SLOVENSKI STANDARD
SIST EN ISO 20813:2023

01-maj-2023

Analiza molekularnih biomarkerjev - Analitske metode za odkrivanje in prepoznavanje živalskih vrst v živilih in živilskih proizvodih (metodana osnovi nukleinskih kislin) - Splošne zahteve in definicije (ISO 20813:2019)

Molecular biomarker analysis - Methods of analysis for the detection and identification of animal species in foods and food products (nucleic acid-based methods) - General requirements and definitions (ISO 20813:2019)

Untersuchung auf molekulare Biomarker - Verfahren zur Identifizierung und zum Nachweis von Tierarten in Lebensmitteln (Nukleinsäureverfahren) - Allgemeine Anforderungen und Definitionen (ISO 20813:2019)

Analyse moléculaire de biomarqueurs - Méthodes d'analyse pour la détection et l'identification des espèces animales dans les aliments et les produits alimentaires (méthodes basées sur l'utilisation des acides nucléiques) - Exigences générales et définitions (ISO 20813:2019)

Ta slovenski standard je istoveten z: **EN ISO 20813:2022**

ICS:

67.050	Splošne preskusne in analizne metode za živilske proizvode	General methods of tests and analysis for food products

SIST EN ISO 20813:2023 **en,fr,de**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 20813

December 2022

ICS 67.050

English Version

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. EN ISO 20813:2022 E

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European foreword

The text of ISO 20813:2019 has been prepared by Technical Committee ISO/TC 34 "Food products" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 20813:2022 by Technical Committee CEN/TC 460 "Food Authenticity" the secretariat of which is held by DIN.

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Endorsement notice

The text of ISO 20813:2019 has been approved by CEN as EN ISO 20813:2022 without any modification.

INTERNATIONAL STANDARD

ISO 20813

First edition
2019-05

Molecular biomarker analysis — Methods of analysis for the detection and identification of animal species in foods and food products (nucleic acid-based methods) — General requirements and definitions

Analyse moléculaire de biomarqueurs — Méthodes d'analyse pour la détection et l'identification des espèces animales dans les aliments et les produits alimentaires (méthodes basées sur l'utilisation des acides nucléiques) — Exigences générales et définitions

Reference number
ISO 20813:2019(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 34, *Food products,* Subcommittee SC 16, *Horizontal methods for molecular biomarker analysis*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Molecular biomarker analysis — Methods of analysis for the detection and identification of animal species in foods and food products (nucleic acid-based methods) — General requirements and definitions

1 Scope

This document specifies minimum requirements of performance characteristics for the detection of nucleic acid sequences (DNA) by molecular methods, such as the polymerase chain reaction (PCR), including different post-PCR detection methods, real-time PCR, single and/or multiple probe-based detection techniques as well as the combination of such methods.

The document is applicable to the detection, identification and quantification of DNA from animal species of higher and lower taxonomic groups in foodstuffs, and the validation of applicable methods.

It is applicable to mammals, birds, reptiles, amphibians, fishes, molluscs, crustaceans and insects. Typical examples for each are listed in Annex A.

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.

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

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 16577, ISO 24276 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
basic local alignment search tool
BLAST
sequence comparison algorithm optimized for speed that is used to search sequence databases for optimal local alignments to a query

Note 1 to entry: This algorithm directly approximates alignments that optimize a measure of local similarity, the maximum signal pair (MST) score or high-scoring segment pair (HSP) score.

Note 2 to entry: See Reference [2].

Note 3 to entry: BLASTn is applicable to nucleotide sequence comparison.

3.2
conventional polymerase chain reaction
conventional PCR
PCR method that requires a post-PCR step such as gel electrophoresis for detection or visualization of amplification products to provide a qualitative result

4 Performance characteristics of the methods

4.1 General

The methods to be used for animal species analysis shall meet the performance characteristics in accordance with this document. The results of all interlaboratory and/or single-laboratory validations and the performance characteristics shall be described.

NOTE Some guidelines are available for implementation of methods, see Reference [10].

4.2 Scope of the method

Information regarding the intended use and the limitations of the methods shall be provided. In particular, information shall indicate that the criteria set out in this document have been fulfilled.

4.3 Scientific basis

An overview of the principles and references to relevant scientific publications should be provided.

4.4 Units of measurement

Qualitative analyses indicate the presence or absence (lack of detection) of a certain target.

In quantitative analyses, the measured value is calculated as ratio of DNA copy numbers (c/c). The use of this ratio should examine possible influences, including the number of DNA copies with regard to the target in the genome. Other units (e.g. ratio of masses) can be employed. The principles of calculation of the ratio shall be reported.

If a quantitative method is intended to judge the mass/mass ratio of different animal species ingredients in a sample, it should be indicated that the values measured for the DNA copy number ratio cannot reflect in all cases the mass/mass ratio of animal constituents in the sample.

4.5 Applicability

When assessing if a method is fit for purpose, the following aspects regarding the nature of the target should be considered:

— the location of the target (nuclear or mitochondrial);

— the copy number per cell;

— the length of the target sequence.

For quantitative species-specific methods, a nuclear gene, excluding mitochondrial DNA shall be targeted. The target sequence shall be present as a single copy per haploid genome or the copy number shall be determined/known.

When assessing if a method is fit for purpose, the following aspects regarding the matrix should be considered:

— the nature of the potential sample matrices;

— the degree of processing of the sample constituents;

