SLOVENSKI STANDARD
SIST EN ISO 18330:2004

01-maj-2004

Mleko in mleļ ni proizvodi - Navodila za standardizirani opis za imuno analizo ali receptor analizo za detekcijo antimikrobnih ostankov (ISO 18330:2003

Milk and milk products - Guidelines for the standardized description of immunoassays or receptor assays for the detection of antimicrobial residues (ISO 18330:2003)

Milch und Milchprodukte - Anleitung für die vereinheitlichte Beschreibung von Immunoassays oder Rezeptorassays zum Nachweis von Rückständen antimikrobiell wirksamer Stoffe (ISO 18330:2003)

Laits et produits laitiers - Lignes directrices pour la description normalisée des essais immunologiques et des essais récepteur pour la détection des résidus antimicrobiens (ISO 18330:2003)

Ta slovenski standard je istoveten z: **EN ISO 18330:2003**

ICS:

67.100.01	Mleko in mleļ ni proizvodi na sploġno	Milk and milk products in general

SIST EN ISO 18330:2004 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18330

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English version

Milk and milk products - Guidelines for the standardized description of immunoassays or receptor assays for the detection of antimicrobial residues (ISO 18330:2003)

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This European Standard was approved by CEN on 7 August 2003.

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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 Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN ISO 18330:2003) has been prepared by Technical Committee ISO/TC 34 "Agricultural food products" in collaboration with 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of an identical text or by endorsement, at the latest by March 2004, and conflicting national standards shall be withdrawn at the latest by March 2004.

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

Endorsement notice

The text of ISO 18330:2003 has been approved by CEN as EN ISO 18330:2003 without any modifications.

INTERNATIONAL STANDARD

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Milk and milk products — Guidelines for the standardized description of immunoassays or receptor assays for the detection of antimicrobial residues

Laits et produits laitiers — Lignes directrices pour la description normalisée des essais immunologiques et des essais récepteur pour la détection des résidus antimicrobiens

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Foreword

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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.

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ISO 18330 | IDF 188 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 the National Committees casting a vote.

ISO 18830 | IDF 188 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 *Antimicrobials and other veterinary medical residues*, of the Standing Committee *Analytical methods for additives and contaminants*, under the aegis of its project leader, Mr E. Märtlbauer (DE)

Introduction

Because of the method of detection, the tests described in this International Standard may have limitations so that they cannot be used for quantification. For example, receptor assays have group-specific detection and not chemical-specific detection. Consequently, positive results cannot be subject to quantitation without knowledge of the identity of the specific contaminant. Moreover, assays based on a visual evaluation of colour development may not measure the degree of colour and thus may not provide a quantitative value.

Within an integrated system for antimicrobial residue detection, immunoassays and receptor assays may be used as primary-screening methods (e.g. for screening of compounds which can not be detected at regulatory levels by microbiological inhibition assays). These methods may also be used as post-screening methods for preliminary identification and quantification of compounds in samples with a positive result in a microbiological inhibition assay.

Depending on whether a certain test complies with the specifications given, immunoassays and receptor assays may be used for routine quality control, especially if the absence/presence of a certain compound in concentrations exceeding a certain level [e.g. maximum residue limit (MRL)] has to be determined. Substances which are not approved or for which no MRLs have been fixed, may require specific consideration. For legal purposes in many countries, positive results obtained by immunoassays or receptor assays require confirmation by an accepted physico-chemical method.

Milk and milk products — Guidelines for the standardized description of immunoassays or receptor assays for the detection of antimicrobial residues

1 Scope

This International Standard gives guidelines for the standardized description of immunoassays or receptor assays for the detection of antimicrobial residues in milk and milk products.

It is intended to provide a framework and basis for the evaluation/validation of tests based on the binding of an antimicrobial compound to its specific antibody or to other types of detecting molecules.

In addition to immunoassays [e.g. enzyme-immunoassay (EIA) and radio-immunoassay (RIA)], there are several quantitative, semi-quantitative and qualitative test formats based on the binding of antimicrobial compounds to microbial receptors or to receptor proteins. Enzymatic assays and particle-based assays based on receptor proteins are referred to as receptor assays in this International Standard.

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 13969, *Milk and milk products — Guidance for a standardized description of microbial inhibitor tests*

3 Terms and definitions

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

3.1
false positives
percentage of positive results when testing negative samples

3.2
false negatives
percentage of negative results at the claimed detection level(s)

3.3
specificity
extent to which the presence of substances with chemical structures similar to that of the target analyte will result in a positive result (cross-reaction)

3.4
limit of detection for qualitative tests
concentration level at which a defined percentage of samples is detected, e.g. 95 % together with the respective confidence level.