
**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*

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Contents

Page

Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Performance characteristics of the methods	2
4.1 General.....	2
4.2 Scope of the method.....	2
4.3 Scientific basis.....	2
4.4 Units of measurement.....	2
4.5 Applicability.....	2
4.6 Specificity.....	3
4.6.1 General.....	3
4.6.2 Requirements for inclusivity testing.....	3
4.6.3 Requirements for exclusivity testing.....	3
4.7 Sensitivity.....	4
4.7.1 General.....	4
4.7.2 Limit of detection (LOD).....	4
4.8 Specific requirements for quantitative methods.....	5
4.8.1 General.....	5
4.8.2 Limit of quantification (LOQ).....	5
4.8.3 Dynamic range.....	5
4.8.4 Determination of precision and trueness for quantitative methods.....	6
4.9 Robustness.....	6
4.9.1 General.....	6
4.9.2 Robustness determination by interlaboratory study.....	6
4.9.3 Robustness determination by a multifactorial orthogonal test design.....	6
5 Single-laboratory validation	6
6 Interlaboratory study (collaborative study)	7
6.1 General.....	7
6.2 Qualitative methods.....	7
6.3 Quantitative methods.....	7
7 General laboratory and procedural requirements	7
7.1 General.....	7
7.2 Facilities, materials and equipment.....	8
7.3 Sample preparation and DNA extraction.....	8
7.4 Use of controls.....	9
7.5 Data analysis.....	9
7.5.1 Control.....	9
7.5.2 Conventional PCR.....	10
7.5.3 Real-time PCR amplification curves.....	10
7.6 Expression of results.....	10
7.6.1 Expression of positive results.....	10
7.6.2 Expression of negative results.....	11
7.6.3 Expression of quantitative results.....	11
8 Test report	11
Annex A (informative) List of typical species used for inclusivity and exclusivity testing	12
Annex B (informative) Examples of unit conversion methods from DNA copy numbers to the ratio of masses	17
Bibliography	26

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

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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.