SLOVENSKI STANDARD
SIST EN 15842:2019

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Nadomešča:
SIST EN 15842:2010

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 Verfahrensvalidierung

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

Ta slovenski standard je istoveten z: **EN 15842:2019**

ICS:

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

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English Version

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

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

Lebensmittel - Nachweis von Lebensmittelallergenen - Allgemeine Betrachtungen und Verfahrensvalidierung

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 15842:2019) 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of an identical text or by endorsement, at the latest by April 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.

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

This document supersedes EN 15842:2010.

Significant technical changes between this standard and EN 15842:2010 are as follows:

a) documents under normative references removed (2);

b) updated terms and definitions (3);

c) general considerations for methods and reference materials added (4.1);

d) requirements regarding the production and storage of reference materials deleted (4.3);

e) clause on "Quality assurance requirements" deleted;

f) the test report should comply with EN ISO/IEC 17025;

g) updated bibliography.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

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

The analysis of 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, *Foodstuffs — Detection of food allergens by immunological methods — Part 1: General considerations*

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

For the use of this document the term:

— ‘shall’ indicates a requirement;

— ‘should’ indicates a recommendation;

— ‘may’ indicates a permission; and

— ‘can’ indicates a possibility and/or a capability.

1 Scope

This document 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 can 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

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1 Method performance characteristics

3.1.1
fitness for purpose
degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose

Note 1 to entry: The measurement process can be based on a screening method, a confirmatory method or a reference method.

Note 2 to entry: For further information refer to [10].

3.1.2
screening method
method that will rapidly and reliably eliminate (screen) a large number of negative (or positive) test samples and restrict the number of test samples requiring the application of a rigorous method

Note 1 to entry: See [11].

3.1.3
practicability
ease of operations, in terms of sample throughput and costs, to achieve the required performance criteria and thereby meet the specified purpose

[SOURCE: EN ISO 24276:2006+A1:2013, 3.1.22]

3.1.4
selectivity
extent to which a method can determine particular analyte(s) in mixtures or matrices without interferences from other components

Note 1 to entry: See [12].

3.1.5
sensitivity
change in the response divided by the corresponding change in the concentration of a standard (calibration) curve

Note 1 to entry: See [12].

3.1.6
specificity
property of a method to respond exclusively to the characteristic or analyte under investigation

Note 1 to entry: See [12].

3.1.7
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 1 to entry: For further information refer to [12].

3.1.8
applicability range
interval of quantity values within which the analytical procedure has been demonstrated by collaborative trial or other appropriate validation to have a suitable level of precision and accuracy

3.1.9
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

3.1.10
limit of quantitation
limit of determination
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 trial or other appropriate validation

Note 1 to entry: For further information refer to [13].

3.1.11
precision
closeness of agreement between independent test/measurement results obtained under stipulated conditions

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

Note 2 to entry: 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 to entry: Quantitative measures of precision depend critically on the stipulated conditions. Repeatability conditions and reproducibility conditions are particular sets of extreme stipulated conditions.

[SOURCE: ISO 3534-2:2006, 3.3.4]

3.1.12 Repeatability related terms

3.1.12.1
repeatability
precision under repeatability conditions

Note 1 to entry: Repeatability can be expressed quantitatively in terms of the dispersion characteristics of the results.

[SOURCE: ISO 3534-2:2006, 3.3.5]

3.1.12.2
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 1 to entry: Repeatability conditions include:

— the same measurement procedure or test procedure;

— the same operator;

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

— the same location;

— repetition over a short period of time.

[SOURCE: ISO 3534-2:2006, 3.3.6]

3.1.12.3
repeatability limit
r
repeatability critical difference for a specified probability of 95 %

[SOURCE: ISO 3534-2:2006, 3.3.9]

3.1.12.4
repeatability standard deviation
standard deviation of test results or measurement results obtained under repeatability conditions

Note 1 to entry: It is a measure of the dispersion of the distribution of test or measurement results under repeatability conditions.

Note 2 to entry: Similarly "repeatability variance" and "repeatability coefficient of variation" can be defined and used as measures of the dispersion of test or measurement results under repeatability conditions.

[SOURCE: ISO 3534-2:2006, 3.3.7]

3.1.13
collaborative 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 1 to entry: Guidelines for performing collaborative trials are elaborated in ISO 5725-1 [3] and in IUPAC harmonized protocol 1995 [14].

3.1.14 Reproducibility related terms

3.1.14.1
reproducibility
precision under reproducibility conditions

Note 1 to entry: Reproducibility can be expressed quantitatively in terms of the dispersion characteristics of the results.

Note 2 to entry: Results are usually understood to be corrected results.

[SOURCE: ISO 3534-2:2006, 3.3.10]

3.1.14.2
reproducibility conditions
observation conditions where independent test/measurement results are obtained with the same method on identical test/measurement items in different test or measurement facilities by different operators using different equipment

[SOURCE: ISO 3534-2:2006, 3.3.11]

3.1.14.3
reproducibility limit
R
reproducibility critical difference for a specified probability of 95 %

[SOURCE: ISO 3534-2:2006, 3.3.14]

3.1.14.4
reproducibility standard deviation
standard deviation of test results or measurement results obtained under reproducibility conditions

Note 1 to entry: It is a measure of the dispersion of the distribution of test or measurement results under reproducibility conditions.

Note 2 to entry: Similarly, "reproducibility variance" and "reproducibility coefficient of variation" can be defined and used as measures of the dispersion of test or measurement results under reproducibility conditions.

[SOURCE: ISO 3534-2:2006, 3.3.12]

3.1.15
recovery
proportion of the amount of analyte, present in or added to the analytical portion of the test material, which is extracted and determined for measurement

Note 1 to entry: See [15].

3.1.16
metrological traceability
property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

[SOURCE: JCGM 200:2012, 2.41, modified — notes were removed]

3.1.17
trueness
closeness of agreement between the expectation of a test result or a measurement result and a true value

Note 1 to entry: The measurement of trueness is usually expressed in terms of bias.

Note 2 to entry: Trueness is sometimes referred to as "accuracy of the mean". This usage is not recommended.

Note 3 to entry: In practice, the accepted reference value is substituted for the true value.

[SOURCE: ISO 3534-2:2006, 3.3.3]

3.1.18
accuracy
closeness of agreement between a test result or measurement result and the true value

Note 1 to entry: In practice, the accepted reference value is substituted for the true value.

Note 2 to entry: 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 to entry: Accuracy refers to a combination of trueness and precision.

[SOURCE: ISO 3534-2:2006, 3.3.1]