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Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods

*Produits alimentaires — Méthodes d'analyse pour la détection des
organismes génétiquement modifiés et des produits dérivés —
Méthodes qualitatives basées sur l'utilisation des acides nucléiques*



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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 21569 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*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Introduction

The search for a genetically modified origin of ingredients is performed by means of the following successive (or simultaneous) steps. After sample collection, nucleic acids are extracted from the test portion. Extracted nucleic acids can be further purified, simultaneously or after the extraction process. Afterwards, they are quantified (if necessary), diluted (if necessary) and subjected to analytical procedures (such as PCR). These steps are detailed in this International Standard and in the following series of International Standards with the general title *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products*:

- *Sampling* (ISO 21568);
- *Quantitative nucleic acid based methods* (ISO 21570);
- *Nucleic acid extraction* (ISO 21571).

Further information about general requirements and definitions involving the steps cited above are collected in ISO 24276.

The qualitative detection of DNA target sequences is performed in order to obtain a yes or no answer to the question whether a certain target sequence is detected or not relative to appropriate controls and within the detection limits of the analytical method used and test portion analysed.

The specificity of the methods, as described in Annexes A to D, ranges from screening methods to detect common DNA sequences characteristic of GMOs, to specific identification of a genetic construct or a specific transformation event.

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 a patent concerning the PCR technology.

ISO takes no position concerning the evidence, validity and scope of this patent right.

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

and

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

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