Molecular Biomarker Analysis at the International Organization for Standardization (ISO)

Current Status of "ISO Horizontal Methods for Molecular Biomarker Analysis" regarding Seed

ISO/TC 34/SC 16

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ISO-UPOV Background

- At the 10th BMT - the BMT was informed that the International Organization for Standardization (ISO) and the Codex Alimentarius Commission were developing guidelines for molecular marker selection and database construction.
- At the 12th BMT Dr. Michael Sussman (Chairman of the Subcommittee ISO/TC 34/SC 16 (molecular biomarker analysis)) made a presentation to explain that ISO collaborated with other standard setting organizations
  - ISO had provided methods to the Codex Alimentarius Commission and had sought to avoid overlap with ISTA work on seed.

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ISO (International Organization for Standardization) Background

- World's largest developer of voluntary International Standards.
- International Standards give state of the art specifications for products, services and good practice, helping to make industry more efficient and effective.
- Developed through global consensus, they help to break down barriers to international trade.

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How Does ISO develop standards?

- Developed by a panel of experts, within a technical committee.
- Once the need for a standard has been established, these experts meet to discuss and negotiate a draft standard.
- As soon as a draft has been developed it is shared with ISO's members who are asked to comment and vote on it.
- If a consensus is reached the draft becomes an ISO standard, if not it goes back to the technical committee for further edits.
- Horizontal Technical Committees provide standards for the needs of any relevant subject area.

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Biomolecular Standards for Seed in ISO

Standard*	Description	Stage	ICS
ISO/DIS 13484	Foodstuffs -- General requirements for molecular biology analysis for detection and identification of destructive organisms in plants and derived products	40.60	67.050
ISO/DIS 13495	Foodstuffs -- Principles of selection and criteria of validation for the varietal identification methods using specific nucleic acid analysis	40.99	67.050
ISO/NP 16393	Molecular biomarker analysis -- Qualitative methods -- Determination of the performance characteristics and method validation	10.99	67.050
ISO/CD 16577	Molecular biomarker analysis -- Terms and definitions	30.99	67.050
ISO/DIS 16578	Molecular biomarker analysis -- General definitions and requirements for microarray detection of specific nucleic acid sequences	40.99	67.050
ISO/WD TR 17622	Molecular biomarker analysis -- SSR analysis of sunflower	20.20	67.050
ISO/WD TR 17623	Molecular biomarker analysis -- SSR analysis of maize	20.20	67.050
ISO/TS 21098:2005	Foodstuffs -- Nucleic acid based methods of analysis of genetically modified organisms and derived products -- Information to be supplied and procedure for the addition of methods to ISO 21569, ISO 21570 or ISO 21571	90.93	67.050
ISO 21569:2005	Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Qualitative nucleic acid based methods	90.93	67.050

*No Letters=final international standard; ICS= International Classification for Standards; DIS= draft international standard; NP=new project; CD=committee draft; WD=working draft; TR=technical reference; TS=technical specification

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Biomolecular Standards for Seed in ISO (continued)

Standard	Description	Stage	ICS
ISO/TS 21569-2:2012	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	60.60	67.050
ISO/21570:2005	Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Quantitative nucleic acid based methods	90.93	67.050
ISO 21571:2005	Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Nucleic acid extraction	90.93	67.050
ISO 21572	Foodstuffs -- Molecular biomarker analysis -- Protein-based methods	60.00	67.050
ISO 21572:2004	Foodstuffs -- Methods for the detection of genetically modified organisms and derived products -- Protein based methods	90.92	67.050
ISO 24276:2006	Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- General requirements and definitions	90.93	67.050

*No Letters=final international standard;; TS=technical specification

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Biomolecular standards in ISO

- Written by experts from Technical Committee (TC) 34/Subcommittee (SC) 16
- TC 34 = Food Products
  - Standardization in the field of human and animal foodstuffs, covering the food chain from primary production to consumption, as well as animal and vegetable propagation materials, in particular, but not limited to, terminology, sampling, methods of test and analysis, product specifications, food and feed safety and quality management and requirements for packaging, storage and transportation
  - 125 participating and observing countries
  - 23 subcommittees

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Biomolecular standards in ISO

- TC 34/SC 16
  - Subcommittee 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.
    - Scope includes methods that analyse nucleic acids [e.g., polymerase chain reaction (PCR), genotypic analysis and sequencing], proteins [e.g. enzyme linked immunosorbent assay (ELISA)], and other suitable methods.
    - Scope also includes variety identification and detection of plant pathogens.

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Experts in TC 34/SC 16

Participating Countries (21)		
Argentina (IRAM)	India (BIS)	Norway (SN)
Canada (SCC)	Iran, Islamic Republic of(ISIRI)	Russian Federation (GOSTR)
China (SAC)	Ireland (NSAI)	Sweden (SIS)
Denmark (DS)	Japan (JISC)	Switzerland (SNV)
Egypt (EOS)	Korea Rep. (KATS)	Thailand (TISI)
France (AFNOR)	Namibia (NSI)	United Kingdom (BSI)
Germany (DIN)	Netherlands (NEN)	USA (ANSI)
Observing Countries (11)		
Poland (PKN)	Spain (AENOR)	Cyprus (CYS)
Romania (ASRO)	Austria (ASI)	Czech Republic (UNMZ)
Serbia (ISS)	Belgium (NBN)	Italy (UNI)
Slovakia (SUTN)	Croatia (HZN)	
Liaison Organizations (6)		
European Commission (EC)	AACC International	The International Plant Protection Convention (IPPC)
American Oil Chemists' Society (AOCS)	European and Mediterranean Plant Protection Organization (EPPO)	Functional Genomics Data Society (FGED)

National Standards Body abbreviations in parentheses following each country/organization

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SC 16 Organizational Structure

Secretariat:	American National Standards Institute (ANSI) / American Oil Chemists Society (AOCS)
Secretary:	Dr. Richard Cantrill, USA
ISO Central Secretariat Contact:	Marie Noelle Bourquin
Chairman:	Dr. Michael Sussman, USA, 2013

SC 16 Working Groups

TC 34/SC 16/WG 2	Information to be supplied and procedure for the addition of methods
TC 34/SC 16/WG 3	Varietal identification
TC 34/SC 16/WG 4	Plant pathogens
TC 34/SC 16/WG 5	Qualitative methods

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ISO TC 34/SC 16 Website

- http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=560239

Contacts

TC 34/SC 16 - Secretariat

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Other - ISO Workshop "International Standards for Biotechnology" held October 25-26, 2011

- Objective: promoted a dialogue among the organizations most active in standardization for biotechnology
- Participants: 40 experts from 12 countries
- Proposed scope for new work:
  - Horizontal issues concerning the set-up, undertaking and results of assays, such as:
    - Sample preparation
    - Sample processing and handling
    - Experimental methodologies
    - Data structuring an processing
    - Reporting
  - Bioscience/biotechnology disciplines and their characterization in relation to specific applications, such as:
    - Genomics (health care)
    - Proteomics (biopharmaceutical)
    - Functional genomics (cell characterization)
    - Metabolomics (toxicogenetics, food safety)

  Website: http://www.iso.org/sites/biotechnology2011/index.html

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Other - New ISO Biotechnology Technical Committee

- Scope (standardization of the following aspects)*:
  - 1. Terms and definitions
  - 2. Analytical methods in the realm of "–omics" technologies, i.e. proteomics, metabolomics, genomics; based on the conceptual framework proposed at the ISO Biotechnology Workshop in October 2011.
  - 3. Computing tools, bioinformatics for international comparability and integrability of data.
  - 4. Bioresources, biobanking.
  - 5. Bioreactors.
  - 6. Metrology aspects of biotechnology (e.g. enzymology).

*ISO/TC Biotechnology will work closely with related committees in order to identify demands, standardization gaps, and organize collaborations avoiding duplications and overlapping standardization activities, see proposed list of liaisons. The scope will exclude the standardization of forensic science, academic and SME research, as well as applications for the agricultural-, food-, and medical industries

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