SLOVENSKI STANDARD
oSIST prEN 15634-1:2018

01-september-2018

Živila - Odkrivanje prisotnosti alergenov v živilih z metodami molekularne biologije - 1. del: Splošne ugotovitve

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

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

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

Ta slovenski standard je istoveten z: **prEN 15634-1**

ICS:

07.100.30	Mikrobiologija živil	Food microbiology
67.050	Splošne preskusne in analizne metode za živilske proizvode	General methods of tests and analysis for food products

oSIST prEN 15634-1:2018 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 15634-1

May 2018

ICS 07.100.30

Will supersede EN 15634-1:2009

English Version

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

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This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 275.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. prEN 15634-1:2018 E

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European foreword

This document (prEN 15634-1:2018) has been prepared by Technical Committee CEN/TC 275 “Food analysis - Horizontal methods”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 15634-1:2009.

Introduction

This document 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 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.

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

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 15842:2010, *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 15842:2010 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 http://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 and EN ISO 24276:2006/A1:2013, 3.2.1, modified – note was added]

3.1.2
DNA purification
method resulting in a higher purity of the extracted DNA

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

[SOURCE: EN ISO 24276:2006 and EN ISO 24276:2006/A1:2013, 3.2.2, modified – more detailed definition]

3.1.3
PCR quality DNA
DNA template of sufficient length, chemical purity, and structural integrity to be amplified by PCR

[SOURCE: ISO 16577:2016, 3.139, modified – change in wording]

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 or higher taxa

3.2.2
identification of amplified nucleic acid sequences
identification (amplicons) by comparison with a reference nucleic acid fragment pattern/sequence

Note 1 to entry Identification of PCR-amplified DNA sequences is possible by e.g. hybridization with a probe, matching restriction digest profiles or matching nucleic acid sequences by sequencing.

Note 2 to entry: In a standard PCR method the confirmation of the identity of the amplified target sequence by either of the methods according to Note 1 is mandatory.

3.3 Definitions referring to controls

3.3.1
positive DNA target control
reference DNA, or DNA extracted from a certified reference material, or known positive samples representative of the sequence or target under study

Note 1 to entry: The control is intended to demonstrate the result of analyses of test sample containing the sequence under study.

[SOURCE: EN ISO 24276:2006 and EN ISO 24276:2006/A1:2013, 3.4.1, modified – replaced organism by target, note was changed]

3.3.2
negative DNA target control
reference DNA, or DNA extracted from a certified negative (blank matrix) reference material, or known negative sample not containing the sequence under study

Note 1 to entry The control is intended to demonstrate the result of analyses of test samples not containing the sequence under study.

[SOURCE: EN ISO 24276:2006 and EN ISO 24276:2006/A1:2013, 3.4.2, modified – note was changed]

3.3.3
PCR inhibition control
control containing known amounts of positive template DNA added in the same or less amount as analyte DNA to the reaction

Note 1 to entry: This control allows the detection of the presence of soluble PCR inhibitors, particularly necessary in case of negative amplification and of quantitative PCR.

3.3.4
amplification reagent control
control containing all the reagents, except extracted test sample template DNA

Note 1 to entry: Instead of the template DNA, a corresponding volume of nucleic acid free water is added to the reaction.

Note 2 to entry: The water used should be double distilled or equivalent, free from DNA and nucleases (molecular biology grade).

3.3.5
extraction blank control
control performing all steps of the extraction procedure, except addition of the test portion

EXAMPLE: by substitution of water for the test portion.

Note 1 to entry: It is used to detect possible contaminating nucleic acid during extraction.

Note 2 to entry: The water used should be double distilled or equivalent, free from DNA and nucleases (molecular biology grade).

[SOURCE: EN ISO 24276:2006 and EN ISO 24276:2006/A1:2013, 3.4.5, modified – change in wording]

3.3.6
positive extraction control
control sample to demonstrate that the nucleic acid extraction procedure has been performed in a way that will allow extraction and subsequent amplification of the target nucleic acid, i.e. by using a sample material known to contain the target nucleic acid

Note 1 to entry: Information about controls can be found in EN ISO 24276 and EN ISO 24276:2006/A1:2013.

4 General laboratory requirements

4.1 General

A European Standard dealing with General considerations and validation criteria of methods was adopted as EN 15842:2010.

4.2 Laboratory organization

Compliance with applicable requirements with respect to safety regulations shall be followed and manufacturer's safety recommendation should be taken into account.

Accidental contamination of DNA can originate from dust or spreading aerosols. As a consequence, the organization of the work area in the laboratory is logically based on:

— the systemic containment of the methodological steps involved in the analysis, and

— a forward flow principle for sample handling.

A minimum of three separately designated work areas with their own apparatus is required:

a) a work area for extraction of the nucleic acid from the test portion (sample);

b) a work area dedicated to the set-up of PCR/amplification reactions; and