

## **Milk and milk products - Guidelines for a standardized description of microbial inhibitor tests**

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## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 13969:2004 sisaldab Euroopa standardi EN ISO 13969:2004 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 23.11.2004 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 13969:2004 consists of the English text of the European standard EN ISO 13969:2004.</p> <p>This document is endorsed on 23.11.2004 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p><b>Käsitlusala:</b></p> <p>This International Standard gives guidance for a standardized description of microbial inhibitor tests for milk and milk products. It is intended to give a framework and basis for the evaluation/validation of microbial inhibitor tests, allowing the comparison of data obtained from different tests and experimental studies.</p>	<p><b>Scope:</b></p> <p>This International Standard gives guidance for a standardized description of microbial inhibitor tests for milk and milk products. It is intended to give a framework and basis for the evaluation/validation of microbial inhibitor tests, allowing the comparison of data obtained from different tests and experimental studies.</p>
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Võtmesõnad:

English version

Milk and milk products - Guidelines for a standardized  
description of microbial inhibitor tests (ISO 13969:2003)

Lait et produits laitiers - Lignes directrices pour une  
description normalisée des méthodes microbiologiques de  
dépistage d'inhibiteurs microbiens (ISO 13969:2003)

Milch und Milchprodukte - Anleitung für eine vereinheitlichte  
Beschreibung mikrobiologischer Hemmstofftests (ISO  
13969:2003)

This European Standard was approved by CEN on 1 October 2003.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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Management Centre: rue de Stassart, 36 B-1050 Brussels

## Foreword

The text of ISO 13969:2003 has been prepared by Technical Committee ISO/TC 34 "Agricultural food products" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 13969:2004 by Technical Committee CEN/TC 302 "Milk and milk products - Methods of sampling and analysis", the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2005, and conflicting national standards shall be withdrawn at the latest by February 2005.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

## Endorsement notice

The text of ISO 13969:2003 has been approved by CEN as EN ISO 13969:2004 without any modifications.

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a standardized description of microbial  
inhibitor tests**

*Lait et produits laitiers — Lignes directrices pour une description  
normalisée des méthodes microbiologiques de dépistage d'inhibiteurs  
microbiens*



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Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://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](mailto:info@fil-idf.org)  
Web [www.fil-idf.org](http://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 13969 | IDF 183 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.

## 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 IDF National Committees casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. IDF shall not be held responsible for identifying any or all such patent rights.

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All work was carried out by the Joint ISO/IDF/AOAC Action Team *Antimicrobials and other veterinary medical residues*, of the Standing Committee on *Analytical methods for additives and contaminants*, under the aegis of its project leader, Mrs G. Suhren (DE).



## Introduction

The parameters outlined in this International Standard may not need to be evaluated completely for every test, depending on

- a) the field of application of the test under study (e.g. screening or reference method, type of milk, i.e. animal species or raw/heat treated milk),
- b) the information needed [e.g. the introduction of a new substance with fixed maximum residue limit (MRL)], and
- c) the detection pattern (e.g. sensitivity of the test microorganism to a broad or narrow variety of antimicrobial compounds).

Thus “the terms of reference” between the producer and user of a certain test should be agreed upon in the context of these guidelines omitting, for example, those aspects that are not relevant to the intended field of application.

A general disadvantage related to the interpretation of microbial inhibitor tests is that they are usually evaluated in a subjective way and in very few steps, i.e. negative, questionable, and positive by comparison with positive and/or negative control samples.

In cases where the medium contains an indicator, the type of the resultant colour change can depend upon the type of antimicrobial present. This sometimes makes it difficult to obtain a clear distinction between positive and negative results. Test interpretation in few steps also means that small alterations or minor colour developments, which may be of importance in a validation programme, need major experimental effort.

# Milk and milk products — Guidelines for a standardized description of microbial inhibitor tests

## 1 Scope

This International Standard gives guidance for a standardized description of microbial inhibitor tests for milk and milk products. It is intended to give a framework and basis for the evaluation/validation of microbial inhibitor tests, allowing the comparison of data obtained from different tests and experimental studies.

## 2 Terms and definitions

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

### 2.1

#### **false positives**

percentage of positive results when testing negative samples

### 2.2

#### **false negatives**

percentage of negative results at the claimed detection level(s)

### 2.3

#### **limit of detection**

concentration level at which a defined percentage of samples is detected

EXAMPLE 95 % together with the respective confidence level.

## 3 Information needed from the developer/manufacturer

### 3.1 Methodology

The developer or manufacturer of the test should provide information regarding methodology by mentioning the following:

- a) description of the method;
- b) principle of the method;
- c) technical design of the procedure (e.g. degree of automation, data processing);
- d) evaluation of test results (e.g. scores, scale and definition of what to consider “positive” or “negative”);
- e) capacity (e.g. sample throughput);
- f) special requirements for sampling, preservation and testing;