

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

ICS 67.050

National foreword

This British Standard is the UK implementation of EN ISO 24276:2006+A1:2013. It is identical to ISO 24276:2006 incorporating amendment 1:2013. It supersedes BS EN ISO 24276:2006, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee AW/275, Food analysis – Horizontal methods.

A list of organizations represented on this committee can be obtained on request to its secretary.

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 6 March 2006

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Published by BSI Standards Limited 2013

ISBN 978 0 580 71467 2

Amendments/corrigenda issued since publication

Date	Comments
30 June 2013	Implementation of ISO amendment 1:2013 with CEN endorsement A1:2013

English Version

Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - General requirements and definitions (ISO 24276:2006)

Produits alimentaires - Méthodes d'analyse pour la détection des organismes génétiquement modifiés et des produits dérivés - Exigences générales et définitions (ISO 24276:2006)

Lebensmittel - Verfahren zum Nachweis von gentechnisch modifizierten Organismen und ihren Produkten - Allgemeine Anforderungen und Definitionen (ISO 24276:2006)

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Foreword

This document (EN ISO 24276:2006) has been prepared by Technical Committee CEN/TC 275 "Food analysis - Horizontal methods", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 34 "Agricultural food products".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2006, and conflicting national standards shall be withdrawn at the latest by August 2006.

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Foreword to amendment A1

This document (EN ISO 24276:2006/A1:2013) has been prepared by Technical Committee ISO/TC 34 "Food products" in collaboration with Technical Committee CEN/TC 275 "Food analysis - Horizontal methods" the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 24276:2006 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2013, and conflicting national standards shall be withdrawn at the latest by November 2013.

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Endorsement notice

The text of ISO 24276:2006/Amd 1:2013 has been approved by CEN as EN ISO 24276:2006/A1:2013 without any modification.

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Introduction

-  The purpose of an analysis for the detection of genetically modified organisms and derived products is to identify and optionally quantify genetic elements or proteins common to genetically modified organisms (GMOs) and their derived products in a given matrix.

These steps are detailed in this International Standard and in the following documents:

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*

ISO 21571, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Nucleic acid extraction*

ISO 21572, *Foodstuffs — Methods for the detection of genetically modified organisms and derived products — Protein based methods*

Specific information pertaining to protein detection methods is found in ISO 21572. 

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

1 Scope

A1 This International Standard specifies how to use the standards for nucleic acid extraction (ISO 21571), qualitative nucleic acid analysis (ISO 21569), quantitative nucleic acid analysis (ISO 21570) and protein-based methods (ISO 21572), and explains their relationship in the analysis of genetically modified organisms in foodstuffs. **A1**

It 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).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

3 Terms and definitions

For the purpose of this document, the terms and definitions given in ISO 5725-1 concerning validation, those in Reference [1] and the following apply.

3.1 General definitions

3.1.1

target taxon

taxon to which the genetically modified organism belongs

NOTE In this context, taxon usually means species but it could be of lower or higher taxonomic rank.

A1 3.1.2

laboratory sample

sample received by the laboratory and intended for inspection or testing

NOTE Adapted from ISO 7002:1986,^[9] A.19.

3.1.3

test sample

representative fraction of the laboratory sample to be ground **A1**

 3.1.4

test portion

portion of the test sample as prepared for testing or analysis, the whole quantity being used for analyte extraction at one time

NOTE Adapted from ISO 6887-2:2003,[5] 3.2.

3.1.5

specificity

property of a method to respond exclusively to the characteristic or analyte under investigation

3.1.6

sensitivity

change in the response divided by the corresponding change in the concentration of a standard (calibration) curve

NOTE This is the slope of the analytical calibration curve.

3.1.7

limit of detection

LOD

minimum amount or concentration of the analyte in a test sample which can be detected reliably but not necessarily quantified, as demonstrated by a collaborative trial or other appropriate validation

NOTE See Reference [2] for collaborative trial and Reference [3] for validation.

3.1.8

limit of quantification

LOQ

lowest concentration or amount of the analyte in a test sample which can be quantitatively determined with an acceptable level of precision and accuracy, as demonstrated by a collaborative trial or other appropriate validation

NOTE See Reference [2] for collaborative trial and Reference [3] for validation.

3.1.9

accuracy

closeness of agreement between a test result and the accepted reference value

[ISO 5725-1:1994, 3.6].

3.1.10

trueness

closeness of agreement between the average value obtained from a large series of test results and an accepted reference value

NOTE 1 The measure of trueness is usually expressed in terms of bias. Trueness has been referred to as "accuracy of the mean".

NOTE 2 Adapted from ISO 5725-1:1994, 3.7.

3.1.11

precision

closeness of agreement between independent test results obtained under stipulated conditions

NOTE 1 Precision depends only on the distribution of random errors and does not relate to the true value or to the specified value.

NOTE 2 The measure of precision usually is expressed in terms of imprecision and computed as a standard deviation of the test results. Lower precision is reflected by a larger standard deviation. 