

DIN EN ISO 20813:2023-04 (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 (ISO 20813:2019)

	Page
Contents	Page
European foreword	3
Foreword	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	5
4 Performance characteristics of the methods	6
4.1 General	6
4.2 Scope of the method	6
4.3 Scientific basis	6
4.4 Units of measurement	6
4.5 Applicability	6
4.6 Specificity	7
4.6.1 General	7
4.6.2 Requirements for inclusivity testing	7
4.6.3 Requirements for exclusivity testing	7
4.7 Sensitivity	8
4.7.1 General	8
4.7.2 Limit of detection (LOD)	8
4.8 Specific requirements for quantitative methods	9
4.8.1 General	9
4.8.2 Limit of quantification (LOQ)	9
4.8.3 Dynamic range	9
4.8.4 Determination of precision and trueness for quantitative methods	10
4.9 Robustness	10
4.9.1 General	10
4.9.2 Robustness determination by interlaboratory study	10
4.9.3 Robustness determination by a multifactorial orthogonal test design	10
5 Single-laboratory validation	10
6 Interlaboratory study (collaborative study)	11
6.1 General	11
6.2 Qualitative methods	11
6.3 Quantitative methods	11
7 General laboratory and procedural requirements	11
7.1 General	11
7.2 Facilities, materials and equipment	12
7.3 Sample preparation and DNA extraction	12
7.4 Use of controls	13
7.5 Data analysis	13
7.5.1 Control	13
7.5.2 Conventional PCR	14
7.5.3 Real-time PCR amplification curves	14
7.6 Expression of results	14
7.6.1 Expression of positive results	14
7.6.2 Expression of negative results	15
7.6.3 Expression of quantitative results	15
8 Test report	15
Annex A (informative) List of typical species used for inclusivity and exclusivity testing	16
Annex B (informative) Examples of unit conversion methods from DNA copy numbers to the ratio of masses	21
Bibliography	30