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S.R. CEN/TR 16338:2012

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

S.R. CEN/TR 16338:2012

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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.

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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

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