

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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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

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

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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of an identical text or by endorsement, at the latest by April 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.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.