INTERNATIONAL STANDARD

ISO 24276

First edition
2006-02-01

AMENDMENT 1
2013-04-15

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

AMENDMENT 1

Produits alimentaires — Méthodes d'analyse pour la détection des organismes génétiquement modifiés et des produits dérivés — Exigences générales et définitions

AMENDEMENT 1

Reference number
ISO 24276:2006/Amd.1:2013(E)

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

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.

Amendment 1 to ISO 24276:2006 was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 16, *Horizontal methods for molecular biomarker analysis*.

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

AMENDMENT 1

Page v, Introduction

Replace the existing text with the following.

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.

Page 1, Scope

Replace the existing first paragraph with the following.

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.

Page 1, 3.1

Replace 3.1.2 to 3.1.26 with the following.

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

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.

NOTE 3 "Independent test results" means results obtained in a manner not influenced by any previous result on the same or similar test object. Quantitative measures of precision depend critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme conditions.

[ISO 5725-1:1994, 3.12]

3.1.12
repeatability
precision under repeatability conditions

[ISO 5725-1:1994, 3.13]

3.1.13
reproducibility
precision under reproducibility conditions

[ISO 5725-1:1994, 3.17]

3.1.14
repeatability conditions
conditions where independent test results are obtained with the same method on identical test items in the same laboratory by the same operator using the same equipment within short intervals of time

[ISO 5725-1:1994, 3.14]

3.1.15
reproducibility conditions
conditions where test results are obtained with the same method on identical test items in different laboratories with different operators using different equipment

[ISO 5725-1:1994, 3.18]

NOTE When different methods give test results that do not differ significantly, or when different methods are permitted by the design of the experiment (as in a proficiency study or a material certification study for the establishment of a consensus value of a reference material), the term "reproducibility" may be applied to the resulting parameters. The conditions should be explicitly stated.

3.1.16
repeatability standard deviation
standard deviation of test results obtained under repeatability conditions

[ISO 5725-1:1994, 3.15]

NOTE Repeatability standard deviation is a measure of the dispersion of the distribution of test results under repeatability conditions. Similarly "repeatability variance" and "repeatability coefficient of variation" could be defined and used as measures of the dispersion of test results under repeatability conditions.

3.1.17
reproducibility standard deviation
standard deviation of test results obtained under reproducibility conditions

[ISO 5725-1:1994, 3.19]

NOTE Reproducibility standard deviation is a measure of the dispersion of the distribution of test results under reproducibility conditions. Similarly "reproducibility variance" and "reproducibility coefficient of variation" could be defined and used as measures of the dispersion of test results under reproducibility conditions.

3.1.18
repeatability limit
value less than or equal to which the absolute difference between two test results obtained under repeatability conditions may be expected to be with a probability of 95 %

NOTE 1 The symbol used is r.

[ISO 5725-1:1994, 3.16]

NOTE 2 When examining two single test results obtained under repeatability conditions, the comparison should be made with the repeatability limit $r = 2{,}8s_r$, where s_r is the standard deviation of repeatability.

3.1.19
reproducibility limit
value less than or equal to which the absolute difference between two test results obtained under reproducibility conditions may be expected to be with a probability of 95 %

NOTE 1 The symbol used is R.

[ISO 5725-1:1994, 3.20]

NOTE 2 When examining two single test results obtained under reproducibility conditions, the comparison should be made with the reproducibility limit $R = 2{,}8s_R$, where s_R is the standard deviation of reproducibility.

3.1.20
collaborative trial
interlaboratory study
study in which several laboratories detect and/or determine an analyte in one or more "identical" portions of homogeneous, stable materials under documented conditions

NOTE Guidelines for performing collaborative trials are elaborated in ISO 5725-2[8] and the ISO/AOAC/IUPAC harmonized protocol (Reference [6]).

3.1.21
fitness for purpose
applicability
scope of application of the method which identifies the matrix, analyte or species being measured, its concentration range and the type of study/monitoring effort for which the procedure, as judged from its performance characteristics, is suited

NOTE It also describes the known limitations of the method (Reference [3]).

3.1.22
practicability
ease of operations, in terms of sample throughput and costs, to achieve the required performance criteria and thereby meet the specified purpose

3.1.23
applicability range
range of quantification/linearity/dynamic range
quantity interval within which the analytical procedure has been demonstrated by a collaborative trial or other appropriate validation to have a suitable level of precision and accuracy

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

3.1.24
measurement uncertainty
parameter associated with the result of a measurement, which characterizes the dispersion of the values that could reasonably be attributed to the analyte

3.1.25
screening method
method that rapidly and reliably eliminates (screens) a large number of negative (or positive) test samples and restricts the number of test samples requiring the application of a rigorous method

NOTE 1 See Reference [4].

NOTE 2 In this International Standard, a screening method detects gene products (such as proteins) or genetic elements (such as promoters, terminators, or other genetic elements of interest) common to several GMOs.

3.1.26
construct-specific method
method that targets a combination of inserted DNA sequences that are only found in GMO-derived material

3.1.27
event-specific method
method that detects a specific sequence that is only present in a specific transformation event

NOTE This is commonly targeted at the integration-border region.

Page 8, Figure 1

Replace Figure 1 with the following.