SLOVENSKI STANDARD
SIST EN 15633-1:2019

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SIST EN 15633-1:2009

Živila - Odkrivanje prisotnosti alergenov v živilih z imunološkimi metodami - 1. del: Splošne ugotovitve

Foodstuffs - Detection of food allergens by immunological methods - Part 1: General considerations

Lebensmittel - Nachweis von Lebensmittelallergenen mit immunologischen Verfahren - Teil 1: Allgemeine Betrachtungen

Produits alimentaires - Détection des allergènes alimentaires par des méthodes d'analyse immunologiques - Partie 1: Considérations générales

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

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EUROPEAN STANDARD

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English Version

Foodstuffs - Detection of food allergens by immunological methods - Part 1: General considerations

Produits alimentaires - Détection des allergènes alimentaires par des méthodes d'analyse immunologiques - Partie 1 : Considérations générales

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

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European foreword

This document (EN 15633-1:2019) 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of an identical text or by endorsement, at the latest by April 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.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 15633-1:2009.

Significant technical changes between this standard and EN 15633-1:2009 are as follows:

a) updated terms and definitions (clause 3);

b) updated pre-requisite requirements for analysis (clause 5);

c) updated method validation parameters (clause 6);

d) updated specific influences on results (clause 7).

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

A specific protein or group of proteins or peptides deriving from these proteins can serve as a marker for the presence of food or food ingredients provoking allergic reactions. This document describes the procedure to qualitatively detect and/or quantitate protein-derived analytes or proteins/peptides or proteinaceous entities as a marker for potentially allergenic ingredients or constituents by analysing the protein extracted from the sample under test. Appropriate procedures for extraction of the protein are included in each method. The focus of this document is on antibody-based methods where a protein or group of proteins or peptides (deriving from these proteins) representative for the allergen source is qualitatively or quantitatively determined.

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 provides an overall framework covering qualitative and quantitative methods for the determination of food allergens and allergenic ingredients using antibody-based methods in foods. This document specifies general guidelines and performance criteria for antibody-based methods for the detection and quantification of proteins that serve as markers for the presence of allergy provoking foods or food ingredients. Other methods than those described can also detect and identify the proteins. Guidelines, minimum requirements and performance criteria laid down in this document are intended to ensure that reproducible results are obtained by different analysts in private and/or official control laboratories or when conducting onsite food testing.

This document is intended to be used in addition to EN 15842.

NOTE This document could also be applicable to other sample types where the same principles for method validation and verification would apply.

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 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 15842 and the following 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 General terms

3.1.1
denaturation of proteins
treatment (whether thermal, chemical, enzymatic or other) that affects the conformation of proteins (i.e. the secondary, tertiary and quaternary structure) to such an extent that only the primary structure or parts thereof remain (either intact, fragmented or hydrolysed)

Note 1 to entry: The denaturation can modify functional, enzymatic or antigenic properties of the protein.

3.1.2
cross-linkage of proteins
chemical reaction and/or physical interaction between proteins

Note 1 to entry: Cross-linkage can modify extractability of a protein within a food matrix.

3.2 Antibody-related terms

3.2.1
antibody
protein (immunoglobulin) produced and secreted by B lymphocytes in vertebrates in response to a molecule recognised as foreign (antigen)

Note 1 to entry: The antibody is capable of binding to that specific antigen or related peptide structures e.g. epitopes.

Note 2 to entry: The antigen induces an immune response.

[SOURCE: EN ISO 21572:2013, 3.2.1, modified — informative part of definition is described in Note 1 to entry and Note 2 to entry was added]

3.2.2
antigen
substance recognised by an antibody (namely the substance that is recognised as 'foreign' by the immune system and elicits an immune response)

Note 1 to entry: The antigen reacts *in vivo* and *in vitro* specifically with the generated antibodies.

Note 2 to entry: The antigen induces an immune response.

3.2.3
allergen
antigen that induces an immunoglobulin-E mediated allergic reaction (except gluten)

Note 1 to entry: An allergen within the scope of this document is of proteinaceous nature.

3.2.4
clone
population of identical cells derived from a single cell

[SOURCE: EN ISO 21572:2013, 3.2.3]

3.2.5
monoclonal antibody
antibody produced from a single hybridoma clone and directed to a single epitope on the antigen

Note 1 to entry: Antibodies produced from a B-cell clone with identical physical, biochemical and immunological properties

3.2.6
polyclonal antibodies
antibodies produced by several B cells that recognise different epitopes of the same antigen

3.2.7
specificity of an antibody
ability of an antibody to specifically bind to a particular antigen epitope and not to other similar structures on the same or other antigens

Note 1 to entry: The ability of antibodies to recognize and distinguish between related structures.

3.2.8
cross-reactivity
binding of an antibody to substances other than the antigen of primary interest

Note 1 to entry: The ability of antibodies to bind to similar epitopes present on different antigens.

Note 2 to entry: The reaction of an antibody with another antigen than those used for immunization.

[SOURCE: EN ISO 21572:2013, 3.2.4, modified — notes 1 and 2 were added]

3.2.9
epitope
region of an antigen (e.g. linear sequence or conformational) specifically recognised by an antibody or by receptors on cells

3.2.10
conjugate
material produced by attaching two or more substances together

Note 1 to entry: Conjugates of antibodies/proteins with fluorochromes, coloured particles, gold nanoparticles, radio-labelled substances, or enzymes are often used in immunoassays.

Note 2 to entry: A conjugate is an antibody or substance (e.g. Avidin) that is linked to a detector moiety such as an enzyme, fluorochrome, radioactive or solid particle, allowing the production of a detectable signal. Enzyme-linked conjugates require the addition of specific substrates to form measurable (e.g. coloured) reaction products.

3.3 Method-related terms

3.3.1
immunoblotting
transfer of proteins (i.e. the protein of interest), following electrophoretic separation, to a binding surface (membrane) and visualisation of the antigen(s) with specific antibody-reporter conjugates

Note 1 to entry: Transfer of electrophoretically-separated proteins to a polymer sheet or nitrocellulose membrane.

Note 2 to entry: This term is not further discussed in this document.

3.3.2
enzyme-linked immunosorbent assay
ELISA
in vitro assay for the detection of antigens that combines enzyme-linked antibodies (or antigen) and a specific substrate to form a coloured or fluorescent reaction product

Note 1 to entry: Depending on the application, this assay can be used for qualitative or quantitative purposes.

Note 2 to entry: The ELISA assay is usually performed in the microwell plate format.