SLOVENSKI STANDARD
SIST EN 15633-1:2009

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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

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

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Ta slovenski standard je istoveten z: **EN 15633-1:2009**

ICS:

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

SIST EN 15633-1:2009 **en,fr,de**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 15633-1

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ICS 67.050

English Version

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

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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 Management Centre has the same status as the official versions.

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Foreword

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of an identical text or by endorsement, at the latest by July 2009, and conflicting national standards shall be withdrawn at the latest by July 2009.

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

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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 European Standard describes the procedure to qualitatively detect and/or quantitate a protein as a marker for potentially allergenic ingredients or constituents by analysing the protein extracted from the sample under study. Appropriate procedures for extraction of the protein are included in each method. The main focus of this European Standard will be on antibody based methods.

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1 Scope

This European Standard provides the overall framework of qualitative and quantitative methods for the determination of allergens and allergenic ingredients in foodstuffs using antibody-based methods. This European Standard specifies general guidelines and performance criteria for antibody-based methods for the detection and quantification of proteins that serve as a marker for the presence of allergy provoking foods or food ingredients. Other methods than those described may also detect and identify the proteins. Guidelines, minimum requirements and performance criteria laid down in the European Standard are intended to ensure that comparable and reproducible results are obtained in different laboratories. This European Standard has been established for food matrices.

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.

prEN 15842:2008, *Foodstuffs – Detection of food allergens – General considerations and validation of method*s

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in prEN 15842:2008 and the following apply.

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3.1 General terms

3.1.1
denaturation of proteins
treatment (thermal or chemical), which destroys or modifies the secondary and/or tertiary structure of a protein

NOTE The denaturation may modify functional, enzymatic or antigenic properties of the protein.

3.2 Terms relative to antibodies

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

[adapted from EN ISO 21572:2004] [1]

NOTE 1 The antibody is capable of binding to that specific antigen.

NOTE 2 Antibodies recognise specific areas in the antigen called epitopes.

3.2.2
antigen
substance that is recognised as foreign by the immune system and elicits an immune response

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[EN ISO 21572:2004] [1]

NOTE 1 The antigen reacts *in vivo* and *in vitro* specifically with the generated antibodies.

NOTE 2 The antigen elicits an immune response to that antigen.

3.2.3
allergen
antigen with special properties to induce an allergic reaction

3.2.4
clone
population of identical cells derived from a single cell line

[EN ISO 21572:2004] [1]

3.2.5
cross-reactivity
binding of the antibody to substances other than the analyte of primary interest

[EN ISO 21572:2004] [1]

NOTE 1 The ability of antibodies to bind to similar epitopes present on different antigens.

NOTE 2 The reaction of an antibody with another antigen than those used for immunisation.

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3.2.6
monoclonal antibody
antibody produced from a single hybridoma clone and directed to a single antigen determinant

[EN ISO 21572:2004] [1]

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NOTE Antibodies produced from a B-cell clone with identical physical, biochemical and immunological properties.

3.2.7
polyclonal antibodies
antibodies produced by several clones of lymphocytes

[EN ISO 21572:2004] [1]

NOTE Antibodies produced by several B-cells that recognise different epitopes in the same antigen.

3.2.8
specificity of an antibody
ability of an antibody to specifically bind to an antigen determinant and not to other similar structures on that or other antigens

[EN ISO 21572:2004] [1]

NOTE The ability of antibodies to recognise and distinguish between related structures.

3.2.9
epitope
molecular structure of an antigen specifically recognised by antibodies or receptors on cells

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3.3 Terms relative to methods

3.3.1
conjugate
material produced by attaching two or more substances together

[EN ISO 21572:2004] [1]

NOTE 1 Conjugates of antibodies with fluorochromes (e.g. coloured particles), radio-labelled substances, or enzymes are often used in immunosassays.

NOTE 2 A conjugate (including conjugated antibody) is an antibody or substance (e.g. Avidin), that is linked to an enzyme, fluorochrome, radioactive or solid particle.

3.3.2
western blotting
transfer of an antigen (i.e. the protein of interest), following electrophoretic separation, to a binding surface and visualisation of the antigen with a specific radio-labelled or enzyme-conjugated antibody

[EN ISO 21572:2004] [1]

NOTE Transfer of electrophoretically separated proteins to a polymer sheet.

3.3.3
ELISA – enzyme linked immunosorbent assay
in vitro assay that combines enzyme-linked antibodies and substrate to form a coloured reaction product, whereas depending on the application, this assay can be used for qualitative or quantitative purposes

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[adapted from EN ISO 21572:2004] [1]

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NOTE 1 *In vitro* assay by use of enzyme-linked antibodies or antigens and a substrate that forms a coloured (or fluorescent) reaction product.

NOTE 2 The ELISA assay is usually performed in the microwell plate format.

3.3.4
immunochromatographic methods
rapid immunoassay formats including lateral flow devices (LFDs), strips and cards, where an antibody or an analyte is coated to a solid surface

3.3.5
RIE – rocket immunoelectrophoresis
in vitro assay where the antigen moves electrophoretically in an antibody containing gel

NOTE Precipitation zones are obtained in the shape of rockets at equivalence between the antigen and the corresponding antibody.

3.3.6
dip stick format
qualitative and rapid assay format, where an antibody or an analyte is coated to a solid surface

[adapted from EN ISO 21572:2004] [1]

3.3.7
biosensor
equipment designed to study the affinity or avidity of interacting molecules such as antigens, allergens and antibodies