
**Molecular biomarker analysis —
Methods of analysis for the detection
and identification of animal species
in food and feed products (nucleotide
sequencing-based methods) —**

**Part 1:
General requirements**

*Analyse moléculaire de biomarqueurs — Méthodes d'analyse pour la
détection et l'identification d'espèces animales dans les aliments et
les aliments pour animaux (méthodes basées sur le séquençage des
nucléotides) —*

Partie 1: Exigences générales

<https://standards.iteh.ai/catalog/standards/iso/2ac00d5a-52a5-483e-8792-3f2aaf0579dd/iso-22949-1-2021>



iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

ISO 22949-1:2021

<https://standards.iteh.ai/catalog/standards/iso/2ac00d5a-52a5-483e-8792-3f2aaf0579dd/iso-22949-1-2021>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Performance characteristics of the methods	1
4.1 General	1
4.2 Fitness for purpose of the method	2
4.3 Scientific basis	2
4.3.1 General	2
4.3.2 Sanger sequencing	2
4.3.3 Next generation sequencing	2
4.4 Units of measurement	3
4.5 Applicability	3
4.5.1 Meat or food product considerations	3
4.5.2 Sampling plan	3
4.5.3 Genomic considerations	3
4.5.4 Method testing	3
4.6 Primer selection and evaluation	4
4.7 Database construction and evaluation	4
4.8 Selectivity and nucleotide sequence specificity	5
4.8.1 General	5
4.8.2 Requirements for inclusivity testing	5
4.8.3 Evaluation of non-targeted DNA interference	5
4.9 Sensitivity	6
4.9.1 General	6
4.9.2 Limit of detection	6
4.10 Robustness	6
4.10.1 General	6
4.10.2 Robustness determination by inter-laboratory study	6
4.10.3 Robustness determination by a multifactorial orthogonal test design	7
5 Single-laboratory validation	7
6 Interlaboratory study (collaborative study)	7
7 General laboratory and procedural requirements	7
7.1 General	7
7.2 Facilities, materials and equipment	8
7.3 Sample preparation	8
7.3.1 General	8
7.3.2 Category A: single species sample consisting of a single piece	8
7.3.3 Category B: single species product composed by several pieces or units of the same type of tissue	9
7.3.4 Category C: multiple mixed species processed product including those of non-meat origin or different types of tissues as ingredients	9
7.4 DNA extraction	9
7.5 DNA sequencing workflow	10
7.5.1 General	10
7.5.2 Sanger sequencing method	10
7.5.3 Next generation sequencing method	11
7.6 DNA sequence data analysis and interpretation	14
7.7 Expression of results	14
8 Validation of the NGS bioinformatics pipeline	14

8.1	General.....	14
8.2	Quality metrics.....	14
9	Test report.....	15
Annex A (informative) General workflow of the laboratory analytical procedure.....		16
Annex B (informative) Comparison between Sanger sequencing and next generation sequencing.....		17
Annex C (informative) In silico workflow for primer set selection.....		18
Bibliography.....		20

iTeh Standards
(<https://standards.itih.ai>)
Document Preview

ISO 22949-1:2021

<https://standards.itih.ai/catalog/standards/iso/2ac00d5a-52a5-483e-8792-3f2aaf0579dd/iso-22949-1-2021>