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Milk — Quantitative determination of microbiological 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 microbiologique — 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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 302, *Milk and milk products — Methods of sampling and analysis,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement), 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. The main changes compared with the previous edition are as follows:

— the formula describing the conversion relationship has been based on grouped data rather than data from individual samples;

— examples of how to perform outlier tests, and calculation and verification of conversion relationships have been given in a spreadsheet.

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.

IDF (the International Dairy Federation) is a non-profit private sector organization representing the interests of various stakeholders in dairying at the global level. IDF members are organized in National Committees, which are national associations composed of representatives of dairy-related national interest groups including dairy farmers, dairy processing industry, dairy suppliers, academics and governments/food control authorities.

ISO and IDF collaborate closely on all matters of standardization relating to methods of analysis and sampling for milk and milk products. Since 2001, ISO and IDF jointly publish their International Standards using the logos and reference numbers of both organizations.

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This document was prepared by the IDF *Standing Committee on Statistics and Automation* and ISO Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 5, *Milk and milk products*. It is being published jointly by IDF and ISO.

The work was carried out by the IDF/ISO Action Team (S11) of the *Standing Committee on Statistics and Automation* under the aegis of its project leaders, Ms B. Asmussen (DK), Ms V. Tzeneva (NL), Mr R. Kissling (NZ) and Ms B. Müller (DE).

Introduction

Conversion in quantitative microbiology means expressing the result of a quantitative determination of the microbiological 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 document, 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 microbiological 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 microbiological 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 a) to convert results from an alternative method to the anchor basis or b) to convert results/limits, expressed on an 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 that 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 | IDF 128-1, *Milk — Definition and evaluation of the overall accuracy of alternative methods of milk analysis — Part 1: Analytical attributes of alternative methods*

ISO 8196-2 | IDF 128-2, *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 16140-1, *Microbiology of the food chain — Method validation — Part 1: Vocabulary*

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.

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
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 test sample pre-treatment, materials and instruments) required for the execution of the method.