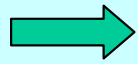
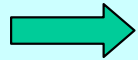


GMO DETECTION ANALYSIS

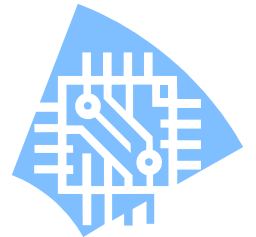


International Standards (ISO)



Accreditation

Dr. Sofia BEN TAHAR
Chair ISO/WG7



XVth Eurofins International Seminar - February 22nd and 23rd, 2007 - Paris, France

International ISO Standards

Covering the detection of Genetically Modified Organisms and Derived Products

Published

→		
→	ISO/TS	21098 : 2005
→	ISO	21569 : 2005
→	ISO	21570 : 2005
→	ISO	21571 : 2005
→	ISO	21572 : 2004
→	ISO	24276 : 2006



Working project
pr EN/ISO 24274

ISO 24276 : 2006

« Foodstuffs – Methods of analysis for the detection of Genetically Modified Organisms and derived products –

General requirements and definition »



Abstract

This standard **specifies how to use the standards** for sampling strategies ([EN/TS 21568](#)), nucleic acid extraction ([ISO 21571](#)), qualitative nucleic acid analysis ([ISO 21569](#)) and quantitative nucleic acid analysis ([ISO 21570](#)), and their relationship **in the analysis of genetically modified organisms** in foodstuffs, and contains general definitions, **requirements and guidelines for laboratory set-up, method validation requirements, description of methods and test reports.**

It has been established for **food matrices**, but could also be applied to other matrices (e.g. **seeds, feed and plant samples** from the environment).

ISO 21571 : 2005

« Foodstuffs – Methods of analysis for the detection of Genetically Modified Organisms and derived products –

Nucleic acid extraction »



Abstract

This standard provides **general requirements** and **specific methods for DNA extraction/purification** and quantification. These methods are described in Annexes A and B.

ISO 21571 : 2005 has been established for **food matrices**, but could also be applicable to other matrices, such as **grains and feed**.

It has been designed as an integral part of nucleic-acid-based analytical methods, in particular [ISO 21569](#) on qualitative analytical methods, and [ISO 21570](#) on quantitative analytical methods.

ISO 21569 : 2005

« Foodstuffs – Methods of analysis for the detection of Genetically Modified Organisms and derived products –

Qualitative nucleic acid based methods »



Abstract

Describes the **procedure to qualitatively detect Genetically Modified Organisms (GMOs)** and derived products by **analysing the nucleic acids extracted** from the sample under study. The main focus is on polymerase chain reaction (PCR) based amplification methods.

It gives **general requirements for the specific detection and identification of target nucleic acid sequences (DNA)** and for the **confirmation of the identity of the amplified DNA sequence**.

Guidelines, minimum requirements and performance criteria laid down in [ISO 21569 : 2005](#) are intended to ensure that comparable, accurate and reproducible results are obtained in different laboratories.

[ISO 21569 : 2005](#) has been established for **food matrices**, but could also be applied to other matrices (e.g. **feed and plant samples** from the environment).

Specific examples of methods are provided in Annexes A to D

ISO 21570 : 2005

« Foodstuffs – Methods of analysis for the detection of Genetically Modified Organisms and derived products –

Quantitative nucleic acid based methods »



Abstract

This standard provides the overall framework of quantitative methods for the detection of Genetically Modified Organisms (GMO) in foodstuffs, using the polymerase chain reaction (PCR).

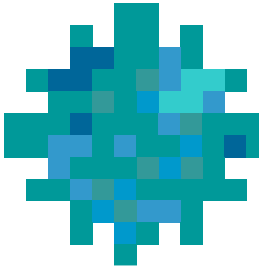
It defines the **general requirements for the specific amplification of DNA target sequences in order to quantify the relative GMO-derived DNA content** and to **confirm the identity** of the amplified DNA sequence.

Guidelines, **minimum requirements and performance criteria** laid down in **ISO 21570 : 2005** are intended to **ensure that comparable, accurate and reproducible results are obtained in different laboratories.**

ISO 21570 : 2005 has been established for **food matrices**, but is also applicable to other matrices, e.g. **feed and plant samples** from the environment.

ISO 21572 : 2004

« Foodstuffs – Methods for the detection of Genetically Modified Organisms
and derived products –
Protein based methods »



Abstract

This standard provides general guidelines and **performance criteria for methods for the detection and/c quantitation of specific proteins derived from genetically modified (GM) plant material** in a specific matrix.

These general guidelines address **existing antibody based methods**. Methods other than those described in annex A may also detect the protein. The same criteria as outlined in this standard generally apply



ISO/TS 21098 : 2005

« Foodstuffs – Nucleic acid based methods of analysis of Genetically Modified Organisms and derived products »

Information to be supplied and procedure for the addition of methods to

- ISO 21569
- ISO 21570
- ISO 21571

Abstract

Defines the principles and specifies the nature of **the information to be supplied for acceptance of a method as an annex to ISO 21569, ISO 21570 or ISO 21571**. It also specifies the process for adding, amending and retaining methods annexed to these standards.

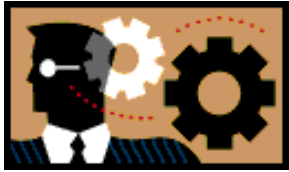
ISO/TS 21098 : 2005 is necessary in order to attain **consistency in methods that are to be employed as part of the standards**.

It does not cover the specifics of the development of a method or laboratory set-up.

This TS was developed in order to **provide guidance and to define the performance characteristics that should be supplied for each method** in order to ensure the global relevance of the Standards and to delineate the process for adding, amending and retaining methods annexed to the Standards.

Project EN/ISO 24274

« Foodstuffs – Detection of Genetically Modified Organisms
in oil seed »

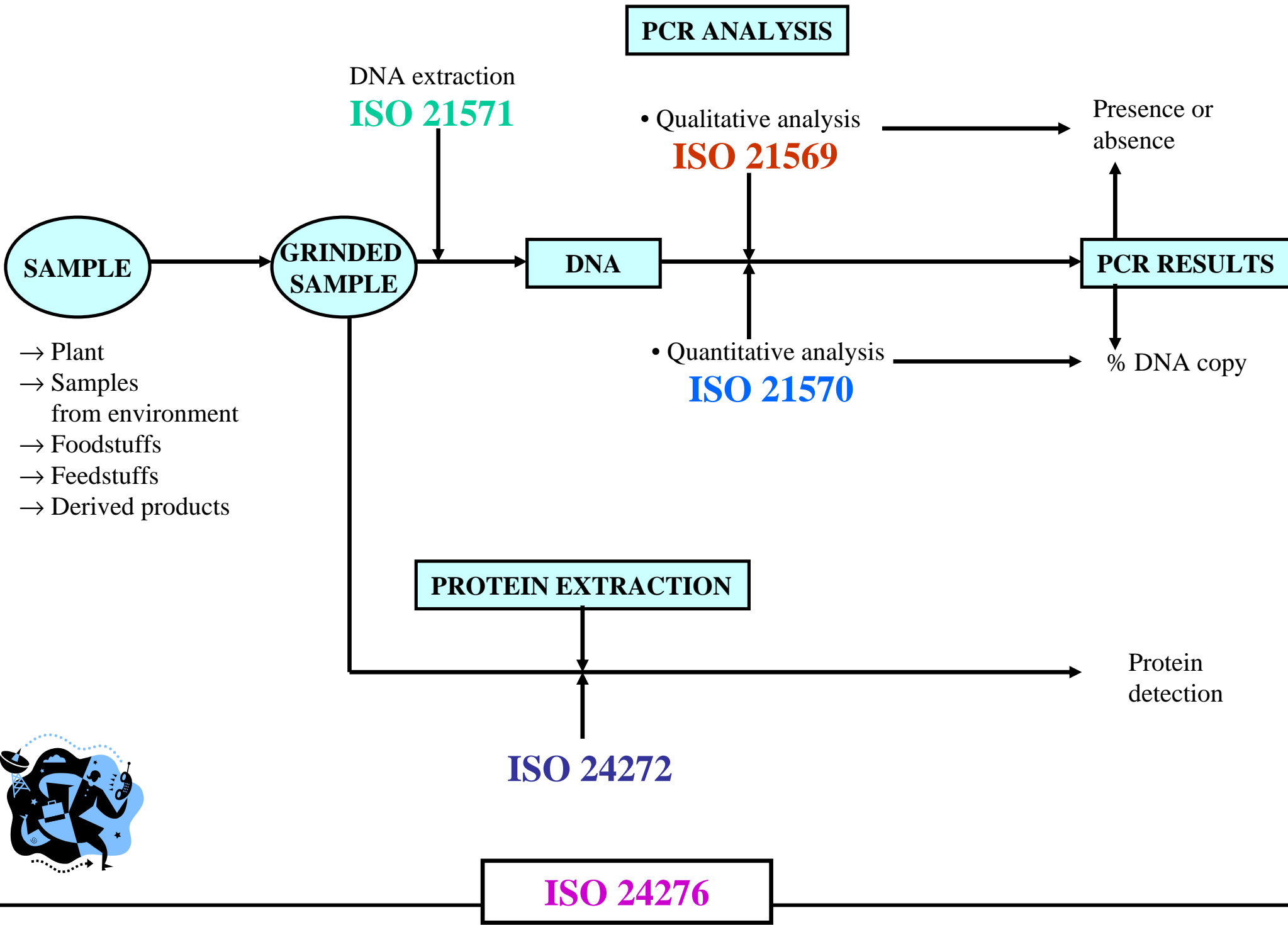


Abstract

« Detection of the event GTS 40-3-2 in soja seeds using Real time quantitative PCR »

Iran has now the coordination of this project.

Ring – trials need to be organised.



ISO/Tc 34

**Technical Committee
Foodstuffs**

Presidency : France

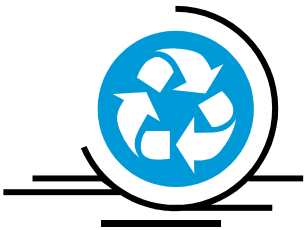
Secretariat : Brazil and France

WG7

**Detection of Genetically Modified Organisms
and Derived Products**

Presidency : France

Secretariat : France



WG7 was created in year 2000.

The following countries have nominated experts to be member of the **WG7** :

- | | | | |
|-------------|---------------------------|----------------------|--------------------|
| -Allemagne | -Germany | -Italie | -Italy |
| -Argentine | -Argentina | -Jamaïque | -Jamaica |
| -Barbade | -Barbados | -Japon | -Japan |
| -Belgique | -Belgium | -Kenya | -Kenya |
| -Canada | -Canada | -Malaisie | -Malaysia |
| -Chine | -China | -Norvège | -Norway |
| -Danemark | -Denmark | -Pays-Bas | -Netherlands |
| -Espagne | -Spain | -Philippines | -Philippines |
| -Etats-Unis | -United-States of America | -Portugal | -Portugal |
| -Hongrie | -Hungary | -République de Corée | -Republic of Korea |
| -Inde | -India | -Royaume-Uni | -Great Britain |
| -Iran | -Islamic Republic of Iran | -Suisse | -Switzerland |
| -Irlande | -Ireland | -Thaïlande | -Thailand |
| | | -France | -France |



ACCREDITATION

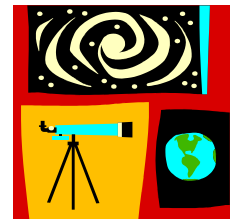
Accreditation is based on criteria and procedures specially conceived for technical competency evaluation.

Accreditation will verify the similarity to standard requirements and will also have to prove the technical competency of a body.

It is validation of a competency and relevance of a quality organisation.

Being accredited is a proof of trust for companies, clients, consumers.

In the actual open economy, accreditation is a precious tool to facilitate and accelerate international exchanges.

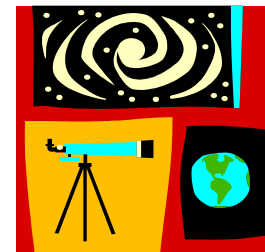


Multilateral agreements (**MLA**) are in place which means that an accreditation obtained in country X will be recognised in the whole world.

Therefore accredited clients in different parts of the world (companies, administration, collectivities...) do not need any more to have multiple accreditations.

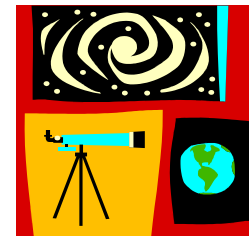
A certificate with accreditation logo is such as having an international passport.

Accreditation is therefore a stimulation for export / import.



ILAC (International Laboratory Accreditation Cooperation) and **IAF** (International Accreditation Forum) are worldwide organisations implied in accreditation of laboratories and certification.

ILAC and **IAF** have multilateral agreements with **EA** (European Accreditation), **APLAC** (Asia Pacific Laboratory Accreditation) and **PAC** (Pacific Accreditation Cooperation for Certification) in Pacific Asia.



EA

European Co-operation for Accreditation

www.european-accreditation-org

- In Europe 32 countries have one or more accredited bodies
- In Europe the **MLA** for laboratory testings have been signed with the following countries :

Germany	BAMDAP – DACH DASMIN – DATech	Lithuania	LA
Austria	BMwA	Norway	NA
Belgium	BELTEST	Netherlands	RuA
Danemark	DANAK	Poland	PCA – POLSKIE CENTRUM AKREDYTACJI
Spain	ENAC	Portugal	IPAC
Estonia	EAK	Czech Republic	CAI
Finland	FINAS	Roumania	RENAR
France	COFRAC	UK	UKAS
Greece	ESYD	Slovaquia	SNAS
Ireland	NAB	Slovenia	SA
Italy	SINAL	Sweden	SWEDAC
Letonia	LATAK	Switzerland	SAS
		Turkey	TURKAK



Accreditation for Testing Laboratories

Each of these accreditation bodies has a list of documents for accreditation that are found on their respective internet site according to the type of test performed.

For GMO testing laboratories :

The objective is to have the testing laboratories accredited according to

⇒ [ISO/CEI 17025](#)

⇒ internal methods validation

⇒ Standards specific to the domain ([ISO 21569](#), [21570](#), [21571](#), [21572](#), [24276](#))



Example of request from an accreditation body to have a GMO testing laboratory accredited.

Case of **COFRAC** (France)

→If the laboratory has developed internal methods, in this case, previous to the audit, an admissibility dossier will have to be submitted to **COFRAC** for evaluation by an expert.

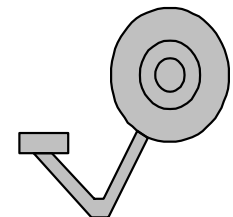
→The laboratory has to apply the different **ISO** standards

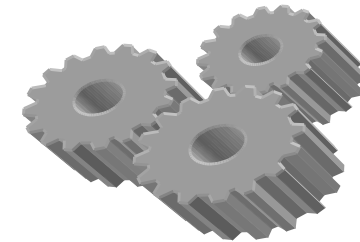
→The scope of analysis will have to be defined, example :

- * Matrices crops (corn grain or seed, starch, processed products...)

- * Type of detection (PCR primers)

- generic (promoter, terminator, other ...)
- construct specific
- event specific





- * Validation of each set of primers
→ on which event (list of events)

- * Method applied
 - qualitative
 - quantitative

- * Reference of the documents applied for the testing

- **COFRAC** has published a technical guide of accreditation for detection and quantification of DNA from Genetically Modified Crops Organism.
 - The new version of the guide is under revision
 - This guide will take into account the French standard document **AFNOR/V03E N00 17** called
 « **Guide for applying ISO standards** »
 Analytical methods for Genetically Modified Organisms and derived products
- ⇒ Based on the provided information and on this guide, the **COFRAC** evaluation will perform the laboratory audit.