



ASTM INTERNATIONAL
Helping our world work better

Update from ASTM D37 on Cannabis

Established Cannabis Products and Relevant Standardization Needs

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June 13th, 2018
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Agenda



- Introduction to ASTM D37 and its scope
- Current Standards Underdevelopment
- Cannabis is More Than Flower and Resin
- Potential Standards for Cannabis Fiber
- Potential Standards for Cannabis Seed
- Call for Participation
- Next D37 Committee Meeting



What is ASTM?



An International Standards Development Organization

- Established in 1898; became an ISDO in 1974
- 148 Committees & 12,700+ Standards
- 30,000+ members
 - 8,000+ International Members from 135 countries
 - 7,700 ASTM standards used in 75 countries
- Accreditation:
 - American National Standards Institute (ANSI)
 - Standards Council of Canada (SCC)
- Process complies with WTO principles: Annex 4 of WTO/TBT Agreement



ASTM in Europe



European Participation

Over 1,100 technical experts from European Member States work collaboratively with their peers from more than 100 other countries to develop global standards and solutions that improve performance and operability in manufacturing, materials, products, processes and more.

Opened an ASTM Office of European Affairs in 2013 in Brussels, Belgium, to interface with European institutions, ESOs, trade federations, consumer groups, companies and research institutes.

400+ references to ASTM standards in EU legislation

ASTM Standards & Engineering Digital Library used by universities in UK, Denmark, France, Germany, Poland, Spain

Important. Every Day.



The Role of ASTM Standards

- **Ensures safety, quality and reliability**
- **Emerging Industry Support:** standards are a foundation to build upon
- **Responsive:** innovations, new challenges, new technology and new markets
- **Industry Lead:** effective and relevant across diverse markets
- **Built on Consensus:** 90% approval; balanced and equal
- **Helping Everyone:** all stakeholders involved directly impacts content
- **Voluntary until Referenced:** contracts, regulations, codes, and laws around the world



Over a Century of Openness

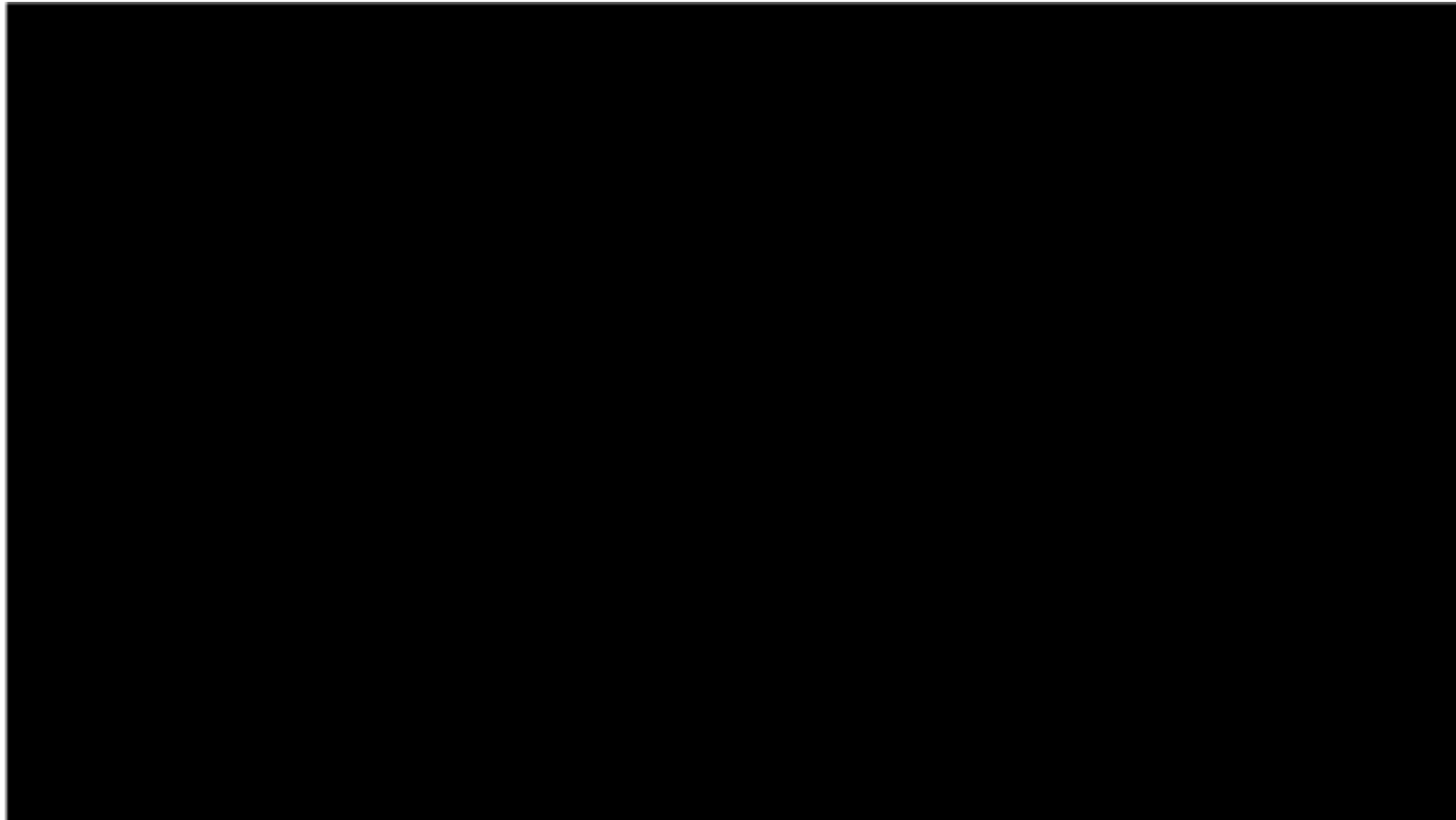


How ASTM Works

- **Provides Infrastructure and Tools**
 - Templates, Online balloting, Online collaboration areas, meetings support, managers, administrative support, editors, promotional support
- **Facilitates Collaboration**
 - Exchange expertise and knowledge
 - Participating in a transparent process – **open to anyone, anywhere**
- Staff does not write standards, remain neutral
- Participants are the content creators



The Need for Cannabis Standards: ASTM Committee D37



<https://youtu.be/Pdo5WWoLBiE>

D37 on Cannabis



Overview

Formed in 2017
300+ Members representing 12 Countries

Scope: The development & maintenance of standards and guidance materials for cannabis and its products and processes.

The work of this committee will be coordinated with other ASTM committees and other organizations having mutual interest.

- [D37.01](#) Indoor and Outdoor Horticulture and Agriculture
- [D37.02](#) Quality Management Systems
- [D37.03](#) Laboratory
- [D37.04](#) Processing and Handling
- [D37.05](#) Security and Transportation
- [D37.06](#) Personnel Training, Assessment, Credentialing
- [D37.91](#) Terminology

Represented by

- Associations
- Academia
- Laboratories
- Suppliers
- Cultivation Centers
- Government
- Transportation Services
- Software Providers
- Accreditation bodies
- And others

Collaborating to
Develop Robust
Solutions Toolbox

Areas of Consideration



Indoor and Outdoor Horticulture and Agriculture	Laboratory	Processing & Handling -- Security & Transportation	Personnel Training, Assessment, Credentialing
- Integrated pest management - Inputs - Seed and/or plant material selection - Genetic modifications - Selection of water, - Processing of water, - Quality considerations, - Water cultivation practices - Water system mgmt - Environmental site assessments - Biodiversity - Sustainability - Indoor/outdoor cultivation - Bulk sampling - Supply chain due diligence - Energy usage and mgmt. - Waste Mgmt - Harvest drying and curing	3rd party attestation / verification - Sampling – overall - Bulk - Laboratory specifics - Stability testing - Extraction – plant extraction and - Purity testing - Contaminant – testing, removal and permissible levels, levels based on patient - Analytical methods - Validation methods - Laboratory proficiency testing - GLP - GMP - QMS (ASTM E11) - Laboratory specific - Critical control testing - process/final product	- Harvest drying and curing - Harvest trimming - Exposure management - Waste Management - Product storage - Temperature/moisture management - Stability - Labeling requirements / recommendations - Recall traceability - Packaging – including specifications during all stages - Shipping - Data mgmt. / integrity / security - Risk assessment and mitigation - Occupational health & safety - Environmental health & safety - Product remediation	- Lab technicians - PPE / clean room - Engineering controls - Qualifications - Background checks - Cultivator training - QA inspectors/auditors - Code officials (all levels) - First responders and law enforcement - Occupational health & safety - Environmental health & safety - Patient education - Physician education

A Collaborative Effort



Contributing Organizations to D37

- Foundation for Unified Cannabis Standards (FOCUS)
- American Herbal Products Association (AHPA)
- Americans for Safe Access (ASA)
- Hemp Industries Association (HIA)
- Indian Industrial Hemp Association (IIHA)
- European Industrial Hemp Association (EIHA)
- American Trade Association of Cannabis and Hemp (ATACH)



Open to Anyone, Anywhere



Be apart of the effort

- [Join D37](#):
 - Its free to participate
 - Voting requires membership
- Next Meeting:
 - [June 2018 Committee Week](#)
June 24th – 26th, San Diego, CA – USA
 - January 2019 Committee Week
January 27th – 29th, Houston, TX – USA
- Fall 2018 European Workshop:
 - More Information Coming Soon



Registered Work Items



D37.01 Cultivation and Agriculture

WK61409 Specification for Grading Cannabis*

WK62003 Horticultural Stages of Cannabis

WK63268 Cleaning and Disinfection at a Cannabis Cultivation Center*

WK63517 Determining the Evapotranspiration Rates and Lighting Requirements for Indoor Agricultural Facilities

D37.02 Quality Management Systems

WK60084 Quality Management System (QMS) on Corrective Action Preventive Action (CAPA) for Cannabis Cultivation, Processing, Manufacturing, Testing and Distribution

WK60819 Review of AHPA and FOCUS Standards for Quality Management System Elements

WK61355 Establishing an Effective Quality Management System (QMS) in the Cannabis Industry

WK62845 Practice for Standard Operating Procedures and Records for a Cannabis Quality System

WK63546 Developing Recall/Removal Procedures and Records for Products in the Cannabis Industry

D37.03 Laboratory

WK60319 Standard Test Method for Rapid Analysis for e. Coli in Cannabis Products

WK60479 Quality Assurance and Quality Control for Cannabis Analytical Methods and Laboratories

WK61249 Review FOCUS, AHPA, and other Documents for other Laboratory Requirements, and Propose Initial Derivative Standards

More Work Items



D37.04 Processing and Handling

WK60039 Standard Practice for the Labeling of Packaged Cannabis Products for Wholesale Distribution*

WK60043 Qualitative and Quantitative Standards of Products Resulting from the Processing of Cannabis Raw Materials and Manufactured from these Derivatives

WK60134 Standard Practice for Determining Water Activity in Cannabis Flower

WK60135 Acceptable Water Activity (Aw) Range for Dry Cannabis Flower

WK60434 Specifications for Non-Solvent Based Cannabis Extraction Equipment

WK60435 Specifications for Solvent Based Cannabis Extraction Equipment

WK60446 Standard for Labeling and Packaging of Cannabis Product for Consumer Use (i.e., recreational/adult and medical use)*

WK60643 Standard practice for the development and functionality of pressurized metered dose inhalers (pMDI) for the cannabis industry

WK61239 Techniques for the Refinement of Cannabis Extracts*

D37.05 Security and Transportation

WK61980 Standard Guide for the Use of Video Surveillance System

WK61983 Standard Guide for Access Control System (ACS)) Ballot D37.05 (18-02) Item 001

WK61984 Standard Guide for Intrusion Detection System (IDS) Ballot D37.05 (18-02) Item 002

D37.06 Personnel Training, Assessment, Credentialing

WK61961 Standard Practice for Certificate Programs in Cannabis Laboratory

D37.91 Terminology

WK60576 Standard for Terminology Relating to Cannabis

First Published Standards



D37.04 Processing and Handling

- [D8196-18](#): Standard Practice for Determination of Water Activity (a_w) in Cannabis Flower
- [D8197-18](#): Standard Specification for Maintaining Acceptable Water Activity (a_w) Range (0.55 to 0.65) for Dry Cannabis Flower





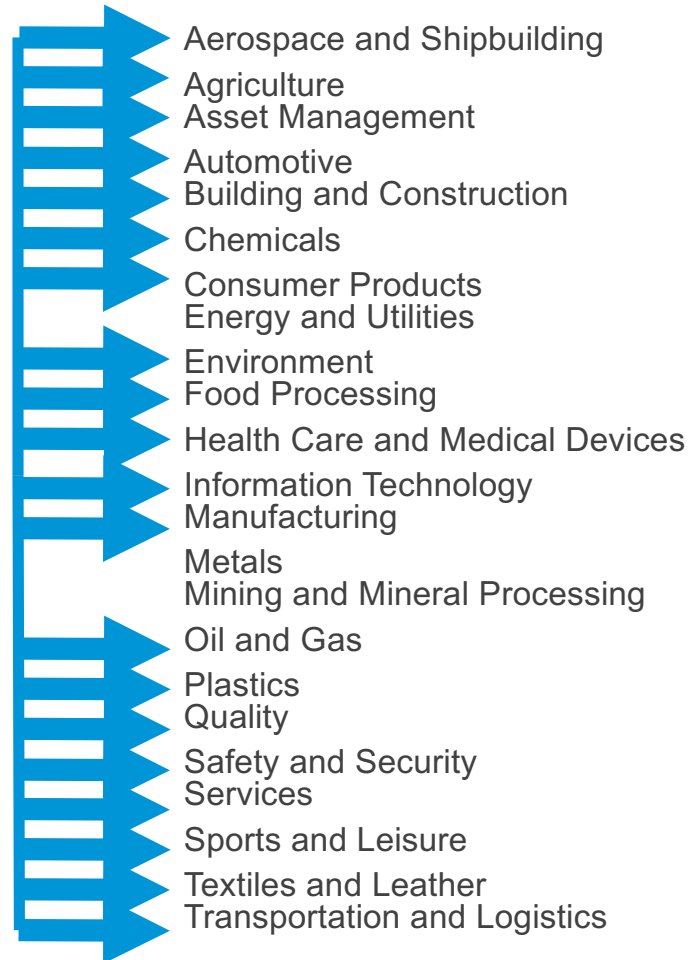
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Cannabis is more than just Flower and Resin

ASTM Standards and Cannabis



Cannabis



Standards for Cannabis



- Modernizing how we talk about *Cannabis*
- Easing regulatory burden
- Standards Development – New Industry*
 - Terminology:
 - Cannabis = Hemp
 - Classifications:
 - Types of seed, fiber, resin, etc.
 - Specifications
 - Qualitative – Aesthetics, Olfactory response, etc.
 - Quantitative – THC content, Contaminant limits, etc.
 - Test Methods
 - For identifying grades and validating specifications
 - Guides
 - For cultivation, processing, handling, distribution, testing, etc.
 - Practices
 - For safety, security, data entry, recordkeeping, quality management, etc.

Dry vs Wet Decortication

Retting & Dry Decortication

- Traditional, “in the field”, preparation process
- Renders the stalk viable for decortication
- Fields are flooded and then allowed to dry
 - Bacteria in the ground prepares the stalk for further processing
- Decortication is the physical process of separating the bast and hurd fibers
 - Aggressive process which can damage dried natural fibers

Standards needed for products resulting from these two methods to validate equivalency and ensure social equity.

Wet Decortication

- New process under development on the commercial scale
- Separates the bast and hurd fibers while still “fresh” (i.e. wet)
- Produces a better end product
- Introduces new post processing challenges for drying the fibers



Potential Standards for Cannabis Fibers



- Terminology
 - Hurd
 - Bast
 - Retting
 - Decortication
- Classification of fiber type (technical, textile)
 - Types of products
 - Grades (A, B, etc.)
- Specifications for fiber (technical, textile, composites, insulation, plastics, construction)
 - Chemical properties
 - Physical properties
 - Structural properties
- Test Methods for validating specifications
 - Tensile strength, flexure under loading, compression analysis
 - Identification of materials, measurement of samples
- Guides and Practices for growing, harvesting, retting, dry/wet decortication, processing, material handling, disposal, etc.



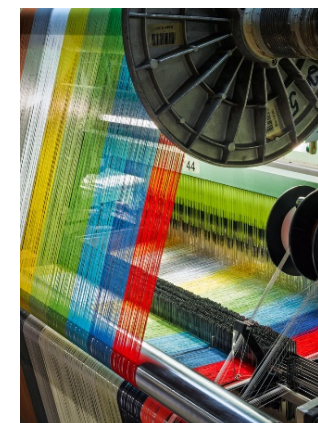
Commoditizing the Cannabis Plant



INDUSTRIAL PRODUCTS

Areas where standards would aid in acceptance:

- Aerospace & Shipbuilding
- Agriculture
- Asset Management
- Automotive
- Building & Construction
- Chemicals
- Consumer Products
- Environment
- Information Technology
- Manufacturing
- Medical Devices
- Oil and Gas
- Plastics
- Quality
- Safety & Security
- Services
- Textiles & Leather
- Transportation & Logistics



THC Content in Food



How much is too much?

- Varies from country to country
- US:
 - 5 ppm in seed oil
 - 1.5 ppm in hulled seed
- Canada:
 - 10 ppm in seed oil
 - 10 ppm in whole seed
- NOVA-Institute & EIHA Recommendations:
 - 10 ppm in seed oil
 - 5 ppm in whole seed
 - 2.5 ppm in hulled seed
 - 3.5 ppm in flour/protein powder
- What about other foods? [Scientifically Sound Guidelines for THC in Food in Europe](#)



Standards for THC content in food products will allow for greater market acceptance of cannabis-based nutritional goods.

Potential Standards for Cannabis Seeds



- Terminology
 - Threshing
 - Chaf
 - Grain?
 - Hempseed vs Hemp seed*
- Classification of seed type (planting, edible, inedible)
 - Grades (A, B, etc.)
- Classification of seed oil type (edible, inedible)
 - Grades
- Specifications for seeds, seed oils and food products (THC content, Omega-3 & Omega-6 content)
 - Chemical properties
 - Physical properties
- Test Methods for validating specifications
 - Nutritional value, protein versus fiber content, visual and chemical analysis
 - Analytical equipment, limits of detection, reference standards
- Guides and Practices for growing, harvesting, processing, handling, packaging, labeling, etc.



Commoditizing the Cannabis Plant



NUTRITIONAL PRODUCTS

Areas where standards would aid in acceptance:

- Agriculture
- Asset Management
- Consumer Products
- Environment
- Information Technology
- Manufacturing
- Quality
- Safety & Security
- Services
- Sports & Leisure
- Transportation & Logistics



Join the Standards Development Effort



Participation is Key

- Majority of D37s standards are focused on Flower and Resins
- Need more voices from the industrial hemp community to ensure the concerns of seed and fiber producers are not overlooked.
- **Influence Direction**
 - Through participation in the standards development process you can help drive the effort in a direction which benefits everyone.
- **Create Content**
 - Actively take part in the drafting of standards to ensure they do not negatively impact your interests.
- **Shape an Industry**
 - Take your destiny into your own hands. Help create the market place you wish to operate in.

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For More Information



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Thank You for Listening

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