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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 pour l'évaluation et la validation des méthodes quantitatives alternatives d'analyse du lait

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

International Dairy Federation
Diamant Building • Boulevard Auguste Reyers 80 • B-1030 Brussels
Tel. + 32 2 733 98 88
Fax + 32 2 733 04 13
E-mail info@fil-idf.org
Web www.fil-idf.org

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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 8196-3|IDF 128-3 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.

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.

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All work was carried out by the Joint ISO-IDF 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 8196-3|IDF 128-3, together with ISO 8196-1|IDF 128-1 and ISO 8196-2|IDF 128-2, cancels and replaces IDF 128:1985, which has been technically revised.

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Introduction

This part of ISO 8196|IDF 128 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 too small a 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 part of ISO 8196|IDF 128 specifies a harmonized protocol for such a method validation by an expert laboratory. It lists the evaluation steps, 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, only a limited number of evaluations should suffice for a decision on approval either by national bodies or by an international organization for the application of the methods and/or equipment in their area. An example is given for the evaluation of a method for the determination of fat, protein, lactose, urea and somatic cell count in milk.