



联合国
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Food and Agriculture
Organization of the
United Nations

Organisation des Nations
Unies pour l'alimentation
et l'agriculture

Продовольственная и
сельскохозяйственная организация
Объединенных Наций

Organización de las
Naciones Unidas para la
Alimentación y la Agricultura

منظمة
الأغذية والزراعة
للأمم المتحدة

COMMISSION ON PHYTOSANITARY MEASURES

Fifteenth Session

Virtual Meeting, 16, 18 March and 1 April 2021

**Written reports from international organizations - Report from the ISO
Secretariat**

Agenda item 15.2

Prepared by the ISO Secretariat

English only



ISO TC 34 Food Products/ SC 16 Horizontal Methods for Molecular Biomarker Analysis

Report of the Secretariat 2021/01/19

Secretariat: United States – [ANSI \(via the American Oil Chemist's Society \(AOCS\)\)](#)

Secretary :[Dr Michael Sussman](#)

Chairperson (until end 2021): Dr Ray Shillito

ISO Technical Program Manager: [Mme Marie-Noëlle Bourquin](#)
ISO Editorial Program Manager: [Ms Nicola Perou](#)

Creation date: 2008 (12 years)

1. MEMBERS: Participating Countries (24)/ Observing Countries (20): Delegates (182)

Participating Countries (24)

Austria (ASI)	Japan (JISC)	Indonesia (BSN)
Belgium (NBN)	Namibia (NSI)	Korea, Republic of (KATS)
Canada (SCC)	Netherlands (NEN)	Mongolia (MASM)
China (SAC)	Portugal (IPQ)	Poland (PKN)
Denmark (DS)	Russian Federation (GOSTR)	Romania (ASRO)
Egypt (EOS)	Slovenia (SIST)	Serbia (ISS)
France (AFNOR)	Switzerland (SNV)	Slovakia (SOSMT)
Germany (DIN)	Thailand (TISI)	Spain (AENOR)
Hungary (MSZT)	United Kingdom (BSI)	Suriname (SSB)
India (BIS)	United States (ANSI)	Syrian Arab Republic (SASMO)
Iran, Islamic Republic of (ISIRI)	Observing Countries (20)	Sweden (SIS)
Ireland (NSAI)	Argentina (IRAM)	Uganda (UNBS)
Israel (SII)	Chile (INN)	Ukraine (DSTU)
Italy (UNI)	Croatia (HZN)	Zimbabwe (SAZ)
	Cyprus (CYS)	
	Czech Republic (UNMZ)	
	Hong Kong (ITCHKSAR)	

2. Liaison Committees to ISO/TC 34/SC 16

ISO/CASCO, ISO/REMCO, ISO/TC 34/SC 4, ISO TC 34/SC 6, ISO/TC 34/SC 9, TC 38, ISO/TC 69/SC 6, ISO/TC 93, ISO/TC 212, ISO/TC 276

3. Liaison Committees from ISO/TC 34/SC 16

ISO/TC 34/SC 4, ISO TC 34/SC 6, ISO/TC 34/SC 9, ISO/TC 69, ISO/TC 69/SC 6, ISO/TC 93, ISO/TC 212, ISO/TC 276

4. Organizations in liaison (Category A)

AACCI, AOAC International, AOCS, EC – European Commission, EPPO, IPPC, ISTA, USP

michael.sussman@usda.gov, +1-202-260-9106, United States Department of Agriculture, Agricultural Marketing Service, Livestock and Poultry Programs, Agricultural Analytics Division, 1400 Independence Ave., S.W., Room 2607, Mailstop 0262, Washington, DC 20250-9911, U.S.A.

5. Scope

Standardization of biomolecular testing methods applied to foods, feeds, seeds and other propagules of food and feed crops including:

Methods that analyze nucleic acids [e.g., polymerase chain reaction (PCR), genotypic analysis and sequencing], proteins [e.g. enzyme linked immunosorbent assay (ELISA)], and other suitable methods. Variety identification and detection of plant pathogens.

*The scope does not include food microbiological methods.

6. Working Groups

Working Group	Name (number of documents)
ISO/TC 34/SC 16/WG 8	Meat speciation (3)
ISO/TC 34/SC 16/WG 9	Subsampling of seeds and grains (1)
ISO/TC 34/SC 16/WG 10	Rapid nucleic acid amplification methods (1)
ISO/TC 34/SC 16/WG 11	Biobanking for agriculture and food production (1)
ISO/TC 34/SC 16/JWG 12	Molecular biomarkers of agricultural fiber (1)
ISO/TC 34/SC 16/WG 13	Genetically engineered content detection and quantification (pending)

7. Document Statistics

29 published standards; 10 standards under development; 4 withdrawn standards and 4 projects deleted

8. Meetings*

2020 8 September 2020 Plenary (Virtual)

2021 7 January 2021 ISO 16577 Revision (Virtual)

 19 January 2021 Plenary (Virtual)

 16 March 2021 Plenary (Virtual)

*as a result of the global pandemic all meetings are being held virtually

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Standards	Stage	ICS
<p><u>IWA 32:2019</u> Screening of genetically modified organisms (GMOs) in cotton and textiles</p> <p><i>This IWA was successfully transferred to the stewardship of ISO TC 34/SC 16. A new working group convened by Luis Burzio has been created to support the development of this work as a stable ISO deliverable. All of the documents from the development of the IWA now reside in the JWG 12 documents list.</i></p>	90.92	67.050
<p>ISO/AWI 5354 Molecular biomarkers of agricultural fibers — Screening of genetically modified organisms (GMOs) in cotton and textiles</p> <p><i>This document represents the IWA-32 converted intact to the ISO standard template by the TC 34/SC 16 committee manager. The document was supplied to JWG-12 to enable their work in developing this standard as a stable ISO deliverable. JWG-12 will hold its first meeting on January 15, 2021.</i></p>	20.00	67.050
<p><u>ISO/PWI 5382</u> Biobanking for agriculture and food production: agricultural animals</p> <p><i>This is new work for WG 11. Harvey Blackburn is the convener. We are now waiting for a working draft.</i></p>	00.60	67.050
<p><u>ISO 13495:2013</u> Foodstuffs -- Principles of selection and criteria of validation for varietal identification methods using specific nucleic acid</p> <p><i>Reviewed and confirmed in 2019. The current document has not been revised for the terms or content since it was first approved for DIS (2013). We have disbanded WG 3, the committee might consider assigning the committee manager to update the document with respect to terms and time sensitive content. The document completed a systematic review in 2019.</i></p>	<u>90.93</u>	<u>67.050</u>
<p><u>ISO/TS 16393</u> Molecular biomarker analysis -- Determination of the performance characteristics of qualitative measurement methods and validation of methods</p> <p><i>Published in May, 2019</i></p>	<u>60.60</u>	<u>67.050</u>

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<p><u>ISO 16577:2016 (ISO/CD 16577 ed. 2)</u> Molecular biomarker analysis -- Terms and definitions</p> <p><i>ISO 16577 is under revision. The last CD ballot did not reach a consensus and has been revised according to the recent comment set. Pending a meeting of the revision committee the revised document will be submitted again for a CD vote.</i></p>	<p><u>60.60</u> <u>(30.92)</u></p>	<p><u>67.050</u></p>
<p><u>ISO 16578:2013(ISO/AWI 16578 ed. 2)</u> Molecular biomarker analysis -- General definitions and requirements for microarray detection of specific nucleic acid sequences</p> <p><i>This document has been revised and is currently out on a CIB for comments. After the CIB the document will be submitted for a CD ballot. The current consensus requires the authors to develop a parametric statistic for assay performance (e.g. POD).</i></p>	<p><u>90.92</u> <u>(10.99)</u></p>	<p><u>67.050</u></p>
<p><u>ISO/TR 17622:2015</u> Molecular biomarker analysis -- SSR analysis of sunflower</p> <p><i>This document has undergone a systematic review and is now stable at stage 90.92.</i></p>	<p><u>90.92</u></p>	<p><u>67.050</u></p>
<p><u>ISO/TR 17623:2015</u> Molecular biomarker analysis -- SSR analysis of maize</p> <p><i>This document has undergone a systematic review and is now stable at stage 90.93.</i></p>	<p><u>90.93</u></p>	<p><u>67.050</u></p>
<p><u>ISO/PWI 20148</u> Molecular biomarker analysis — Species identification of meat and meat products by multiplex PCR</p> <p>We are looking forward to news of the results of the collaborative trial for this document sometime in 2021.</p>	<p><u>00.60</u></p>	<p><u>67.050</u></p>
<p><u>ISO/CD TS 20224-1 [Under development]</u> <u>Molecular biomarker analysis -- Detection of animal derived materials in foodstuffs and feedstuffs by real-time PCR -- Part 1: Bovine DNA detection method</u></p>	<p><u>60.60</u></p>	<p><u>67.050</u></p>

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<p><u>Published in 2020.</u></p>		
<p><u>ISO/NP TS 20224-2 [Under development]</u> <u>Molecular biomarker analysis -- Detection of animal derived materials in foodstuffs and feedstuffs by real-time PCR -- Part 2: Ovine DNA Detection Method</u></p> <p><u>Published in 2020.</u></p>	<p><u>60.60</u></p>	<p><u>67.050</u></p>
<p><u>ISO/NP TS 20224-3 [Under development]</u> <u>Molecular biomarker analysis -- Detection of animal derived materials in foodstuffs and feedstuffs by real-time PCR -- Part 3: Porcine DNA detection method</u></p> <p><u>Published in 2020.</u></p>	<p><u>60.60</u></p>	<p><u>67.050</u></p>
<p><u>ISO/NP TS 20224-4 [Under development]</u> <u>Molecular biomarker analysis -- Detection of animal derived materials in foodstuffs and feedstuffs by real-time PCR -- Part 4: Chicken DNA detection method</u></p> <p><u>Published in 2020.</u></p>	<p><u>60.60</u></p>	<p><u>67.050</u></p>
<p><u>ISO/NP TS 20224-5 [Under development]</u> <u>Molecular biomarker analysis -- Detection of animal derived materials in foodstuffs and feedstuffs by real-time PCR -- Part 5: Goat DNA detection method</u></p> <p><u>Published in 2020.</u></p>	<p><u>60.60</u></p>	<p><u>67.050</u></p>
<p><u>ISO/NP TS 20224-6 [Under development]</u> <u>Molecular biomarker analysis -- Detection of animal derived materials in foodstuffs and feedstuffs by real-time PCR -- Part 6: Horse DNA detection method</u></p> <p><u>Published in 2020.</u></p>	<p><u>60.60</u></p>	<p><u>67.050</u></p>
<p><u>ISO/NP TS 20224-7 [Under development]</u> <u>Molecular biomarker analysis -- Detection of animal derived materials in foodstuffs and feedstuffs by real-time PCR -- Part 7: Donkey DNA detection method</u></p>	<p><u>60.60</u></p>	<p><u>67.050</u></p>

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<p><u>Published in 2020.</u></p>		
<p><u>ISO/CD TS 20224-8 [Under development]</u> <u>Molecular biomarker analysis -- Detection of animal derived materials in foodstuffs and feedstuffs by real-time PCR -- Part 8: detection method for turkey DNA</u></p> <p><i>This document is in the New Project stage. An NWIP is underway.</i></p>	<p><u>10.20</u></p>	<p><u>67.050</u></p>
<p><u>ISO/NP TS 20224-9 [Under development]</u> <u>Molecular biomarker analysis -- Detection of animal derived materials in foodstuffs and feedstuffs by real-time PCR -- Part 9: detection method for goose DNA</u></p> <p><i>This document is in the New Project stage. An NWIP is underway.</i></p>	<p><u>10.20</u></p>	<p><u>67.050</u></p>
<p><u>ISO/CD 20813</u> Molecular biomarker analysis -- Methods of analysis for the identification and the detection of animal species from foods and food products (Nucleic acid-based methods) -- General requirements and definitions</p> <p><i>Published May, 2019</i></p>	<p><u>60.60</u></p>	<p><u>67.050</u></p>
<p><u>ISO 21569:2005</u> Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Qualitative nucleic acid-based methods</p> <p><i>This standard was confirmed under systematic review. A working group is under ballot to coordinate efforts for revision and update of this document, including separating the annexes into separate methods and combining with the amendment. Preparations are underway for a NWIP.</i></p> <p><u>ISO 21569:2005/Amd 1:2013</u></p> <p><i>An action for withdrawal of this amendment is under development.</i></p>	<p><u>90.93</u></p>	<p><u>67.050</u></p>
<p><u>ISO/TS 21569-2:2012 (ISO/CD TS 21569-2.2)</u> Horizontal methods for molecular biomarker analysis -- Methods of analysis for the detection of genetically modified organisms and derived products -- Part 2: Construct-specific real-time PCR method for detection of event FP967 in linseed and linseed products</p>	<p><u>90.93</u> <u>(30.00)</u></p>	<p><u>67.050</u></p>

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<p><i>This standard was confirmed by SR. SR Comments indicated a need for a technical update. A NWIP was launched and successful. The document is now under a CD ballot.</i></p>		
<p><u>ISO/TS 21569-3.2:2020</u> Horizontal methods for molecular biomarker analysis -- Methods of analysis for the detection of genetically modified organisms and derived products -- Part 3: Construct-specific real-time PCR method for detection of P35S-pat-sequence for screening genetically modified organisms</p> <p><i>This document was published 2020-06-29.</i></p>	<u>60.60</u>	<u>67.050</u>
<p><u>ISO/TS 21569-4:2016</u> Horizontal methods for molecular biomarker analysis -- Methods of analysis for the detection of genetically modified organisms and derived products -- Part 4: Real-time PCR based screening methods for the detection of the P-nos and P-nos-nptII DNA sequences</p> <p><i>This standard has been confirmed by SR.</i></p>	<u>90.93</u>	<u>67.050</u>
<p><u>ISO/TS 21569-5:2016</u> Horizontal methods for molecular biomarker analysis -- Methods of analysis for the detection of genetically modified organisms and derived products -- Part 5: Real-time PCR based screening method for the detection of the FMV promoter (P-FMV) DNA sequence</p> <p><i>This standard has been confirmed by SR.</i></p>	<u>90.93</u>	<u>67.050</u>
<p><u>ISO/TS 21569-6:2016</u> Horizontal methods for molecular biomarker analysis -- Methods of analysis for the detection of genetically modified organisms and derived products -- Part 6: Real-time PCR based screening methods for the detection of cryIAb/Ac and Pubi-cry DNA sequences</p> <p><i>This standard has been confirmed by SR.</i></p>	<u>90.93</u>	<u>67.050</u>
<p><u>ISO 21570:2005</u> Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Quantitative nucleic acid-based methods</p>	<u>90.93</u>	<u>67.050</u>

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<p><i>This document was confirmed by SR. Planning is underway to update and revise.</i></p> <p><u>ISO 21570:2005/Amd 1:2013</u></p> <p><i>This document was confirmed by SR. Planning is underway to merge it with its standard</i></p>	<p><u>60.60</u></p>	<p><u>67.050</u></p>
<p><u>ISO 21571:2005</u> Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Nucleic acid extraction</p> <p><i>This document was confirmed by SR. Planning is underway to revise and update.</i></p> <p><u>ISO 21571:2005/Amd 1:2013</u></p> <p><i>This document was confirmed by SR. Planning is underway to merge it with its standard</i></p>	<p><u>90.93</u></p>	<p><u>67.050</u></p>
<p><u>ISO 21572:2019</u> Foodstuffs — Molecular biomarker analysis — Immunochemical methods for the detection and quantification of proteins</p> <p><i>The technical review of this standard is complete. The standard has been published. Note that the title has changed.</i></p>	<p><u>60.60</u></p>	<p><u>67.050</u></p>
<p><u>ISO/AWI 22732</u> Molecular biomarker analysis — General requirements for storage of animal and vegetable propagation materials.</p> <p>There is no project leader for this work. It will soon be removed, if the work does not begin.</p>	<p><u>10.99</u></p>	<p><u>67.050</u></p>
<p><u>ISO/DIS 22753</u> [Under development] Molecular biomarker analysis -- Methods of analysis for the detection of genetically modified organisms -- Semi-quantitative method for the statistical evaluation of weight/weight GMO content in seeds and grains</p> <p><i>This document is now in the enquiry stage under a DIS vote.</i></p>	<p><u>40.20</u></p>	<p><u>67.050</u></p>
<p><u>ISO/CD 22942-1</u> [Under development] Molecular biomarker analysis in foodstuffs -- Nucleic acid isothermal nucleic acid amplification-based methods -- Part 1: General requirements</p>	<p><u>30.20</u></p>	<p><u>67.050</u></p>

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<p><i>This document is currently under a CD ballot..</i></p>		
<p><u>ISO/CD 22949-1.3</u> [Under development] Molecular biomarker analysis — Methods of analysis for the detection and identification of animal species in foods and food products (nucleotide sequencing-based methods) — Part 1: General requirements</p> <p><i>This document is now being prepared for a DIS vote.</i></p> <p><u>ISO/AWI 22949-2</u> [Under development] Molecular biomarker analysis -- Detection and identification of animal species by DNA sequencing methods -- Part 2: Bioinformatics and pipeline validation</p> <p><i>No work has been done on this project.</i></p> <p><u>ISO/AWI 22949-3</u> [Under development] <u>Molecular biomarker analysis -- Detection and identification of animal species by DNA sequencing methods -- Part 3: Metadata and sequence repository</u></p> <p><i>No work has been done on this project.</i></p>	<p><u>30.99</u></p> <p><u>20.00</u></p> <p><u>20.00</u></p>	<p><u>67.050</u></p> <p><u>67.050</u></p> <p><u>67.050</u></p>
<p><u>ISO 24276:2006</u> Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- General requirements and definitions</p> <p><i>This document was confirmed by SR. Planning is underway to revise and update.</i></p>	<p><u>90.93</u></p>	<p><u>67.050</u></p>
<p><u>ISO 24276:2006/Amd 1:2013</u></p> <p><i>This document was confirmed by SR. Planning is underway to merge it with its standard</i></p>	<p><u>60.60</u></p>	<p><u>67.050</u></p>