UPOV

International Union for the Protection of New Varieties of Plants

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Working Group on Biochemical and Molecular Techniques and DNA-Profiling in Particular

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HORIZONTAL METHODS FOR MOLECULAR BIOMARKER ANALYSIS

Document prepared by an expert from the International Organization for Standardization (ISO)

Disclaimer: this document does not represent UPOV policies or guidance

The annex to this document contains a copy of a presentation on “Horizontal Methods for Molecular Biomarker Analysis”, prepared by an expert from the International Organization for Standardization (ISO), to be made at the nineteenth session of the BMT.

[Annex follows]

ISO TC 34 Food Products/SC 16

Horizontal Methods for Molecular Biomarker Analysis

REPORT FROM THE COMMITTEE CHAIR
RAY SHILLITO
2020

TC 34/SC 16

- Established September 2008
- 12 Years Ago

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.

Officers

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The 9th Plenary meeting of ISO/TC 34/SC 16 took place in Saitama, Japan on November 21-23rd, 2019.

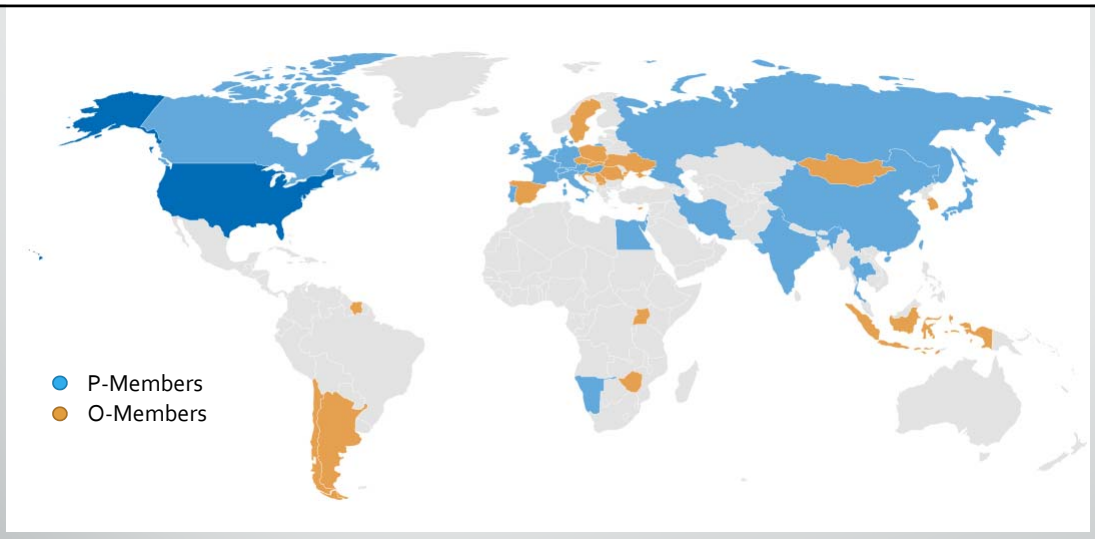
DEMOGRAPHICS

29
published ISO standards *
under the direct responsibility of ISO/TC 34/SC 16

7
ISO standards under review or development
under the direct responsibility of ISO/TC 34/SC 16

24
Participating members

19
Observing members



Technical Committee 34/ Subcommittee 16
Horizontal methods for molecular biomarker analysis

Participating Countries (24) Observing Countries (19)

IOS/TC 34/SC 16 has 5 working groups

- WG 8 Meat speciation (Japan/China Lead)
- WG 9 Subsampling of seeds and grains (Japan Lead)
- WG 10 Rapid (isothermal) nucleic acid amplification methods (US lead)
- WG 11 Biobanking for agriculture and food production (US lead)
- JWG 12 (with TC38 cotton) Molecular biomarkers of agricultural fibers (US lead)

Recently Published Standards

WG 8 Meat Speciation

ISO/TS 20224 parts 1-7:2020
Molecular biomarker analysis — Detection of animal-derived materials in foodstuffs and feedstuffs by real-time PCR
Detection methods for Bovine, Ovine, Porcine, Chicken, Goat, Horse and Donkey DNA
Project Led by Japan and China

Updated and re-issued

ISO 21572:2019
Foodstuffs — Molecular biomarker analysis — Immunochemical methods for the detection and quantification of proteins

Standards under Systematic Review

ISO 21570:2005
Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Quantitative nucleic acid based methods

ISO 21571:2005
Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Nucleic acid extraction

ISO 24276:2006
Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — General requirements and definitions

Recently (Re-)Published Standards

Confirmed by the committee

ISO/TS 21569 Horizontal methods for molecular biomarker analysis — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods

And several methods which are published as parts:

- Part 3: Construct-specific real-time PCR method for detection of P35S-pat-sequence for screening for genetically modified organisms
- Part 4: Real-time PCR based screening methods for the detection of the P-nos and P-nos-nptII DNA sequences
- Part 5: Real-time PCR based screening method for the detection of the FMV promoter (P-FMV) DNA sequence
- Part 6: Real-time PCR based screening methods for the detection of cry1Ab/Ac and Pubi-cry DNA sequences

Standards under Revision

ISO 16578:2013
Molecular biomarker analysis -- General definitions and requirements for microarray detection of specific nucleic acid sequences

ISO/TS 21569-3:2015
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

TC34/SC16 standards have been adopted by Governments

The EU endorses and applies these standards, as do Republic of Korea, Brazil, and many other countries

For example the US National Bioengineered Food Disclosure Standard Guidance on Testing Methods cite the following TC34/SC16 standards:

- ISO 24276:2006 — General requirements and definitions
- ISO 21571:2005 — Nucleic acid extraction
- ISO 21570:2005 — Quantitative nucleic acid based methods
- ISO 21569:2005 — Qualitative nucleic acid based methods
- ISO 16393:2019 – Determination of the performance characteristics of qualitative measurement methods and validation of methods.

In addition, testing laboratories follow these standards worldwide.

Summary

- Global trade requires that there be robust internationally agreed standards
- ISO is a key contributor to standards
- ISO/TC 34/SC 16 is a committee with a broad scope covering biomolecular methods in food and food products
- ISO/TC 34/SC 16 has an increasing and evolving suite of standards that are used worldwide
- ISO/TC 34/SC 16 is a fun and impactful committee to be engaged in!
- ISO/TC34/SC16 has worked on standards for variety identification

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[End of Annex and of document]