

ISO 20813:2019 (E)

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

Contents

	Foreword
1	Scope
2	Normative references
3	Terms and definitions
4	Performance characteristics of the methods
4.1	General
4.2	Scope of the method
4.3	Scientific basis
4.4	Units of measurement
4.5	Applicability
4.6	Specificity
4.6.1	General
4.6.2	Requirements for inclusivity testing
4.6.3	Requirements for exclusivity testing
4.7	Sensitivity
4.7.1	General
4.7.2	Limit of detection (LOD)
4.7.2.1	Absolute LOD
4.7.2.2	Relative LOD
4.7.2.3	Asymmetric LOD (for multiplex methods only)
4.8	Specific requirements for quantitative methods
4.8.1	General
4.8.2	Limit of quantification (LOQ)
4.8.3	Dynamic range
4.8.4	Determination of precision and trueness for quantitative methods
4.9	Robustness
4.9.1	General
4.9.2	Robustness determination by interlaboratory study
4.9.3	Robustness determination by a multifactorial orthogonal test design
5	Single-laboratory validation
6	Interlaboratory study (collaborative study)
6.1	General
6.2	Qualitative methods
6.3	Quantitative methods
7	General laboratory and procedural requirements
7.1	General
7.2	Facilities, materials and equipment
7.3	Sample preparation and DNA extraction
7.4	Use of controls
7.5	Data analysis
7.5.1	Control
7.5.2	Conventional PCR
7.5.3	Real-time PCR amplification curves
7.6	Expression of results
7.6.1	Expression of positive results

- 7.6.2 Expression of negative results
- 7.6.3 Expression of quantitative results

8 Test report

Annex A (informative) List of typical species used for inclusivity and exclusivity testing

Annex B (informative) Examples of unit conversion methods from DNA copy numbers to the ratio of masses

- B.1 General**
- B.2 Example for converting measurement results expressed in the ratio of DNA copy numbers into the ratio of masses using reference materials**
- B.3 Example of relative quantification of animal species content in meat products**
 - B.3.1 Analytical results reported in mass fraction**
 - B.3.2 Conversion of measurement results expressed in copy number per haploid genome equivalent (cp/HGE) into mass fraction**
 - B.3.2.1 General**
 - B.3.2.2 Example: Relative quantification based on reference gene (standard curve method)**
 - B.3.2.3 Example: Relative quantification of amplified DNA % (ng/μl) using normalization**
 - B.4 Example of calculation with copy number of single-copy gene**

Page count: 27