First edition 2005-11-01

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

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



### **PDF** disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

#### © ISO 2005

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

<b>Contents</b>		age	
Forewo	ord	v	
Introdu	ıction	. vi	
1	Scope	1	
2	Normative references	1	
3	Terms and definitions	1	
4 4.1 4.2 4.3	Principle  General  Amplification, detection and confirmation of PCR products  Quantitation of PCR products	2 2	
5	Reagents	2	
6	Apparatus and equipment	2	
7 7.1 7.2 7.3 7.4 7.5	Guidelines concerning the procedure  General  Target sequence stability  Calibration of the analysis  Quantitation considerations  Quality assurance requirements	3 3 3	
8	Interpretation	4	
9	Expression of results	4	
10	Test report	5	
Annex A (informative) Target taxon-specific methods		6	
<b>A</b> .1	Target taxon-specific method for the absolute quantitation of the adh1 gene DNA of maize using real-time PCR	6	
Annex	B (informative) Screening methods	12	
B.1	Screening method for the relative quantitation of the 35S-promoter DNA of soya bean line GTS 40-3-2 using real-time PCR	12	
Annex	C (informative) Construct-specific methods	20	
C.1	Construct-specific method for the quantitation of soya bean line GTS 40-3-2 DNA using real-time PCR (Method 1)	20	
C.2	Construct-specific method for the quantitation of soya bean line GTS 40-3-2 DNA using real-time PCR (Method 2)	27	
C.3	Construct-specific method for the quantitation of Event176 maize DNA using real-time PCR	34	
C.4	Construct-specific method for the quantitation of soya bean line GTS 40-3-2 DNA using real-time PCR	41	
C.5	Construct-specific method for the quantitation of maize line MON 810 DNA using real-time PCR	49	
C.6	Construct-specific method for the quantitation of maize line Event176 DNA using real-time PCR		
C.7	Construct-specific method for the quantitation of maize line Bt11 DNA using real-time PCR		

# ISO 21570:2005(E)

This is a preview of "ISO 21570:2005". Click here to purchase the full version from the ANSI store.

C.8	Construct-specific method for the quantitation of maize line GA21 DNA using real-time PCR	71
C.9	Construct-specific method for the quantitation of maize line T25 DNA using real-time PCR	78
Annex	D (informative) Event-specific methods	87
D.1	Event-specific method for the absolute and relative quantitation of maize line Bt11 DNA based on real-time PCR	87
D.2	Event-specific method for the relative quantitation of maize line MON 810 DNA using real-time PCR	93
Bibliog	ıraphy	100

## **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 21570 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).

## Introduction

The search for ingredients of genetically modified origin 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 the present and in the following International Standards:

ISO 21569, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods

ISO 21570, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Quantitative nucleic acid based methods

Further information about definitions and general items involving the steps cited above are collected in:

ISO 24276, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — General requirements and definitions.

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 these patent rights.

ISO has been informed that Applied Biosystems, Roche Molecular Systems, Inc. and Hoffman-La Roche hold patent rights concerning 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

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