Foodstuffs - Detection of food allergens - General considerations and validation of methods

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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 15842:2010 sisaldab Euroopa standardi EN 15842:2010 ingliskeelset teksti.	This Estonian standard EVS-EN 15842:2010 consists of the English text of the European standard EN 15842:2010.
Standard on kinnitatud Eesti Standardikeskuse 31.03.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.03.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 10.02.2010.	Date of Availability of the European standard text 10.02.2010.
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Foodstuffs - Detection of food allergens - General considerations and validation of methods

Produits alimentaires - Détection des allergènes alimentaires - Considérations générales et validation des méthodes

Lebensmittel - Nachweis von Lebensmittelallergenen - Allgemeine Betrachtungen und Validierung von Verfahren

This European Standard was approved by CEN on 25 December 2009.

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Foreword

This document (EN 15842:2010) 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of an identical text or by endorsement, at the latest by August 2010, and conflicting national standards shall be withdrawn at the latest by August 2010.

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

The main focus of this European Standard is on immunoassays, chromotographic and nucleic acid based methods for the determination of food allergens. However, because of the rapid developments in this area, other technologies may be considered.

The search for food allergens is performed by means of the following successive (or simultaneous) steps. After sample collection, proteins, nucleic acids or other markers are extracted from the test portion. Extracted analytes can be further purified, simultaneously or after the extraction process. Afterwards, they are diluted (if necessary) and subjected to analytical procedures such as immunoassays (e.g. ELISA), nucleic acid based assays (e.g. PCR) or chromatographic (e.g. LC-MS).

These steps are detailed in this document and in the following documents:

EN 15633-1:2009, *Foodstuffs — Detection of food allergens by immunological methods — Part 1: General considerations*

EN 15634-1:2009, *Foodstuffs — Detection of food allergens by molecular biological methods — Part 1: General considerations*

1 Scope

This European Standard specifies how to use the standards for immunoassays, nucleic based and chromatographic methods and their relationship in the analysis of food allergens; and contains general definitions, requirements and guidelines for laboratory set-up, method validation requirements, description of methods, and test reports.

This document also specifies general guidelines for the requirements and use of reference materials for the determination of allergenic commodities in food products. The term "reference materials" in this document includes certified reference materials as well as quality control materials. Currently only a limited number of reference materials for food allergen determination are available. As new materials become accepted and validated, they may be appended as an annex to this document.

This document does not deal with sampling issues. It simply details processes involved from receipt of the laboratory sample to the end result.

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.

EN ISO/IEC 17025, *General requirement for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)*

EN ISO 17511:2003, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)*

ISO Guide 31, *Reference materials — Contents of certificates and labels*

ISO Guide 35, *Reference materials — General and statistical principles for certification*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
accepted reference value
value that serves as an agreed-upon reference for comparison and which is derived as:

— theoretical or established value, based on scientific principles,

— an assigned value, based on experimental work of some national or international organization,

— consensus value, based on collaborative experimental work under the auspices of a scientific or engineering group

[ISO Guide 30:1992]

3.2
accuracy
closeness of agreement between a test result or measurement result and the true value