

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 15634-1:2009 sisaldab Euroopa standardi EN 15634-1:2009 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 15634-1:2009 consists of the English text of the European standard EN 15634-1:2009.</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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English Version

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

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

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

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## Foreword

This document (EN 15634-1:2009) 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of an identical text or by endorsement, at the latest by July 2009, and conflicting national standards shall be withdrawn at the latest by July 2009.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

This European Standard describes the procedure to qualitatively detect and/or quantitate DNA as markers for potentially allergenic ingredients or constituents by analysing the nucleic acids extracted from the sample under study.

The qualitative detection of DNA targets is performed in order to get a yes or no answer to the question whether a certain DNA fragment is detected or not relative to appropriate controls and within the detection limits of the analytical method used and the test portion analysed.

The quantitative detection of DNA targets is performed to express the quantity of DNA targets, relative to the quantity of a specific reference, appropriate calibrants and controls and within the dynamic range of the analytical method used and the test portion analysed. Appropriate procedures for extraction of nucleic acids are included in each method.

The main focus of this European Standard will be on PCR based amplification methods. However, because of the rapid rate of technological change in this area, other amplification technologies and detection methods may be considered.

## 1 Scope

This European Standard provides the overall framework for detection of sequences corresponding to species containing allergens using the polymerase chain reaction (PCR). It relates to the requirements for the specific amplification of target nucleic acid sequences (DNA) and for the confirmation of the identity of the amplified nucleic acid sequence.

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 Terms relative to extraction and purification of DNA

#### 3.1.1

##### **DNA extraction**

separation of DNA from the other components in a test sample

[EN ISO 24276:2006] [1]

NOTE The factors of major importance for the isolated DNA are: a) purity, b) amount or concentration and c) quality (integrity).

#### 3.1.2

##### **DNA purification**

method resulting in a higher purity of the extracted DNA

NOTE In this context, purity refers to the reduction of observable measurable effects of PCR inhibitors.

#### 3.1.3

##### **PCR quality**

DNA template of sufficient quality to be amplified by PCR

### 3.2 Terms relative to amplification of DNA

#### 3.2.1

##### **species (class/order/family/genus) specific target sequence**

sequence known to be specific for the species