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

Part 1: Analytical attributes of alternative methods

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

Partie 1: Attributs analytiques des méthodes alternatives



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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 8196-1|IDF 128-1 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 8196-1|IDF 128-1 cancels and replaces the first edition (ISO 8196-1:2000) 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*

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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 8196-1|IDF 128-1 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 8196-1|IDF 128-1, together with ISO 8196-2|IDF 128-2 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 definitions of the relevant performance characteristics for quantitatively evaluating the overall accuracy of an analytical method, through the application of proper experimental designs and recommended statistical procedures.

Performance characteristics of an analytical method can be defined as a set of quantitative and experimentally determined values, or criteria, of fundamental importance in assessing the suitability of a method for any given purpose. The general concepts apply to all analytical methods, but special emphasis is given to rapid physico-chemical methods which are currently in use for compositional testing of milk.

In analytical methods where measurements result from combinations of multiple output signals of measurement channels either in series or in parallel (e.g. methods in which multivariate mathematical models are applied), the process of combining the primary raw information is considered as a full part of the method itself. For the purpose of ISO 8196|IDF 128 (all parts), this process is considered as a closed device ("black box"). As such, this process is assumed to be optimized prior to the assessments and evaluations done within the scope of ISO 8196|IDF 128 (all parts).

ISO 8196-2|IDF 128-2 provides practical details and recommendations for the calibration of instruments and quality control in routine dairy laboratories including checking compliance with a specification value or limit.

ISO 8196-3|IDF 128-3 is intended to complement this part of ISO 8196|IDF 128 as an alternative to the evaluation of new methods to which this part of ISO 8196|IDF 128 cannot apply, e.g. when the organization of interlaboratory studies is hampered by the number of new instruments available, which is too small for such a protocol.

While this part of ISO 8196|IDF 128 and ISO 8196-3|IDF 128-3 are mainly intended for experts to assess new methods of analysis, ISO 8196-2|IDF 128-2 aims to be a guide for routine laboratories using these methods.

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).