SLOVENSKI STANDARD
SIST EN 15842:2010

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Živila - Odkrivanje prisotnosti alergenov v živilih - Splošne ugotovitve in validacija metod

Foodstuffs - Detection of food allergens - General considerations and validation of methods

Lebensmittel - Nachweis von Lebensmittelallergenen - Allgemeine Betrachtungen und Validierung von Verfahren

Produits alimentaires - Détection des allergènes alimentaires - Considérations générales et validation des méthodes

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ICS:

67.050	Splošne preskusne in analizne metode za živilske proizvode	General methods of tests and analysis for food products

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Foodstuffs - Detection of food allergens - General considerations and validation of methods

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 15842:2010) has been prepared by Technical Committee CEN/TC 275 “Food Analysis − Horizontal Methods”, the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by August 2010, and conflicting national standards shall be withdrawn at the latest by August 2010.

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Introduction

The main focus of this European Standard is on immunoassays, chromotographic and nucleic acid based methods for the determination of food allergens. However, because of the rapid developments in this area, other technologies may be considered.

The search for food allergens is performed by means of the following successive (or simultaneous) steps. After sample collection, proteins, nucleic acids or other markers are extracted from the test portion. Extracted analytes can be further purified, simultaneously or after the extraction process. Afterwards, they are diluted (if necessary) and subjected to analytical procedures such as immunoassays (e.g. ELISA), nucleic acid based assays (e.g. PCR) or chromatographic (e.g. LC-MS).

These steps are detailed in this document and in the following documents:

EN 15633-1:2009, *Foodstuffs — Detection of food allergens by immunological methods — Part 1: General considerations*

EN 15634-1:2009, *Foodstuffs — Detection of food allergens by molecular biological methods — Part 1: General considerations*

1 Scope

This European Standard specifies how to use the standards for immunoassays, nucleic based and chromatographic methods and their relationship in the analysis of food allergens; and contains general definitions, requirements and guidelines for laboratory set-up, method validation requirements, description of methods, and test reports.

This document also specifies general guidelines for the requirements and use of reference materials for the determination of allergenic commodities in food products. The term "reference materials" in this document includes certified reference materials as well as quality control materials. Currently only a limited number of reference materials for food allergen determination are available. As new materials become accepted and validated, they may be appended as an annex to this document.

This document does not deal with sampling issues. It simply details processes involved from receipt of the laboratory sample to the end result.

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.

EN ISO/IEC 17025, *General requirement for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)*

EN ISO 17511:2003, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)*

ISO Guide 31, *Reference materials — Contents of certificates and labels*

ISO Guide 35, *Reference materials — General and statistical principles for certification*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
accepted reference value
value that serves as an agreed-upon reference for comparison and which is derived as:

— theoretical or established value, based on scientific principles,

— an assigned value, based on experimental work of some national or international organization,

— consensus value, based on collaborative experimental work under the auspices of a scientific or engineering group

[ISO Guide 30:1992]

3.2
accuracy
closeness of agreement between a test result or measurement result and the true value

NOTE 1 In practice, the accepted reference value is substituted for the true value.

NOTE 2 The term "accuracy", when applied to a set of test or measurement results, involves a combination of random components and a common systematic error or a bias component.

NOTE 3 Accuracy refers to a combination of trueness and precision.

[ISO 3534-2:2006]

3.3
applicability range
quantity interval within which the analytical procedure has been demonstrated by collaborative trial or other appropriate validation to have a suitable level of precision and accuracy

[EN ISO 24276:2006]

3.4
bias
difference between the expectation of a test result or measurement result and a true value

NOTE 1 Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value.

NOTE 2 The bias of a measuring instrument is normally estimated by averaging the error of indication over an appropriate number of repeated measurements. The error of indication is the "indication of a measuring instrument minus a true value of the corresponding input quantity".

[ISO 3534-2:2006]

3.5
Certified Reference Material
CRM
reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realisation of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence

[ISO Guide 30:1992]

3.6
certified value
for a CRM, value that appears in the certificate accompanying the material

[ISO Guide 30:1992]

3.7
characterization
for a reference material, determination of one or more physical, chemical, biological, or technological property values that are relevant to its intended end use

[ISO Guide 30:1992]

3.8
collaborative study
interlaboratory study
interlaboratory study in which each laboratory uses a defined method of analysis to analyse identical portions of homogenous material to assess the performance characteristics obtained for the method of analysis

NOTE Guidelines for performing collaborative trials are elaborated in ISO 5725-1 [3] and in IUPAC harmonized protocol 1995 [16].

3.9
commutability of a material
closeness of agreement between the mathematical relationship of the measurement results obtained by two measurement procedures for a stated quantity in a given material, and the mathematical relationship obtained for the quantity in routine samples

[EN ISO 17511:2003]

3.10
consensus value (of a given quantity)
for a reference material, value of the quantity obtained by interlaboratory testing, or by agreement between appropriate bodies or experts

[ISO Guide 30:1992]

3.11
fitness for purpose
applicability
degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose

NOTE See [17].

3.12
homogeneity
condition of being of uniform structure or composition with respect to one or more specified properties

NOTE A reference material is said to be homogeneous with respect to a specified property if the property value, as determined by tests on samples of specified size, is found to lie within the specified uncertainty limits, the samples being taken either from different supply units (bottles, packages, etc.) or from a single supply unit.

[Adapted from ISO Guide 30:1992]

3.13
laboratory sample
sample as prepared for sending to the laboratory and intended for inspection or testing

[ISO 78-2:1999]

3.14
limit of detection
LOD
minimum amount or concentration of the analyte in test sample which can be detected reliably but not necessarily quantified, as demonstrated by a collaborative trial or other appropriate validation

3.15
limit of detection for quantitative determinations
amount of an analyte corresponding to the lowest measurement signal which with a closely defined confidence may be interpreted as indicating that the analyte is present in the sample, but without allowing exact quantification

3.16
limit of detection for qualitative determinations
threshold concentration below which positive identification is unreliable according to the established requirements for reliability

NOTE See [24].

3.17
limit of quantitation
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 collaborative trail or other appropriate validation

NOTE See [24].

3.18
limit of quantification
limit of determination
lowest amount of an analyte which can be determined quantitatively with a closely defined confidence

NOTE See [24].

3.19
linearity
ability to elicit test results that are directly, or by means of well defined, mathematical transformations, proportional to the concentration of analyte in samples within a given range

NOTE See [15].

3.20
matrix
all compounds in the sample with the analyte

NOTE Each matrix has generally a common name which permits classification.

[EN ISO 21572:2004]

3.21
outlier
member of a set of values which is inconsistent with the other members of that set

NOTE ISO 5725 specifies the statistical tests and the significance level used to identify outliers in trueness and precision experiments.

[ISO 5725-1:1994]

3.22
practicability
ease of operations, in terms of sample throughput and costs, to achieve the required performance criteria and thereby meet the specified purpose

[EN ISO 24276:2006]

3.23
precision
closeness of agreement between independent test/measurement 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 the specified value.

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

NOTE 3 Quantitative measures of precision depend critically on the stipulated conditions. Repeatability conditions and reproducibility conditions are particular sets of extreme stipulated conditions.

[ISO 3534-2:2006]

3.24
primary standard
standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity, within a specified context

[ISO Guide 30:1992]

3.25
recovery
proportion of the amount of analyte, present in or added to the analytical portion of the test material, which is extracted and presented for measurement

NOTE See [18].

3.26
reference material
material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials

[ISO Guide 30:1992]

3.27
reference method
thoroughly investigated method, clearly and exactly describing the necessary conditions and procedures, for the measurement of one or more property values that has been shown to have accuracy and precision commensurate with its intended use and that can therefore be used to assess the accuracy of other methods for the same measurement, particularly in permitting the characterisation of a reference material

[ISO Guide 30:1992]

3.28
repeatability
precision under repeatability conditions

NOTE Repeatability can be expressed quantitatively in terms of the dispersion characteristics of the results.

[ISO 3534-2:2006]

3.29
repeatability conditions
observation conditions where independent test/measurement results are obtained with the same method on identical test/measurement items in the same test or measuring facility by the same operator using the same equipment within short intervals of time

NOTE Repeatability conditions include:

— same measurement procedure or test procedure;

— same operator;

— same measuring or test equipment used under the same conditions;

— same location;