CU. (ISO 2 Foodstuffs - Molecular biomarker analysis - Proteinbased methods (ISO 21572:2013)



EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 21572:2013	This Estonian standard EVS-EN ISO 21572:2013	
sisaldab Euroopa standardi EN ISO 21572:2013	consists of the English text of the European standard	
ingliskeelset teksti.	EN ISO 21572:2013.	
S		
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	This standard has been endorsed with a notification	
avaldamisega EVS Teatajas.	published in the official bulletin of the Estonian Centre for Standardisation.	
	Date of Availability of the European standard is	
	13.02.2013.	
kättesaadavaks 13.02.2013.		
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for	
	Standardisation.	

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 67.050

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega: Aru 10, 10317 Tallinn, Eesti; www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation: Aru 10, 10317 Tallinn, Estonia; www.evs.ee; phone 605 5050; e-mail info@evs.ee

EUROPEAN STANDARD

EN ISO 21572

NORME EUROPÉENNE EUROPÄISCHE NORM

February 2013

ICS 67.050

Supersedes EN ISO 21572:2004

English Version

Foodstuffs - Molecular biomarker analysis - Protein-based methods (ISO 21572:2013)

Produits alimentaires - Analyse des biomarqueurs moléculaires - Méthodes basées sur les protéines (ISO 21572:2013) Lebensmittel - Untersuchung von molekularen Biomarkern - Proteinverfahren (ISO 21572:2013)

This European Standard was approved by CEN on 12 January 2013.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 21572:2013) has been prepared by Technical Committee ISO/TC 34 "Food products" in collaboration with Technical Committee CEN/TC 275 "Food analysis - Horizontal methods" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.

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.

This document supersedes EN ISO 21572:2004.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: 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.

Endorsement notice

The text of ISO 21572:2013 has been approved by CEN as EN ISO 21572:2013 without any modification.

Cor	tents	Page
Fore	vord	iv
1	Scope	
2	Normative references	1
3	Terms and definitions 3.1 General 3.2 Terms relating to antibodies 3.3 Terms relating to techniques 3.4 Terms relating to control 3.5 Terms relating to validation	
4	Principle	6
5	Reagents	6
6	Laboratory equipment	
7	Sampling	6
8	Procedure 8.1 General 8.2 Preparation of sample solution 8.3 Extraction 8.4 Preparation of calibration curves, positive controls and reference materials. 8.5 Assay procedure	
9	Interpretation and expression of results 9.1 General 9.2 Quantitative and semiquantitative analysis 9.3 Qualitative analysis	8 8
10	Specific parameters which may influence results 10.1 General 10.2 Special considerations 10.3 Assay applicability	
11	Confirmation method	10
12	Test report	10
Anno	x A (informative) Detection of a protein by ELISA	12
	x B (informative) Detection of protein(s) by lateral flow devices	
Bibli	ography	29
		5

Foodstuffs — Molecular biomarker analysis — Proteinbased methods

WARNING — Follow all instructions provided by the kit/reagent manufacturers and other standard laboratory safety procedures. Read and implement the material safety data sheets (MSDS).

1 Scope

This International Standard provides general guidelines and performance criteria for methods for the detection and/or quantification of specific proteins or protein(s) of interest [POI(s)] in a specified matrix.

These general guidelines address existing antibody based methods. Methods other than those described in <u>Annex A</u> or <u>Annex B</u> can also detect the POI. The same criteria as outlined in this International Standard apply generally.

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.

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

3 Terms and definitions

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

3.1 General

3.1.1

sample

subset of a population made up of one or more sampling units

[SOURCE: ISO 3534-2:2006, 1.2.17]

3.1.2

laboratory sample

sample (3.1.1) as prepared for sending to the laboratory and intended for inspection or testing

[SOURCE: ISO 78-2:1999, 3.1]

3.1.3

test sample

sample (3.1.1) as prepared for testing or analysis, the whole quantity or part of it being used for testing or analysis at one time

[SOURCE: ISO 3534-2:2006, 5.3.11]

3.1.4

test portion

part of a *test sample* (3.1.3) which is used for testing or analysis at one time

[SOURCE: ISO 3534-2:2006, 5.3.12]