SLOVENSKI STANDARD
oSIST prEN ISO 21187:2019

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Mleko - Kvantitativno določanje bakteriološke kakovosti - Navodilo za ugotavljanje in preverjanje konverzijske povezave med rezultati alternativne metode in rezultati uveljavljene metode (ISO/DIS 21187:2019)

Milk - Quantitative determination of bacteriological quality - Guidance for establishing and verifying a conversion relationship between results of an alternative method and anchor method results (ISO/DIS 21187:2019)

Milch - Quantitative Bestimmung der bakteriologischen Qualität - Leitfaden für die Erarbeitung einer Übertragungsbeziehung zwischen den Messwerten von Routine- und Bezugsverfahren sowie deren Verifizierung (ISO/DIS 21187:2019)

Lait - Mesure quantitative de la qualité bactériologique - Lignes directrices pour établir et vérifier une relation de conversion entre les résultats de la méthode alternatif et les résultats de la méthode d'ancrage (ISO/DIS 21187:2019)

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Milk — Quantitative determination of bacteriological quality — Guidance for establishing and verifying a conversion relationship between results of an alternative method and anchor method results

Lait — Mesure quantitative de la qualité bactériologique — Lignes directrices pour établir et vérifier une relation de conversion entre les résultats de la méthode alternatif et les résultats de la méthode d'ancrage

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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 5, *Milk and milk products* and the International Dairy Federation (IDF). It is being published jointly by ISO and IDF.

This second edition cancels and replaces the first edition (ISO 21187 | IDF 196:2004), which has been technically revised.

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.

Foreword

IDF (the International Dairy Federation) is a non-profit organization representing the dairy sector worldwide. IDF membership comprises National Committees in every member country as well as regional dairy associations having signed a formal agreement on cooperation with IDF. All members of IDF have the right to be represented at the IDF Standing Committees carrying out the technical work. IDF collaborates with ISO in the development of standard methods of analysis and sampling for milk and milk products.

The main task of Standing Committees is to prepare International Standards. Draft International Standards adopted by the Standing Committees are circulated to the National Committees for endorsement prior to publication as an International Standard. Publication as an International Standard requires approval by at least 50 % of IDF National Committees casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. IDF shall not be held responsible for identifying any or all such patent rights.

ISO 21187|IDF 169 was prepared by the International Dairy Federation (IDF) and Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 5, *Milk and milk products*. It is being published jointly by IDF and ISO.

All work was carried out by the Joint ISO-IDF Actio Team (S11) of the Standing Committee on *Statistics and automation* under the aegis of its project leaders, Mrs. B. Asmussen (DK), Mr. R. Kissling (NZ) and Mrs. B. Müller (DE).

Introduction

Conversion in quantitative microbiology means expressing the result of a quantitative determination of the bacteriological status of a test sample obtained with an alternative method in units of another method, generally an anchor method. Through this, quantitative results obtained with alternative methods can be compared to values or limits that are stated in anchor method units. For establishing and applying a conversion relationship, a number of prerequisites should be met. These are referred to in this International Standard, but are generally described elsewhere.

Although a considerable part of the applied principles for conversion coincides with those applied for the calibration of indirect or alternative methods against an anchor method, or by means of (certified) reference materials, it is stressed that the background and aims for applying conversion are different from those for calibration. Calibration involves the determination of the adjustment needed for each level of an analyte to closely approximate the true value of its concentration or number. However, in quantitative microbiology, a true value in its strict sense cannot be established and is only defined by the method description applied. When applying alternative methods in the quantitative determination of bacteriological quality, one is often dealing with different methodological principles and therefore also other units. Conversion is used to transfer results obtained with different methods to a common scale.

Milk — Quantitative determination of bacteriological quality — Guidance for establishing and verifying a conversion relationship between results of an alternative method and anchor method results

1 Scope

This document gives guidelines for the establishment of a conversion relationship between the results of an alternative method and an anchor method, and its verification for the quantitative determination of the microbiological quality of milk.

NOTE The conversion relationship can be used (1) to convert results from an alternative method to the anchor basis or (2) to convert results/limits, expressed on a anchor basis, to results in units of an alternative method.

2 Normative references

The following documents are referred to in the text in such a way tht some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8196-1, *Milk — Definition and evaluation of the overall accuracy of alternative methods of milk analysis — Part 1: Analytical attributes of alternative methods*

ISO 8196-2, *Milk — Definition and evaluation of the overall accuracy of alternative methods of milk analysis — Part 2: Calibration and quality control in the dairy laboratory*

ISO 11095, *Linear calibration using reference materials*

ISO 16140-1, *Microbiology of the food chain — Method validation — Part 1: Vocabulary*

ISO 16140-2, *Microbiology of the food chain — Method validation — Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method*

ISO 16297, *IDF 161, Milk — Bacterial count — Protocol for the evaluation of alternative methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8196-1|IDF 128-1, ISO 8196-2|IDF 128-2, ISO 16140-1 and the following apply.

3.1
alternative method
method of analysis allowing quantification of the microbiological status of a test sample

Note 1 to entry: The method can be proprietary or non-commercial.

Note 2 to entry: The term 'alternative' in this document refers to the entire method. It includes all aspects (such as sample pretreatment, materials and instruments) required for the execution of the method.

3.2
anchor method
method of analysis internationally recognized by experts or by agreement between parties, and used, for instance, in legislation when expressing official limits for microbiological quality

Note 1 to entry: It is stressed that, in quantitative microbiology, any obtained value is only defined by the method description applied. This applies to any alternative method as well as, for instance, to the standard plate count for the enumeration of microorganisms.

3.3
analyte
component or property which is measured by the method of analysis

Note 1 to entry: The analyte may be the microorganism, stained particles (e.g. microsopic count), components of microorganisms (e.g. lipopolysaccharides), the result of their ability to multiply (e.g. colony-forming units) or their metabolic activity (e.g. change in conductivity/impedance).

3.4
organizing body
organization, possibly appointed by a competent authority, having the qualified staff and skills to organize, to coordinate and to report on the outcome of the activities for the establishment of the maintenane of a conversion relationship

3.5
measuring range
range in which reliable data can be obtained with an alternative method. Precision data for this range were determined in a validation study (e.g. by the instrument manufacturer or a responsible organization)

3.6
range of interest
numerical values in which the routine samples analysed in a laboratory can appear. This includes also values which appear only infrequently. The range of interest also includes official limits and limits related to specific quality schemes

4 Principles

4.1 General

The establishment and verification of a conversion relationship is based on the examination of test samples with an alternative method and an anchor method.

4.2 Requirements for applied methods and laboratories

For establishing and verifying a conversion relationship between the results of an alternative method and the anchor method, the following prerequisites apply.

The alternative method should have been evaluated and validated according to ISO 16140-2 and/or ISO 16297 | IDF 161. Procedures for sampling, test sample preservation, sample transport, sample storage, sample pre-treatment, analysis and calculation of results should be documented, strictly standardized and controlled in agreement with ISO/IEC 17025, Eurachem Guide 'Accreditation for Microbiological Laboratories' or comparable standards[1)].

The anchor method should have been validated, documented, strictly standardized and controlled in agreement with ISO/IEC 17025, Eurachem Guide 'Accreditation for Microbiological Laboratories' or comparable standards[1)].

1) Regular participation in proficiency tests and training according to the relevant standards, e.g. ISO 4833-1 and ISO 14461 | IDF 169, is strongly recommended.

The protocol for the establishment of the conversion relationship and its verification should be documented. It should follow the guidelines of this International Standard.

4.3 Organizational set-up

There are a number of situations which can be distinguished, e.g. both the alternative and the anchor method are fully carried out in the same laboratory, or several laboratories are involved in the trial.

Due to the instability and variability of the microbiological status of milk samples, the most robust conversion relationships will be obtained where the alternative method and the anchor method are undertaken on the same test samples, at the same place, at the same time. It shall be ensured that either the sequence of testing do not impose significant influence on the test results or the method with the lowest influence on the milk sample is applied first.

Subsampling should be avoided. However, in case of two or more participating laboratories subsamples may be necessary.

In all cases, the organizational set-up should include all the necessary provisions to guarantee that the obtained conversion relationship is representative of the circumstances under which the alternative method is carried out and the resulting conversion relationship is later applied. Factors to consider are listed in Clause 5.

The organizing body should provide guidance to the collaborating laboratories. Furthermore, it should collect information on critical points in the procedure. All collaborators should be asked to record relevant information, such as details on the method(s) used, details on the testing of samples, quality control data, and possibly data about storage and transport conditions.

5 Consideration of factors influencing the conversion relationship

5.1 General

A number of factors can influence the outcome of alternative method or anchor method determinations, or both. The relative magnitude of the effects can differ between test samples and is not necessarily the same for both methods. This implies that certain factors can also influence the conversion relationship. In the evaluation of an alternative method, all relevant factors should be identified and should be considered since it is necessary to cover the consequences of their variation in one conversion relationship, or otherwise to establish distinct conversion relationships.

In general, when distinction between samples cannot be made, or is not being made in routine testing circumstances, the variation in the underlying variables should be covered in one conversion relationship. Where a factor is shown to have a significant effect on the conversion relationship, more than one conversion relationship may need to be established and applied.

Influencing factors are grouped into environmental factors affecting the milk sample e.g. content of psychrotrophic bacteria or background noise from the sample matrix and analytical factors, which relate to the analysis itself, e.g. reagents.

Below are listed some factors which can possibly influence the conversion relationship in raw milk analysis. Some of these factors may be applied also to other situations.

5.2 Environmental factors

The microbiological flora of a milk sample, i. e. the type of microorganisms, their growth phase or metabolic activity, influences the outcome of analytical methods depending on the principle of the measurement[2)] and thus can have a significant impact on the conversion relationship. The normal variation of microbiological flora should be included in a conversion relationship.

2) For example plate count method contrary to the flow-cytometric method counts only aerobic microorganisms while anaerobic strains cannot be determined.