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Milk and milk products — Quality control in microbiological laboratories —

Part 1: Analyst performance assessment for colony counts

*Lait et produits laitiers — Contrôle de qualité en laboratoires
microbiologiques —*

*Partie 1: Évaluation de la performance des analystes effectuant les
comptages de colonies*



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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 14461-1|IDF 169-1 was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 5, *Milk and milk products*, and the International Dairy Federation (IDF), in collaboration with AOAC International. It is being published jointly by ISO and IDF and separately by AOAC International.

ISO 14461|IDF 169 consists of the following parts, under the general title *Milk and milk products — Quality control in microbiological laboratories*:

- *Part 1: Analyst performance assessment for colony counts*
- *Part 2: Determination of the reliability of colony counts of parallel plates and subsequent dilution steps*

Foreword

IDF (the International Dairy Federation) is a worldwide federation of the dairy sector with a National Committee in every member country. Every National Committee has the right to be represented on the IDF Standing Committees carrying out the technical work. IDF collaborates with ISO and AOAC International in the development of standard methods of analysis and sampling for milk and milk products.

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 the 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.

This part of International Standard ISO 14461-1|IDF 169 was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 5 *Milk and milk products*, and the International Dairy Federation (IDF), in collaboration with AOAC International. It is being published jointly by ISO and IDF and separately by AOAC International.

All work was carried out by the Joint ISO/IDF/AOAC Action Team, *Statistics of analytical data*, of the Standing Committee on *Quality assurance, statistics of analytical data and sampling*, under the aegis of its project leaders, Dr. H. Glaeser (EU) and Prof. Dr. H. Weiss (DE).

This edition of ISO 14461-1|IDF 169-1, together with ISO 14461-2|IDF 169-2, cancels and replaces IDF 169:1994, which has been technically revised.

ISO 14461|IDF 169 consists of the following parts, under the general title *Milk and milk products — Quality control in microbiological laboratories*:

- *Part 1: Analyst performance assessment for colony counts*
- *Part 2: Determination of the reliability of colony counts of parallel plates and subsequent dilution steps*

Introduction

Every microbiological method consists of several steps that are followed in a specific sequence (sub-sampling, diluting, plating and counting). The final result has a margin of uncertainty that is determined by the variability of all the steps involved.

In order to obtain results with a margin of uncertainty not much larger than what can be expected from the correct application of the method, it is necessary to follow the rules of Good Laboratory Practice (GLP).

The three most important factors in obtaining a correct plate count are

- the homogeneity of the sample material,
- the exactness with which the dilutions are performed, and
- the technique of inoculation and/or counting of the plates.

By homogenizing a sample material very well, making multiple dilution series, and inoculating several plates from the same dilution, it is possible to assess how well a laboratory can perform the colony-count technique, taking into account the expected variability of the method.

A too large variability indicates that at least one of the steps in the performance of the method is out of control. The identification of those steps is done by comparison of the replicate inoculations, the different dilution levels and the dilution series. When the steps with excessive variability have been identified, the necessary measures should be taken to bring these steps under control.

Milk and milk products — Quality control in microbiological laboratories —

Part 1: Analyst performance assessment for colony counts

1 Scope

This part of ISO 14461|IDF 169 describes a procedure for testing the performance of the colony-count technique within a laboratory by establishing the within-laboratory variability of its technique and identifying those steps that are associated with excessive variability.

The procedure is also suitable for checking the proper observance of Good Laboratory Practice (GLP), which may be a prerequisite for participation in interlaboratory tests of colony-count methods.

EXAMPLE Appropriate test samples are raw milk, pasteurized milk and dried milk.

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 648:1977, *Laboratory glassware — One-mark pipettes*

ISO 835-4, *Laboratory glassware — Graduated pipettes — Part 4: Blow-out pipettes*

ISO 4788, *Laboratory glassware — Graduated measuring cylinders*

ISO 7218, *Microbiology of food and animal feedings stuffs — General rules for microbiological examinations*

ISO 8261|IDF 122, *Milk and milk products — Preparation of samples and dilutions for microbiological examination*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

colony-count technique

counting of the number of microorganisms as determined by the procedure specified in this part of ISO 14461|IDF 169

NOTE The number of microorganisms is expressed per gram or per millilitre of test sample.