SLOVENSKI STANDARD
SIST-TP CEN/TR 16338:2012

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Živila - Odkrivanje prisotnosti alergenov - Predloga za zagotavljanje informacij o imunoloških in molekularno bioloških metodah

Foodstuffs - Detection of food allergens - Template for supplying information about immunological methods and molecular biology methods

Lebensmittel - Nachweis von Lebensmittelallergenen - Vorlage zur Bereitstellung von Informationen über immunologische und molekularbiologische Verfahren

Produits alimentaires - Élément central - Élément complémentaire

Ta slovenski standard je istoveten z: **CEN/TR 16338:2012**

ICS:

67.050	Splošne preskusne in analizne metode za živilske proizvode	General methods of tests and analysis for food products

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TECHNICAL REPORT

RAPPORT TECHNIQUE

TECHNISCHER BERICHT

CEN/TR 16338

May 2012

ICS 67.050

English Version

Foodstuffs - Detection of food allergens - Template for supplying information about immunological methods and molecular biological methods

Produits alimentaires - Détection des allergènes alimentaires - Modèle pour la mise à disposition d'informations sur les méthodes d'analyse immunologique et les méthodes d'analyse de biologie moléculaire

Lebensmittel - Nachweis von Lebensmittelallergenen - Vorlage zur Bereitstellung von Informationen über immunologische und molekularbiologische Verfahren

This Technical Report was approved by CEN on 4 March 2012. It has been drawn up by the Technical Committee CEN/TC 275.

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Foreword

This document (CEN/TR 16338:2012) has been prepared by Technical Committee CEN/TC 275 “Food analysis - Horizontal methods”, the secretariat of which is held by DIN.

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.

1 Scope

This Technical Report describes necessary information for method providers which needs to be provided with proposals for new work items for consideration in CEN/TC 275/WG 12 "Food allergens".

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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.*

EN 15842:2010, *Foodstuffs — Detection of food allergens — General considerations and validation of methods*

ISO 5725-1:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

3 Terms, definitions and abbreviations

For the purpose of this document, the terms and definitions given in EN 15633-1:2009, EN 15634-1:2009 and EN 15842:2010 apply.

4 Necessary elements for method applications

Each method should include:

a) general information (e. g. title, purpose, relevance and scientific basis, scope and test principle);

b) a detailed description of the method (e. g. reagents, equipment, procedure, calculations, reporting);

c) validation and performance criteria.

All necessary elements for immunological and molecular biological methods are given in Annex A and Annex B respectively.

5 Estimation of measurement uncertainty

Uncertainty arises from many sources, including the size of the laboratory sample, sampling of the test sample from the laboratory sample, measurement of the allergen concentration in the extracts, etc. An estimate of the

measurement uncertainty for each matrix in the area of application will be estimated either from intra/inter-laboratory study data, or from estimates of the components as described by ISO/IEC Guide 98-3:2008 [1] and ISO 5725-2:1994 [2].

6 Physical/environmental conditions

Specify conditions (if there are special environmental conditions for performing the analysis), such as normal laboratory conditions, or use of a cold room, performance of certain steps at specific temperatures etc.

7 Instrument calibration

Instruments should be calibrated as specified in EN ISO/IEC 17025:2005 [3].

8 Safety precautions/safety measures

Describe any particular safety measures (not including country/region specific issues) that shall be brought to the attention of the analyst.

9 Pollution prevention/waste disposal

The best, most appropriate local practices shall be adhered to.

10 Appendices

The method shall include such diagrams and tables as are necessary for use by the analyst as informative data from the internal validation study and informative data from the collaborative trial.

Annex A
(informative)

General elements for immunological method proposals

A.1 Title

The title of the method should include an indication of the species and event or sequence to be detected.

It is suggested that the name and address of the person or institution submitting the method also be included in the following manner: author submitting company and independent laboratories (if participants). This information however shall not appear in the published document.

A.2 Purpose, relevance and scientific basis

A description on the purpose of the assay and the scientific background shall be written.

A.3 Scope

A description of the parameters shall be stated in the methods prepared to be a CEN Technical Specification for the immunological measurements of allergens in food. The allergen and matrix on which the method has been validated shall be described.

A.4 Test principle/summary and analysis steps for immunological methods

A.4.1 General

A.4.1.1 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 15842:2010 and EN 15633-1:2009 apply.

A.4.1.2 Description of method

The area of application shall be defined. A short description of the method including the method principle shall be given.

EXAMPLE State which antibodies are used to determine the analyte. Include the specificity of the antibodies (polyclonal, monoclonal, recombinant, etc.). Describe against which source the antibodies are raised (defined allergen, protein, marker to be specified. Finally, state the immunoassay format used.

It is mandatory to describe the design of the assay as well as a detailed description of the used antibodies (including information regarding their purification, characterised affinity and against which substances they are raised). References to relevant scientific publications are also desirable inclusions.

A.4.1.3 Sample type and matrices

The material used for test calibration shall be given (i.e. whether it is whole extract, non-purified, purified, fractionated, etc.). Give also a short description of the type of samples and matrices upon which the method has been validated and can be applied.

A.4.1.4 Interferences

List conditions and materials, which are known to interfere in both a positive and a negative fashion with the method, such as samples derived from matrices that interfere with the method.

A.4.2 Apparatus and equipment for immunological methods

All the specific equipment used, including for example spectrophotometers, blenders or other grinding apparatus, sieves, apparatus or equipment for measuring concentrations (but excluding general laboratory disposables and equipment), shall be stated. Examples for sources of equipments and reagents including the relevant disclaimer/non-endorsement should be stated as footnotes.

A.4.3 Reagents (supplies)

A.4.3.1 General

List all the reagents needed. Include at least all those described in EN 15633-1:2009 and all additionally specified reagents. This listing shall also include all used buffers for assay completion, used reagents and solutions used for sample treatment. The quality of the reagents and the specific reagents used shall be indicated. All ingredients and components (for example buffers, including the chemical composition of buffer), shall be listed.

A.4.3.2 Reagents preparation

If some reagents need to be handled before use (e. g. diluted), the general preparation guidelines shall be given.

A.4.4 Analysis steps

A.4.4.1 General

In this Clause, give a detailed description of each step of the analysis, from sample preparation to the immunoassay procedure, so that a trained analyst can perform the method, including all steps involved.

A.4.4.2 General instructions/recommendations

If there are general recommendations to assure a good test performance, this shall be stated (e. g. at which temperatures the reagents should be used).

A.4.4.3 Preparation of sample for immunological methods

A.4.4.3.1 Sample type and amounts, including sample identification

Give details of the type of laboratory and test samples required (analyte and matrix), with particular reference to issues of sampling. All samples shall be identified unambiguously.

A.4.4.3.2 Sample collection, transport, preservation and storage

Describe any provisions regarding sample collection and sampling, as well as storage conditions.

A.4.4.3.3 Test sample preparation

Outline the steps of the test sample preparation. Include such details as the

— grinding and sieving steps,

— sample amount to be weighed in,

— additional reagents,

— amount, kind and composition of buffer,

— extraction time and temperature.

Describe the method used to extract allergens from the matrix; if applicable use the method from the kit insert.

A.4.4.4 Immunoassay procedure/operational scheme

Describe the procedure in sufficient detail that a trained analyst can perform the method, including any special steps involved.

A.4.5 Reading/interpretation and test result report (calculations, reporting) for immunological methods

A.4.5.1 Identification

If the result of the analysis can be verified, indicate how this can be achieved.

A.4.5.2 Calculations

Describe any calculations or mathematical models used to derive the analytical result. Recommendations for the best curve-fitting model shall be described (e. g. 4-parameter, cubic spline or linear regression model) for the standard curve (method dependent). Describe any calculations or models used to derive the analytical result, including conversion factors from, for example, specific or total protein amount to the amount of allergenic component.

A.4.5.3 Acceptance/rejection criteria

A validated method includes criteria from which an observed measurement result can be accepted as valid. Describe the acceptance/rejection criteria for the analysis.

A.4.5.4 Reporting

Record keeping should be in conformity with EN ISO/IEC 17025:2005 [3]. Describe how data should be reported. Normally the mathematical models can be calculated from the usual software delivered with each ELISA-reader. If no software is available for calculations, alternatives shall be given (e. g. semi-logarithmic mm-paper, x-axis conc. Standard mg/kg, y-axis ABS standard).

A.5 Validation status and performance criteria/method performance for immunological methods

A.5.1 General

A summary of the validated performance claims as well as the following the data collected from the internal validation (including precision, sensitivity, accuracy, specificity and ruggedness), shall be given. If a collaborative trial was also undertaken, information about such a trial (how many laboratories participated, outlier elimination, mean values, repeatability r, S_r, RSD_r, reproducibility R, S_R, RSD_R, etc.), shall be given.

A.5.2 Internal validation (manufacturer´s in house study)

Give information obtained from the intra-laboratory trial, including the RSD_r.