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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

Microbiologie des aliments — Réaction de polymérisation en chaîne (PCR) pour la détection des micro-organismes pathogènes dans les aliments — Exigences relatives à la préparation des échantillons pour la détection qualitative



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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.

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

ISO 20837 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 detection of food-borne pathogens by PCR is usually performed by means of the following successive (or simultaneous) steps:

- homogenization of the sample;
- (cultural) enrichment of the pathogen under study and sample treatment;
- nucleic acid extraction (optional);
- amplification of nucleic acids from the pathogen under study;
- detection of the amplified DNA from the pathogen under study.

References to International Standards concerning enrichment of bacteria from food matrices are given in Annex A. An example of a specific method for sample preparation is given in Annex B.

This International Standard is related to a series of 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)
- Performance testing for thermal cyclers (ISO/TS 20836)
- Requirements for amplification and detection for qualitative methods (ISO 20838).

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 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

and

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

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