SLOVENSKI STANDARD
SIST EN ISO 22118:2011

01-oktober-2011

Mikrobiologija živil in krme - Odkrivanje prisotnosti in kvantifikacija patogenih mikroorganizmov v živilih s polimerazno verižno reakcijo (PCR) - Izvedbena merila (ISO 22118:2011)

Microbiology of food and animal feeding stuffs - Polymerase chain reaction (PCR) for the detection and quantification of food-borne pathogens - Performance characteristics (ISO 22118:2011)

Mikrobiologie von Lebensmitteln und Futtermitteln - Polymerase-Kettenreaktion (PCR) zum Nachweis und zur quantitativen Bestimmung von pathogenen Mikroorganismen in Lebensmitteln - Leistungsmerkmale (ISO 22118:2011)

Microbiologie des aliments - Réaction de polymérisation en chaîne (PCR) pour la détection et la quantification des micro-organismes pathogènes dans les aliments - Caractéristiques de performance (ISO 22118:2011)

Ta slovenski standard je istoveten z: **EN ISO 22118:2011**

ICS:

07.100.30	Mikrobiologija živil	Food microbiology

SIST EN ISO 22118:2011 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22118

July 2011

ICS 07.100.30

English Version

Microbiology of food and animal feeding stuffs - Polymerase chain reaction (PCR) for the detection and quantification of food-borne pathogens - Performance characteristics (ISO 22118:2011)

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 22118:2011: E

Contents

Page

Foreword

This document (EN ISO 22118:2011) has been prepared by Technical Committee CEN/TC 275 “Food analysis - Horizontal methods”, the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 34 “Food products”.

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of an identical text or by endorsement, at the latest by January 2012, and conflicting national standards shall be withdrawn at the latest by January 2012.

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INTERNATIONAL STANDARD

ISO 22118

First edition
2011-07-15

Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection and quantification of food-borne pathogens — Performance characteristics

Microbiologie des aliments — Réaction de polymérisation en chaîne (PCR) pour la détection et la quantification des micro-organismes pathogènes dans les aliments — Caractéristiques de performance

Reference number
ISO 22118:2011(E)

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Published in Switzerland

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.

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ISO 22118 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 275, *Food analysis — Horizontal methods*, in collaboration with Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Introduction

Molecular detection methods have been developed during the last few decades, and are now available for the majority of food-borne pathogens. Some of these methods have the potential for quantitative analysis.

Although until now most methods have been based on the polymerase chain reaction (PCR) and real-time PCR, other molecular detection and quantification principles should be kept under consideration.

To compare molecular methods with conventional methods or with other principles, it is necessary to generate minimum requirements for performance characteristics of the methods to be developed.

This International Standard is part of a series of documents under the general title *Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection of food-borne pathogens*:

ISO/TS 20836, *Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection of food-borne pathogens — Performance testing for thermal cyclers*

ISO 20837, *Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection of food-borne pathogens — Requirements for sample preparation for qualitative detection*

ISO 20838, *Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection of food-borne pathogens — Requirements for amplification and detection for qualitative methods*

ISO 22118, *Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection and quantification of food-borne pathogens — Performance characteristics*

ISO 22119, *Microbiology of food and animal feeding stuffs — Real-time polymerase chain reaction (PCR) for the detection of food-borne pathogens — General requirements and definitions*

ISO 22174, *Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection of food-borne pathogens — General requirements and definitions*

The following Technical Specification is in preparation:

ISO/TS 13136, *Microbiology of food and animal feeding stuffs — Horizontal method for the detection of Shiga toxin-producing* Escherichia coli (*STEC*) *belonging to O157, O111, O26, O103 and O145 serogroups — Qualitative real-time polymerase chain reaction (PCR)-based method*

Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection and quantification of food-borne pathogens — Performance characteristics

1 Scope

This International Standard specifies minimum requirements of performance characteristics for the detection of nucleic acid sequences (DNA or RNA) by molecular methods. This International Standard applies to the detection of food-borne pathogens in foodstuffs and isolates obtained from them using molecular detection methods based on the polymerase chain reaction (PCR).

This International Standard is also applicable, for example, to the detection of food-borne pathogens in environmental samples and in animal feeding stuffs.

NOTE Because of the rapid progress in this field, the examples given are those most frequently in use at the time of development of 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 16140:2003, *Microbiology of food and animal feeding stuffs — Protocol for the validation of alternative methods*

ISO 22174:2005, *Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection of food-borne pathogens — General requirements and definitions*

3 Terms and definitions

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

3.1
analyte
component detected or measured by the method of analysis

NOTE 1 The analyte can be a microorganism or virus, its components or products.

NOTE 2 Adapted from ISO 16140:2003, 3.4.

3.2
qualitative method
method of analysis whose response is either the presence or absence of the analyte detected either directly or indirectly in a certain amount of sample

[ISO 16140:2003, 3.5.]