

# 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)

<b>Contents</b>	<b>Page</b>
<b>European foreword</b> .....	<b>3</b>
<b>Foreword</b> .....	<b>4</b>
<b>1 Scope</b> .....	<b>5</b>
<b>2 Normative references</b> .....	<b>5</b>
<b>3 Terms and definitions</b> .....	<b>5</b>
<b>4 Performance characteristics of the methods</b> .....	<b>6</b>
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
<b>5 Single-laboratory validation</b> .....	<b>10</b>
<b>6 Interlaboratory study (collaborative study)</b> .....	<b>11</b>
6.1 General.....	11
6.2 Qualitative methods.....	11
6.3 Quantitative methods.....	11
<b>7 General laboratory and procedural requirements</b> .....	<b>11</b>
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
<b>8 Test report</b> .....	<b>15</b>
<b>Annex A (informative) List of typical species used for inclusivity and exclusivity testing</b> .....	<b>16</b>
<b>Annex B (informative) Examples of unit conversion methods from DNA copy numbers to the ratio of masses</b> .....	<b>21</b>
<b>Bibliography</b> .....	<b>30</b>