INTERNATIONAL STANDARD

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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 ét la me 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.

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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 <u>www.iso.org/members.html</u>.

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ISO 21187:2021(E) IDF 196:2021(E)

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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.

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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

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 <u>https://www.iso.org/obp</u>
- IEC Electropedia: available at <u>http://www.electropedia.org/</u>

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.