



BMT/15/7

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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

Geneva

**WORKING GROUP ON BIOCHEMICAL AND MOLECULAR
TECHNIQUES AND DNA PROFILING IN PARTICULAR**

Fifteenth Session

Moscow, Russian Federation, May 24 to 27, 2016

UPOV AND ISO TC 34/SC 16
FROM THE US TECHNICAL ADVISORY GROUP AND ANSI LED HOST OF ISO TC 34/SC 16: FOOD
PRODUCTS; HORIZONTAL METHODS FOR MOLECULAR BIOMARKER ANALYSIS

Document prepared by the International Organization for Standardization (ISO)

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The Annex to this document contains a copy of a presentation "UPOV and ISO TC 34/SC 16 From the US Technical Advisory Group and ANSI led host of ISO TC 34/SC 16: Food Products; horizontal methods for molecular biomarker analysis" to be made at its fifteenth session of the Working Group on Biochemical and Molecular Techniques and DNA-Profiling in particular (BMT).

[Annex follows]

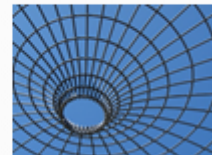
UPOV and ISO TC 34/SC 16

From the US Technical Advisory Group and ANSI led host of ISO TC 34/SC 16: Food Products; horizontal methods for molecular biomarker analysis



What is ISO?

- “International Organization for Standardization”
- An independent, non-governmental international consortium of 162 national standards bodies.
- A framework for international standard development permitting harmonized growth across technical, regulatory and commercial sectors.



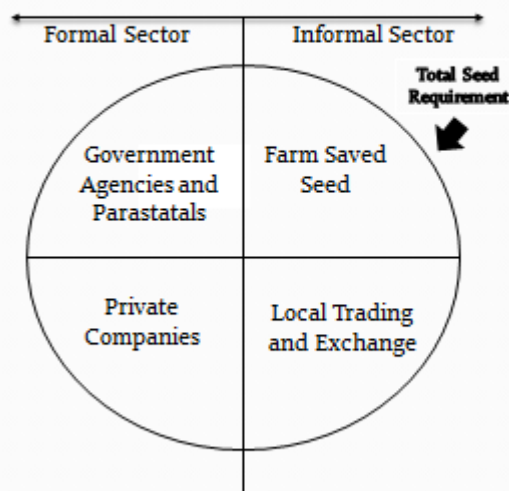
ISO Standards



- An ISO standard is a published document providing requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.
- ISO standards should have a measureable economic benefit for organizations choosing to develop them and their users.
- Standard development is performed across countries, organizations of governments, private organizations, academic institutions, commerce, business sectors, etc.
- 100% voluntary, Not regulatory, No treaties; But ISO standards may be adopted in whole or part by governments and organizations of governments as regulations, rules and laws.

International Standards/Community Standards and ISO

- Standards developing organizations (SDO) often experience competition
- Community standards may be developed that are more or less stringent or different from the organizations of governments' standards
- ISO standards are useful to coordinate requirements between governments and the private community



ISO Standards for Seeds and Plants (Examples)

- Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of yeasts and moulds – Part 2: Colony count technique in products with water activity less than or equal to 0,95
- Oilseeds – Determination of oil content (Reference method)
- Agricultural machinery – Safety – Part 9: Seed drills
- *Foodstuffs – Principles of selection and criteria of validation for varietal identification methods using specific nucleic acid
- *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
- Vanilla – Vocabulary
- Agricultural machinery – Equipment for sowing – Minimization of the environmental effects of fan exhaust from pneumatic systems

* [Standards produced by ISO TC 34/SC 16](#)

ISO Standards for Seeds and Plants (Examples)

- Traditional Chinese medicine – Ginseng seeds and seedlings – Part 1: *Panax ginseng* C.A. Meyer
- Oilseeds – Determination of acidity of oils
- Cardamom (*Elettaria cardamomum* (Linnaeus) Maton var. *minuscule* Burkill) – Specification – Part 2: Seeds
- Cardamom (*Elettaria cardamomum* (Linnaeus) Maton var. *minuscule* Burkill) – Specification – Part 1: Whole capsules
- Celery seed (*Apium graveolens* Linnaeus) – Specification
- Durum wheat (*Triticum durum* Desf.) – Specification
- Soil quality – Determination of the effects of pollutants on soil flora – Screening test for emergence of lettuce seedlings (*Lactuca sativa* L.)
- *Foodstuffs – Methods of analysis for the detection of genetically modified organisms and derived products – General requirements and definitions
- Cereals, pulses and by-products – Determination of ash yield by incineration

* [Standards produced by ISO TC 34/SC 16](#)

TC 34/SC 16 Scope*



- TC 34 Food Production
“Standardization in the field of human and animal foodstuffs, covering the food chain from primary production to consumption”
- SC 16 Horizontal Methods for Molecular Biomarker Analysis
“Standardization of biomolecular testing methods applied to foods, feeds, seeds and other propagules of food and feed crops”
- *SC 16 Scope is consistent with the work of UPOV’s BMT*

*The scope does not include food microbiological methods.
TC=technical committee
SC=subcommittee

SC 16 Administrative Structure

- TC 34/SC 16 —hosted by the American National Standards Institute (ANSI-USA)
 - Secretary: Dr. Richard Cantrill, USA,
(richard.cantrill@aocs.org)
 - ISO-Central Secretariat Technical Project Manager:
Marie Noelle Bourquin
 - Committee Chair: Dr. Michael Sussman, USA
(michael.sussman@ams.usda.gov)
 - ISO Presenter: Dr. Paul Zankowski, USA
(paul.zankowski@ams.usda.gov)

SC 16 International Structure

National standards bodies join TC 34/SC 16, because biotechnology experts have in their nations have an interest in leveraging international standardization.

Participating Countries (25)		
Argentina (IRAM)	Germany (DIN)	Russian Federation (GOSTR)
Austria (ASI)	India (BIS)	Slovenia (SIST)
Belgium (NBN)	Iran, Islamic Republic of(ISIRI)	Sweden (SIS)
Canada (SCC)	Ireland (NSAI)	Switzerland (SNV)
Chile (INN)	Jamaica (BSJ)	Thailand (TISI)
China (SAC)	Japan (JISC)	United Kingdom (BSI)
Denmark (DS)	Korea Rep. (KATS)	United States (ANSI)
Egypt (EOS)	Namibia (NSI)	
France (AFNOR)	Netherlands (NEN)	

Observing Countries (10)		
Croatia (HZN)	Italy (UNI)	Serbia (ISS)
Cyprus (CYS)	Poland (PKN)	Slovakia (SUTN)
Czech Republic (UNMZ)	Romania (ASRO)	Spain (AENOR)
Hungary (MZST)		

National Standards Body abbreviations in parentheses following each country/organization

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SC 16 Formal Liaisons

Liaison organizations join TC 34/SC 16, to ensure interoperability of standards, controlled vocabularies and data formats and avoid duplication of work.

- ISO/TC 34/SC 9 (Microbiology)
- ISO/TC 69 (Applications of statistical methods)
- ISO/TC 69/SC 6 (Measurement methods and results)
- ISO/TC 93 (Starch)
- ISO TC 276 (Biotechnology)
- TC 212 (Clinical laboratory testing and *in vitro* diagnostic test systems):proposed
- American Association of Cereal Chemists International
- American Oil Chemists' Society
- European Communities
- European Environmental Citizens Organization for Standardization
- European and Mediterranean Plant Protection Organization
- International Plant Protection Convention

UPOV-BMT and ISO TC 34/SC 16

- UPOV requires distinctness, uniformity and stability of phenotypic characteristics of plants as a part of the condition for the granting of plant breeders' rights.
- ISO provides harmonized standards for biomolecular technologies used to identify and characterize plants and animals in agriculture.
- ISO is a standards development body
- International certification organizations such as OECD and ISTA already incorporate ISO standards by reference or adoption respectively into their schemes and rules.



UPOV-BMT and ISO TC 34/SC 16

- ISO cannot determine the uses of molecular biomarkers for DUS in relation to plant breeders' rights.
- ISO can provide standards for the characterization and quantification of molecular biomarkers including those that quantitatively and qualitatively differentiate species, subspecies and varieties, serovars, etc.
- ISO SC 16 standardizes methods, processes and quality assurance associated with current and new technologies in PCR, DNA sequence determination and interpretation, ELISA, mass spectrometry and data integration to ensure verifiable interpretation of data



How UPOV-BMT can interact with ISO TC 34/SC 16

- Reference or adopt existing ISO standards related to molecular biomarker analysis.
- Participate in standard development to share costs with a wider group of academics and industries working in the same field.
- Request a liaison with ISO TC 34/SC 16 to share in new standard development



How does work on a standard get started

- A person representing a group(s) of organizations or people with common interests in standardization submits a standardized form (Form 04: *New Work Item Proposal*) to an ISO national standards body describing the item or process and requesting that it be internationally standardized.
- ISO reviews the proposal and sends it out to its memberships asking:
 - 1) Does the members national standards body want to work on the project
 - 2) Does the country have and want to provide experts to work on it

The ISO Working Group

- A majority electronic approval from the subcommittee's member nations and technical approval permits the work to get started.
- With approval of the work, an ISO working group is established for the project.
- A project leader is assigned to the project by SC 16 and a request is sent out for experts.
- Anyone with expertise can join and participate in the online dialogs, teleconferences and face to face meetings needed to write and develop the new standard.

The ISO Approval Process

- Experts in a working group represent themselves and their expertise. Each working group member has an equal say in the work.
- Technical work is monitored as it continues. Project leaders provide regular reports to the subcommittee.
- The ISO working group drafts and develop a draft document through a review based process, once completed the working group submits the draft to the subcommittee where it is reviewed and considered for deliverable status.
- If approved the standard is published by ISO and maintained via a five year systematic review.



Our Website

[http://www.iso.org/iso/standards_development/technical committees/other bodies/iso technical committee.htm?commid=560239](http://www.iso.org/iso/standards_development/technical_committees/other_bodies/iso_technical_committee.htm?commid=560239)

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