Milk - Bacterial count - Protocol for the evaluation of alternative methods (ISO 16297:2020)

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 16297:2020 sisaldab Euroopa standardi EN ISO 16297:2020 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 16297:2020 consists of the English text of the European standard EN ISO 16297:2020.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 22.01.2020.	Date of Availability of the European standard is 22.01.2020.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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English Version

Milk - Bacterial count - Protocol for the evaluation of alternative methods (ISO 16297:2020)

Lait - Dénombrement bactériologique - Protocole pour l'évaluation de méthodes alternatives (ISO 16297:2020)

Milch - Bestimmung der Gesamtkeimzahl - Protokoll für die Bewertung alternativer Verfahren (ISO 16297:2020)

This European Standard was approved by CEN on 3 January 2020.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 16297:2020) has been prepared by Technical Committee ISO/TC 34 "Food products" in collaboration with Technical Committee CEN/TC 302 “Milk and milk products - Methods of sampling and analysis” the secretariat of which is held by NEN.

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 July 2020, and conflicting national standards shall be withdrawn at the latest by July 2020.

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

This document supersedes EN ISO 16297:2014.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 16297:2020 has been approved by CEN as EN ISO 16297:2020 without any modification.

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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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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 16297 | IDF 161:2013), which has been technically revised with the following main changes:

— the number of samples and the calculation of the lower limit of quantification has been changed and aligned with ISO 16140-2;

— an example of carry-over effect given in Figure 1 has been omitted;

— the requirements for the evaluation of the accuracy of the estimate and the accuracy profile have been clarified and aligned with ISO 16140-2;

— Annex A (informative) has been omitted.

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 (S18) of the *Standing Committee on Statistics and Automation* under the aegis of its project leaders, Mrs V. Tzeneva (NL) and Mrs I. Andersson (SE).

Introduction

Any quantitative measurement in microbiology should consider that there is a requirement for the microbiological state in a sample to be regarded as one point within the coordinates of a multidimensional system, which is to be projected on to the one-dimensional scale of the method applied, i.e. plate count, flow cytometry. Aspects such as flora (types and numbers of microorganisms and their distribution), growth phase, sub-lethal damage, metabolic activity, and history, influence to a greater or lesser extent any parameter that is measured. It is evident that any projection of an *n*-dimensional situation onto a one-dimensional scale is bound to provide a picture of the real situation that is rather restricted. In this respect, one has to bow to the inevitable, regardless of which method of measurement is preferred.

The term “anchor method” in this document means a method internationally recognized by experts, used in legislation or by agreement between the parties. There are requirements for evaluation of an alternative method to refer to the anchor method and to be based on the examination of suitable samples for its intended use.

Milk — Bacterial count — Protocol for the evaluation of alternative methods

1 Scope

This document specifies a protocol for the evaluation of instrumental alternative methods for total bacterial count in raw milk from animals of different species.

NOTE The document is complementary to ISO 16140-2 and ISO 8196 | IDF 128 (all parts).

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 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

ISO 5725-2, *Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*

ISO 8196 | IDF 128 (all parts), *Milk — Definition and evaluation of the overall accuracy of alternative methods of milk analysis*

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

ISO 21187 | IDF 196, *Milk — Quantitative determination of bacteriological quality — Guidance for establishing and verifying a conversion relationship between results of an alternative method and anchor method results*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 5725-1, ISO 5725-2, ISO 8196-1 | IDF 128-1, ISO 8196-2 | IDF 128-2, ISO 8196-3 | IDF 128-3 and ISO 16140-1 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/

4 Transformation of results

A prerequisite for statistics most common in the evaluation of measuring methods is the approximation of a normal distribution of the data. The exponential multiplication of microorganisms usually leads to a right-tailed distribution with quantitative microbiological parameters. Thus, in general, transformation of the raw data is necessary for approximation of normality. This is usually a common logarithmic transformation. The most appropriate transformation can be checked by comparing histograms. All statistics are then computed from the transformed data, unless specified otherwise, and only the final results are re-transformed to give a more expressive idea of the situation to the user (see Reference [2]).