food microbiology, based on the general guidelines for expressing MU. It reached a consensus for quantitative determinations, and was aware that there was also a need to estimate MU for qualitative determinations, but this would need more time, and would be covered by a separate later publication.

In order to expedite publication of a document to provide a harmonized approach that could be applied for accreditation purposes, ISO/TC 34/SC 9 decided to prepare a Technical Specification rather than an International Standard. It was believed that this would encourage users of this publication to report their experience on the implementation of the approach described. ISO/TC 34/SC 9 could then review the document in the light of the experience gained.

Introduction

The *Guide to the expression of uncertainty in measurement* (GUM) [15] is a widely adopted standard approach that recommends, as illustrated in the examples provided, the estimation of the individual sources of variability that contribute to uncertainty in the measurement process. The global uncertainty is then derived using formal principles of uncertainty propagation. This approach has been described in a more practical way for analytical measurements, mainly of chemical nature, by the EURACHEM/CITAC Guide [16] and also for microbiology in Reference [17].

ISO/TC 34/SC 9 considers that this “step-by-step” approach does not apply satisfactorily in the case of the microbiological analysis of food, where it is difficult to build a really comprehensive model of the measurement process. Because of the possibility of overlooking a significant source of uncertainty, there is a high risk of underestimating the true measurement uncertainty (MU) value. Furthermore, it appears difficult to quantify accurately the contribution of each individual step of the analytical process in food microbiology, 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.

In other words, the microbiological analyses do not enable a metrologically rigorous and statistically valid estimation of MU.

ISO/TC 34/SC 9 has therefore chosen a “top-down” or “global” approach to MU, which is based on a standard deviation of reproducibility of the final result of the measurement process. This is an approach based on experimental results (with replication of the same analysis) which, in the case of microbiology, seems more meaningful than the step-by-step approach.

The global approach has been endorsed for a more general use by ISO/TS 21748 elaborated by ISO/TC 69, *Application of statistical methods*, SC 6, *Measurement methods and results*. This document clarifies that the step-by-step approach and the global approach are not mutually exclusive, since all the MU components can be considered to be included in the overall performance of the analytical process, which can be characterized by the observable precision and bias.

Microbiology of food and animal feeding stuffs — Guidelines for the estimation of measurement uncertainty for quantitative determinations

1 Scope

This Technical Specification gives guidance for the estimation and expression of measurement uncertainty (MU) associated with quantitative results in food microbiology.

It is applicable to the quantitative analysis

— of products intended for human consumption and the feeding of animals, and

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

typically carried out by enumeration of microorganisms using a colony-count technique, but applicable also to quantitative analysis by alternative instrumental methods.

This Technical Specification is not applicable to

— enumeration using a most probable number technique, or

— the analysis of low levels of microorganisms.

In this Technical Specification, MU associated with “low” numbers of organisms [1)], as described by ISO 7218, is not estimated due to a lack of a simple agreed approach to cover this case.

The approach of this Technical Specification is a global approach, based on the standard deviation of reproducibility of the final result of the measurement.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
uncertainty (of measurement)
parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

NOTE 1 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 Uncertainty of measurement 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.

1) That is below 10 colonies counted on at least one plate, normally corresponding to less than 100 cfu per gram or per millilitre, or 1 000 cfu per gram or per millilitre of product depending on the volume of the inoculum (1 ml or 0,1 ml).