

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 15842:2019 sisaldab Euroopa standardi EN 15842:2019 ingliskeelset teksti.	This Estonian standard EVS-EN 15842:2019 consists of the English text of the European standard EN 15842:2019.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
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English Version

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 Validierungsverfahren

This European Standard was approved by CEN on 12 August 2019.

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European foreword

This document (EN 15842:2019) 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of an identical text or by endorsement, at the latest by April 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.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 15842:2010.

Significant technical changes between this standard and EN 15842:2010 are as follows:

- a) documents under normative references removed (2);
- b) updated terms and definitions (3);
- c) general considerations for methods and reference materials added (4.1);
- d) requirements regarding the production and storage of reference materials deleted (4.3);
- e) clause on "Quality assurance requirements" deleted;
- f) the test report should comply with EN ISO/IEC 17025;
- g) updated bibliography.

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

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

The analysis of 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, *Foodstuffs — Detection of food allergens by immunological methods — Part 1: General considerations*

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

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 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 can 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

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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 Method performance characteristics

3.1.1

fitness for purpose

degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose

Note 1 to entry: The measurement process can be based on a screening method, a confirmatory method or a reference method.

Note 2 to entry: For further information refer to [10].

3.1.2

screening method

method that will rapidly and reliably eliminate (screen) a large number of negative (or positive) test samples and restrict the number of test samples requiring the application of a rigorous method

Note 1 to entry: See [11].