SLOVENSKI STANDARD
oSIST prEN 17855:2022

01-september-2022

Živila - Minimalne zahteve za kvantitativno merjenje alergenov v živilih: mleko, jajca, arašidi, lešniki, mandlji, orehi, indijski oreščki, pekan (ameriški) orehi, brazilski orehi, pistacije, makadamij, 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: **prEN 17855**

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

oSIST prEN 17855:2022 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 17855

June 2022

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, ¿uf, arachide, noisette, amande, noix, noix de cajou, noix de pécan, noix du Brésil, pistache, noix de macadamia, blé, lupin, sésame

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

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 275.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN 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.

CEN members are the national standards bodies of 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 United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It [illegible] review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

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

Contents

Page

European foreword

This document (prEN 17855:2022) has been prepared by Technical Committee CEN/TC 275 “Food analysis – Horizontal methods”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

Introduction

Allergic reaction to food components and legislation

Eating is not only necessary to sustain life but it also enhances the quality of life for most individuals. Unfortunately, some individuals react in an adverse, IgE-mediated way (allergic reaction) to certain food commodities. The reactions can range from mild symptoms up to life-threatening anaphylactic shock. The most important non-IgE but immune-mediated disease is coeliac disease, which is triggered by gluten from certain cereals (see EN 17254).

Allergic consumers react to the proteins from a food commodity, which are always 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. There are huge differences in how different allergic consumers react to different proteins from one commodity. Furthermore, consumers from different parts of the world show different abundancies of allergic reactions to food commodities. This is mirrored by food allergen legislations in these regions, e.g. Europe, Canada, Australia/New Zealand, the USA or Japan. All these different legislations are important because the worldwide food trade is an existing fact, and consumers in different regions need to be protected from contact with commodities that they are allergic to, irrespective of where the food comes from.

Until today, there are no regulatory limits for allergens in food. Nevertheless, the so-called VITAL values act as a common base of understanding and a way to handle results [1]. These values are absolute amounts of protein from the allergenic commodity below which more than 95 % or 99 % of all 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 (given as mg allergenic protein commodity per kg of food) is quite challenging.

Measurement of food allergens

As can be deduced from the facts already mentioned above, it is not advisable to quantify only one single allergenic protein because it simply does not reflect the complexity of an allergic reaction in the population. It is often better to measure one or more major marker proteins that represent a significant part of the protein content of the food commodity. In cases where the allergenic food commodity is fractionated into e.g. two commodities, such as casein and whey in the case of milk, test kit manufacturers often develop systems that measure the main protein of these fractionated commodities.

The presence of an allergenic food commodity in food samples can be determined by different methods. Although the use of mass spectrometry and nucleic acid-based methods (e.g. PCR) is often possible, the most commonly used techniques are the enzyme-linked immunosorbent assay (ELISA) and lateral flow devices (LFD).

The ELISA and LFD use specific monoclonal or polyclonal antibodies that target epitopes that are specific for the allergenic food commodity but not necessarily specific for their allergenicity. In most cases, sandwich ELISA is currently used to quantify the protein level by comparing colour reactions of sample solutions to calibrator solutions. For some ELISA systems, conversion factors need to be applied. Most LFDs deliver qualitative results in food allergen analysis. However, quantitative LFDs are also possible.

The analytical target of a PCR method is a defined DNA sequence that codes for a protein from the commodity of interest. Until today, it is complicated to quantify the numbers of DNA copies from an extracted sample, and it is even more complicated to calculate protein concentrations based on the estimated numbers of DNA copies due to the lack of certified reference materials. Due to the extremely low level of DNA in milk and egg, PCR is not suitable for detection of these allergens.

For LC-MS/MS analysis, proteins from a sample are extracted and enzymatically digested into peptides. Specific marker peptides from this peptide mixture are used for separation (by chromatography), fragmentation and quantification by LC-MS/MS using (isotopically labelled) peptide calibrators. Using conversion factors, the concentration of a single marker peptide is re-calculated to single proteins and

finally to the total allergenic protein content for a given allergen. Recently, an LC-MS/MS method for quantification of milk proteins was published that comes without a conversion factor [2].

Reliable analytical methods are required for compliance with national and international regulations in all areas of the world. Currently, 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 method developer. Some guidance is provided by an AOAC publication [3].

1 Scope

This document specifies minimum performance requirements for methods that quantify the food allergens 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 in raw and processed foodstuffs. Within the scope of this document, minimum requirements for an LOQ (Limit of Quantification) will be derived from threshold data of allergic consumers. For quantitative antibody-based methods, a normative annex will describe what specific information the method developer needs to deliver and how performance characteristics shall be validated. Regarding PCR and LC-MS/MS, information on performance characteristics are in parts covered by EN 15634-1 and EN 17644[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 methods that deliver qualitative results only. Methods that cover gluten-containing cereals (wheat, rye, and barley) with regard to coeliac disease are covered by EN 17254.

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

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

EN 17254, *Foodstuffs - Minimum performance requirements for determination of gluten by ELISA*

EN 17644[1], *Foodstuffs* - Detection of food allergens by liquid chromatography - mass spectrometry (LC-MS) methods - General considerations

CEN/TR 16338:2012, *Foodstuffs - Detection of food allergens - Template for supplying information about immunological methods and molecular biological 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:

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

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

[1] Under preparation. Stage at the time of publication: FprEN 17644:2022.

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.

Note 2 to entry: The European Commission Notice 2017/C428/01 [4] 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 to be covered by this document, this is a labelling issue and not an analytical issue.

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.

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 [5].

Note 3 to entry: The European Commission Notice 2017/C428/01 [4] 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 hypogea* 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 [6].

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* L. and *Corylus maxima Mill*. 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
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 integrifolia, Macadamia tetraphylla, Macadamia temifolia 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* (Wangenh.) K. Koch without shell

3.12
lupine
seeds from plants of the genus *Lupinus*

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

3.13
sesame
seeds 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)
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".

3.15
soybean
seed from *Glycine max*

Note 1 to entry: The term 'soybean' is often used as a synonym for soy (seeds).

Note 2 to entry: Soybeans are always processed to remove (or obtain) oil or to remove/deactivate unwanted substances like enzyme inhibitors.

Note 3 to entry: Soy is added as flour, protein concentrate, and protein isolate during food production by various separation and extraction processes.

Note 4 to entry: Soy lecithin is often used as emulsifier in foods, which contains only trace amounts of soy protein.

Note 5 to entry: Refer to Codex Alimentarius General Standard for Soy Protein Products CXS 175-1989 [7].

3.16
celery
edible parts of the plants from *Apium graveolens*

Note 1 to entry: Consumers exert allergies against leafs, stalks, seeds, and roots of *Apium graveolens*.

Note 2 to entry: *Apium graveolens* var. *graveolens* is called celery.

Note 3 to entry: *Apium graveolens* var. *rapaceum* is called celeriac or celery root.

Note 4 to entry: *Apium graveolens* var. *secalinum* is called leaf celery.

3.17
fish
species from the classes *Osteichthyes and Chondrichthyes* suitable for the use as food for human consumption

Note 1 to entry: The diversity of all different fish species worldwide is enormous (more than 30 000) so that a clear definition lacks completeness.

Note 2 to entry: Although not all of these 30 000 species are of commercial relevance, the diversity of actually eaten fish worldwide and in the EU is still very large.

Note 3 to entry: Any method that targets "fish" shall clearly describe what clade (monophyletic group) and species is included.

Note 4 to entry: Allergic people do not necessarily react to all fish species or show at least different levels of reactivity for different fish species.

Note 5 to entry: Later in this document, fish is specified to be finfish.