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

Part 2:
Calibration and quality control in the dairy laboratory

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

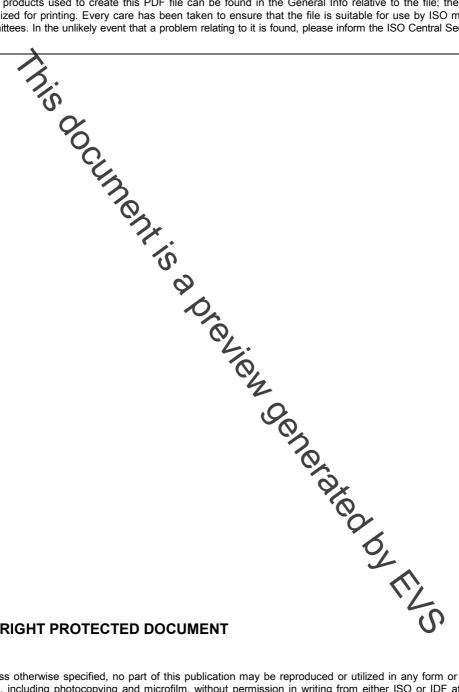*Partie 2: Calibrage et contrôle qualité dans les laboratoires laitiers*

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 8196-2|IDF 128-2 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 of ISO 8196-2|IDF 128-2 cancels and replaces the first edition (ISO 8196-2:2000), which has been technically revised.

ISO 8196|IDF 128 consists of the following parts, under the general title *Milk — Definition and evaluation of the overall accuracy of alternative methods of milk analysis*:

— *Part 1: Analytical attributes of alternative methods*

— *Part 2: Calibration and quality control in the dairy laboratory*

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

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 Action Teams and Standing Committees are circulated to the National Committees for voting. 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 8196-2|IDF 128-2 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 ISO and IDF.

All work was carried out by the Joint IDF-ISO Action Team on *Automated methods* of the Standing Committee on *Quality assurance, statistics of analytical data and sampling* under the aegis of its project leader, Mr. O. Leray (FR).

This edition of ISO 8196-2|IDF 128-2, together with ISO 8196-1|IDF 128-1 and ISO 8196-3|IDF 128-3, cancels and replaces IDF 128:1985, which has been technically revised.

ISO 8196|IDF 128 consists of the following parts, under the general title *Milk — Definition and evaluation of the overall accuracy of alternative methods of milk analysis*:

— *Part 1: Analytical attributes of alternative methods*

— *Part 2: Calibration and quality control in the dairy laboratory*

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

Introduction

The main purpose of this part of ISO 8196|IDF 128 is to provide practical details and recommendations for the calibration of instruments and quality control in routine dairy laboratories, including the checking of compliance with a specification value or limit.

ISO 8196-1|IDF 128-1 is mainly intended for users to assess alternative methods of analysis and gives guidance for routine laboratories using these methods.

This part of ISO 8196|IDF 128 relates directly to ISO 8196-1|IDF 128-1 for the definition of the relevant performance characteristics, for the quantitative evaluation of the overall accuracy and the establishment of relevant standard limit values to comply with in analytical quality assurance as described. The general concepts apply to all analytical methods, but special emphasis is given to rapid physicochemical methods which are currently in use for the compositional testing of milk.

ISO 8196|IDF 128 (all parts) only specifies the single linear regression model as a simplified approach to allow users to determine equivalence of an alternative method with a reference method. However, the linear regression approach is valid as a determination of method equivalence only in limited circumstances or if a high correlation between the results of the reference method and the routine method is achieved. If a high correlation is not achieved, recourse should be made to other data handling and measurement error modelling techniques. Although these techniques are referred to, they are not specified in ISO 8196|IDF 128 (all parts).

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

Part 2:
Calibration and quality control in the dairy laboratory

1 Scope

This part of ISO 8196|IDF 128 gives guidelines for the calibration of instruments and quality control procedures for milk analysis in dairy laboratories.

2 Normative references

The following referenced documents are indispensable for the application 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 128-1:2009, *Milk — Definition and evaluation of the overall accuracy of alternative methods of milk analysis*

ISO 8196-3|IDF 128-3:2009, *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*

3 Terms, definitions, and symbols

3.1 Terms and definitions

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

3.1.1
standardization of an instrument
experimental evaluation of the exactness of the calibration of an instrument by reference to the true values given either by a reference method or by standard materials or a standard instrument

3.1.2
calibration of an instrument
adjustment of the signal from an instrument so that, at each level of the component, the mean of individual test results given by the instrument closely approximates the true value of the component concentration

IMPORTANT — Even if the term "calibration" is often used for both the standardization and calibration of instruments (see Clause 4), the use of these words according to the definitions in 3.1.1 and 3.1.2 is strongly recommended.