TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN/TS 16707

October 2014

ICS 67.050

English Version

Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Polymerase chain reaction (PCR) based screening strategies

Produits alimentaires - Méthodes d'analyse pour la détection des organismes génétiquement modifiés et des produits dérivés - Stratégies de criblage basées sur l'utilisation de la réaction de polymérisation en chaîne (PCR)

Lebensmittel - Verfahren zum Nachweis von gentechnisch veränderten Organismen und ihren Produkten - Strategien für das Screening mit Polymerase-Kettenreaktion (PCR)

This Technical Specification (CEN/TS) was approved by CEN on 28 June 2014 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. CEN/TS 16707:2014 E

Contents

Page

Foreword

This document (CEN/TS 16707:2014) 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.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

Largely, detection of materials derived from genetically modified organisms (GMOs) in a given sample employs polymerase chain reaction (PCR) analysis, specifically real-time PCR.

A general strategy for GMO detection and identification by means of PCR analysis and a stepwise approach is described.

In initial screening analysis, DNA sequences of genetic elements common to many GMOs are targeted. According to its purpose, screening is a test to rapidly and reliably sort samples into groups. Once the samples are grouped, screening facilitates and potentially reduces subsequent analytical work and results interpretation. The screening strategy should be adjusted to the scope (food, feed or seed, crop-specific etc.) of the test(s).

This document takes the general principle of GMO detection strategies as a basis and describes the underlying analytical steps for complex screening (known as the matrix-approach [2]).

The document is written primarily for screening strategies applying real-time PCR methods. Other PCR methodologies may be applicable in the same way.

The terms “screening method” and “screening strategies” are not interchangeable and have different meanings in this document.

1 Scope

This Technical Specification describes screening strategies for the detection of genetically modified (GM) DNA in food products by means of PCR methods. The strategies have been established for food matrices, but it can also be applied to other matrices (e.g. feed, seed and samples from field grown plants).

Detection of GM DNA is based on PCR methods targeting segments of transgenic DNA sequences (genetic elements, genetic constructs or insertion sites of transgenes). Various combinations of these PCR methods are involved in screening strategies. The methods are applied simultaneously or hierarchically. The general strategy is based on the matrix approach. Examples for the implementation and application of this approach are described.

In order to ensure reliable analytical results, the document also provides guidelines for the validation of the performance of qualitative PCR methods applied in screening approaches.

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 ISO 21569, *Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Qualitative nucleic acid based methods (ISO 21569)*

EN ISO 21570, *Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Quantitative nucleic acid based methods (ISO 21570)*

EN ISO 21571, *Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Nucleic acid extraction (ISO 21571)*

EN ISO 24276, *Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - General requirements and definitions (ISO 24276)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 24276 and the following apply:

3.1
GMO method matrix
relational presentation (e.g. a table) of symbols or numbers

Note 1 to entry: One dimension (e.g. columns) corresponds to genetic elements and genetic constructs detected by a defined PCR method and the other dimension (e.g. rows) corresponds to GM events. The entered symbols or numbers indicate the detectability or non-detectability of the target sequence for the GM event.

Note 2 to entry: The term matrix is commonly used for a defined composition of food, but this definition is not relevant here.

3.2
GMO target matrix
relational presentation (e.g. a table) of symbols or numbers

Note 1 to entry: One dimension corresponds to genetic elements or genetic constructs present in a GMO and the other dimension (e.g. rows) corresponds to GM events. The entered symbols or numbers indicate the presence or absence of the target for the GM event and copy number, if available.

Note 2 to entry: In contrast to GMO method matrix, the GMO target matrix is independent from a detection method.