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

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National foreword

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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 of 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.

A.5.2.1 Precision (intra- and inter-assay variation)

A.5.2.1.1 Intra-assay variation

Standards shall be measured from a sufficient number of repetitions. Standard deviations and intra-assay CVs (coefficient of variation) should be given, including the mean CV. Spiked samples can also be measured.

A.5.2.1.2 Inter-assay variation

For the inter-assay variation, standards shall be measured in duplicates in a minimum of six independent runs. The mean CVs should be calculated. Spiked samples can also be measured.

A.5.2.2 Sensitivity

A.5.2.2.1 Limit of detection (LOD) (range of application)

The detection limit and range of application of the method should be given in terms of concentrations. The amount of substance in the analysed sample, in mg/kg, should be given, together with the methods used to determine these values, the matrices used. Explain also how the calculation was done (i.e. whether based on 3 times the standard deviation of the concentration in a matrix blank or on one fortified with an analyte close to this level). The number of determinations should preferably be at least 10, which means that the relevant matrices shall be used with 10 preparations (extractions) each, measured in duplicates. These limits are typically expressed at a 95 % confidence level which means that all errors are random, normal and α and ß are set at 0,05. Thus there is a 95 % chance of analyte concentrations exceeding the LOD being detected; blanks have only have a 5 % chance of being mistakenly “detected”. If the recovery of the method for a specific matrix is less than 100 %, the LOD should be corrected for this recovery.

A.5.2.2.2 Limit of quantitation (LOQ)

The LOQ is the lowest analyte concentration in the sample which can be quantitatively determined with acceptable levels of precision and accuracy. The acceptable degree of performance in terms of RSD % should be given. Often RSD = 10 % is quoted, but it would be more reasonable to set typical values of acceptable relative standard deviations for the LOQ. Preferably, 20 independent determinations with the method should be carried out with a sample known to contain the analyte between 2 to 5 times the estimated LOD. Thereof the relative standard deviation should be calculated using the following formula:

$$RSD\ (s/x_{\text{mean}}) \times 100\ \%$$

where

s is the standard deviation;

x_{mean} is the mean measured value.

A.5.2.3 Accuracy/Trueness

To determine the accuracy, several approaches may be chosen. The listing below appears in order of desirability in terms of providing increased measurement reliability [4]:

— usage of certified reference material;

— usage of, as far as available, a sufficiently well characterised material, e. g. reference material, proficiency test material, etc.;

— usage of a reference method/standard method with little or no systematic error;

— usage of the method when participating in a proficiency testing scheme;

— usage of spiked samples, based on blank or positive samples.

A.5.2.4 Specificity/selectivity (interferences)

Describe the allergenic commodity and analyte that is targeted by the method and the ability to discriminate between the analyte or species to be determined and other materials in the test sample (cross reactivities). Between 40 to 60 relevant commodities shall be tested. The conditions or materials which are known to interfere (in a positive or negative fashion) with the method shall be listed, such as different matrices that yield samples that interfere with the method. Because it is not possible to demonstrate specificity in all cases (due to still remaining/known interferences, practical limitations of testing potential substances etc.), a list with all tested substances shall be given. Any known information about interferences resulting from mixtures of the matrix with other matrices or special foodstuffs should be added if available.

EXAMPLE Measurements can be done with the method at a 100 % level (undiluted extract) of investigated interfering substances and at a 100 mg/kg level.

A.5.2.5 Robustness of the method (Ruggedness)

Critical parameters and even minor changes thereof that influence the final result of the analysis shall be indicated. The aspects in the experimental conditions leading to deviations in the method should be identified. These might include temperature changes (18 °C, room temperature, 37 °C), changed incubation times (recommended and +/- alteration) or incubation volume (recommended, +/- alterations).

Conditions leading to deviations in the method should be identified. These might include temperature changes (recommended and +/- alterations), changed incubation times (recommended and +/- alteration) or incubation volume (recommended, +/- alterations).

A.5.2.6 Calibration curve

The calibration curve is the graphic representation of the measuring signal (y-axis) as a function of the quantity of the analyte (x-axis) and shall be given to assess the mathematical relationship (e. g. linear, quadratic or cubic). The correct form of the calibration plot and the mathematical formula should be given, in order to be able to accurately describe the graph.

A.5.2.7 Stability test/data

Specify any special environmental conditions under which the analysis is performed, such as normal laboratory conditions, use of a cold room, performance of certain steps at specific temperatures, time frame etc. Data from at least 3 batches (independent from each other) for each specified condition shall be shown.

A.5.3 Collaborative trial

If a collaborative trial was carried out, all the information obtained from this multi-laboratory trial, including the RSD_R, should be provided. The parameters to be listed include:

— number of participating laboratories;

— laboratories after outlier elimination (also provide the calculation method used);

— number of outliers;

— means;

— repeatability r, S_r, RSD_r;

— reproducibility R, S_R, RSD_R.

Annex B
(informative)

General elements for molecular biological method proposals

B.1 Title

The title of the method shall include the species to be detected. The title should also incorporate the definition, qualitative or quantitative, and define the technique (e. g PCR/real-time PCR).

B.2 Purpose, relevance and scientific basis

An overview of the principles of the method shall be provided.

NOTE It is suggested that the name and address of the person or institution submitting the method be included.

B.3 Scope

Species, gene and DNA sequence shall be included. The matrix on which the method has been validated should be described.

B.4 Test principle/summary and analysis steps for molecular biological methods

B.4.1 General

B.4.1.1 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 15842:2010, EN 15634-1:2009 and ISO 5725-1:1994 apply.

B.4.1.2 Description of the method

Give a general description of the process which forms the basis of the analytical method. References to relevant scientific publications are desirable.

B.4.1.3 Sample type and matrices

Give a short description of the type of samples and matrices upon which the method has been validated and upon which it can be applied.

B.4.1.4 Interferences

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

B.4.2 Apparatus and equipment for molecular biological methods

Except the standard laboratory equipment, describe all the necessary specific equipment used, (e. g. thermocycler, spectrophotometer, centrifuges, disposals).

B.4.3 Reagents

B.4.3.1 General

List all the reagents needed, at least those described in EN 15634-1.

B.4.3.2 Extraction Reagents

List the reagents needed for the extraction of DNA.

B.4.3.3 PCR reagents

B.4.3.3.1 General

List all the method-specific reagents needed.

B.4.3.3.2 Thermostable DNA-polymerase, buffers, etc.

Give a description of the required characteristics of these reagents.

B.4.3.3.3 Primers - Probes

Describe the sequences of the primers and probes, and the preparation and/or quality grade, e. g. purification of the primers, as well as other components or probes.

To avoid confusion between bases, a lower-case 'g' shall be used to clearly differentiate between 'G' and 'C' in the description (i. e. C g A and T shall be used to indicate bases).

B.4.4 Analysis steps

B.4.4.1 General

B.4.4 gives a detailed description of each step of the analysis.

B.4.4.2 Test sample preparation

Give details of the test sample preparation (e. g. grinding and sieving steps).

B.4.4.3 Preparation of extracts

B.4.4.3.1 Extraction

Describe the method used to extract DNA from the matrix.

B.4.4.3.2 Controls

Describe all necessary extraction controls including extraction blank control and positive extraction control.

B.4.4.3.3 Quantitation of DNA

Give the method used to determine the amount of DNA extracted from the test sample.

B.4.4.3.4 DNA integrity evaluation

Give the method used to determine the integrity of DNA obtained from the extractions.

B.4.4.4 Procedure: PCR set-up

B.4.4.4.1 General

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

B.4.4.4.2 Reaction mix

Describe the reaction mix, giving the total volume, its constituents, the volume of each reagent and the final concentrations. If possible, provide a table with this information.

B.4.4.4.3 Controls

List all necessary controls including extraction (B.4.4.3.2) and PCR controls.

Describe all necessary PCR controls, including positive DNA target control, negative DNA target control, amplification reagent control and PCR inhibition control.

B.4.4.4.4 Preparation of standards

Describe the preparation of standards.

B.4.4.4.5 Temperature/time-program (PCR)

Describe the temperature-time-program used and the type of apparatus used to supply these cycles (e. g. block cyclers). If possible, provide a table with this information.

B.4.5 Reading/interpretation and test result report (calculations, reporting) for molecular biological methods

B.4.5.1 Identification

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

B.4.5.2 Calculations

Describe any calculations or models used to derive the analytical result.

B.4.5.3 Accept/reject criteria

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

B.4.5.4 Reporting

Describe how data is reported.

B.5 Validation status and performance criteria for molecular biological methods

B.5.1 General

Summary of the validated performance claims and data collected from the internal validation study shall be given. Additionally, if a collaborative trial was undertaken, the relevant information shall also be given. The list of performance criteria for quantitative methods should include precision, LOQ, range of application, trueness, specificity and robustness. For qualitative methods, data concerning LOD, specificity, sensitivity and robustness should be presented.

B.5.2 Internal validation (manufacturer's in house study)

B.5.2.1 Matrices, sample type and amounts

Describe in detail the type of samples and matrices upon which the method has been validated as well as sample amounts and amount of allergenic constituent.

B.5.2.2 DNA extraction and purification

Give any information obtained during validation study, concerning DNA concentration, DNA fragmentation state and purity of DNA extracts and describe any limiting level that may influence the quality of subsequent analysis.

B.5.2.3 Precision - Relative Repeatability Standard Deviation (RSD_r)

Repeatability should be obtained from a sufficient number of test results. The relative repeatability standard deviation should be ≤ 25 % over the working range of the method. For qualitative methods, the performance characteristics like precision should be given as κ (kappa) values.

B.5.2.4 Limit of detection (LOD)

The detection limit should be given in terms of the copy number of DNA converted to mg allergenic constituents/kg food. The conversion factor should be presented. These limits are typically expressed at a 95 % confidence level. If a target concentration exists (e. g. a legislative threshold), the LOD should be less than 1/20th of the target concentration.

B.5.2.5 Limit of quantitation (LOQ)

The limit of quantitation should be given in terms of the copy number of DNA converted to mg allergenic constituents/kg food. The conversion factor should be presented. These limits are typically expressed at a 95 % confidence level. If a target concentration exists (e. g. a legislative threshold), the LOQ should be less than 1/10th of the target concentration with an RSD_r ≤ 25 %.

B.5.2.6 Range of application (working range)

The working range of concentrations should cover a linear region with a level of trueness ≤ 25 %. The range of application of the method should be given in terms of the copy numbers of DNA converted to mg allergenic constituent/kg food. If a target concentration exists (e. g. a legislative threshold), the working range of the method should include the 1/10th and at least 5 times the target concentration.

B.5.2.7 Trueness

To determine the trueness, several approaches may be chosen. The listing below appears in order of desirability in terms of providing increased measurement reliability [4]:

— usage of certified reference material;

— usage of, as far as is available, sufficiently well characterized material (e. g. reference material, proficiency test material, etc.);

— usage of a reference method/standard method with little or no systematic error;

— usage of the method when participating in a proficiency testing scheme;

— usage of spiked samples, based on blank or positive samples.

The trueness shall be within ± 25 % of the accepted reference value over the whole working range.

B.5.2.8 Specificity

Describe the DNA sequence that is targeted by the method. The specificity of the target sequence shall be verified theoretically and experimentally.

Report the result of the sequence homology search for DNA sequences in data bank searches.

NOTE 1 Such searches can be performed, for example, in the data banks of the NCBI (National Center for Biotechnology Information; http://www.ncbi.nlm.nih.gov/Database/) and EMBL (European Molecular Biology Laboratory; http://www.ebi.ac.uk/embl/index.html).

Include the type of search and the date the search was performed. Describe the experiments designed to test specificity (e. g. experimental demonstration of the absence of amplification products when the target sequence specific assay is applied to individual PCRs of pure genomic DNA other than the target).

NOTE 2 It is recommended to include a representative sample of the closely related species in the specificity test.

B.5.2.9 Sensitivity

For qualitative methods, sensitivity should be calculated as the ratio of the number of true positive samples per number of known positive samples (true positives / (true positives + false negatives)). Sensitivity should be ≥ 95 %. The minimum amount or concentration at which sensitivity is ≥ 95 % is the limit of detection of the method (LOD).

B.5.2.10 Robustness of the method (Ruggedness)

Give information about the variations in reaction conditions that have been tested. In addition, list the conditions which are known to interfere (in a positive or negative way) with the method. Critical factors that may interfere are: different thermal cycler models, temperature profile and time profile, concentrations (primers, probe, magnesium chloride and dNTP), DNA polymerase and uracyl-n-glycosylase.

B.5.3 Collaborative trial

B.5.3.1 General

Give information obtained from the collaborative trial, including the organizer, protocol, number of participating laboratories, number of outliers, means and reproducibility R, S_R, RSD_R.

B.5.3.2 Precision - Relative Reproducibility Standard Deviation (RSD_R)

Reproducibility should be obtained from a sufficient number of test results. The relative reproducibility standard deviation (RSD_R) should be ≤ 35 % over the working range of the method. At low concentrations, RSD_R values ≤ 50 % may be acceptable. For qualitative methods, performance characteristics like precision should be given as κ (kappa) values.

B.5.3.3 Trueness

To determine the trueness of the collaborative trial, the approaches mentioned in B.5.2.7 may be chosen.

The trueness shall be within ± 25 % of the accepted reference value over the whole working range.

Bibliography

[1] ISO/IEC Guide 98-3:2008 *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

[2] ISO 5725-2:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*

[3] EN ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)*

[4] Harmonised Guidelines for the in-house validation of methods of analysis; Pure Appl. Chem., Vol. 74, No. 5, pp. 835–855

[5] EN ISO 24276:2006, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — General requirements and definitions (ISO 24276:2006)*

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