

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

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## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 22174:2005 sisaldab Euroopa standardi EN ISO 22174:2005 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 28.04.2005 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 22174:2005 consists of the English text of the European standard EN ISO 22174:2005.</p> <p>This document is endorsed on 28.04.2005 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 the general requirements for the in vitro amplification of nucleic acid sequences (DNA or RNA). It is applicable to the testing of foodstuffs and isolates obtained from foodstuffs for food-borne pathogens using the polymerase chain reaction (PCR).</p>	<p><b>Scope:</b></p> <p>This International Standard gives the general requirements for the in vitro amplification of nucleic acid sequences (DNA or RNA). It is applicable to the testing of foodstuffs and isolates obtained from foodstuffs for food-borne pathogens using the polymerase chain reaction (PCR).</p>
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**Võtmesõnad:** food technology, laboratory t, microbial foods, microbiological analysis, microbiology, microorganisms, micro-organisms, minimum requirements, nucleic acids, pcr, polymerase, polymerase chain reaction, specification (approval), specifications, testing, verification

English version

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

Microbiologie des aliments - Réaction de polymérisation en  
chaîne (PCR) pour la recherche de micro-organismes  
pathogènes dans les aliments - Exigences générales et  
définitions (ISO 22174:2005)

Mikrobiologie von Lebensmitteln und Futtermitteln -  
Polymerase- Kettenreaktion (PCR) zum Nachweis von  
pathogenen Mikroorganismen in Lebensmitteln -  
Allgemeine Anforderungen und Begriffe (ISO 22174:2005)

This European Standard was approved by CEN on 20 October 2004.

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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 Central Secretariat has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## Foreword

This document (EN ISO 22174:2005) 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 "Agricultural 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 August 2005, and conflicting national standards shall be withdrawn at the latest by August 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.

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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.

ISO 22174 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

The polymerase chain reaction (PCR) is a fast, sensitive and specific method for the detection of food-borne pathogens. Although a relatively young technology, the application of PCR-based methods in food analysis is increasing.

In brief, existing protocols can be divided in two main groups, depending on the type of nucleic acid used as target for amplification:

- RNA-based amplification (RT-PCR);
- DNA-based amplification (PCR).

Numerous variations of both methods have been established and can be characterized by their degree of complexity and automation. The level of specificity of the methods varies from screening assays which detect nucleic acid sequences common to a microbiological genus, to specific assays which identify nucleic acid sequences unique to an individual strain- or type-specific nucleic acid sequence.

This International Standard presents a comprehensive list of requirements for PCR-based methods used for the detection of microorganisms in food samples. It contains terms and definitions used in reference to PCR and RT-PCR.

ISO 22174 is part of a series of International Standards and a Technical Specification under the general title *Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection of food-borne pathogens*:

- *General requirements and definitions* (ISO 22174);
- *Requirements for sample preparation for qualitative detection* (ISO 20837) <sup>1)</sup>;
- *Requirements for amplification and detection for qualitative methods* (ISO 20838) <sup>1)</sup>;
- *Performance testing for thermal cyclers* (ISO/TS 20836) <sup>1)</sup>.

The International Organization for Standardization (ISO) draws attention to the fact that it is claimed that compliance with this document may involve the use of one or more patents concerning the PCR technology.

ISO takes no position concerning the evidence, validity and scope of these patent rights.

ISO has been informed that Applied Biosystems, Roche Molecular Systems, Inc. and F. Hoffman-La Roche Ltd. hold patent rights concerning the PCR technology. The companies have assured the ISO that they are willing to negotiate licences under reasonable and non-discriminatory terms and conditions with applicants throughout the world. In this respect, the statements of the holders of these patent rights are registered with ISO. Information may be obtained from:

Licensing Department  
Applied Biosystems  
850 Lincoln Centre Drive  
Foster City, CA 94404  
USA

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1) To be published.

and

Roche Molecular Systems, Inc.  
Licensing Department  
1145 Atlantic Avenue  
Alameda, CA 94501  
USA

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights other than those identified above. ISO shall not be held responsible for identifying any or all such patent rights.

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

**WARNING** — The use of this standard may involve hazardous materials, operations and equipment. This standard does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determines the applicability of regulatory limitations prior to use.

## 1 Scope

This International Standard gives the general requirements for the *in vitro* amplification of nucleic acid sequences (DNA or RNA). It is applicable to the testing of foodstuffs and isolates obtained from foodstuffs for food-borne pathogens using the polymerase chain reaction (PCR).

The minimum requirements laid down in this International Standard are intended to ensure that comparable and reproducible results are obtained in different laboratories.

This International Standard has been established for food-borne pathogens in or isolated from food and feed matrices, but is also applicable to other matrices (e.g. environmental samples) and for the detection of non-pathogenic microorganisms.

## 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 3534-1, *Statistics — Vocabulary and symbols — Part 1: Probability and general statistical terms*

ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

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/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. For definitions concerning validation, see ISO 3534-1 and ISO 5725-1.