

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

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## EESTI STANDARDI EESSÕNA

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<p>Käesolev Eesti standard EVS-EN 15633-1:2009 sisaldab Euroopa standardi EN 15633-1:2009 ingliskeelset teksti.</p> <p>Standard on kinnitatud Eesti Standardikeskuse 23.02.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 14.01.2009.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 15633-1:2009 consists of the English text of the European standard EN 15633-1:2009.</p> <p>This standard is ratified with the order of Estonian Centre for Standardisation dated 23.02.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.</p> <p>Date of Availability of the European standard text 14.01.2009.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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ICS 67.050

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ICS 67.050

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

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

This European Standard was approved by CEN on 1 December 2008.

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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of an identical text or by endorsement, at the latest by July 2009, and conflicting national standards shall be withdrawn at the latest by July 2009.

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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.

## 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 methods*

## 3 Terms and definitions

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

### 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