

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

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 22118:2011 sisaldab Euroopa standardi EN ISO 22118:2011 ingliskeelset teksti.</p> <p>Standard on kinnitatud Eesti Standardikeskuse 29.07.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.07.2011.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 22118:2011 consists of the English text of the European standard EN ISO 22118:2011.</p> <p>This standard is ratified with the order of Estonian Centre for Standardisation dated 29.07.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.</p> <p>Date of Availability of the European standard text 15.07.2011.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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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)

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)

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

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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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.]