

Advancing the Field of Cannabis/Hemp Through Standardization

The Jacobsen Hemp Conference

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About Your Speaker

- Owner/Founder – TSOC LLC
- Engineer – Process Design & Implementation
- Subcommittee Vicechair – ASTM International D37.04 on Cannabis Processing and Handling
- Subcommittee Co-chair – ASTM International D37.07 on Industrial Hemp
- Chair – NCIA Cannabis Manufacturing Committee
- 15-year Industry Veteran



Agenda

- Introduction to ASTM D37 on Cannabis
- Standards & the Development Process
- Standard Terminology
- Standard Classifications
- Standard Specifications
- Standard Test Methods
- Standard Guides & Practices
- Where do we go from here?

ASTM D37 on Cannabis

- Formed: Spring of 2017
- 1000 members from 30 countries
- 17 published standards!!!
- Scope:

The development and maintenance of standards and guidance materials for the cannabis plant, its parts, products, and associated processes.



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Helping our world work better



ASTM D37 on Cannabis

- Subcommittees:
 - D37.01 on Cultivation
 - D37.02 on Quality Management
 - D37.03 on Test Methods & Laboratory Practices
 - D37.04 on Processing & Handling
 - D37.05 on Security & Transportation
 - D37.06 on Personnel Credentialling
 - D37.07 on Industrial Hemp
 - D37.08 on Appliances & Devices
 - D37.91 on Terminology

*** 17 Published Standards ***

- **D8196-18** Standard Practice for Determination of Water Activity (aw) in Cannabis Flower
- **D8197-18** Standard Specification for Maintaining Acceptable Water Activity (aw) Range (0.55 to 0.65) for Dry Cannabis Flower
- **D8219-19** Standard Guide for Cleaning and Disinfection at a Cannabis Cultivation Center
- **D8229-19** Standard Guide for Corrective Action and Preventive Action (CAPA) for the Cannabis Industry
- **D8233-19** Standard Guide for Packaging and Labeling of Consumer Resin Cannabis Products for Sale to Adult Consumers, Legally Authorized Medical Users, and Caregivers in a Business-to-Consumer Retail Environment (Retailers)

*** 17 Published Standards ***

- **D8245-19** Standard Guide for Disposal of Resin-Containing Cannabis Raw Materials and Downstream Products
- **D8250-19** Standard Practice for Applying a Hazard Analysis Critical Control Points (HACCP) System for Cannabis Consumable Products
- **D8282-19** Standard Practice for Laboratory Test Method Validation and Method Development
- **D8286-19** Standard Guide for Processing Cannabis Product Complaints
- **D8308-20** Standard Practice for Cannabis/Hemp Operation Compliance Audits
- **D8205-20** Standard Guide for Video Surveillance System

*** 17 Published Standards ***

- **D8217-20** Standard Guide for Access Control System
- **D8218-20** Standard Guide for Intrusion Detection System (IDS)
- **D8270-20** Standard Terminology Related to Cannabis
- **D8220-20** Standard Guide for Conducting Recall/Removal Procedures for Products in the Cannabis Industry
- **D8244-20** Standard Guide for Analytical Laboratory Operations Supporting the Cannabis Industry
- **D8334/D8334M-20** Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses

Hot Button Issues

- Testing (in general)
- Labeling (adult-use vs medicinal-use)
- Remediation (THC, heavy metal, microbial, etc.)
- Cannabinoid adulteration in “hemp” foods
- Sustainability (practical action items)
- Equity, Diversity, and Inclusion
(more than window dressing)



Current Standards Under Development

- D37.01 on Cultivation
 - Grading System for Cured Cannabis/Hemp Inflorescence
 - Elemental Contaminants Workshop/Symposium
- D37.02 on Quality Management
 - Establishing a Quality Management System (QMS) for Consumer Use Cannabis/Hemp Products
 - Practice for Standard Operating Procedures and Records for a Cannabis Quality System
 - Internal Auditing and Self-Inspection in the Cannabis Industry
 - Cannabis Supplier Lifecycle Management

Current Standards Under Development

- D37.03 on Test Methods & Laboratory Practices
 - Proper Estimation of Concentrations of Delta-9 Tetrahydrocannabinol (D9-THC) in Low-THC Cannabis and Cannabis Products Defined on a Dry-Weight Basis
 - Sensory Evaluation of Products Containing Cannabinoids
 - Determination of Cannabinoid Concentration in Cannabis Using High Performance Liquid Chromatography
- D37.04 on Processing & Handling
 - Specifications for International Universal Symbols (THC & Others)
 - Specifications for the Packing, Transportation, and Storage Conditions for Cannabis/Hemp Inflorescence
 - Specifications for Distilled Cannabinoid Extracts of a Cannabis Plant

Current Standards Under Development

- D37.05 on Security and Transportation
 - Transportation Security
 - Implementing Cybersecurity in a Cannabis Operation
- D37.06 on Personnel Credentialling
 - Classifications for Vocations within the Cannabis/Hemp Industry
 - Guide to Certification and Accreditation Programs within the Cannabis/Hemp Industry
 - Certification Requirements for Quality Professional, Analytical Laboratory, and Transportation and Logistics Vocations within the Cannabis/Hemp Industry

Current Standards Under Development

- D37.07 on Industrial Hemp
 - Specifications for Shives Intended for Insulative Hempcrete Applications
 - Specifications for Raw Bast Fibers of a Cannabis Plant Intended for Textile Applications
 - Specifications for Cannabinoid Adulteration of Hemp Foods
- D37.08 on Appliances and Devices
 - Classifications for Cannabis/Hemp Herbal Vaporization Devices
 - Classifications for Cannabis/Hemp Resin Extract Vaporization Devices
- D37.91 on Terminology
 - Harmonization efforts are ongoing...



What are standards?

- Certifications
- Laws
- Regulations
- Aspirational goals
- Something different

What are standards?

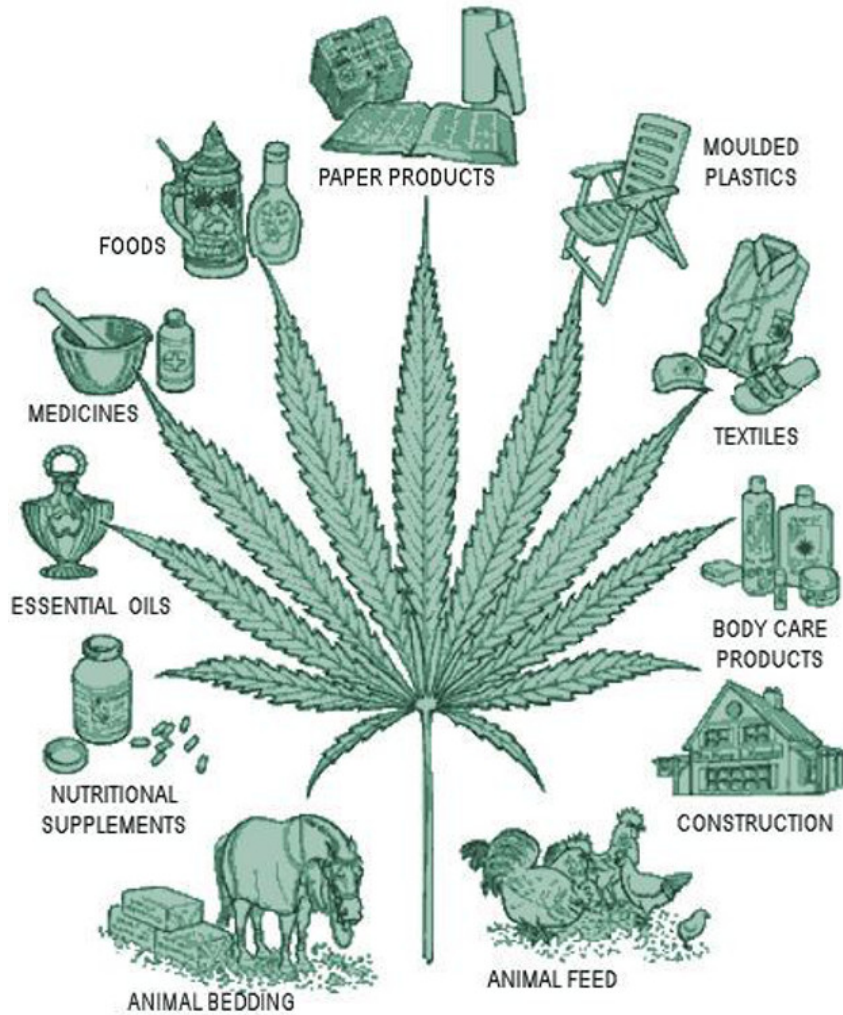
- A means of facilitating communication and the transfer of information
- Form the foundation of certification programs
- When referenced in regulation become law



Goal of the Standards Development Process

- Consumer safety
- Environmental protection
- Commodification
- Ease regulatory burden



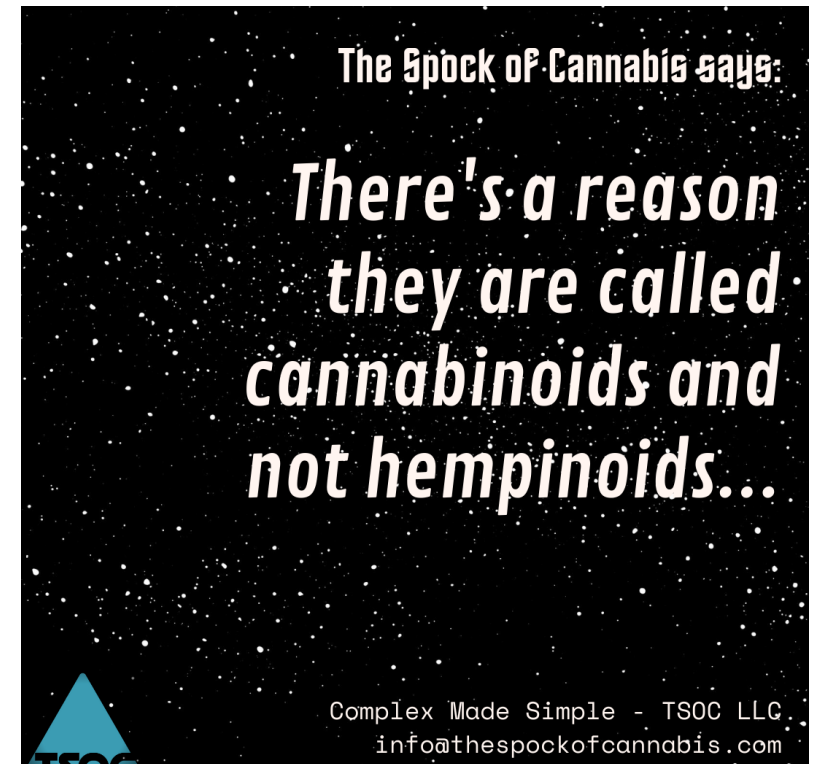


Types of Standards

- Terminology
- Classifications
- Specifications
- Test Methods
- Practices
- Guides

Standard Terminology

- Why is standardization of terminology important?
- Modernizes the way we talk about the cannabis plant.
- Which terms get adopted and which ones do not?
- Example
 - Cannabis and Marijuana and Hemp



Standard Classifications

- Allow for the categorization of things based on a set of commonalities
- Grades and Types
- Medical Grade?
- What distinguishes each grade/type from one another?



Standard Classifications

- Granular (product affecting) vs General (category affecting)
- Classifications of Cannabis Plants and Cannabis Products
 - Adult-Use
 - Medicinal-Use
 - Spiritual-Use
 - Nutritional-Use
 - Cosmetic-Use
 - Industrial-Use
 - Breeding
 - Scientific/R&D-Use
 - Hemp*

Standard Specifications

- Are used as the attributes/metrics that differentiate between each grade/type
- Economic driver of any industry – if it's a higher quality it fetches a higher price
- Why are these needed?
 - For verification
 - For quality assurance and control
 - For harmonization



Standard Specifications

- Identity metrics
 - Does it look like weed?
- Physical properties
 - Length, width, height, etc.
 - Density, viscosity, porosity, etc.
 - Tensile strength, hardness, elasticity, etc.
- Chemical properties
 - Cannabinoid, terpene, etc.
- Contaminant limits
 - Pesticides, heavy metals, microbes, toxins, residual solvents, allergens, etc.
- Other quality attributes
 - Water activity, foreign matter, ash content, etc.

Standard Test Methods

- Verification a sample meets specifications
- Verify or Deny the claims of a manufacturer or concerns of a regulator
- Defined analytical techniques and equipment for quantitation of analytes of interest
- Intended to be used by any lab anywhere in the world



Standard Test Methods

- Intralaboratory vs Interlaboratory Studies
 - Intralaboratory study – submission of test methods for peer review within ASTM's network of labs
 - Interlaboratory study – submission of test methods for peer review outside of the ASTM network
- Precision and Bias Statement
 - What makes ASTM standards different than everyone else – an internal recognition of each test method's faults/limitations. (“correctness”/“applicability”)

Standard Test Methods

- Difficulties associated with cannabis products:
 - Number of differing matrixes
 - Lack of certified reference materials
 - Prohibition makes it difficult to procure samples

Standard Guides & Practices

- Guides are used as recommendations/suggestion on how to do something, whereas practices are more definitive and provide instruction on how to perform a task.
- A good example of the differences, is labeling: you would use a guide for how to design a label; you would use a practice for how to apply the label to a package/container.
- Guides and practices are really the backbone of the other standards.
- These allow the user to implement the methods, policies, and procedures necessary to produce products that meet or exceed specifications.



Examples of Where Standards are Needed

- Extractables and Leachables from Packaging
- Example:
 - Extracts of THC exceeding 70% w/w react with silicone and form a white film on the product and the container.

Examples of Where Standards are Needed

- Solvent safety...
- Reaction molecules:
 - Botanical matrices are complex and some of the solvents used in the cannabis space are very reactive.
 - What byproducts are coming along for the ride with the cannabinoids?
- Cannabinoid-like molecules:
 - Are there potentially dangerous molecules posing as cannabinoids that are created during the extraction process?



Examples of Where Standards are Needed

- Cannabinoid Adulteration in Foods
 - What should this limit be?
 - 20 PPM for total cannabinoids?
 - 10 PPM for d9-THC?
 - Too much, too little?
 - How do you define too much or too little?
 - What is being measured – intoxication?



Where do we go from here?

- You shape the process.
- By participating directly in the standards development process, you get a say in, what will one day be, a standard that will be used to certify the safety of cannabis products around the world.
- If you don't like the way a standard is headed, you can redirect its path.
- A single voter has the power to change the outcome of the process.

Join the Effort

- 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.

Join the Effort

- All ASTM standards are developed on a volunteer basis
- Join the D37 today
 - Its free to participate
 - Voting requires membership
- Next Meeting:
 - **2021 January/February Committee Week**
 - January 25th through February 5th, Virtual WebEx Conference



Thank you
for listening



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For more information about the D37 and how to join, please visit:
www.astm.org/COMMITTEE/D37.htm

TSOC LLC – Complex Made Simple
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