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)



#### EESTI STANDARDI EESSÕNA

#### NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 20813:2022 sisaldab Euroopa standardi EN ISO 20813:2022 ingliskeelset teksti.

This Estonian standard EVS-EN ISO 20813:2022 consists of the English text of the European standard EN ISO 20813:2022.

Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.

This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.

Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 21.12.2022.

Date of Availability of the European standard is 21.12.2022.

Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.

The standard is available from the Estonian Centre for Standardisation and Accreditation.

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

#### ICS 67.050

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# **EUROPEAN STANDARD**

### **EN ISO 20813**

## NORME EUROPÉENNE ..

**EUROPÄISCHE NORM** 

December 2022

ICS 67.050

#### **English Version**

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)

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)

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

This European Standard was approved by CEN on 18 December 2022.

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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.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

#### **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.

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 June 2023, and conflicting national standards shall be withdrawn at the latest by June 2023.

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.

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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.

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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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

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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 <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

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 <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

# 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  $\frac{Annex A}{A}$ .

#### 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 <a href="https://www.iso.org/obp">https://www.iso.org/obp</a>
- IEC Electropedia: available at <a href="http://www.electropedia.org/">http://www.electropedia.org/</a>

#### 3.1

## basic local alignment search tool

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.