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Irish Standard
I.S. EN 15634-1:2019

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

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National Foreword

I.S. EN 15634-1:2019 is the adopted Irish version of the European Document EN 15634-1:2019, Foodstuffs - Detection of food allergens by molecular biological methods - Part 1: General considerations

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 15634-1

October 2019

ICS 07.100.30

Supersedes EN 15634-1:2009

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

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

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Ref. No. EN 15634-1:2019 E

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European foreword

This document (EN 15634-1:2019) 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of an identical text or by endorsement, at the latest by April 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.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 15634-1:2009.

Significant technical changes between this standard and EN 15634-1:2009 are as follows:

a) updated terms and definitions (3);

b) requirements regarding the preparation of samples changed (6.1);

c) clause 6.3 on DNA quantitation changed;

d) clause 7.2.1 on primer design changed;

e) requirements regarding quantitation of PCR products (8.2) changed;

f) clause on "Quality assurance requirements" deleted;

g) the test report should comply with EN ISO/IEC 17025;

h) 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.

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Introduction

This document describes the procedure to qualitatively detect and/or quantitate DNA fragments 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 sequence 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 document 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.

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.

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1 Scope

This document 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 European Standards are intended to ensure that comparable and reproducible results are obtained in different laboratories. This document has been established for food matrices.

This document is intended to be used in addition to EN 15842.

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 Terms relative to extraction and purification of DNA

3.1.1
DNA extraction
separation of DNA from the other components in a test sample

Note 1 to entry: The factors of major importance for the isolated DNA are:

a) purity,

b) amount or concentration and

c) quality (integrity).

[SOURCE: EN ISO 24276:2006, 3.2.1, modified — note was added]

3.1.2
DNA purification
method resulting in a DNA intended to reduce observable measurable effects of PCR inhibitors

Note 1 to entry: In this context, purity refers to the reduction of observable measurable effects of PCR inhibitors.

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