
**Milk — Definition and evaluation of
the overall accuracy of alternative
methods of milk analysis —**

**Part 3:
Protocol for the evaluation and
validation of alternative quantitative
methods of milk analysis**

*Lait — Définition et évaluation de la précision globale des méthodes
alternatives d'analyse du lait —*

*Partie 3: Protocole d'évaluation et de validation des méthodes
quantitatives alternatives pour l'analyse du lait*



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Forewords

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 8196 | IDF 128-3:2009), which has been technically revised. The main changes are as follows:

- the validation scheme has been simplified for phase II and it is possible to validate a new instrument with the comparison with a previous validated instrument.

A list of all parts in the ISO 8196 | IDF 128 series can be found on the ISO website.

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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The work was carried out by the IDF/ISO Action Team (S14) of the *Standing Committee on Statistics and Automation* under the aegis of its project leader, Dr S. Orlandini (IT).

Introduction

This document is complementary to ISO 8196-1 | IDF 128-1. It describes a protocol for the evaluation of new alternative methods for which ISO 8196-1 | IDF 128-1 cannot apply, e.g. when the organization of interlaboratory studies is hampered by a limited number of new instruments available for study.

The latter is generally the case with dedicated instrumental methods (e.g. milk payment analysis, milk recording analysis) of which the commercialization depends on official approvals for use. An application for such an official approval is to be accompanied by one or more assessments of the relevant performance characteristics.

This document specifies a harmonized protocol for such a method validation by expert laboratories. It lists the evaluation steps and provides a criteria-based approach for the assessment of the performance characteristics, including guidance for checking statistical compliance.

On the basis of such a harmonized protocol, a limited number of evaluations should suffice for a decision by an approval body for the application of the method and/or equipment. Examples with indicative limits are given for the evaluation of a method for the determination of fat, protein, lactose, urea and somatic cell count in milk. The guideline can also be applied to other parameters such as freezing point and pH in milk.

Milk — Definition and evaluation of the overall accuracy of alternative methods of milk analysis —

Part 3:

Protocol for the evaluation and validation of alternative quantitative methods of milk analysis

1 Scope

This document specifies a protocol for the evaluation and validation of alternative quantitative methods of milk analysis. This document is also applicable for the validation of new alternative methods where, due to a limited number of operational instruments, the execution of an interlaboratory study and ISO 8196-1 | IDF 128-1 is not feasible.

The protocol is applicable to milk parameters such as, for example, fat, protein, lactose, urea and somatic cells in milk. It can also be extended to other parameters.

This document also establishes the general principles of a procedure for granting international approvals for the performance of the alternative methods. These principles are based on the validation protocol defined in this document.

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 3534-1, *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

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

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/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534-1, ISO 5725-1, ISO 8196-1 | IDF 128-1, ISO 8196-2 | IDF 128-2 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 <https://www.electropedia.org/>