SLOVENSKI STANDARD
SIST EN 17855:2024

01-julij-2024

Živila - Minimalne zahteve za kvantitativno določanje alergenov v živilih: mleko, jajca, arašidi, lešniki, mandlji, orehi, indijski oreščki, pekan (ameriški) orehi, brazilski oreščki, pistacije, makadamije, pšenica, volčji bob, sezam, gorčica, soja, zelena, ribe, mehkužci in raki

Foodstuffs - Minimum performance requirements for quantitative measurement of the food allergens milk, egg, peanut, hazelnut, almond, walnut, cashew, pecan nut, brazil nut, pistachio nut, macadamia nut, wheat, lupine, sesame, mustard, soy, celery, fish, molluscs and crustaceans

Lebensmittel - Minimal-Leistungsanforderungen für die Bestimmung der Lebensmittelallergene Milch, Ei, Erdnuss, Haselnuss, Mandel, Walnuss, Cashew, Pekannuss, Paranuss, Pistazie, Macadamia, Weizen, Lupine, Sesam, Senf, Soja, Sellerie, Fisch, Weichtiere und Schalentiere

Produits alimentaires - Performances minimales requises pour la mesure quantitative des allergènes alimentaires lait, oeuf, arachide, noisette, amande, noix, noix de cajou, noix de pécan, noix du Brésil, pistache, noix de macadamia, blé, lupin, sésame, moutarde, soja, céleri, poisson, mollusques et crustacés

Ta slovenski standard je istoveten z: **EN 17855:2024**

ICS:

07.100.30	Mikrobiologija živil	Food microbiology
67.050	Splošne preskusne in analizne metode za živilske proizvode	General methods of tests and analysis for food products

SIST EN 17855:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 17855

May 2024

ICS 07.100.30; 67.050

English Version

Foodstuffs - Minimum performance requirements for quantitative measurement of the food allergens milk, egg, peanut, hazelnut, almond, walnut, cashew, pecan nut, brazil nut, pistachio nut, macadamia nut, wheat, lupine, sesame, mustard, soy, celery, fish, molluscs and crustaceans

Produits alimentaires - Performances minimales requises pour la mesure quantitative des allergènes alimentaires du lait, de l'œuf, de l'arachide, de la noisette, de l'amande, de la noix, de la noix de cajou, de la noix de pécan, de la noix du Brésil, de la pistache, de la noix de macadamia, du blé, du lupin, du sésame, de la moutarde, du soja, du céleri, du poisson, des mollusques et des crustacés

Lebensmittel - Mindestleistungsanforderungen für die quantitative Bestimmung der Lebensmittelallergene Milch, Ei, Erdnuss, Haselnuss, Mandel, Walnuss, Cashew, Pekannuss, Paranuss, Pistazie, Macadamianuss, Weizen, Lupine, Sesam, Senf, Soja, Sellerie, Fisch, Mollusken und Krustentiere

This European Standard was approved by CEN on 8 April 2024.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. EN 17855:2024 E

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European foreword

This document (EN 17855:2024) 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 November 2024, and conflicting national standards shall be withdrawn at the latest by November 2024.

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.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

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, Türkiye and the United Kingdom.

Introduction

Allergic reaction to food components and legislation

While eating is necessary to sustain life and to enhance the quality of life for most individuals, some individuals experience adverse, Immunoglobulin E (IgE)-mediated (allergic) reactions to certain food commodities. The reactions can range from mild symptoms up to life-threatening anaphylactic shock. As Coeliac disease is not an allergy, there is a separate document for minimum performance requirements for determination of gluten by ELISA (see EN 17254 [1]).

Allergic consumers react mostly to the proteins found in a food commodity, which always consist of a mixture of different proteins; for example, milk proteins are composed of α/β/γ/κ-caseins, β-lactoglobulin, α-lactalbumin and several minor proteins. Allergic consumers react differently to various proteins from a given commodity. Furthermore, allergenic reactions to food commodities vary among consumers from different parts of the world, as shown by the corresponding regional food allergen legislations in Europe, Canada, Australia/New Zealand, the USA or Japan. These legislations are essential due to the established global food trade, as they ensure the protection of the consumers across the various regions against exposure to allergenic commodities, regardless of the food's origin.

While no regulatory limits for allergens in food are established yet, the VITAL (Voluntary Incidental Trace Allergen Labelling) values act as a common base of understanding and a way to handle results [2]. These values are absolute amounts of protein from the allergenic commodity below which more than 95 % or 99 % of the susceptible consumers will not react in an adverse way. Since this amount of protein could occur in any amount of food that will be ingested, the linkage to an analytical result (reported as mass of total protein of the allergenic food ingredient per mass of food, expressed as mg kg^{-1}) is quite challenging.

Measurement of food allergens

It is often advisable to measure one or more major marker proteins that represent a significant part of the protein content of the food commodity. When the allergenic food commodity is fractionated into more than one commodity, such as casein and whey in milk, test kit manufacturers often develop systems to measure the main protein of each fraction.

The amount of an allergenic food commodity in food samples can be quantified by different methods. While mass spectrometry and nucleic acid-based methods (e.g. PCR, Polymerase chain reaction) can be applied, the enzyme-linked immunosorbent assay (ELISA) and lateral flow devices (LFD) are the most commonly used techniques.

The ELISA and LFD use specific monoclonal or polyclonal antibodies targeting epitopes that are specific for the allergenic food commodity. Currently, sandwich ELISA is generally used to quantify the protein level by comparing the colour reactions of sample solutions to calibrators. Some ELISA systems require conversion factors to be applied. These factors are either (i) included in the calibration (when the results are expressed as "total protein content") or (ii) require the use of a calibration factor (when the results refer to the content of specific protein(s), such as caseins in milk). Most LFDs provide qualitative results in food allergen analysis.

The PCR method aims to detect a specific DNA sequence that codes for a protein in the investigated commodity. At present, quantifying the numbers of DNA copies from an extracted sample is challenging. The complexity further increases when estimating the corresponding protein concentrations from estimated DNA copy numbers due to the lack of certified reference materials. For example, PCR is not suitable for the detection of DNA in milk and egg due to the extremely low level of specific DNA to be detected.

In LC-MS (Liquid chromatography mass spectrometry) analysis, proteins are extracted from a sample and enzymatically digested into peptides. The peptides, including specific marker peptides, undergo separation by chromatography, followed by fragmentation and quantification by LC-MS. Isotopically labelled peptides are used as internal standards, while synthetic natural peptides (with well characterized purity) are used for calibration. The concentration of a single marker peptide is re-calculated to single proteins applying conversion factors and finally to the total allergenic protein content for a given allergen. Recently, an LC-MS method for quantification of milk proteins was published that does not require any conversion factor [3].

While reliable analytical methods are required for compliance with national and international regulations worldwide, there are no harmonized guidelines available regarding specific requirements on performance of quantitative methods for food allergenic commodity and regarding specific information to be provided by the test kit manufacturers. Some guidance is provided by an AOAC publication [4].

1 Scope

This document specifies minimum performance requirements for methods that quantify the following food allergens in raw and processed foodstuffs: milk, egg, peanut, hazelnut, almond, brazil nut, macadamia nut, cashew, pistachio nut, walnut, pecan nut, lupine, sesame, mustard, soy, celery, fish, molluscs, crustaceans, and wheat. The minimum requirements for the Limit of Quantification (LOQ), presented in this document, are derived from the reference doses (RfD) and VITAL eliciting dose (ED05) published by the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations.

Annex A provides specific information for quantitative antibody-based methods, which should be supplied by the method developers. In addition, it provides guidance on how performance characteristics should be determined in the form of a validation study. The principles described in this document equally apply to PCR and LC-MS/MS methods.

More information on performance characteristics is available in EN 15634-1 [5] and EN 17644 [6]. Methods that describe gluten-containing cereals (wheat, rye, and barley) with regard to coeliac disease are covered by EN 17254 [1].

This document does not apply to fragmented or hydrolysed food allergens, such as casein hydrolysates or soy sauce. It also does not apply to qualitative methods.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 15633-1, *Foodstuffs - Detection of food allergens by immunological methods - Part 1: General considerations*

EN 15842, *Foodstuffs - Detection of food allergens - General considerations and validation of methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 15633-1 and EN 15842 and the following apply.

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

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

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

3.1
milk
secretion of mammary glands from all farmed mammals such as cows, buffalos, goats and sheep

Note 1 to entry: Milk consists of the casein and whey fraction, which are often used separated during food production. [7]

Note 2 to entry: The European Commission Notice 2017/C 428/01 [8] mandates to declare milk from farmed mammals; it should be noted that only milk of species that will be consumed in significant amounts by consumers in Europe are of interest.

Note 3 to entry: This document explicitly exempts plant derived “milks” e.g. from almond or soy from the definition of milk.

3.2
egg
oval, thin-shelled reproductive body of a bird, especially that of a hen, used as food

Note 1 to entry: Egg consists of egg yolk and egg white, which are often used in a fractionated way during food production. [9][10]

Note 2 to entry: Whole egg is a combination of pasteurized chicken (*Gallus gallus domesticus*) egg whites and egg yolks blended together in their entity in natural proportions as described in AOAC SMPR 2017.020 [11].

Note 3 to entry: The European Commission Notice 2017/C 428/01 [8] mandates to declare eggs from all farmed animals; it should be noted that only eggs of species that will be consumed in significant amounts by consumers in Europe are of interest.

3.3
peanut
seed from *Arachis hypogaea* without pods but with husks

Note 1 to entry: Peanuts are sometimes defatted and nearly always roasted during food production.

Note 2 to entry: If empty pods are used in any food e.g. in spice mixtures these will also contain traces of peanut seeds.

Note 3 to entry: Refer to Codex Alimentarius Standard for peanuts CXS 200-1995 [12].

3.4
hazelnut
seed from *Corylus avellana* without shell but with husks

Note 1 to entry: In accordance with United Nations Economic Commission for Europe (UNECE) standards, varieties grown from *Corylus avellana* and *Corylus maxima* and their hybrids.

Note 2 to entry: Seeds from *Corylus colurna* are also edible.

Note 3 to entry: Hazelnuts are sometimes defatted and often roasted during food production.

3.5
almond
seed from *Amygdalus communis*, Syn. *Prunus dulcis* without shell but with husks

Note 1 to entry: *Prunus dulcis* var. *fragilis/amara* are also consumed.

Note 2 to entry: *Prunus dulcis* var. *amara* (bitter almond) is toxic to all consumers but assumed to be as allergic as *Prunus dulcis* var. *dulcis* (sweet almond).

3.6
Brazil nut
seed from *Bertholletia excelsa* without shell but with husks

3.7
macadamia nut
seed of the stone fruit of the genus *Macadamia* without shell

Note 1 to entry: In accordance with UNECE standards, varieties (cultivars) grown from *Macadamia (M.) integrifolia*, *M. tetraphylla*, *M. ternifolia* and their hybrids.

Note 2 to entry: Macadamia nuts are also called Queensland nut.

3.8
cashew
seed from *Anacardium occidentale* without shell

3.9
pistachio nut
seed from *Pistacia vera* without shell

Note 1 to entry: Pistachio nuts are consumed roasted or un-roasted.

3.10
walnut
seed of the stone fruit of the genus *Juglans regia* without shell but with husks

Note 1 to entry: *Juglans nigra* (Black walnut) is not used commercially but edible.

3.11
pecan nut
seed from *Carya illinoinensis* without shell

3.12
lupine
seed from plants of the genus *Lupinus*

Note 1 to entry: *Lupinus (L.) albus*, *L. angustifolius*, and *L. luteus* are of commercial interest.

3.13
sesame
seed from *Sesamum indicum*

Note 1 to entry: The most traded sesame is off-white coloured, but other common colours are buff, tan, gold, brown, reddish, gray and black.

3.14
mustard
seed from *Sinapis alba, Brassica nigra,* and *Brassica juncea*

Note 1 to entry: *B. nigra* and *B. juncea* do not belong to the genus *Sinapis* but are also used as “mustard”.