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BSI Standards Publication

Foodstuffs - General guidelines for the validation of qualitative real-time PCR methods

Part 2: Collaborative study

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee AW/275, Food analysis - Horizontal methods.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

Foodstuffs - General guidelines for the validation of qualitative real-time PCR methods - Part 2: Collaborative study

Denrées alimentaires - Lignes directrices générales pour la validation des méthodes de PCR qualitative en temps réel - Partie 2 : Étude interlaboratoires

Lebensmittel - Allgemeine Anleitung für die Validierung qualitativer Realtime-PCR-Verfahren - Teil 2: Ringversuch

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European foreword

This document (CEN/TS 17329-2:2019) 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 shall not be held responsible for identifying any or all such patent rights.

This Technical Specification consists of two parts:

— Part 1: Single-laboratory validation

— Part 2: Collaborative study

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Introduction

Qualitative real-time polymerase chain reaction (PCR) methods currently find broad application for the detection of specific DNA sequences in food, e.g. for the detection and identification of genetically modified organisms and the products derived thereof, for food authentication and speciation and other purposes. It is important that results obtained from different laboratories by such food analytical methods satisfy certain performance characteristics and quality criteria. The performance of a method is validated in a step-wise process from in-house (single laboratory) validation to a pre-validation study by few laboratories followed by a full validation in a collaborative study to gain information and data on the reproducibility of the analysis results obtained by different laboratories.

The aim of this document is to provide practical guidance for a collaborative validation study of qualitative real-time PCR methods which are applied for food analysis. The procedure described is a recommendation that is underpinned by practical experience in several collaborative trial studies. It is possible to apply alternative approaches for which it can be shown that the performance criteria mentioned in the present document are achieved.

1 Scope

This document provides information on how the performance characteristics of qualitative (binary) real-time polymerase chain reaction (PCR) methods for detection of specific DNA sequences present in foods should be evaluated and validated by conducting a collaborative study.

The guidelines are applicable for validation of qualitative PCR methods used for detection of DNA sequences derived from genetically modified foodstuffs. They can be applicable also for PCR methods used for detection of other target sequences in foodstuffs, e.g. for species detection and identification.

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

ISO 16577, *Molecular biomarker analysis — Terms and definitions*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 16577 and EN ISO 24276 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
probability of detection
POD
probability of a positive analytical outcome of a qualitative method for a given matrix at a given concentration

NOTE For a qualitative real-time PCR method it describes the probability that, for a given number of DNA copies of the target sequence, PCR amplification will take place.

3.2
laboratory standard deviation
σ_L
expression of the standard deviation between laboratories which describes the dispersion of the log-transformed laboratory-specific values for the LOD95%

3.3
mean amplification probability
λ
probability that, for a randomly selected DNA copy of the target sequence, PCR amplification will occur

3.4
slope parameter
b
slope of the POD curve (across laboratories) that indicates the deviation from the ideal POD curve (with b = 1)

NOTE The ideal POD curve is based on the assumption that the mean amplification probability is independent of the number of DNA copies of the target sequence.