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

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



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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).

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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) ¹⁾;
- *Requirements for amplification and detection for qualitative methods* (ISO 20838) ¹⁾;
- *Performance testing for thermal cyclers* (ISO/TS 20836) ¹⁾.

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
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