



## **D37 Hemp Cannabis Industry Workshop**

Dates: 10-11 October, 2017

Location: Berlin Marriott Hotel | Inge-Beisheim-Platz 1, 10785 Berlin, Germany

#### **Workshop Description:**

The hemp and cannabis industry is rapidly evolving globally, which encompasses everything from building materials, textiles, semiconductors to nutritional, dietary and pharmaceutical goods. As these bourgeoning industries emerge, various aspects of the market have common challenges and learned experiences from which all industry can benefit. From seed to sale, standards will play a critical role to ensure safety, efficiency and quality. ASTM International technical committee D37 on Cannabis is hosting a free technical workshop where you can engage with other industry experts, with presentations and interactive working scenarios, to better leverage the collective knowledge of your peers. Topics include:

- Agricultural and horticulture standardisation
- Quality management systems in cultivation, processing, testing and distribution
- Laboratory methods for detection and extraction of oils, contaminants and more
- Processing and handling of raw materials and products
- Security and compliance

The workshop intends to cover market needs, policy drivers, and compliance considerations. At the same time, attendees will learn about ASTM International, the drivers behind the initiation of D37 and the future of standards for all international players. Each presentation session will be concluded by panel discussions with experts in industry about the obstacles they face and what they are aiming to accomplish for industry.

> ~Presentations from the Events follow where Permission to share was approved~

100 Barr Harbor Drive PO Box C700 West Conshohocken, PA fax +1.610.832.9555 19428-2959 USA

service@astm.org tel +1.610.832.9500 www.astm.org

#### **WORKSHOP AGENDA & SCHEDULE**

~ Day One: 1300 - 1600 ~

#### **Welcome and Opening Remarks**

Sara Gobbi, Director of European Affairs, ASTM International, sqobbi@astm.org

#### Session 1: Current Initiatives

**ASTM International:** Standards making a Global Impact

Robert Morgan, Director of Technical Committee Operations, rmorgan@astm.org

ATACH and ASTM: What is Water and Why do we Care?

 Charlie Rutherford, Director, Business Development, Boveda Inc., charles.rutherford@bovedainc.com

#### **Canadian Hemp and Cannabis Initiatives**

 Ralph Paroli, National Research Council of Canada, Ralph.Paroli@nrc-cnrc.gc.ca \*Presentation not attached, may be available upon request

Learning from the Experts: Panel Discussion and Q&A

~ Day Two: 0900 - 1700 ~

#### **Welcome and Opening Remarks**

Hemp and Cannabis in Berlin - Marijn Roersch van der Hoogte, Berlin Hanf Museum, demuts@gmail.com

#### Session 2: What is the Industry and what have we Learned?

What is Hemp? What is Cannabis? De-mystification!

- Susan Audino, Audino, S.A.Audino & Associates, LLC, susan.audino@gmail.com Challenges for the medicinal and adult use of cannabis: Lessons learned from pharma, devices and smoking industry succession
- Uri Baruch, Cambridge Design Partnership, ueb@cambridge-design.co.uk Learning from the Experts: Panel Discussion and Q&A

#### **Session 3: Quality Control and Quality Assurance**

**Quality Management Systems and Good Manufacturing Practices for Pharmaceutical Grade Cannabis** 

Andrew Samann, Orion Corp., andrew@oriongmp.com

#### **Cannabis Testing in Germany**

- ❖ Tobias Wiezorek, Quality Services International GmbH, tobias.wiezorek@qsi-q3.de Standardized Cannabis Testing and its Influence in the International Marketplace
- Susan Audino, S.A.Audino & Associates, LLC, susan.audino@gmail.com
- Learning from the Experts: Panel Discussion and Q&A

100 Barr Harbor Drive service@astm.org
PO Box C700 tel +1.610.832.9500
West Conshohocken, PA fax +1.610.832.9555 19428-2959 USA

www.astm.org

#### Session 4: Challenges to Compliance

Cannabis as a Commodity Crop: Navigating the legal and regulatory nuances between marijuana and hemp

Darwin Millard, Plant Consulting Group LLC, dmillard@plantconsultingllc.com

#### Cannabis and Cannabis Derived Products: Risk and Role of Standards

❖ Martin Masilko, ICCI, martin.masilko@icci.science

Learning from the Experts: Panel Discussion and Q&A

#### Session 5: Let's Talk Impact

Led by Andrew Samann, Orion Corp, andrew@oriongmp.com

Interactive sessions with the engagement of all attendees in order to learn from commonalities among industry, develop solutions for shared challenges and determine where standards can provide solutions.

#### Case Scenarios and Considerations (Cold Press; Harvesting; Packaging)

- How to implement standards from seed to sale?
  - Varying raw materials or species
- What are the benefits and challenges?
  - Standardisation without Limitations
- ❖ And More!

#### **Session 6: Strategies and Solutions Moving Forward**

**Early Stage Engagement:** Leveraging the research

❖ Christine DeJong, Director, Business Development, ASTM International, cdejong@astm.org

#### **Proactive and Effective Engagement**

❖ Robert Morgan, Director, Technical Committee Operations, ASTM International, rmorgan@astm.org

\*Effective Participation Guidance

#### Closing Remarks

Sara Gobbi, Director of European Affairs, ASTM International, sgobbi@astm.org

#### **Resource Information**

- ❖ ASTM International Website: www.astm.org
- ❖ D37 Cannabis Website: www.astm.org/COMMITTEE/D37.htm
- ❖ Membership Information: www.astm.org/MEMBERSHIP
- ❖ Technical Committee Information: www.astm.org/COMMIT/newcommit.html



## ASTM INTERNATIONAL Helping our world work better

# Welcome to ASTM International: Hemp and Cannabis Industry Workshop

Berlin, Germany 10 October 2017

Sara Gobbi, Director of European Affairs

www.astm.org

# Hemps and Cannabis Industry Workshop – Today's objectives



## What will you learn

- What is ASTM International
- What are the drivers behind the initiation of D37 on Cannabis.
- How to engage in our standard development process
- From seed to sale, what role is there for standards

#### What will we discuss

- Market needs
- Common challenges and lessons learned
- Policy drivers
- Compliance considerations

## **About ASTM**



#### Introduction

- Organized in 1898 addressing technical challenges of the growing US railroad network
- One of the worlds largest standards developing organizations
- Publish standards, specifications, test methods, books, journals, conference papers etc.
- Training classroom and online
- Proficiency testing programs 4,000+ laboratories take part worldwide
- Close relationship with 100 governments worldwide
- Internationally recognized and accepted
- HQ Philadelphia, USA; 5 regional offices (Washington, Brussels, Ottawa, Beijing & Lima)
- Not for profit organisation



# Helping Our World Work Better





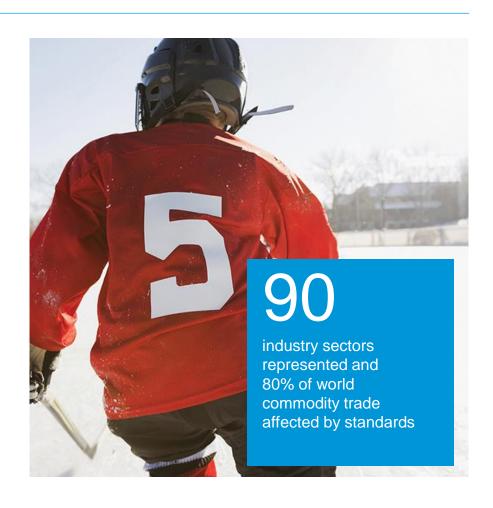
© ASTM International 10 October 2017

# Touching Every Part of Everyday Life



#### How we work

- ASTM collaborates with businesses,
   governments and experts worldwide
- Combining market relevance and technical quality
- Building on good science, good engineering, good judgment
- Going beyond safety also help things work appropriately, efficiently, profitably
- Influencing entire industries and encouraging growth
- Relevant, effective and timely in a fastchanging world

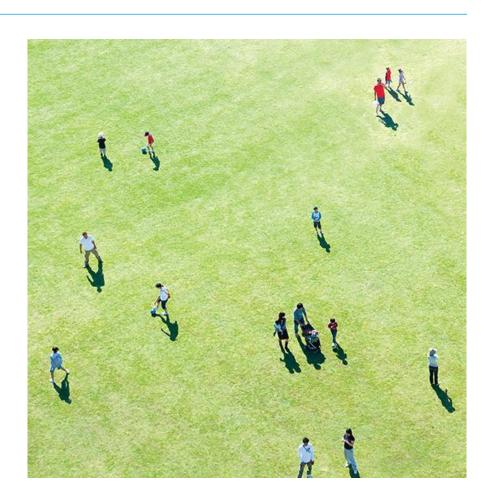


© ASTM International 10 October 2017

## **ASTM Standards Cover**



- Aerospace and Shipbuilding
- Agriculture
- Asset Management
- Automotive
- Building and Construction
- Chemicals
- Consumer Products
- Energy and Utilities
- Environment
- Food Processing
- Health Care and Medical Devices
- Information Technology
- Manufacturing
- Metals
- Mining and Mineral Processing
- Oil and Gas
- Plastics
- Quality
- Safety and Security
- Services
- Sports and LeisureTextiles and Leather
- Transportation and Logistics



# Important. Every Day.



### The Role of ASTM Standards

- Ensures safety, quality and reliability
- Constantly responding to new challenges, new technology and new markets
- Built on principle of voluntary consensus: giving everyone an opportunity to participate
- Effective and relevant across diverse markets
- Helping everyone: consumers, businesses, manufacturers, innovators and governments

@ ASTM International

 Incorporated into contracts, regulations, codes, and laws around the world; they support established and emerging economies and free and fair global trade.



# Over a Century of Openness



## Our strength

- Worldwide acceptance and trust comes from the principle of openness
- Experts, individuals, organizations, academia, governments, trade associations, consultants and consumers come together
- Over 30,000 members from 155 countries
- Exchanging expertise and knowledge
- Participating in a transparent process open to anyone, anywhere
- Timely and relevant. Fully representative of sectors. An aid to innovation, not a hurdle to overcome



© ASTM International 10 October 2017

# Universal Equality of Opportunity



## **Operating Globally**

- ASTM is one of the world's largest Standards Developing Organizations, with global reach and influence
- Embracing all the principles of the World Trade Organization's Agreement on Technical Barriers to Trade
- Working across political, cultural and geographic borders
- Recognizing expertise, not country of origin
- Trusted for market relevance and technical quality
- The choice for many global industries
  50% outside USA
- Our global outreach activities increase understanding
- Our Memorandum of Understanding Program provides tangible encouragement to developing economies



# **ASTM's Membership Globally**





STM/MOU

ASTM International's Memorandum of Understanding (MOU) program supports the principles of the World Trade Organizations' Technical Barriers to Trade Agreement.

ASTM has memoranda of understanding with 98 National standards bodies around the globe Both ASTM Members and MOU Partners

ASTM MOU Partners Only

ASTM Members Only

July 2017

# 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.

400+ references to
ASTM standards in EU
legislation
ASTM Standards &
Engineering Digital
Library used by
universities in UK,
Denmark, France,
Germany, Poland, Spain

# Activities and engagement



### European Members from:

- Multinational Corporations,
- SMEs,
- Universities,
- Research Institutes,
- Testing Laboratories,
- Government Agencies,
- Consumer and Environmental Groups

## Exchanges with European players:

- Bio-based products;
- Tyres recycling;
- Toys and consumer products;
- Raw materials;
- Nuclear;
- Additive Manufacturing

# European companies on ASTM Board of Directors:

- PANalytical in Almelo, the Netherlands
- AREVA, in Pierrelatte, France

# Recent ASTM committee meetings and workshops in Europe focused on:

- F44 Aviation (Germany)
- F42 Additive manufacturing (Sweden)
- D24 Carbon black (Belgium)
- E55 Pharmaceutical products (Switzerland)
- F40 Declarable substances (Germany)
- D37 Cannabis (Germany)
- F24 Amusement Rides and Devices (Germany)

## **ASTM's Brussels Office**



### ASTM's Brussels Office at your service:

- liaising with institutions and stakeholders in Europe and globally;
- liaising with European and National Standard Organizations (CEN, CENELEC, DIN, BSI, etc);
- facilitating technical and political connections;
- building relationships with ASTM members worldwide;
- helping identify and address relevant EU policies;
- educating Europeans on ASTM and addressing misperceptions on the US standards system.

### **European Membership Benefits:**

- develop new and revise existing standards;
- have equal say and voting rights in ASTM balloting process;
- network with peers from around the world and gain professional development opportunities;
- receive information on standards that can impact your business or organization on a daily basis.

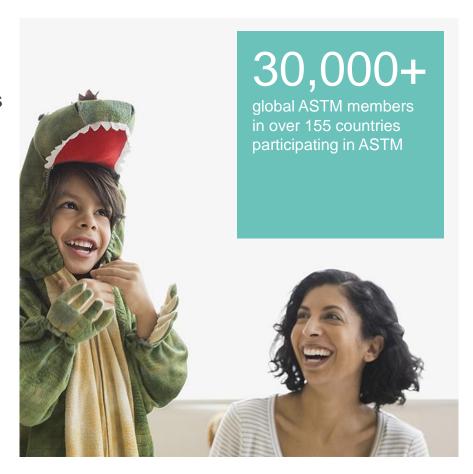
50+% of ASTM standards are distributed outside the United States

# Helping to Make the Difference



## Membership

- Membership is open to anyone who wants to use their expertise to influence standards
- Three types:Participating, Organizational, Student
- Participating Members develop new and revise existing standards – they can also network with peers and gain professional development opportunities
- Organizational Members help shape standards and get privileged access to information. Membership supports growth, trade and employee development
- Student Membership is free and open to all students – it provides a full understanding of the standardization process



# Technical Committee Support from ASTM



- Staff manager for each committee
  - Offers procedural knowledge
  - Facilitates links to HQ resources
  - Assists with opportunities
  - Supports administrative efficiency
- Staff editor for each committee
  - Knowledge of Form & Style manual
  - Edits final approved standard for publication
- Other tools
  - Web conferencing
  - Electronic balloting
  - Draft template for new standards/revisions
  - Collaborative site for draft development
  - Web access to committee information

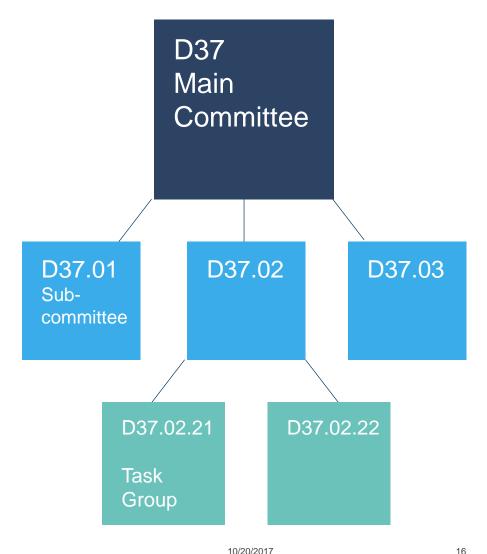


© ASTM International 10 October 2017

# **Technical Committee Organization**



- Technical Committees form to address broad industry needs
  - Title and Scope of work
  - Formal roster
- Subcommittees are established to address subsets of specialized subject matter
  - Jurisdiction of standards work
  - Formal structure
- Task Groups
  - Specific, limited time assignment,
  - Small, informal group



## Standards Maintenance



- Standards are revised and updated as needed – anytime
- Mandatory Five YearReview
- Approx. 1/3 of the
  12,800 standards are
  in the ballot process
  at any given time
  - Supports relevance and quality



## The Last Word in Standards



## In Summary

- Our work and standards influence every aspect of daily life
- We're global, practical and relevant the first choice for companies, organizations and governments around the world
- Our value-added business services ensure that our standards are used to maximum effect

## **Ultimately**

- we're ready to innovate
- we value good sense
- we're willing to share and be accountable
- we're committed to helping our world work better

© ASTM International 10 October 2017



ASTM INTERNATIONAL Helping our world work better

# Thank you!

Sara Gobbi – Director of European Affairs <a href="mailto:sgobbi@astm.org">sgobbi@astm.org</a>



ASTM INTERNATIONAL Helping our world work better

# ASTM International Standards Making a Global Impact

Bob Morgan
Director of Technical Committee Operations
Committee D37 Manager

www.astm.org

# **ASTM International History**



## **Global Solutions Provider**

A Not-for-Profit organization created in 1898 – Steel Rails

Successful formula of bringing stakeholders and technical experts to the table to develop consensus standards

Open and Transparent Process where all stakeholders have an equal voice

End Result – marketplace relevant standards – often adopted by regulators and accepted by industry



## **ASTM International**

## **Global Applications**

- More than 50% of ASTM standards are distributed outside the United States.
- More than 7,500 citations of ASTM standards by 75 nations
- Adopted, referenced, consulted or used as the basis of national standards
- From 110 ASTM technical committees
- 104 MOUs signed with regional and national standards bodies
- Members from 155 countries

7,500
ASTM standards cited in 75 nations

104
Memorandums of Understanding

# Standards Supporting Trade, Innovation, Health, Safety and the Environment



## International Standards – A Multiple Path Approach

- Serve as the basis for technical regulations in concert with the TBT Agreement.
- Come from multiple sources
  - ☐ ASTM International, ASME, UL, ISO, IEC,
- Used by WTO members in technical regulations and by their industries in trade
- Offer choice and flexibility

Participation in the development of ASTM standards is beneficial to multinational and SME companies and national economies

- Let's take a look...



# **Enabling Application of Innovative Solutions**



## **The Escape Rescue Systems Story**

- Innovative high rise emergency evacuation and access option
  - ☐ Buyers wanted the company to demonstrate compliance with recognized standards, but no recognized standards existed
- Initiated work in ASTM Committee E06 on Performance of Buildings
  - ☐ Gathered industry stakeholders in ASTM, including SII; established E06.77 on High Rise Building External Evacuation Devices
  - ☐ Chaired by company principal Jonathan Shimshoni
  - ☐ Two approved standards developed
  - ☐ E2484-08(2015) Standard Specification for Multi-Story Building External Evacuation Controlled Descent Devices
  - ☐ E2513-07(2012) Standard Specification for Multi-Story Building External Evacuation Platform Rescue Systems
- The end result
  - Market entry Supports worldwide product acceptance with regulators, clients and testing laboratories
  - Development Provides design solutions
  - Manufacturing Enables manufacturing through subcontractors

Market entry

Development

Manufacturing

# Protecting Health, Safety and the Environment



### **Ethanol Fuels for Cook Stoves**

- Traditional cooking fuels in developing economies present challenges
  - ☐ Fuels such as wood, charcoal cause illness and death in developing nations
  - ☐ Contributing cause of deforestation
- Developing a specification for denatured ethanol as a cooking and appliance fuel
  - □ Standard Specification E3050-16 for Denatured Ethanol for Use as Cooking and Appliance Fuel
  - ☐ Facilitates opportunity for trade and expedites customs approval into market
  - ☐ Enables use of ethanol-fueled cook stoves and use of ethanol as a safer, environmentally friendlier cooking fuel
  - □ Provides consumers assurance of the quality of fuel being purchased





# Facilitating Market Access



## The POSCO Story

- Doosan Heavy Industries
  - ☐ Components for UAE desalination plant
  - ☐ Required compliance with ASTM A240
- Modification of the ASTM standard for new corrosion-resistant grade of stainless steel
  - □ POSCO participated in ASTM Committee A01 on Steel, Stainless Steel and Related Alloys to offer a revision
- One year later
  - □ Revised standard allowed POSCO's specialty steel to be specified for UAE location
  - ☐ Fulfilled the requirements for the anticipated UAE contract
- The result ~ \$15 million dollars of new POSCO business



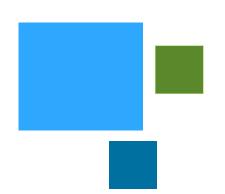
\$15 Million
In new
POSCO
business

## Offering Alternative Technical Options with Economic and Social Benefit



## Biofuels from Jatropha

- Energy dependency
  - ☐ Several African nations import more energy than they produce
- Developing a solution through an existing ASTM standard
  - ☐ ASTM D6751 was designed for soybean-based biofuels
  - □ SAZ (Zimbabwe) saw the potential to adopt the standard to use indigenous Jatropha as a feedstock
  - □ SAZ gathered together industry, manufacturers, academia and government to analyze the existing ASTM standard
  - ☐ ASTM-SAZ MoU allows for adoption of ASTM standards
  - ☐ Standard modified to allow for feedstock options
  - Government agencies are non-government agencies are encouraging the growth of the plant; spurring entrepreneurship and economic development in the agricultural industry
  - Opportunity for more jobs resulting in reduced poverty





# Choosing Standards Based on Merit: The Advantages



#### What is Merit?

- Quality
- Relevance
- Effectiveness

## **Choosing Standards Based on Merit**

- Standards with international recognition
- Standards that are developed and used by a broad base of stakeholder interests
  - ☐ Use of ASTM Standards by US Federal regulators and procurers including DoD, FDA, EPA, CPSC opens the US market to products
  - ☐ Broad-based global application of ASTM standards supports additional market opportunities
  - ☐ Prevents standards from acting as barriers to trade
- Standards that meet expectations and are routinely updated
  - ☐ Enable transfer of cutting edge technology

# The Value of Participating Joining a Global Public/Private Partnership



- ASTM members domestically and internationally represent
  - ☐ Industry, government/regulators, academics, laboratories
  - ☐ Each with equal voice and influence

- Participation offers opportunity for MoU Partners
  - ☐ Assures influence in the development of standards that impact you
  - ☐ Enables an awareness of changes in technology, innovation, and supports transfer of technology
  - ☐ Facilitates contact with customers and competitors
  - □ Builds technical networks

# ASTM Committee D37 on Cannabis Created in 2017



Over 260 members representing 8 countries

### **Technical Subcommittees**

- 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
- D37.90 Executive
- D37.91 Terminology

# Current Activity – Registered Work Items



- WK60039 \* Standard Practice for the Labeling of Packaged Cannabis Products for Wholesale distribution (Technical Contact: Andy Heins)
- WK60043 \* Qualitative and Quantitative Standards of Products Resulting from the Processing of Cannabis Raw Materials and Manufactured from these Derivatives (Technical Contact: Darwin Millard)
- WK60084 Quality Management System on Corrective Action Preventive Action (CAPA) for Cannabis Cultivation, Processing, Manufacturing, Testing and Distribution (Technical Contact: Kathleen May)
- WK60134 Determining Water Activity in Cannabis (Technical Contact: Charles Rutherford)
- WK60135 Acceptable Water Activity (Aw) Range for Dry Cannabis Flower (Technical Contact: Charles Rutherford)

# Registered Work Items Continued...



- WK60319 \* validation requirements for test methods and method development based on a review of FOCUS, APHA, and other documents. (Technical Contact: David Vaillencourt)
- WK60434 \* Cannabis Extraction Equipment (Technical Contact: Craig Brodersen)
- WK60435 \* Solvent Based Cannabis Extraction Equipment (Technical Contact: Craig Brodersen)
- WK60446 \* Standard for labeling and packaging of cannabis product for consumer use (i.e., recreational/adult and medical use) (Technical Contact: Andy Heins)
- WK60455 \* Rapid Analysis for e. Coli in Cannabis Products (Technical Contact: Edward Askew)

## More Work Items....



- WK60479 \* Quality Assurance and Quality Control for Cannabis Analytical Methods and Laboratories (Technical Contact: Edward Askew)
- WK60576 \* Standard Terminology for Cannabis (Technical Contact: Thomas Walsh)
- WK60643 Standard practice for the development and functionality of pressurized metered dose inhalers (pMDI) for the cannabis industry. (Technical Contact: Richard Adams)

#### Thank You!! Questions?



For more information:<a href="https://www.astm.org/COMMITTEE/D37.htm">https://www.astm.org/COMMITTEE/D37.htm</a>

#### **Contacts**

- D37 Staff Manager Bob Morganrmorgan@astm.org, +1.610.832.9732
- D37 Administrative Support Jill DiCicco <u>idicicco@astm.org</u>, +1.610.832.9734
- Business Development Support Christine DeJong cdejong@astm.org, +1.610.832.9734

—



## CHARLIE RUTHERFORD

BUSINESS DEVELOPMENT DIRECTOR, BOVEDA

## WHO IS BOVEDA?

#### WHO IS ATACH?

- ATACH is a 501 c6 trade organization.
- Promote the expansion, protection and preservation of businesses engaged in the legal trade of industrial, medical and recreational cannabis and hemp based products.
- First trade organization to steer an event at the 2016 DNC.
- Only trade organization invited to Conference of Western Attorneys General meeting.



#### WHAT DOES THIS HAVE TO DO WITH ASTM?

- ATACH is the only organization actively organizing our members to participate in ASTM's standards process.
- ATACH is here to listen where we need to listen and help where we need to help.



### WHAT IS WATER ACTIVITY (AW)?

- Aw is the measure of water available for microbial growth.
- Measures free vs bound water.
- It tells us everything we need to know about safe moisture levels in cannabis.



# HOW DOES AW DIFFER FROM MOISTURE CONTENT (MC)?

- MC doesn't tell us anything about safety.
- MC doesn't tell us anything about free water.
- MC is notoriously difficult to measure.



# WHY DOES CANNABIS NEED A MAXIMUM AW STANDARD?

- Consumer safety. Too much moisture = mold, yeast, fungal growth.
- Cannabis Safety Institute recognizes .65 Aw as the maximum.
- California has advanced the idea of enforcing a Moisture Content of 5-13%.

CD1.0_	Lemon	UK_04.2012		UK1_04.2012		ww	
Water	Water	Water	Water	Water	Water	Water	Water
Activity	Content	Activity	Content	Activity	Content	Activity	Content
	% wb		% wb		% wb		% wb
0.091	8.3	0.098	7.34	0.044	6.48	0.097	6.56
0.175	8.55	0.167	7.52	0.098	6.74	0.133	6.71
0.238	8.74	0.22	7.7	0.146	7	0.164	6.85
0.286	8.84	0.263	7.97	0.193	7.23	0.191	6.99
0.329	9.14	0.298		0.237	7.46	0.214	7.12
0.358	9.38	0.329	8.32	0.282	7.61	0.236	
0.394	9.56	0.357		0.317	7.84	0.257	
0.416	9.72	0.382		0.345	7.92	0.276	
0.433	9.83	0.399		0.375	8.12	0.293	
0.456	9.99	0.42		0.4	8.3	0.31	
0.472	9.83	0.435		0.421	8.45	0.324	
0.486	10.27	0.45		0.439	8.67	0.339	
0.499	10.35	0.465		0.458	8.75	0.352	
0.512	10.56	0.478		0.473	8.9	0.364	
0.523	10.69	0.491		0.488	9.12	0.376	
0.536	10.84	0.504		0.502	9.41	0.387	
0.547	10.95	0.515		0.516	9.71	0.399	
0.558	11.1	0.525		0.528	9.73	0.409	
0.568	11.25	0.537		0.543	10.02	0.421	
0.581	11.41	0.546		0.555	10.36	0.432	
0.589	11.56	0.559		0.569	11.01	0.442	
0.602	11.71	0.57		0.58	10.98	0.454	
0.612	11.91	0.581		0.594	11.03	0.465	
0.622	12.06	0.59		0.607	11.22	0.476	
0.634	12.24	0.602		0.619	11.38	0.488	
0.644	12.39	0.613		0.631	11.8	0.498	
0.654	12.71	0.623		0.643	12.06	0.51	
0.666	12.86	0.633		0.656	12.52	0.521	
0.675	13.1	0.643		0.667	12.97	0.531	
0.687	13.32	0.654		0.678	13.25	0.543	
0.695	13.61	0.663		0.692	13.72	0.553	
0.709	13.93	0.674		0.702	13.89	0.564	
0.717	14.19	0.684		0.715	14.16	0.574	
0.727	14.45	0.695		0.728	14.42	0.586	
0.739	14.9	0.705		0.737	14.79	0.596	
0.749	15.3	0.715		0.751	15.33	0.606	
0.759	15.76	0.725		0.762	15.86	0.617	
0.769	16.1	0.736		0.774	16.26	0.627	
0.779	16.6	0.745		0.785	17.3	0.638	
0.789	17.07	0.756		0.797	18.21	0.648	
0.798	17.6	0.766	15.95	0.808	19.14	0.658	11.96



# WHY DOES CANNABIS NEED A MINIMUM AW STANDARD?

- Avoid games played with THC results. Less water = higher THC count.
- Quality control. Give customers what they paid for, not fictional cannabinoids.
- Diversion prevention.



# WHAT SHOULD THE MINIMUM CANNABIS AW BE?

.55 = 55% Relative Humidity



#### THE VOTE ON WATER ACTIVITY STANDARDS

- WK60134 Establish Water Activity as the moisture measurement method.
- WK60135 Establish .55-.65 as the acceptable Water Activity range for dry cannabis.



## **ENJOY BERLIN!**



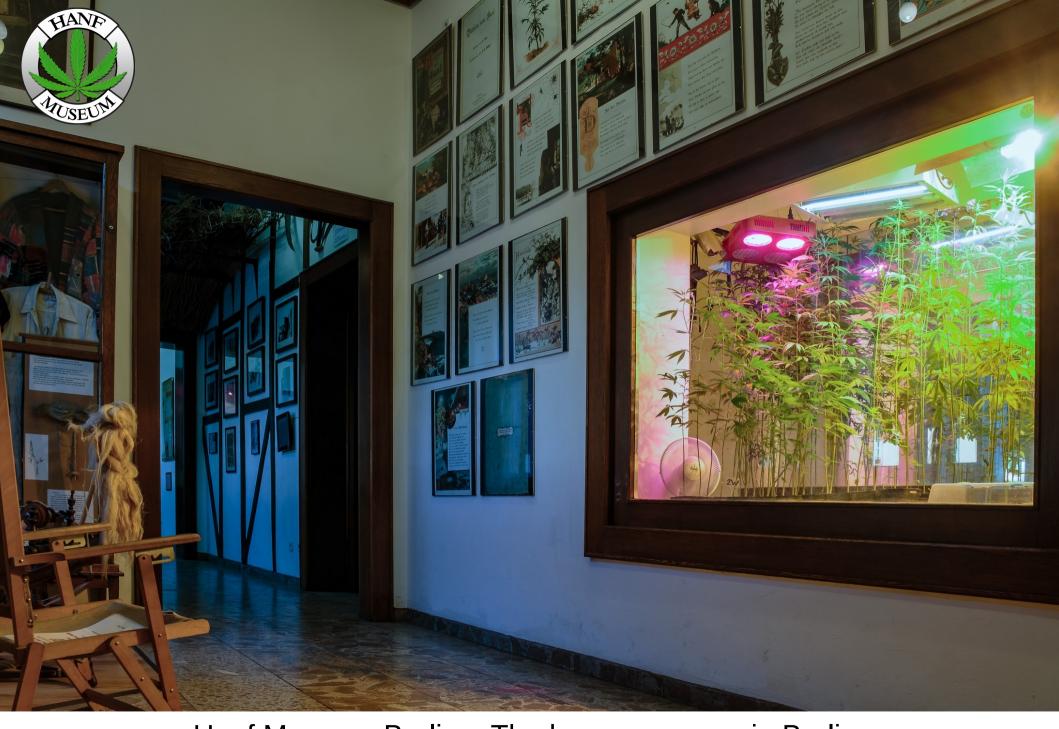
## Canadian Hemp and Cannabis Initiatives

(Not approved for distribution, Contact Ralph for Presentation)

Dr. Ralph M. Paroli, C.Chem.
Director General (acting)
R&D Director, Metrology
Measurement Science and Standards







Hanf Museum Berlin – The hemp museum in Berlin

Marijn Roersch van der Hoogte

ASTM Workshop D37 // 10 October 2017



#### Outline presentation

- 1. Introduction Marijn Roersch van der Hoogte
- 2. Introduction Hanf Museum Berlin
- 3. How it all started
- 4. Financing and organization
- 5. Overview of exhibition
- 6. Other functions of the museum
- 7. Hemp in Berlin
- 8. Summary





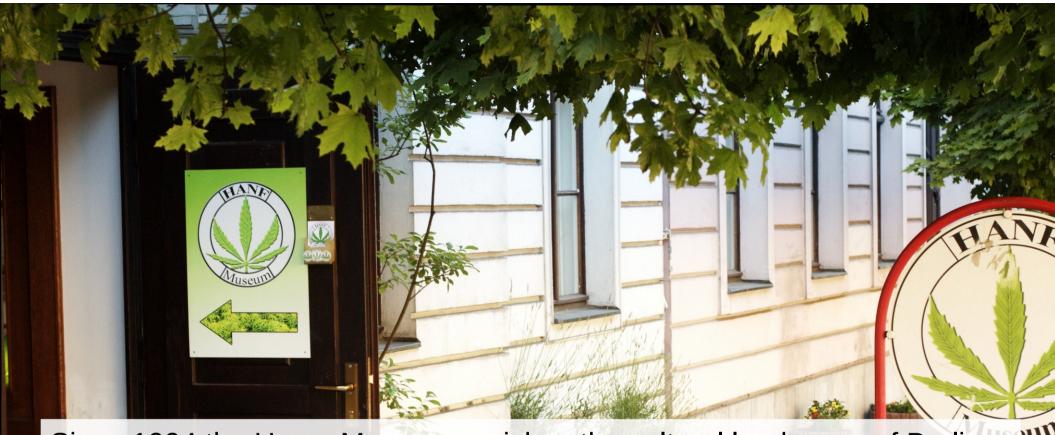


Bsc Biology / University of Utrecht

Dutch / Based in Berlin

Crowdfunding campaign H.E.M.P.

"I see myself as an activist and entrepreneur, pursuing every option to make hemp a standard commodity in our society."



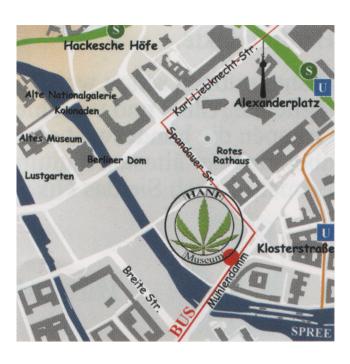
Since 1994 the Hemp Museum enriches the cultural landscape of Berlin. In the Hemp Museum visitors can get an all-encompassing impression of the, often seen as controversial, Cannabis plant. Hemp is being shown in all its economic and social aspects, objectively and without prejudice.

#### Goal of the museum:

To collect, archive and present knowledge of all aspects of the Cannabis plant.



- Exhibition space of >300m<sup>2</sup>
- Permanant exhibition
- Temporary exhibitions around actual themes
- Café and reading space
- Museum shop with wide selections of hemp products







#### **Mission Hemp Museum Berlin**

To create an exposition around the Cannabis plant in order to preserve and present the knowledge of this ancient crop and to prevent it from being forgotten in modern society.

- Inspired on the Haschisch & Marihuana Museum in Amsterdam, NL
- Founded in December 1994
- Three founders, one still active (Rolf "Rollo" Ebbinghaus)



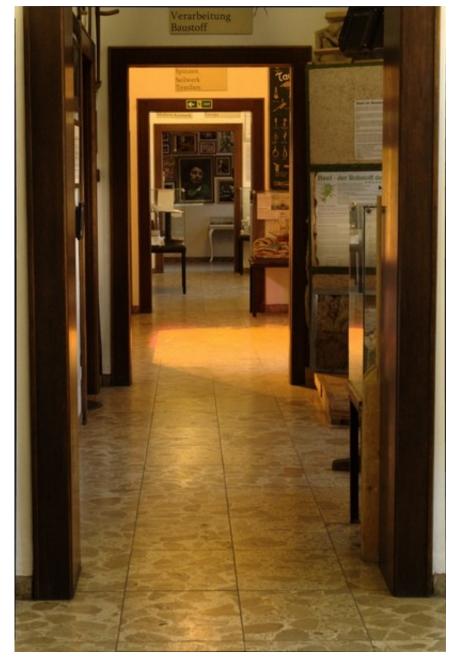
#### **Financing**

- Not funded by government
- Revenue created by tickets and from the giftshop
- Private and commercial sponsors

#### Organization

- Run by the non-profit organisation H.A.N.F. eV
- Total employees varies between 12 and 15 people
- Voluntary basis
- Large network of Cannabis interested people









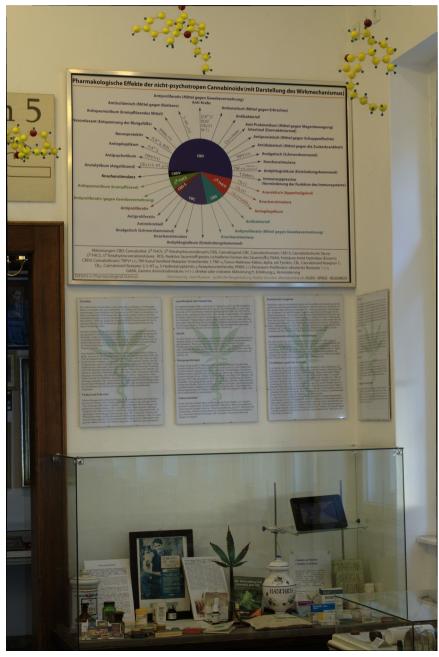
























# HANARA BOZ



Grüne Hilfe Netzwerk e.V.



#### **Cannabis in Berlin**

- New state government more pro Cannabis than previous
- Center of Cannabis legalization movement in Germany DHV / Hanf Museum / Hanfparade / Hanfjournal / etc...
- Big Cannabis users scene "smokers everywhere"
- Anual trade show Mary Jane Berlin / ICBC
- Cannabis restaurant Tom's Hemp
- Many Cannabis related companies



#### Summary

- 20+ years of providing public awareness for the Cannabis plant
- Non-profit basis, run by a team of enthousiastic volunteers
- Platform for other Cannabis organizations and people
- Continuously collecting and archiving Cannabis developments

"The exhibition shows all the different aspects of Hemp in an all-encompassing way, without prejudice, in order to reduce the hysteria and contribute to the demythologization of the plant."



Contact information:

Marijn Roersch van der Hoogte

Hanf Museum Berlin

Mühlendamm 5

10178 Berlin, Germany

E-Mail: info@hanfmuseum.de

E-Mail: mrh@hanffaser.de

Web: www.hanfmuseum.de



Phone: +49(0)30-2424847

Phone: +49(0)1578-5926659

www.hanffaser.de

# What is Hemp? What is Cannabis? De-mystification!

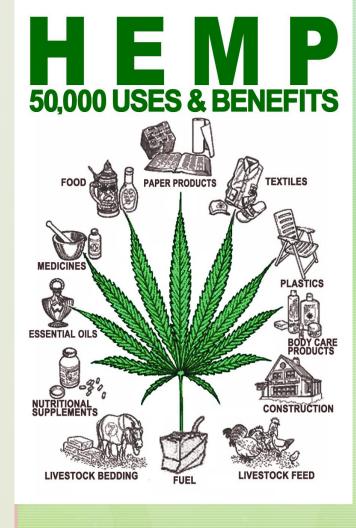
Susan Audino, PhD

S.A.Audino & Associates, LLC

Providence, RI

Susan.Audino@gmail.com

410.459.9208



ASTM BERLIN, GERMANY October 11-12, 2017

## Why are we here today?

- ASTM is in the business of 'standards'
- To move forward, we need to meet at a mutual starting point.
- Hemp Cannabis- Marijuana Sativa Indica Hybrids Cultivars .... what are they?
- Objective of this session: Reach a common ground of understanding of these 'words' to move forward.



## Hemp and Cannabis: Is there a Difference?

- Some attempts have been made to classify cannabis varieties based on chemical composition.
- 1542 Leonard Fuchs described a monotypic species, Cannabis sativa L.
   later identifying two distinctions:
  - Drug type has become known as "marijuana"
  - Fiber or fibrous type known as "hemp"

#### First – Let's Be Clear

- Cannabis, "Marijuana", Hemp are NOT genetically modified plants.
- GMO: transgenic mutation; altering the genetic makeup of an organism with genetics from a different organism.
- Selective Breeding: conscious effort to breed desirable traits of one (plant) with desirable traits of another (plant)
- All Hemp and "Marijuana" are derived from Cannabis L.; selective breeding has resulted in the many hybrids currently available.
- "Marijuana" has become a "very bad" word. We are talking about CANNABIS.



HEMP FACT

1652: British herbalist Nicholas Culpeper writes about medical uses for hemp.

# Functional Differences Between Hemp and Marijuana

#### "Marijuana" - Cannabis

- High △9THC (5%-35%)
- Grown in controlled environment
- Medicinal & recreational uses
- Fatter, shorter plants

#### Hemp

- Low △9THC (<0.3%)</p>
- Grown in most climates
- Applications include: body care, textiles, food, plastic
- Tall and skinny (up to 20 ft)



HEMP FACT

2014: US - The passage of Farm Bill, Section 7606, helped revive the hemp industry. The estimated total retail value of all hemp products sold in the US was 620M, but all were imported from other countries.

#### **Cannabis**

- Traditionally, cannabis used for medicinal purposes belonged to the "drug" type because of the high concentration and bioactivity of THC.
- Moving forward, the community recognized that multiple constituents, including cannabinoids and terpenes, may be involved in the overall effect of the drug.
- At present, no cannabis classification system includes terpenes.



HEMP FACT

US hemp farmers included George Washington, Thomas Jefferson. Historians believe Declaration of Independence was initially drafted on hemp paper.

## Categorization

- Since the publication of the draft genome of cannabis, various studies looked into the genetic analysis of cannabis as a means to identify distinct subgroups.
- Although studies have differentiated hemp from marijuana-type cannabis they have only found moderate positive relationship between cannabis strains and (reported) genetic/DNA ancestry.



# Cultivars

- Cultivar: literally, Cultivated Variety.
- Merriam-Webster: an organism and especially one of an agricultural or horticultural variety or strain originating and persistent under cultivation.

# **Cultivars**

- Plant breeders have attempted to distinguish strains or hybrids based on phenotype or plant morphology.
  - White Widow, Charlottes Web, etc.
- And by anecdotal reports....
  - Sativa is described as "uplifting", "energetic"; "head high"
  - Indica is described as "calming", "grounding", "relaxing"
- This nomenclature is <u>unrelated</u> to traditional scientific and taxonomic classification systems.



HEMP FACT

2012: The European Industrial Hemp Association conducted first and foremost detailed market analysis of European hemp. (www.eiha.org)

# Proposal: Practical Nomenclature of "Cultivars"

### **Intended Purpose: Human and/or Animal Consumption**

- "drug cultivar" refers to any cultivar of *Cannabis* that is cultivated for the purposes of collecting, isolating or extracting the essential oils, resins, saps or glandular trichomes.
- "nutritional cultivar" refers to any cultivar of *Cannabis* that is cultivated for the purposes of seed production or any other purposes except for collecting, isolating or extracting the essential oils, resins, saps or glandular trichomes.



HEMP FACT 2016: France grows more hemp than any other country in the EU. And, marijuana remains illegal.

# Practical Nomenclature of "Cultivars"

### <u>Intended Purpose: Any Product NOT Intended for Human or Animal Consumption</u>

- "industrial cultivar" refers to any cultivar of *Cannabis* that is cultivated for the purposes of fiber, textiles, biofuels, bio/phytoremediation or any other purpose(s) not intended for human and/or animal consumption.
- "multi-purpose cultivar" refers to any cultivar of *Cannabis* that is cultivated for multiple end uses whether as for a combination of drug, nutritional and/or industrial function.
- **NOTE:** Cannabis that is grown for commercial applications may not be appropriate for human/animal consumption and must be assessed on a case by case bases. For example, cannabis grown to remove contamination from irradiated soils should not be used for nutritional or drug product manufacturing, but may be beneficial for other fiber production.



HEMP FACT

2016: The European Industrial Hemp Assoc reported European hemp cultivation of 81,500 acres.

2016: US grew 9,649 acres of hemp during same time period.

# Keep in Mind

### **According to the FDA:**



"A **dietary supplement** is a product intended for ingestion that contains a "dietary ingredient" intended to add further nutritional value to (supplement) the diet."

https://www.fda.gov/aboutfda/transparency/basics/ucm195635.htm

"The FDA has not approved any product containing or derived from botanical marijuana for any indication. This means that the FDA has not found any such product to be safe or effective for the treatment of any disease or condition. Study of marijuana in clinical trial settings is needed to assess the safety and effectiveness of marijuana for medical use."

(https://www.fda.gov/newsevents/publichealthfocus/ucm421168.htm#notapproved)



HEMP FACT

1950: US – Inventions of cheap, synthetic fibers saw the decline of the hemp industry.

1958: The last significant hemp crop in the US

# Benefits of Adopting the *Proposed*Nomenclature

- No one cultivar serves a universal purpose or function.
- No current nomenclature provides adequate 'direction'.
- Specifies intended use, e.g., internal consumption, consumable material, etc.
- Recognizes that some cultivar(s) may require evaluation on case-by-case basis.
- Establishes consistency of nomenclature Cannabis is ...
  Cannabis!



HEMP FACT

Researchers at the University of Alberta created a supercapacitor using raw hemp material, paving the way toward an inexpensive and fast-charging battery fabricated by hemp.

# **Distinctions**

### "Marijuana" - Cannabis

- Horticultural Crop harvested for flowers
  - THC >0.3%
- Not harvested for seeds & stalks
- Produced for medicinal purposes
- Produced for recreational purposes

### Hemp

- Agricultural Crop harvested for seeds & stalks
- Seeds & stalks produce:
  - Food
  - Nutritional supplements
  - Body care products
  - Textiles
  - Building materials
  - Biofuels



HEMP FACT

2017: (U.S.) H.R.3530 – 115<sup>th</sup> Congress: "Industrial Hemp Farming Act of 2017" www.GovTrack.us.2017.

### **Distinctions**





- Originally grown in the Western world on an industrial scale for fiber, oil, and animal feedstuff.
- Plant is characterized as tall with few branches and long, thin leaves.

### Indica



- Originated in South Asia and were historically known as Indian hemp.
- Characterized by shorter, bushy plants and broader leaves that matured quickly.



HEMP FACT

1976: International Association of Plant Taxonomy: "Weed" and "Industrial Hemp" are the same plant- Cannabis sativa.

# Hemp Applications

### Industrial, non-consumption

- Not grown to include buds
- Contains <1.5% THC</li>
- Products derived contain<0.3%THC (<0.2% in Canada)</li>

### Therapeutic or 'nutritional'

- Requires buds which contain most of the THC
- Selectively bred to increaseCBD
- Seeds and oil are rich in protein, fatty acids



# In the End ....

- Hemp and Marijuana are derived from the same plant: Cannabis. So, why does the culture insist on a distinction? Cannabis is Cannabis!
- They are bred for different functions: Fiber, Drug, Nutritional
- They look different: Tall and narrow, short and bushy
- Crop production: Agricultural, Horticultural
- Constituents are essentially the same; concentrations are different,
   particularly THC
- Legalization tends to be defined on the basis of %THC



HEMP FACT

1938: US Popular Mechanics article reported "more than 25,000 uses" of hemp.

2017: Perhaps there are more!

# THANK YOU

#### Susan Audino, PhD

Chemist

A2LA Assessor & Instructor

### S. A. Audino & Associates, LLC

Life Sciences Laboratory Consultants

Analytical • Environmental • Agricultural
Cannabis Chemistry • Chemometrics
Industrial/Organizational Psychology
ISO/IEC 17025

phone: 410.459.9208

email: susan.audino@gmail.com



# CHALLENGES ASSOCIATED WITH MEDICINAL AND ADULT USE CANNABIS

### WHAT'S LOVE GOT TO DO WITH IT?

Uri Baruch



20% RESEARCH // 60% TECHNICAL 10% QUALITY // 10% MARKETING

21
years

50% MEDICAL // CONNECTED 50% INDUSTRIAL // CONSUMER

sectors

CAMBRIDGE, UK // PALO ALTO, USA 2 offices

100+
people

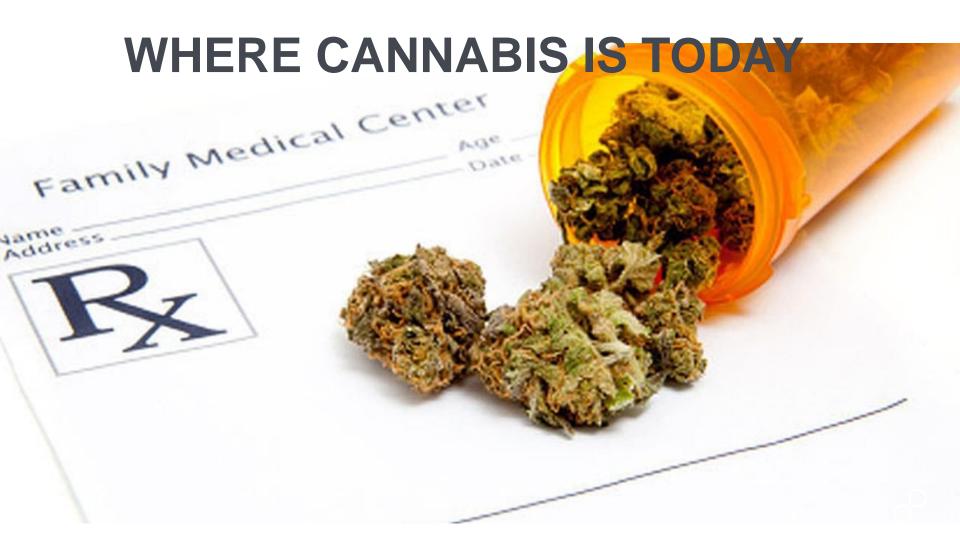
500+
patents

1000+
projects

CAN-0003-PP-A 25 October 2017







### **CANNABIS MARKET**

#### Market

Market size is estimated at \$6bn in 2017 and expected to rise to \$50bn by 2026.

- Medicinal use is expanding in many countries.
- Canada is proposing to legalise adult use in 2018
- Even if it's not legal it is decriminalised.
- Vaping is the fastest growing sector Tabaco companies are entering the market.
- Most of the product is still grown rather than made.



### CHALLENGES IN OTHER INDUSTRIES.

#### REDUCED HARM

> E cigarettes are moving into the medicinal space.

Moving from the consumer space into the medicinal space is not without its

challenges.

There are a few considerations

- Regulation
- Product Quality
- Traceability
- Clinical evidence
- Cost



### CHALLENGES IN OTHER INDUSTRIES.

#### **MEDICINES - COMBINATION PRODUCTS**

- Regulation has changed even in the pharma and Med Dev space
- Accessories are becoming medical devices in their own right
- Combination products are becoming the norm in the US and the EU.
- The rest of the world is soon to follow.
  - EU follows the US on regulation
  - Most other medical regulators follow either the US or EU
- This means higher costs and more work to get a product out.

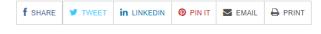


# REGULATION - WHAT'S LOVE GOT TO DO WITH IT?

- > FDA Food and drug administration (including supplements).
  - Even if it is not medication it will be regulated.
  - O Supplement or food substance.
- > FDA has recently issued a warning letter to a bakery as they quoted love as one of the ingredients in their flapjack.
- According to the FDA love is not a food ingredient.
- If you are looking to make any claims on the supplement you have an even higher burden of proof.



### Nashoba Brook Bakery, LLC 9/22/17



Your Nashoba Granola label lists ingredient "Love". Ingredients required to be declared on the label or labeling of food must be listed by their common or usual name [21 CFR 101.4(a)(1). "Love" is not a common or usual name of an ingredient, and is considered to be intervening material because it is not

part of the common or usual name of



Office of Human and Animal Food Operations East Division 1

WARNING LETTER CMS# 532236

### UNITED PARCEL SERVICE SIGNATURE REQUIRED

September 22, 2017

John D. Gates, CEO/Co-Owner Stuart J. Witt, Head Baker/ Co-Owner Nashoba Brook Bakery, LLC. 152 Commonwealth Ave. Concord, MA 01742-2990

Dear Mr. Gates and Mr. Witt:

The United States Food and Drug Administration (FDA) inspected your ready-to-eat manufacturing facility located at 152 Commonwealth Ave. Concord, MA, 01742 from May 25 through June 8, 2017. During the inspection, FDA investigators observed serious violations of the Current Good Manufacturing Practice (CGMP) regulation for foods, Title 21, Code of Federal Regulations (CFR), Part 110 [21 CFR Part 110].[1] At the conclusion of the inspection, you were issued a Form FDA-483, Inspectional Observations, which documented insanitary conditions in your

the ingredient.

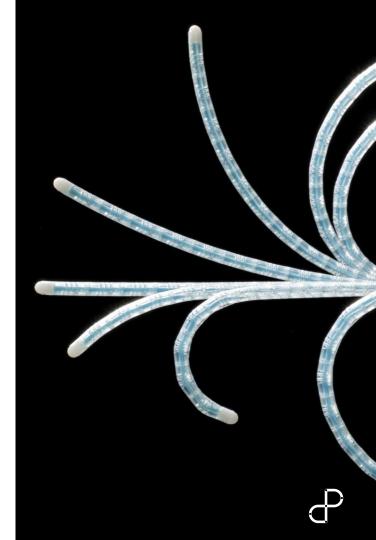
### **APPROACH OF OTHER INDUSTRIES - VAPING**

- > Balancing the desire to make claims vs cost
- Market research vs clinical studies
- Limited testing in a control setting
  - Reduced costs
  - Reduced timeline.
  - Lower regulatory burden
- Quality control of both ingredients and final product.
- > Traceability throughout production and distribution
- > Packaging, labelling and IFU



### APPROACH OF OTHER INDUSTRIES - MED

- > Highly regulated able to make claims on efficacy of therapy
- Need to control dosage accurately.
- Device testing and manufacturing quality is a commitment.
- Substantial testing to submit for regulatory approval
  - High costs for approval
  - Timelines can more than double
  - Quality of product and development process is complicated,
- Post marketing surveillance Customer service with a twist.



### **TAKEAWAY MESSAGES**

- > Be aware of potential changes coming
- Decide which path to follow Med or Rec.
  - Claims vs cost.
- Look at Pharma labelling and packaging for guidance.
- CGMP manufacturing guidelines are a good place to start,





# Thank you



UK OFFICE Church Road, Toft, Cambridge, CB23 2RF, UK Tel: +44 (0) 1223 264428 hello@cambridge-design.co.uk US OFFICE
228 Hamilton Avenue, 3<sup>rd</sup> Floor, Palo Alto,
94301, USA
Tel: +1 (650) 798 5134
www.cambridge-design.co.uk

CAN-0003-PP-A 25 October 2017

# ASTM D37 Hemp and Cannabis Workshop



### Quality Management Systems and Good Manufacturing Practices for Pharmaceutical Grade Cannabis

Andrew Samann, Orion Corp

11 October 2017 Berlin, Germany

Hosted by ASTM International

### **Honorable Mentions**



We are all here because of the people who helped us along the way. We owe thanks to the following groups:





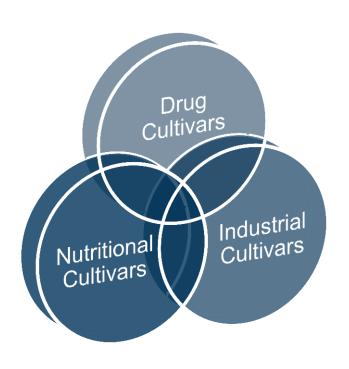




### **ASTM D37 Cannabis Standards Committee**



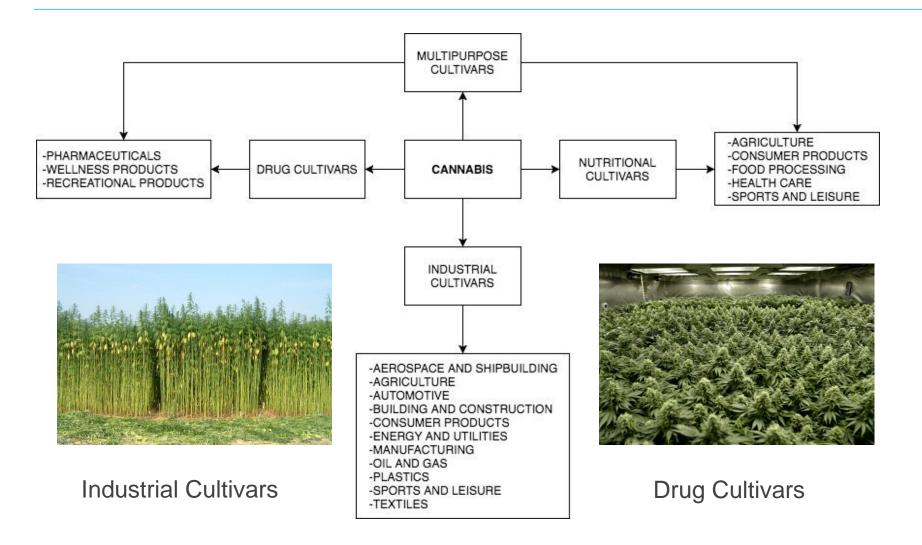
How can we harmonize globalized standards for Cannabis Manufacturing when there are multiple industry segments?



- No internationally accepted standards for cannabis manufacturing.
- 2. Nationally and Internationally uncoordinated industry from regulatory standpoint.
- 3. Lack of clinical research to support health claims, and subjective perceptions on health benefits prevailing.
- 4. Large investments into industry being made without a clear definition of what entails manufacturing.

# Cannabis Product/Market Segments





# Standardized Pharmaceutical Manufacturing



Globally standardized Active Pharmaceutical Ingredient manufacturing has been accomplished through bodies such as the *International Council on Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).* 

#### What are the benefits?

- 1. Standardization of drug products
- 2. Social equity through international trade opportunities
- 3. Decreased costs of manufacturing
- 4. Opportunities for outsourcing manufacturing activities
- 5. Ability to access international pharmaceutical markets

### **ASTM D37 Cannabis Standards Committee**



Globally harmonized consensus standards through the ASTM D37 Cannabis Standards Committee offer the same benefits as the Globally harmonized Active Pharmaceutical Ingredient Manufacturing.

Thousands of clinically tested pharmaceutical products are manufactured around the world, and then distributed around the world. Cannabis will be no different in the future.

### What can we agree about?

- Protect public health and safety before profit.
- 2. Ensure there are technical specifications for all stakeholders to manufacture.
- 3. International opportunities for the Cannabis Industry are greater than an individual nation.
- 4. We will get farther, faster, by working collaboratively.

# Cannabis Good Manufacturing Practices



Application of **Good Manufacturing Practices** should be applied in proportion to the relative risks to public health and safety. A *risk based approach* ensures that manufacturers are not burdened with complex regulatory guidelines, and provide the most flexibility in manufacturing.



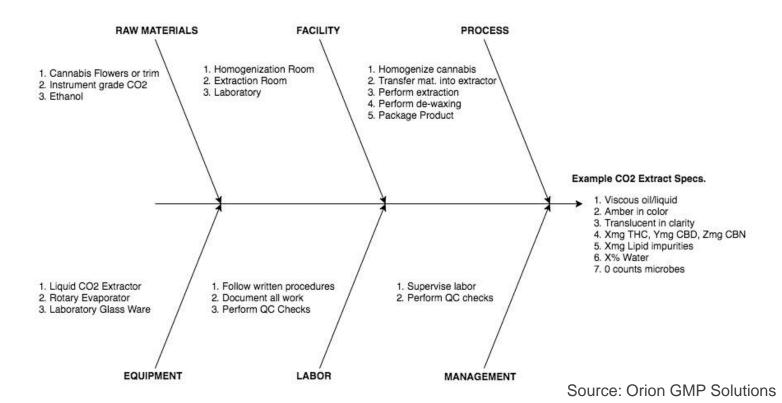
# The Need for Cannabis Standards

Committee on Cannabis (D37)

# Cannabis Product Development



Product Development does not require the application of GMPs or Quality Management Systems. However, it is the stage of the *product lifecycle* where all risks to public health and safety can be evaluated.



© ASTM International

10/20/2017

# Cannabis Risk Management

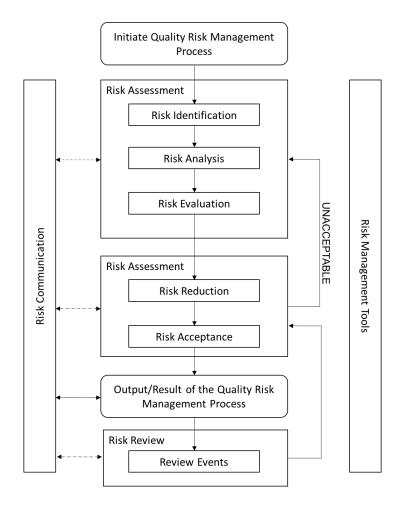


Risk Management can benefit any process, at a minimum protecting *Key Performance Indicators*, and at its best, protecting public health and safety.

Risk Management can be applied to all stages of the product lifecycle:

- 1. Product Development
- 2. Tech Transfer
- 3. Commercial Manufacturing
- Product Discontinuation

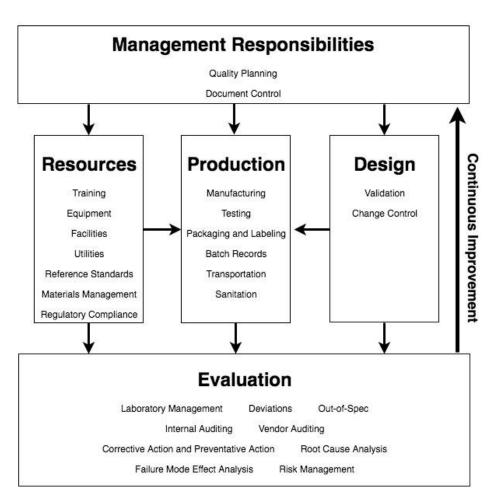
Applying Risk Management to Cannabis manufacturing has few differences from other manufacturing sectors.



Source: ICH Q9, recreated by Orion GMP Solutions

# **Quality Management Systems**





Quality Management is the responsibility of Leaders and Managers. When product quality is poor, all leaders are accountable for not managing the *process*.

### **Major QMS Elements**

- 1. Deviations
- Corrective Action and Preventative Action
- 3. Risk Management
- 4. Change Management
- 5. Management Review

Source: Orion GMP Solutions

# Leaders in Cannabis Manufacturing



Mr. Yaron (Ronnie) Eshal Director of Life Science, iCan

### Leaders create Culture



# Quality means doing it right when no one is looking. Henry Ford

Real integrity is doing the right thing, knowing that nobody's going to know whether you did it or not.

Oprah Winfrey

#### Total control over manufacturing



I believe in the power of asking questions, the power of audits.

First party audits: we ask ourselves questions

Second party audits: we ask our suppliers questions

Third party audits: we are asked questions by others

Audits should be conducted by individuals not having direct responsibility for matters being audited

(remarkable learning opportunity for those above/below and to the side to learn about other parts of the business).

© ASTM International 10/20/2017 13

## Manage the process, not the people





© ASTM International 10/20/2017 1

#### Leadership from beginning to end



#### **ASTM WK60084**

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

A Quality Management System (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organizations activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis. The Corrective Action Preventive Action (CAPA) subsystem is a critical component of an effective QMS. Most regulatory actions taken by the FDA and other regulatory bodies are linked to inadequate CAPA systems. The purpose of the CAPA subsystem is to collect information/data to detect product and quality problems, investigate root cause of product and quality problems, identify and implement appropriate corrective and/or preventive actions to prevent recurrence or occurrence, and monitor effectiveness of implemented corrective and/or preventive actions through a change management system. The change management system is used in verifying and validating corrective and preventive actions prior to implementation, properly disseminating information regarding corrective and preventive actions, and documenting all CAPA related activities are essential to ensuring the CAPA subsystem is compliant, effective and efficient. A CAPA subsystem shall be a closed loop system that quantifies system inputs and outputs. CAPA applies a systematic approach to problem resolution, and must maintain a close relationship with other Quality Systems subsystems. All CAPA related activities shall utilize a risk-based approach to prioritize existing and/or potential issues based on the criticality and magnitude of the situation.

© ASTM International 10/20/2017 15





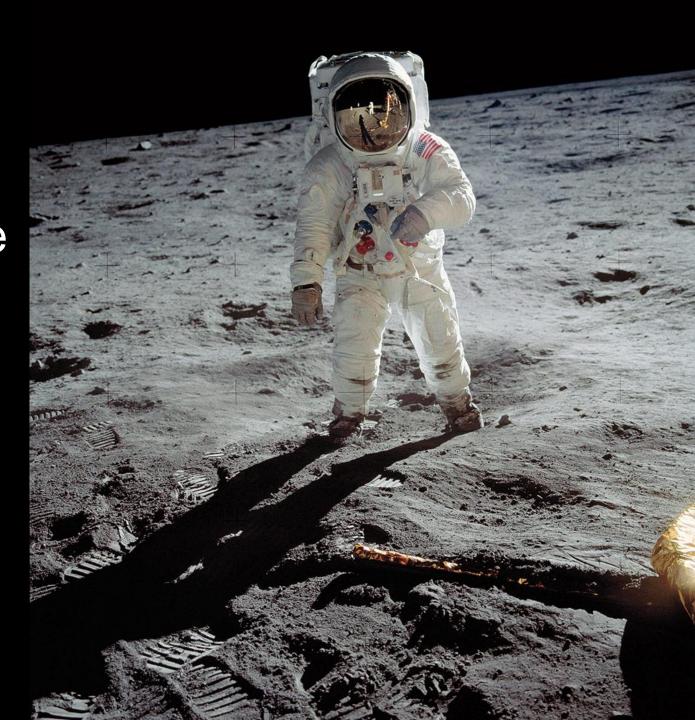


# **Cannabis Testing in Germany**

Adventures, Challenges, Solutions

by Tobias Wiezorek

Or: Why we feel sometimes like this...



#### What we do:









Nutraceutical & Supplement



Agriculture Agrochemical



Agriculture & Environment



Beauty, Wash & Care

- Offering state of the art laboratory testing of food, feed, cosmetic and pharmaceutical products ...
- using analytical, nutritional, microbiological, molecular-biological methods ...
- through an international network of laboratory and office locations following our customers and the chain of custody.

Labs for Life 3

# Tentamus' Worldwide Laboratories and Sites





Labs for Life 4

#### **Short History of Cannabis in Germany**



- used for pharmaceutical and recreational in europe since middle ages (>100 different cannabis based drugs!)
- banned since 1928
- widely used as an illegel drug (worldwide notified as a drug)



## Changes in 2017



#### 10th March 2017:

"Cannabis flos" on prescription (payed by health insurance)

- Permission by Bundesopiumstelle for <u>all</u> participants necessary!
- ➤ Regulated as a pharmaceutical drug → GMP!
- Importer needs to be certificated by state GMP authority
- Laboratory need to have GMP certificate (+manufacturing authorization)
- Methods for testing were published:
  - > Jan. 2016: DAC-method
  - 12th May 2017: DAB-method (replaces DAC)



# 20th April 2017

First release of a Cannabis sample by QSI testreport

#### **German DAB-Method**



#### Identity

- A: Macroscopic Identification
- B: Microscopic Identification
- C: Thin Layer Chromatography

#### Purity

- Foreign Matter (nmt 2%)
- Dry Matter (nmt 10%)
- Cannabinol (nmt 1%)

#### Assay (HPLC-UV)

- Σ THC: ±10% of labeled value
- Σ CBD: ±10% of labeled value

#### Recommended additional Analysis



- Heavy Metals
- Mycotoxins (Aflatoxines)
- Microbiology
- Pesticide Residues (in development)

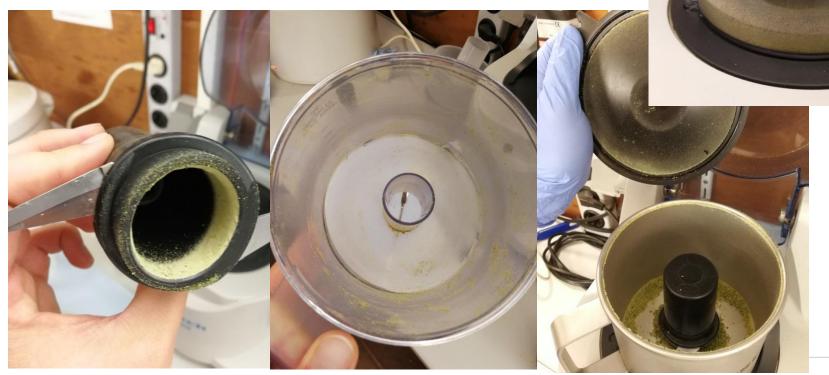


### Sample Milling

no detailed instruction in DAB/DAC

critical process due to possible loss of trichomes

Normally "as finer as better"





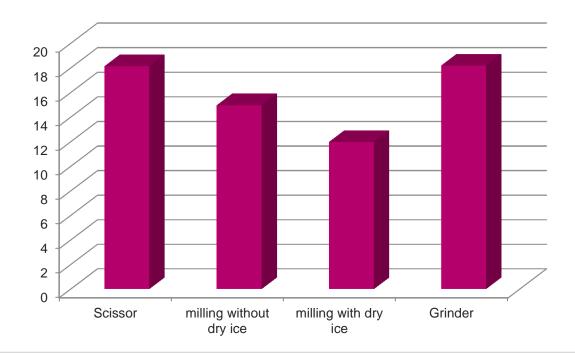
#### Permission by "Bundesopiumstelle"

- min. 6 weeks for permission
- separate permission for d8-THC, d9-THC, cannabis buds
- > extra permission for shipping from supplier to lab
- storage in safe vs. cooling
- excessive documentation (no toleration of loss)
- disposal/waste: no clear regulation



## Sample Milling

- no detailed instruction in DAB/DAC
- critical process due to possible loss of trichomes
- Normally "as finer as better"





#### Reference Standards

- DAB: needs to be qualified by H-NMR (400 MHz) and C-NMR (100 MHz)
  - Sigma: min. 300 €/batch/substance
  - ➤ THC-Pharm: cooperation with QSI substances will be available with full CoA acc. to DAB
- Stability: storage in freezer vs. Security: storage in safe



#### Cannabinoide Profile (HPLC-UV)

- Method in DAB is a possible suggestion (runtime: 45 min!)
- Calibration should be performed separately for every cannabinoid
  - Qualification for instrument: min. 30 hours!

Solution 1: Mixing of reference standards

(total mix not possible due to impurities in the standard)

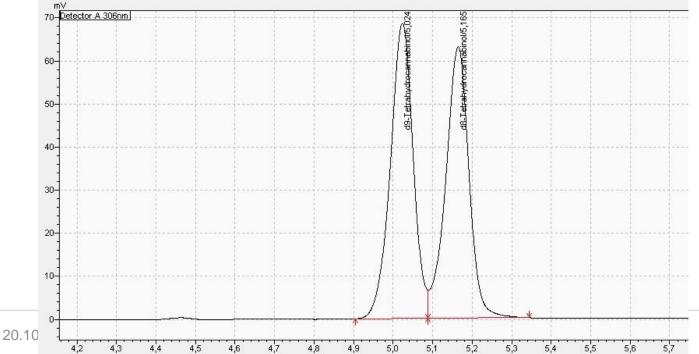
Solution 2: optimized HPLC column and gradient (9 min)



## Cannabinoide Profile (HPLC-UV)

- HPLC: high performance system required, very small dead volume!
- critical resolution between d8-THC and d9-THC!
- switching of wavelength during run

Reference solution extremely instable (AS-cooling)





#### Aflatoxine Testing (LC-MS/MS)

- strong matrix effects on immunoaffinity column
- strong matrix effects during MS ionization in ionsource
  - → low recovery rate
    - → special setting for sample preparation
- $\triangleright$  LOQs at QSI: 0,5 1,0 µg/kg (vs. food: 0,2 µg/kg)
- need for use of state-of-the-art LC-MS/MS (Sciex API5500)



#### Results

- Cannabis in Germany is mostly imported from Canada
  - Canadian producer: sticky product, full of resin on surface
  - > After shipping: product fully dry, not sticky

→ Strict rules for narcotic drugs: no sample exchange, ref. mat., PTs

#### Outlook



We would like to have...

- exchange of reference materials and proficiency test
- 🐲 worldwide standardization of sample grinding/milling
- worldwide standardization of cannabinoid profiling/potency test
- testing under highest possible standard and quality (ISO17025/GMP)

...for serving the best quality in testing of a high quality product!

#### Services of QSI



# Full Range of Cannabis Testing

- Cannabinoid-Profile
  - HPLC (high potency) cannabis buds and extract
  - ➤ LC-MS/MS (low potency) drinks, food, cosmetics, tea
- GMP or ISO17025
- Full Service Provider (by Tentamus)
- TaT: 3-5 days





# Thank you for your attention.

Flughafendamm 9 A, 28199 Bremen

Tel.: +49 - (0)421 - 596 607 81

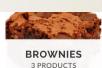
info@qsi-q3.de www.qsi-q3.de

# STANDARDIZED CANNABIS TESTING & ITS INFLUENCE IN THE INTERNATIONAL MARKETPLACE

Susan Audino, PhD

Chemistry, Chemometrics S.A.Audino & Associates, LLC – Providence, RI USA



























**GUMMIES** 5 PRODUCTS



**PASTRIES** 1 PRODUCTS





















4.20 Bar MINIs -30mg THC Available in four delicious varieties: Smooth, creamy classic milk chocolate.

CHOCOLATE

**EDIBLES** Bhang: Nugum Bhang Nugum: 4 pieces per pack in fresh mint flavor Available in: 200mg thc and 50mg thc/50mg cbd 200mg

ASTM – D37 Hemp Cannabis **Industry Workshop** BERLIN, GERMANY OCTOBER 11-12, 2017

## Disclaimer

- The following presentation represents my opinions and observations.
- The most common nomenclature is used.
- Discussion is based on need for third-party testing.
- Discussion makes no claims or assumptions about growing, cultivating, processing any cannabis plant or product(s).
- Discussion is not intended to imply standard test methods or consensus methods should replace regulatory body oversight, nor the proper manufacture of finished products.

# LEGALIZED CANNABIS

# Where is Cannabis Today?

#### USA

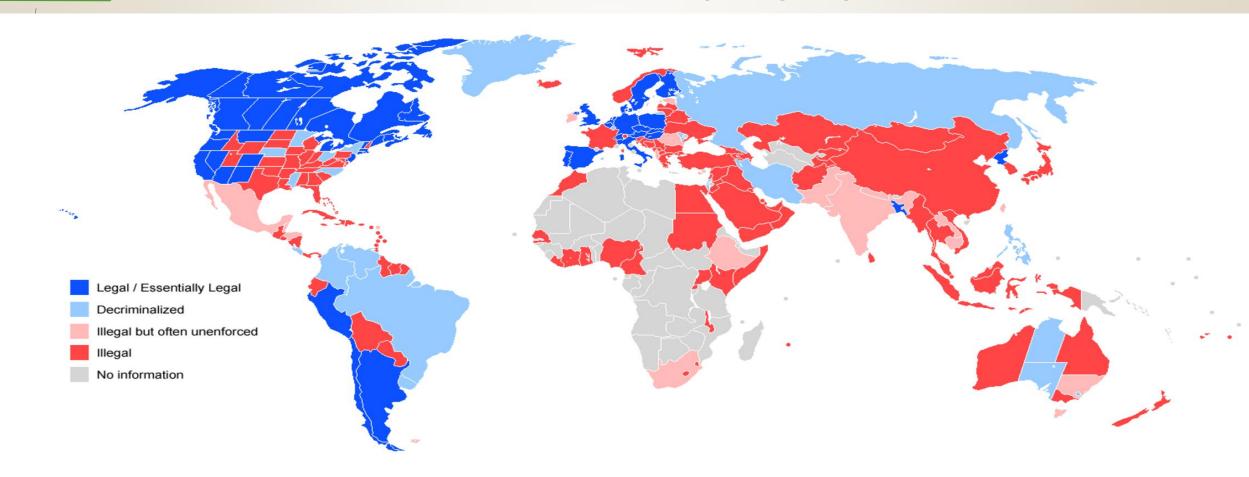
- "Medicinally" legal 30 states, District of Columbia
- "Recreational" or "Adult Use" 8 states
- Decriminalized in most other states

Outside USA (some degree of legal use and/or decriminalization)

• /41

Argentina ~ Australia ~ Austria ~ Belgium ~ Bolivia ~ Canada ~ Chile~ Colombia ~ Costa Rica ~ Croatia ~ Czech Republic ~ Ecuador ~ Estonia ~ Georgia ~ Germany ~ Greece ~ Guam ~ India ~ Israel ~ Italy ~ Jamaica ~ Luxembourg ~ Macedonia ~ Malta ~ Mexico ~ Moldova ~ Netherlands ~ Paraguay ~ Peru ~ Philippines ~ Poland ~ Portugal ~ Puerto Rico ~ Russia ~ Slovenia ~ South Africa ~ Spain ~ Switzerland ~ Turkey ~ Ukraine ~ Uruguay ~ US Virgin Islands

# Where is Cannabis (Legal) Today?



#### Global Medical Cannabis Landscape



# CANNABIS in the USA

# Cannabis Status - USA

- FDA does not oversee nor regulate the production of cannabis as a therapeutic agent nor as a recreational product.
- In the US, each state develops its own requirements for the cultivation, production, distribution, and application/intended recipients of cannabis and cannabis-infused products.

# Consider .....

- State regulatory bodies that develop and oversee their "medical marijuana" programs often require laboratory testing to determine the "potency" of certain constituents such as cannabinoids.
- There's no consistency in cannabis/hemp practice(s) within the international arena.
- "Potency is an expression of the activity of a drug in terms of the concentration or amount of the drug required to produce a defined effect." (National Center for Biotechnology Information, US National Library of Medicine)
- At present, cannabis is semi-treated as a drug in that it is referenced as "medicinal", yet does not enjoy the same rigor of development and assurance as other recognized drugs.

# Analytical Testing – in the US

- Individual states establish their own requirements for analytical testing of raw plant/dried flower and finished products including edibles, salves, tinctures.
- Individual laboratories develop their own testing methodologies.
- Our concern and focus for this presentation is on third party non-pharmaceutical/non-production testing laboratories.

## Consider.....

Until such time that cannabis is fully embraced and treated as a drug, third party analytical testing is necessary to provide analytical data related to the constituents of interest.

Single target, single analyte analysis may not always be best, but it is always necessary.

#### **Testing Needs Include:**

Relative Concentrations of the major cannabinoids:

- CBD
- CBDA
- △9THC
- THCA
- CBN
- CBC
- -/CBCA
- ► CBDVA
- CBG
- CBGA
- CBDV
- △8THC
- THCV
- THCVA

- Pesticide Residues
- Solvent Residue
- Microbial Contaminants
- Process Contaminants
- Natural Contaminants
  - Mycotoxins
    - Aflatoxins B1, B2, G1, G2
    - Ochratoxin A

Although no clear stipulation, it appears the next frontier may focus on Terpene Analyses.

#### TRENDS

#### A Rise in Marijuana's THC Levels

The amount of THC in marijuana has been increasing steadily over the past few decades. For a person who's new to marijuana use, this may mean exposure to higher THC levels with a greater chance of a harmful reaction. Higher THC levels may explain the rise in emergency room visits involving marijuana use.

The popularity of edibles also increases the chance of harmful reactions. Edibles take longer to digest and produce a high. Therefore, people may consume more to feel the effects faster, leading to dangerous results.

Higher THC levels may also mean a greater risk for addiction if people are regularly exposing themselves to high doses.

- The news-worthiness of cannabis is expected to continue.
- Until such time it is treated as a drug, interested parties will want to know the ingredients in a purchased product.
- At present, it is difficult to determine the veracity of product claims because laboratory testing is unique to individual testing labs performing the analyses.

i https://www.drugabuse.gov/publications/drugfacts/marijuana

# THE INTERNATIONAL COMMUNITY HAS AN OPPORTUNITY TO GAIN FROM THE LESSONS LEARNED IN THE US AND ABROAD

# LABORATORY ACCREDITATION Only Part of the Solution

### Quality of Laboratory Testing

- Many states require accreditation to ISO/IEC 17025, the gold standard for laboratory quality assurance.
- This standard does not dictate methods, equipment, or quality control.
- When available, accredited laboratories are required to demonstrate competence to implement standard test methods.
- When not available, accredited laboratories are required to develop in-house methods, or use others, that are valid and sound for the intended purpose.
- Even when standard test methods are available, laboratories may develop in-house methods, or use others, to which they demonstrate equivalency or exceed the requirements of the standard method(s).
- For non-standard methods, laboratories must demonstrate validity, for example, robustness, repeatability, reproducibility, LOQ, MDL, uncertainty, etc

# Quality of Laboratory Testing

- Laboratory competence is often achieved by participation in:
  - ISO/IEC 17043 accredited Proficiency Test Program (PT), or
  - Inter-Laboratory Comparison Program (ILC)
- PT Programs:
  - A suitable substance with known qualities is distributed by a reference laboratory to multiple participating laboratories.
  - Participating laboratories test and submit their results to the PT Provider.
  - Determination is made as to the 'correctness' of the laboratory results with the known substance of the reference laboratory (PT Provider).

#### ILC Programs:

- A suitable substance is distributed to multiple participating laboratories.
- Participating laboratories test and submit their results.
- Performance is evaluated by comparison with all other participating laboratories.

Main Difference: Reference Laboratory in the PT Program

# Challenges in Analytical Method Development

- Accessibility to natural reference materials
- Cost of synthetic certified reference materials
- Lack of ISO/IEC 17043 accredited Proficiency Test Program
- Limited Inter-Laboratory Comparison Programs
- Proprietary Methods
- Rapidly changing state and/or consumer requirements
- Fair market value isn't

# ANALYTICAL TESTING AND CONSUMERS

# Analytical Test Results: Effects on Consumers

- Uncertainty about "trueness" or "correctness" of test results.
- Labels do not always accurately reflect ingredients.
- Aliquots of one product can be sent to multiple labs different results.
  - All of which may be correct
  - All of which may be incorrect
- Difficult for independent result verification by different lab(s)
- Less than adequate testing labs are under-pricing tests, putting better labs out of business.

# Analytical Test Results - So What??



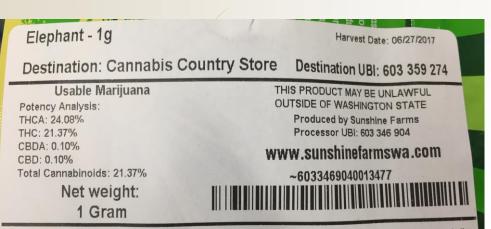








# Analytical Test Results – So What??



WARNING: This product has intoxicating effects and may be habit forming. For use only by adults 21 or older. Marijuana can impair concentration coordination, and judgment. Do not operate a vehicle or machinery while under the influence of this drug. Smoking is hazardous to your health. There may be health risks essociated with consumption of this product. Should not be used by women that are pregant or breast feeding Plant Care: Azamax, Diatomaceous Earth, Green Cleaner, SNS-203 (Clove Oil, Rosemary Oil)

American Baked Co. #603359282 Freedom Market Kelso #603410347-414280 Grl Sout Cookies Extraction: CO2 Made on:

Best by:

Topp Valley Gowers #603350205 Happy Cat Organics #603348814 Potency Analysis: Total 12.20mg, THC 10.30mg, THCA 2.17mg, CBD Oma 05/10/2016



6033 5928 2000 0939

THIS PACKAGE CONTAINS ONE INDIVIDUAL 10mg THC SERVING (10mg TOTAL). EAT ONE, WAIT.

**CAUTION:** This product contains

Cascadia Gardens Shatter .5g-\$24

Gorilla Glue #4 (H) E.B.D.B. (I) (Ewok Bear OG Dutch Blueberry)

Cascadia Gardens Shatter/Co2 1g-\$32

Head Cheese Co2 (H) OG Mix (I) The Candy (S) Sour Diesel Co2 (I)

Cascadia Gardens Absolute Shatter 1g-\$45 Absolute CBD (H)



Agrijuana Sugar Wax 1g-\$25

God's Blend(I)



Liberty Reach Wax .5g-\$19

Strawberry Mango Haze (S) Thai Girl (S)

Liberty Reach Wax 1g-\$44

Memory Loss (S)



LANDRACELABS

Landrace Labs 1g Oil \$29

Co2: Blue Dream (S)

Grapefruit (S)

Orange Kush (I)

Strawberry Creme (S)

Where's My Bike? (S)

THC FARMS-Oil 1g-\$29

Black Russian (I)

Critical Lemon (H)

Dutch Treat (H) Zen-X (S)

Cenex (S)



Sunshine Farms 1g-\$33

Cookie Wreck BHO (H) Gorilla Glue BHO (H) Rise & Shine BHO (S) Sun Tan BHO (H) Sunny Daze BHO (H) Acapulco Lights Sugar (H) Bio Glue (H)
Dutch Dream Sugar (H)
Gorilla Glue Sugar (H) Phantom Fire Wreck Sugar (I) Thunderbud Sugar (H) Cashey's Honey Wax (I) CBD Phantom Elephant Wax (I)



Blue Dream Shatter (S)
Golden Pineapple Shatter (S)



Silica Phoenix Wax .5g-\$17

Blueberry Haze (S) Supernova shatter (S) George Waxington (H) Glen Dabzig (H) Shiskaberry (1)

Silica Phoenix Wax 1g-\$30

Dabby Jones (H) Texas Ranger Shatter

#### Effects on Consumers

- Remember: when used for symptom abatement or compassionate use, many consumers are already immuno-compromised.
- If "Dosing" an incorrect label may lead to adverse effects.
  - Too Little
  - Too much
  - Different relative concentrations of constituents
  - Impurities may have deleterious effects
  - One product may not be the 'same' as a previous purchase
- If using recreationally or 'adult use' could lead to unexpected effects

Risk to Consumer Health and Safety

# CONSENSUS TEST METHODS & STANDARDS

#### Definitions

#### Consensus:

A group of stakeholders who, in conference and through a series of iterations and compromises, come to agree upon the wisest way(s) forward on a specific issue.

#### ■ Standard:

Conformance to an established method or set of requirements based on recognized specifications.

#### In terms of laboratory/analytical methods:

- Both require robust evaluation and vetting by recognized experts.
- Both provide the laboratory with a benchmark for consistent implementation and results within established parameters and margins of error.
- All are VOLUNTARY.

# Gravity of Importance

- High Times, March 2017
- Predict "testing labs (in North America) will be worth \$1.4 billion by 2021."
- Some would argue the accuracy of this statement
- All would agree that their statement "It's safe to say that there will be increasing demand for accurate and reliable marijuana testing and the subsequent clean cannabis ..." <u>Is not only valid, but of paramount</u> <u>importance.</u>

### Value of Standard Methods

- Promote efficiency: process is developed and well characterized.
- Promotes quality assurance: process oriented.
- Established by stakeholders with vested interest;
   developed and reviewed by experts
- Transparency
- No individual to gain or lose
- Reduced business risk

### Without standards ....

 Without standards and without consensus methods, laboratory staff are free to choose whatever methods and instruments they seem fit.

#### Problem:

- sometimes insufficient instruments are used
- Inadequately trained personnel
- Poor methodologies

#### Result:

- Near impossible for an independent lab to confirm or challenge test results
- Consumers are at risk

# STANDARDS & CONSENSUS METHOD DEVELOPMENT

# Method Development

- Analyte of Interest
- Review Available Technologies
- Determine Method of Analysis
- Validate Method of Analysis
- Protocols are determined based on previously validated procedures

# Standard Operating Procedures – QA/Process Oriented

#### Scope

- Specification of intended purpose
- May include limitations and/or restrictions

#### **Materials**

- Instrumentation
- Consumables

#### QC

- Quality ControlProduct oriented
- Confirms standards are followed throughout the process

#### **METHOD**

• Specification of steps necessary to achieve required precision, accuracy, etc.

#### **DATA**

- Specification of data acquisition and processing, including statistical analyses
- Specification of acceptance criteria based on predetermined validation studies

### Overall Function of Standard Methods

**Specified Need** 

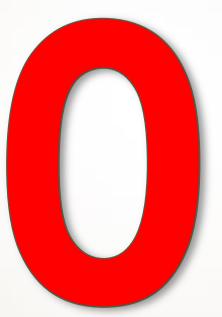
Experts Collaborate

**Process is Well Characterized** 

Standard Method is Published

Test Results Obtained Accurately and with Greater Assurance & Confidence

# Specific Standard/Consensus Methods Currently Available



As of September 2017, there are no standard test methods available to the cannabis industry.

# CONSENSUS/STANDARD METHOD DEVELOPMENT - CANNABIS



# American Society for Testing and Material

- Mission: "Committed to serving global societal needs, ASTM International positively impacts public health and safety, consumer confidence and overall quality of life. We integrate consensus standards, developed with our international membership of volunteer technical experts, and innovative services to improve lives—Helping our world work better." (ASTM.ORG)
- Since 1898 ASTM has developed voluntary technical consensus standards across many industries.
- Methods are established by stakeholder interest and task groups, subsequently approved by sub-committee, full committee, and Society.

#### **Annual Book of ASTM Standards**

The 80+ volume Annual Book of ASTM Standards contains ASTM's 12,000+ standards and is available in print and Online formats.



- Mission: "To attain the vision of "worldwide confidence in analytical results," AOAC serves it's stakeholders by providing the tools and processes necessary to collaborate and through voluntary consensus building, develop fit-for-purpose methods and services for ensuring quality measurements." (AOAC.ORG)
- Since 1884, AOAC International's technical contributions center on the creation, validation, and global publication of reliable analytical test methods, primarily to evaluate the safety of foods, beverages, dietary supplements, and similar materials consumed by humans and animals, or to evaluate purity of materials used in production of foodstuffs and their ingredients.
- Committees of experts are formed to discuss specific analytical need(s).
- The committee formulates Standard Method Performance Requirements which candidate methods must meet.
- Candidate Methods undergo critical evaluation by an Expert Review Panel before moving to the Official Methods Board for first approval.

# AOAC – Status of Cannabis Methods as of September 2017

- SMPR: Standard Method Performance Requirements
- SMPR currently in Development:
  - Identification and Quantitation of (as yet) undetermined pesticide residue in dried plant/flower
- Completed SMPRs:
  - 2017.001: Potency of select Cannabinoids in Concentrates
  - 2017.002: Potency of select Cannabinoids in Dried Plant/Flower
  - 2017.003: Potency of select Cannabinoids in Chocolate

**Technology Required:** Any analytical technique(s) that measure(s) the analytes of interest and meet the method performance requirements.

### Facts about Consensus Methods

#### Intended to ...

- Serve third-party laboratories, however methods may be used to provide status updates during processing.
- Provide opportunity to reproduce test results between and among different laboratories, within stated margins of error.
- of laboratory personnel in the performance of consistent testing practices.
  - Provide clear(er) path to Accurate Test Results.

#### Not Intended to ....

- Replace or take the place of appropriate research methodologies.
- Replace or take the place of pharmaceutical or other regulatory testing.
- Become regulations or laws, although regulatory bodies may adopt consensus methods as requirements.
- Replace or take the place of appropriate product manufacture practices.

# Benefits of Consensus /Standard Test Methods

- Voluntary
- Require specific scope
- Require & develop fitness for purpose
- Specify steps and processes
- Specify required instrumentation (e.g., ICP-OES, HPLC, LCMS, etc.)
- ACCURATE TEST RESULTS
- Multiple laboratories can test the same substance and derive the same (within stated error) results.
  - Transparency
  - Greater accountability
  - Greater assurance of hitting the 'correct' result
  - Third party can evaluate with respect to truth-in-labeling
  - Accurate Test Results
- Occasionally, consensus methods are adopted by regulatory bodies.

# WHY Standards and Why ASTM?

- There are as many Operating Systems as there are states and countries that legalize any use of cannabis (i.e., marijuana, hemp)
- Acknowledging the fact that NEEDS are universal and not state or country specific, brings us all to the same page in the same book.
- Assimilating various specifications and regulations and harmonizing into cohesive standards will benefit regulators, consumers, business, the international marketplace.
- ASTM has proved itself repeatedly on this issues in other industries.
- ASTM standards are developed rigorously, expertly, and through consensus.
- ASTM standards are direct, transparent, and applicable.
- ASTM standards will bring relief to many challenges and will directly benefit consumers.

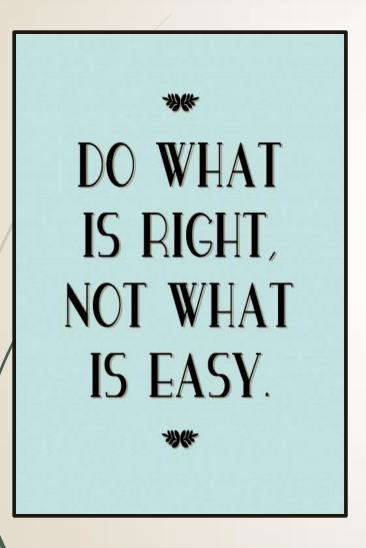
# Some Challenges to Testing Cannabis

- Cannabis is a complex plant with hundreds of known components, including:
  - 100+ cannabinoids
  - 100+ terpenes
- Matrix matching and/or standard addition can be problematic.
- Anecdotal evidence suggests physiologic benefit when the whole plant is used in formulation, referencing a "synergy".
- The plant has a primordial cannabinoid: cannabigerolic acid (GBGA)
- Cannabinoids degrade to cannabinol (CBN), where its presence is less than 1%
- Analytical Methods focus on isolating and evaluating single components.
- By looking at single components, are we missing the mark in this dynamic system? Does isolation of one compound affect other compounds? Is it, itself, affected during the process of extraction and isolation?

### Summary

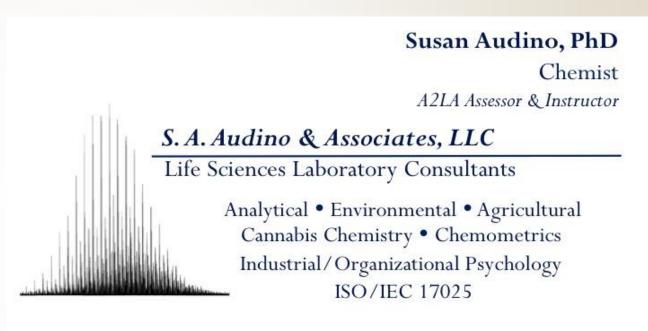
- No consensus or standard methods currently in place for 3<sup>rd</sup> party testing labs.
- Lack of methods: inadequate testing, incorrect instrumentation, poorly trained and/or inappropriately educated analysts and technicians, poor analytical test results.
- International scientific communities ASTM– are actively working on developing standard s and/or consensus analytical test methods.
- Benefits of Consensus Methods: Developed for specific purpose, specifies appropriate instrumentation and analyst skills, reviewed by like-minded experts, consistent testing leading to reproducible test results.
- Benefits of Standards: Consumers will know what to expect. Producers will know how to perform consistently
- Increases the application of established methods that are known to perform in accord with their intended purposes.

#### Summary



- If Cannabis is a Drug treat it as a drug.
  - Clinical trials
  - Formulate according to FDA requirements
  - Report appropriately and consistently as per protocols
  - Engage in sound scientific and sound medical research
- Consumers whether patients or adult users
   have a right to know what they are using.
- Consumers have a right to know the risks associated with the product(s) they are receiving.

# THANK YOU!



phone: 410.459.9208 email: su

email: susan.audino@gmail.com



#### ASTM INTERNATIONAL Helping our world work better

### Cannabis as a Commodity Crop

Navigating the Regulatory Nuances between the Various Parts of the Plant

Berlin Marriott Hotel Inge-Beisheim-Platz 1, 10785 Berlin, Germany October 11<sup>th</sup>, 2017 D37 Industrial Hemp Liaison, Darwin Millard

www.astm.org

#### Agenda



- Introduction
- Overview of the Global Regulation Governing Cannabis
- Cannabis Reform on the Horizon
- Commoditizing the Cannabis Plant
- ASTM Standards and Cannabis

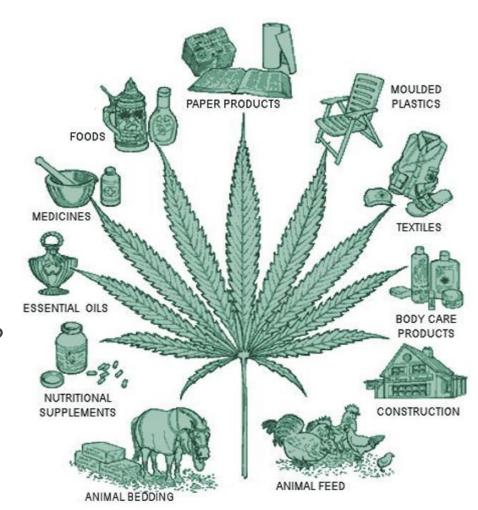


© ASTM International 20 October 2017 2

#### Introduction



- There are many well known uses of the cannabis plant.
- Vastly different regulations governing the different parts of the cannabis plant and the products that can be made from them.
- How do you navigate these regulations based on the end product you wish to manufacture?
- What standards are needed to commoditize cannabis products and ease regulatory burden?

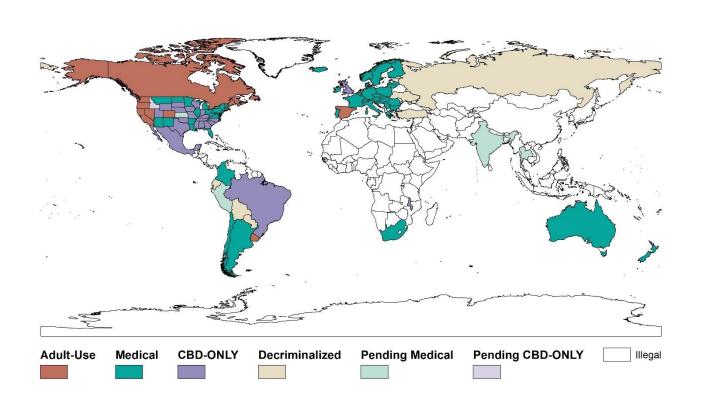


© ASTM International 20 October 2017

#### Global Status of Cannabis



#### Global Cannabis Legalization Map

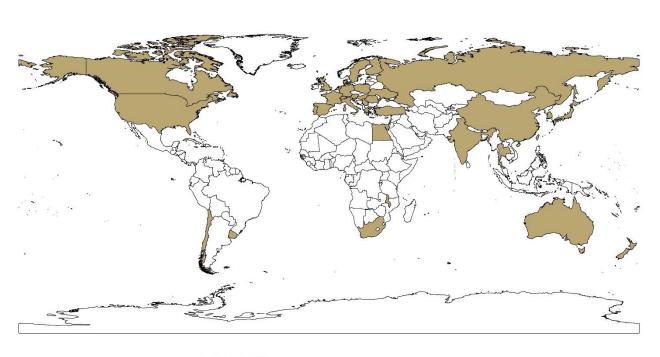


Copyright 2017, Plant Consulting Group LLC

#### Global Status of Cannabis



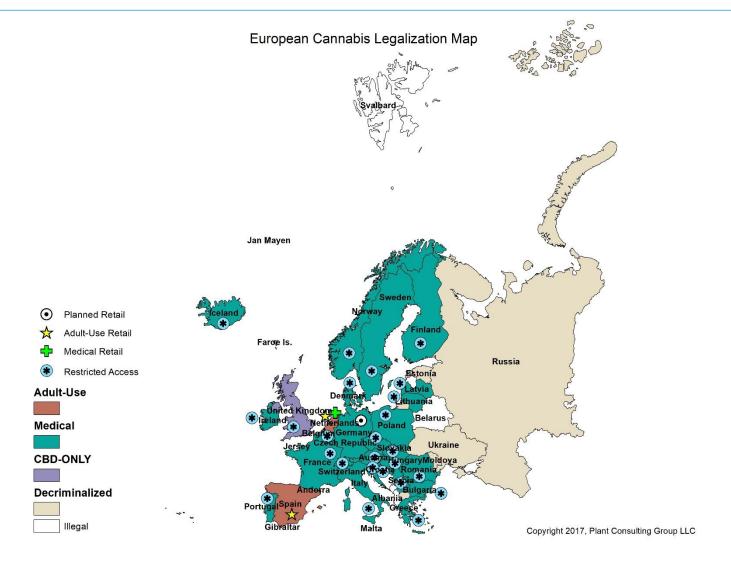
#### Industrial Hemp Producing Nations



**Industrial Hemp** 

#### Global Status of Cannabis





© ASTM International 20 October 2017

### Global Status of Cannabis



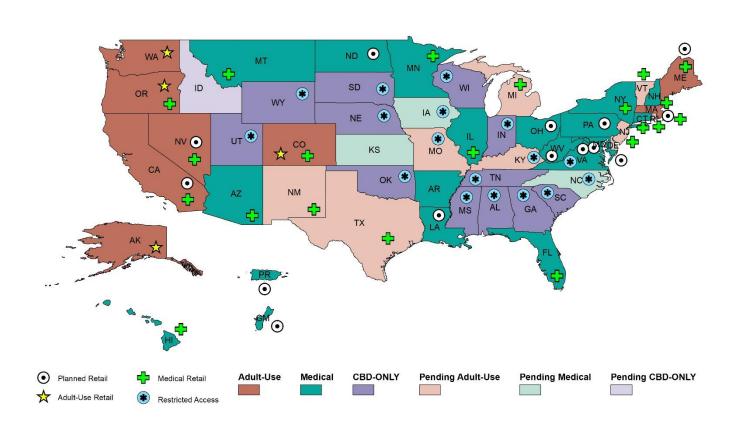
#### Latin American Cannabis Legalization Map



### Global Status of Cannabis



#### United States Cannabis Legalization Map





### **United Nations – Single Convention on Narcotic Drugs ("Single Convention")**

Ratified in 1961 Amended in 1972

#### **Definitions:**

- "Cannabis" means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.
  - i.e. the flowers of the cannabis plant.
- "Cannabis plant" means any plant of the genus Cannabis.
  - i.e. Cannabis sativa (at a minimum) and Cannabis indica and Cannabis afghanica (modern taxonomy)
- "Cannabis resin" means the separated resin, whether crude or purified, obtained from the cannabis plant.
  - i.e. the glandular trichomes (secretor cells of the cannabis plant) and the chemicals contained within.



### **United Nations – Single Convention on Narcotic Drugs ("Single Convention")**

Ratified in 1961 Amended in 1972

#### **Definitions:**

- "Cultivation" means the cultivation of the opium poppy, coca bush or cannabis plant.
- "Drug" means any of the substances in Schedules I and II, whether natural or synthetic.
   i.e. cannabis and cannabis resins.
- "Manufacture" means all processes, other than production, by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs.
- "Preparation" means a mixture, solid or liquid, containing a drug.
- "Production" means the separation of opium, coca leaves, cannabis and cannabis resin from the plants from which they are obtained.

i.e. any process of separating the flowers from the stalk.



#### **United Nations – Single Convention on Narcotic Drugs ("Single Convention")**

Ratified in 1961 Amended in 1972

Article 22 – Special Provisions Applicable to Cultivation:

- Whenever the prevailing conditions in the country or a territory of a Party render the prohibition
  of the cultivation of the opium poppy, the coca bush or the cannabis plant the most suitable
  measure, in its opinion, for protecting the public health and welfare and preventing the diversion
  of drugs into the illicit traffic, the Party concerned shall prohibit cultivation.
- A Party prohibiting cultivation of the opium poppy or the cannabis plant shall take appropriate
  measures to seize any plants illicitly cultivated and to destroy them, except for small quantities
  required by the Party for scientific or research purposes.



**United Nations – Single Convention on Narcotic Drugs ("Single Convention")** 

Ratified in 1961 Amended in 1972

Article 28 – Control of Cannabis:

- If a Party permits the cultivation of the cannabis plant for the production of cannabis [i.e. flowers] or cannabis resin, it shall apply thereto the system of controls as provided in Article 23 respecting the control of the opium poppy.
- This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fiber and seed) or horticultural purposes.
- The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.



#### **United Nations – Single Convention on Narcotic Drugs ("Single Convention")**

Article 23 – National [Cannabis] Agencies:

- A Party that permits the cultivation of the [cannabis plant] for the production of [cannabis and cannabis resin] shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.
- Each such Party shall apply the following provisions to the cultivation of the [cannabis plant] for the production of [cannabis and cannabis resin] and to [cannabis and cannabis resin]:
  - 1. The Agency shall designate the areas in which, and the plots of land on which, cultivation of the [cannabis plant] for the purpose of producing [cannabis and cannabis resin] shall be permitted.
  - 2. Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.
  - 3. Each license shall specify the extent of the land on which the cultivation is permitted.
  - **4. All cultivators** of the [cannabis plant] shall be **required to deliver** their **total crops** of [cannabis and cannabis resin] **to the Agency**. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.
  - 5. The Agency shall, in respect of [cannabis and cannabis resin], have the exclusive right of importing, exporting, wholesale trading and maintaining [inventories] other than those held by manufacturers of [cannabis] alkaloids, medicinal [cannabis] or [cannabis] preparations. Parties need not extend this exclusive right to medicinal [cannabis] and [cannabis] preparations.



#### **United Nations – Single Convention on Narcotic Drugs ("Single Convention")**

Ratified in 1961 Amended in 1972

#### Article 29 – Manufacture:

- The Parties shall require that the manufacture of drugs be under license except where such manufacture is carried out by a State enterprise or State enterprises.
- The Parties shall:
  - (a) Control all persons and enterprises carrying on or engaged in the manufacture of drugs;
  - **(b) Control under license** the **establishments and premises** in which such manufacture may take place; and
  - (c) Require that licensed manufacturers of drugs obtain periodical permits specifying the kinds and amounts of drugs which they shall be entitled to manufacture. A periodical permit, however, need not be required for preparations.
- The Parties shall prevent the accumulation, in the possession of drug manufacturers, of quantities of drugs and poppy straw in excess of those required for the normal conduct of business, having regard to the prevailing *market conditions*.



#### **United Nations – Convention on Psychotropic Substances**

Ratified in 1971

Expanding the regulatory authority of the Single Convention

#### **Definitions:**

- "Psychotropic substance" means any substance, natural or synthetic, or any natural material in Schedule I, II, III or IV.
  - i.e. the cannabinoids explicitly THC and all others implied, such as CBD.
- "Preparation" means: (i) Any solution or mixture, in whatever physical state, containing one or more psychotropic substances, or (ii) One or more psychotropic substances in dosage form.
- "Manufacture" means all processes by which psychotropic substances may be obtained, and includes refining as well as the transformation of psychotropic substances into other psychotropic substances.
   The term also includes the making of preparations other than those made on prescription in pharmacies.



#### **Summary of the Single Convention**

- Licenses are required: (a) to cultivate the cannabis plant for the purposes of producing cannabis and/or cannabis resin, and (b) to manufacture preparations of cannabis and/or cannabis resins.
- Licenses are NOT required: (a) to cultivate the cannabis plant for the purposes of producing fiber and/or seed, or (b) to manufacture products with fiber or seed – so long as these materials are not accompanied by the flowers.

Material/Substance	Schedule (as of 18 Oct. 2017)	Drug Classification
Cannabis	1	Psychotropic substance
Cannabis resin	1	Psychotropic substance
Extracts of Cannabis	1	Preparation
Tinctures of Cannabis	1	Preparation
Tetrahydrocannabinol (THC) and its isomers	1	Psychotropic substance
Seeds (when not accompanied by the flower)	EXEMPT	None
Leaves, Stems and Stalk (when not accompanied by the flower)	EXEMPT	None

### Modernization of Cannabis Regulations



#### **Important Developments**

- In 2016, the World Health Organization (WHO) authorized its Expert Committee on Drug Dependence (ECDD) to conduct its first official review on the effects of *Cannabis*, since the ratification of the Single Convention in 1961, and will rule on these findings sometime in 2018 or 2019<sup>1</sup>.
  - Meaning the rescheduling of the cannabis plant and its derivatives on the global scale is imminent.
- The 39<sup>th</sup> WHO ECDD will meet in Geneva from the 6<sup>th</sup> to 10<sup>th</sup> November 2017, to review [cannabidiol (CBD)'s] potential for dependence, abuse and harm to health, and will make recommendations to the U.N. Secretary-General, on the need for and level of international control of [CBD] at the end of this year<sup>2</sup>.
  - Consequently, CBD may become explicitly scheduled causing a ripple effect throughout the global cannabis industry – jeopardizing the livelihood of many farmers currently cultivating hemp for the purposes of producing phytocannabinoid extracts.

#### **European Industrial Hemp Association – Cologne Declaration on Industrial Hemp (7 June 2017)**<sup>3</sup>

Urges the UN to revise/update Article 22 of the Single Convention to recognize that modern cultivars of the cannabis
plant allow for the opportunity to safely use all parts of the plant...without endangering public health and welfare.
 i.e. hemp.

#### Article 22 – If its to hard to regulate than just ban it completely!

This is a perfect example of where standards would make it easier for regulators to understand the differences between the various types of cannabis and their end uses, greatly increasing the likelihood of a government choosing to regulate rather than ban completely.

• Created a new classification of hemp – medical

This is another example of where standards would simplify the way we view cannabis rather than adding layers of nuances that further complicate an already complex regulatory framework.

### Steps to Commoditization



- Modernizing how we talk about Cannabis
- 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.
  - Guides
    - For cultivation, processing, handling, distribution, testing, etc.
  - Practices
    - For safety, security, data entry, recordkeeping, quality management, etc.







Any cultivar of the cannabis plant that is cultivated for the purposes of collecting, isolating or extracting the flowers, essential oils, resins, saps or glandular trichomes for human and/or animal consumption.



Multi-purpose Cultivar



**Nutritional Cultivar** 

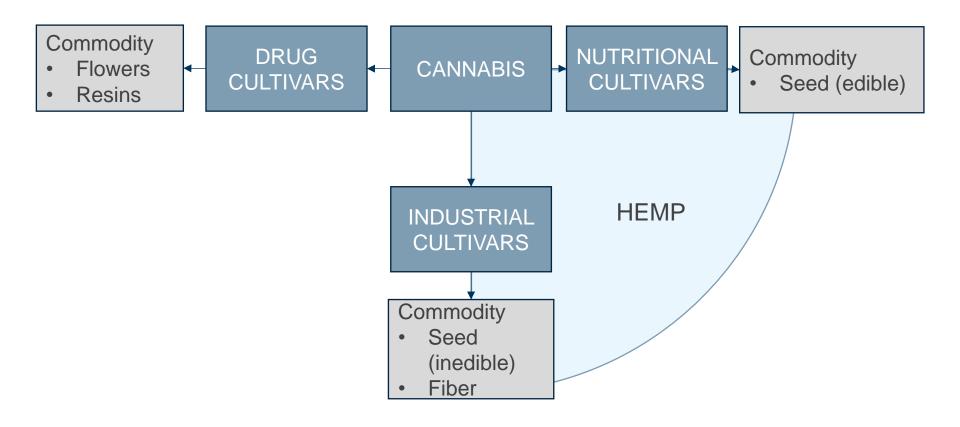
Any cultivar of the cannabis plant that is cultivated for the purposes of seed production or any other purposes intended for human and/or animal consumption except for the purposes of collecting, isolating or extracting the flowers, essential oils, resins, saps or glandular trichomes.



Industrial Cultivar

Any cultivar of the cannabis plant that is cultivated for the purposes of fiber, biofuels, bio/phytoremediation or any other purpose not intended for human and/or animal consumption.







Global Regulatory Status Resulting of		Status After	
Parts of the Cannabis Plant	(as of 18 Oct. 2017)	Processing	Processing
		Ethanol	Not Scheduled
		Resins	Schedule I
		Essential Oils	Schedule I
Flowers		Cannabinoids	Schedule I
& Leaves (when accompanying the flowers)	Schedule I	Glandular Trichomes	Schedule I
		Animal feed	Not Scheduled
Leaves (when separated from the flowers)	Controlled	Compost	Not Scheduled
		Animal Bedding & Feed	Not Scheduled
		Technical & Textile Fibers	Not Scheduled
		Shives	Not Scheduled
		Biochar	Not Scheduled
		Compost	Not Scheduled
		Biofuel & Ethanol	Not Scheduled
Stem/Stalk (fiber)	Exempted	And so much more	Not Scheduled
		Seed	Not Scheduled
		Animal feed	Not Scheduled
Grain (seeded flowers)	Schedule I	Compost	Not Scheduled
		Essential Oils	Not Scheduled
Roots	Not Scheduled	Compost	Not Scheduled
		Unshelled Seed	Not Scheduled
		Shelled Seed	Not Scheduled
		Seed Oil (edible & inedible)	Not Scheduled
Seeds (when separated from the flowers)	Exempted	Cake/Meal	Not Scheduled
		Resins	Schedule I
		Essential Oils	Schedule I
Glandular Trichomes	Schedule I	Cannabinoids	Schedule I



#### Potential Classification Structure – End Use

Cannabis Product	Drug	Nutritional	Industrial
Flowers	X		
Ethanol			X
Resins	X		
Essential Oils*	X	X	
Cannabinoids	X		
Glandular Trichomes	X		
Animal Bedding			X
Animal Feed		X	
Technical & Textile Fibers			X
Shives			X
Biochar			X
Compost			X
Planting Seed	X	X	X
Unshelled Seed		X	
Shelled Seed		X	
Seed Oil		X	Χ
Cake/Meal		X	

<sup>\*</sup>Essential oils from the flowers are Schedule I. Essential oils from the roots are NOT scheduled.



#### CBD and the Other Cannabinoids

- CBD and other cannabinoids are NOT explicitly scheduled, unlike THC and its isomers.
- Cannabis resins are explicitly scheduled.
  - Cannabinoids are produced along with the terpenes and other terpenophenolic secondary metabolites in the glandular trichomes of the cannabis plant.
  - The glandular trichomes are the cannabis plant's secretory cells which produce the resins.
  - CBD = Cannabinoid = Resin = Schedule I, regardless of the variety of the cannabis plant.
- Are cannabinoids nutritionally necessary?
  - Tests need to be created and conducted to determine the level at which cannabinoids are nutritional vs medicinal.
  - From these values, standards can be created for nutritional/dietary supplements, over the counter drugs and prescription medications.
- Diversion of THC is the main concern.
  - Agricultural, Processing & Handling, Quality Management and Testing Standards will assist in mitigating these concerns.









#### **DRUG PRODUCTS**

Areas where standards would aid in acceptance:

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











Areas where standards would aid in acceptance:

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















#### **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



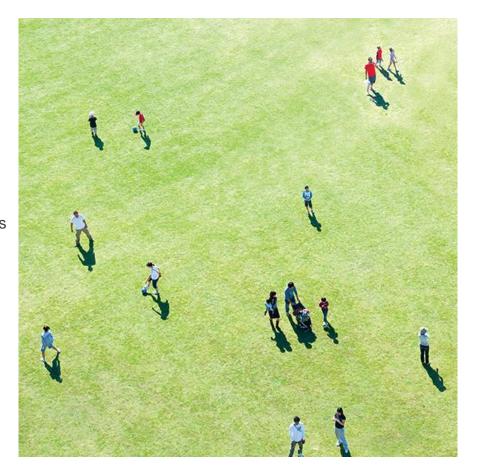




### **ASTM Standards and Cannabis**



Aerospace and Shipbuilding Agriculture Asset Management Automotive Building and Construction Chemicals Consumer Products **Energy and Utilities** Environment Food Processing Health Care and Medical Devices Cannabis Information Technology Manufacturing Metals Mining and Mineral Processing Oil and Gas Plastics Quality Safety and Security Services Sports and Leisure Textiles and Leather Transportation and Logistics





ASTM INTERNATIONAL Helping our world work better

# Thank You for Listening

www.astm.org

### References



- The Global Cannabis Industry, 2017, <a href="https://sensiseeds.com/en/blog/the-global-cannabis-industry-2017/">https://sensiseeds.com/en/blog/the-global-cannabis-industry-2017/</a>
- 2. United States Food and Drug Administration, Request for Comments on the Scheduling of CBD, <a href="https://www.regulations.gov/document?D=FDA-2017-N-4515-0001">https://www.regulations.gov/document?D=FDA-2017-N-4515-0001</a>
- 3. European Industrial Hemp Association, Cologne Declaration on Industrial Hemp, <a href="http://eiha.org/media/2017/07/17-06-06%20EIHA%20Cologne%20Declaration\_final.pdf">http://eiha.org/media/2017/07/17-06-06%20EIHA%20Cologne%20Declaration\_final.pdf</a>



# Cannabis and Cannabis Derived Products Risk and Role of Standards

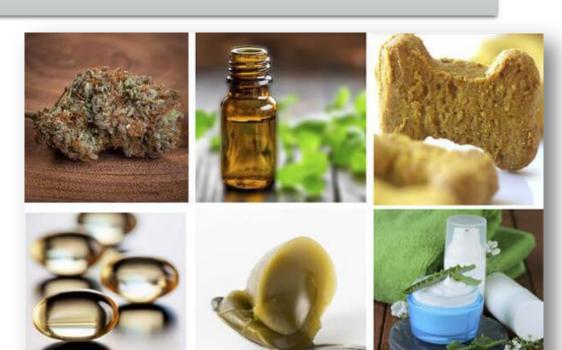




### Wide Range of Various Cannabis Products

Cannabis is consumed by various routes, with the most common route smoking, followed by vaporization, and then by the oral route.

Cannabis products
may be taken by
ingesting edibles,
sublingual or rectal
administration, via
transdermal
delivery, eye drops
and aerosols.





### **Risk Assessment**

- Drawing upon the variety of tools and methods applied in product evaluation and protection programs for other types of products, the Cannabis Compliance Framework identifies activities implemented by:
  - public health agencies,
  - standards management bodies,
  - compliance assurance bodies, and
  - by producers / product handlers
- to evaluate and ensure product quality.

There are various approaches to the assessment and management of hazards that can be applied to Cannabis Products.

### **Cannabis Compliance Framework**

Country Health Surveillance and Compliance Assurance

Best Practices
- Standards
Management

Compliance Assurance **HACCP** 

Hazard Analysis

Critical Control Point **Production Practices** 

**GAP** 

**GMP** 

**GHP** 

**GDP** 

GxP



# Cannabis Consumer Risks (1/4)

#### Cannabinoids

- At a minimum THC, THCA, CBD, and CBDA
- Appropriate dosing for individual use
- Overdose / side-effects
- Metabolomics fingerprinting for specific purposes

#### Heavy Metals

- Lead, mercury, arsenic, cadmium, chromium and others
- Cannabis is a bio-accumulator that recruits heavy metals from the soil into the plant biomass

#### Microbiology

- Mold / Mildew / Microbes / Fungus / Bacteria
- Specifically Aspergillus spp., Escherichia coli and Salmonella
- Potential pathogenic bacteria may be introduced from the soil, fertilizer, or human handling with inadequate hygiene (i.e., handwashing)
- Contamination risk by bacteria and insects is greatest in the indoor environment, is less in greenhouses, and less still in open air cultivation





# Cannabis Consumer Risks (2/4)



No current (2016) method is available:

- to certify organic cannabis culture, and
- there are no guidelines on acceptable pesticide levels for a smoked product.

### **Pesticides / Fungicides**

- An informal survey of California laboratories incidence of only 1–2% (2014)
- Prominent California analytical laboratories observed that 15–35% of samples submitted to them were positive (2014)
- A more formal published survey in California demonstrated qualitative presence of eight pesticides in 33% of samples (2015)
- An informal testing in Washington yielded pesticide residues in 5–10% of tested cannabis inflorescence samples (2014)
- An alarming study has demonstrated the passage of up to 70% of pesticides spiked into herbal cannabis into the captured smoke (2013)
- 26 distinct cannabis samples were purchased (24 concentrates, 2 cannabis inflorescence) from legal stores in Washington and passed via witnessed chain of evidence to a state certified legal licensed laboratory - out of the 26 Washington State samples, 22 tested positively for pesticides (84.6%) (2016)



# Cannabis Consumer Risks (3/4)

#### Radioactivity

 Some government-approved medicinal cannabis programs have utilized gamma-irradiation of cannabis for its sterilization

 No safety studies have been published to attest to the safety of the technique for a smoked or vaporized product

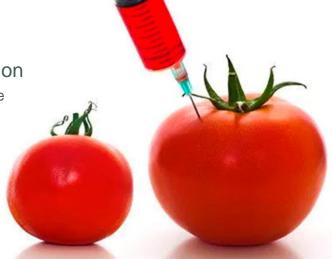
 Where cultivation/harvesting is in proximity to nuclear disasters (for example, Chernobyl and Fukushima)

#### Macroscopic / Microscopic Elements

- Consistency, debris, stems, seeds, contaminants and adulterants
- Added adulterants to plant materials have been documented in many locations to improve the appearance and weight

#### Volatile Organic Compounds (VOCs) - Residual Solvents

- Extracted concentrates of cannabis are formulated into hash oil, wax, butter (budder) and other forms
- Extraction takes place with any several types of solvents such as carbon dioxide, butane, propane, ethanol, isopropanol, acetone and others
- Solvent must be removed from the final product before consumption





# Cannabis Consumer Risks (4/4)

### Environmental Contaminants

 These are organic contaminants found in the environment and which can be found on botanical matter.

### The main ones are:

- Dioxins, furans and dioxinlike Polychlorinated biphenyls (PCBs) which can be found in botanical oils and fats
- Polycyclic aromatic hydrocarbons (PAHs)
  - 20 of 29 (70%) of tested samples of CBD oils / tinctures were carcinogenic (2017)





### **How do Cannabis Standards help?**

**Legitimacy for the Cannabis industry** 

Cannabis is safe for human consumption when proper standards are applied

Safe and stable herbal remedies are available when following standards



- Most of the best practices already exist from other areas (herbs cultivation, food supplements production, ...)
- Cannabis Analytical Testing standards are not so "stabilized"



### Which Best Practices would help most?

- Full disclosure / traceability principle in the cannabis value chain
- Batch sampling / testing
  - At least 10% of lots must be tested for contaminants
- Labelling
  - 95% confidence
- Certification
  - Representativeness of samples
  - CoA
  - Management systems
    - Hazard Analysis Critical Control Points (HACCP)
      - Good Manufacturing Practice (GMP)
      - Good Hygiene Practice (GHP)
      - Good Agriculture Practice (GAP)
      - Good Distribution Practice (GDP)

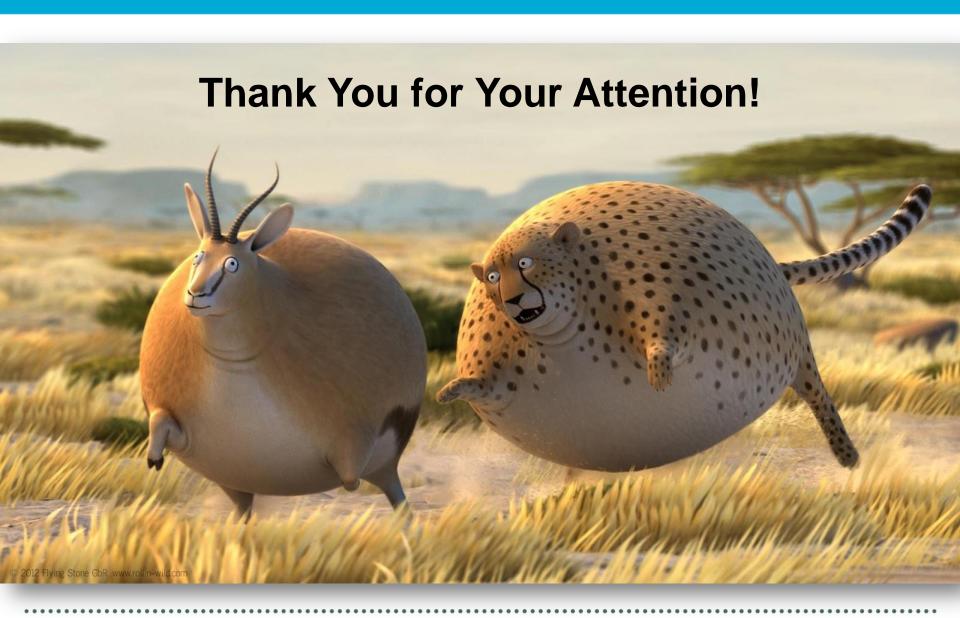




# **Questions?**









#### **ASTM INTERNATIONAL**

Helping our world work better

# Let's talk impact...

Implementing Standards

### Let's talk Impact - Agenda



**1400-1410** – Let's talk Impact – Background and Agenda

1410-1415 - Terminology - Darwin Millard

**1415-1430** – Audience Participation – Commonalities of Cannabis

**1430-1445** – Agriculture – Jeremy Applen

1445-1500 - Break

**1500-1515** – Audience Participation – How can we apply Agricultural Standards?

**1515-1530** – Processing – Darwin Millard

**1530-1545** – Audience Participation – How can we apply Processing Standards?

1545-1600 – Quality Management Systems – Andrew Samann

**1600-1615** – Audience Participation – How can we apply Quality Management Systems?

© ASTM International 10/20/2017 2

#### Let's talk Impact – What we're missing



D37.03 Laboratory

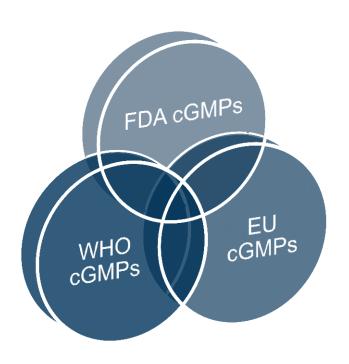
D37.05 Security and Transportation

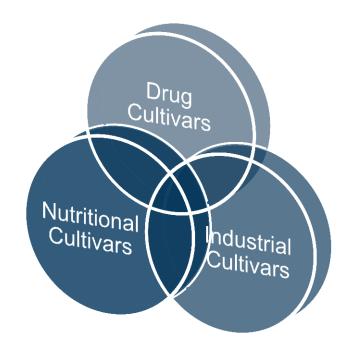
D37.06 Personnel Training, and Certifications

#### ASTM D37 – Where is the *Middle Ground?*



Pharmaceutical Good Manufacturing Practices have met the middle ground through global harmonization. How can we create *Cannabis Standards* that meet the needs of all market segments?





#### **ASTM Harmonized Cannabis Standards**



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, and Credentialing



### Barriers to Implementing Standards



- High startup costs
- Undefined processes
- Limited experience with cannabis manufacturing
- Limited budgets
- Start-up problems overwhelm new facilities long-term is not in sight
- Failing to plan (planning to fail)
- Over estimating revenue on decreasing commodity price
- Current high commodity price and lack of regulation provides insufficient impetus for standardizing process and practices
- Lack of leadership
- Lack of regulations requiring standards
- Consumer perceptions have not yet realized value of standards

## Project Management for Implementation



## Standards implementation requires project management.

- People Management
- Risk Management
- Project Initiation
- Project Delivery Planning
- Design Planning and Delivery
- Implementation
- Testing and Commissioning
- Project Close-Out

Most implementation failures are caused by **failing to plan**.

F	<ul><li>Company Planning</li></ul>	01/01/18	05/02/18	88d
P	Establish Executive Team	01/01/18	01/31/18	23d
	Establish Company Budget	02/01/18	02/14/18	10d
P	Conduct Market Research and Develop Strategy	02/14/18	02/28/18	11d
P	Complete Business PLan	02/28/18	03/16/18	13d
F	<b>Determine Products for Success</b>	03/01/18	03/09/18	7d
P	Establish Product Technology	03/09/18	03/23/18	11d
	Determine Quantity for Market	03/09/18	03/16/18	6d
P	Determine Processes for Product	03/23/18	04/06/18	11d
P	Determine Equipment for Processes	04/06/18	04/25/18	14d
P	Review Budgets, Costs, Expectations and Revise	04/25/18	05/02/18	6d
	Facility Planning	05/02/18	06/14/18	32d
P	Determine Equipment Footprints	05/02/18	05/08/18	5d
P	Find Suitable Location	05/08/18	06/06/18	22d
P	Facility Walk-through to Access State			
	Verify Location Will Meet Laws and Regulations	06/06/18	06/14/18	7d
P	Facility Design	05/07/18	05/09/18	3d
P	■ Contract OGS	05/07/18	05/08/18	2d
P	Design Facility for Process	05/07/18	05/08/18	2d
P	Determine Utility Needs	05/09/18	05/09/18	1d
F	Facility Review and Approval	05/02/18	05/09/18	6d
P	Contract Engineer or Architect	05/02/18	05/04/18	3d

Source: Orion GMP Solutions

## Audit Checklist Approach



#### **Audit Checklist Approach**

- Build processes around standards
- Ensure all elements are in place to meet standards
- Baseline future management review and quality audits
- Delegates tasks according to department

211.63 - equipment design, size, and	Is all equipment of appropriate design for its intended use?
location	Is all equipment of adequate size for its intended use?
location	Is all equipment suitably located to facilitate operations of its use and for its cleaning and maintenace?
	Is the equipment constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or adsorptive
	so as to alter the safety, identity, strength, quality, or purity of the drug?
211.65 - Equipment construction	Do any of the substances required for operation, such as lubricants or coolants, come in contact with components, drug product containers, closures, in-
	process materials, or drug products so as to alter the safety, indentity, strength, quality, or purity of the drug product beyon the official or other established
	requirements?
	Is all equipment and untensils cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions or contamination that would alter the
	SISQP of the drug product?
	Are there written procedures that are established and followed for cleaning and maintenance of equipment, including utensils, used in
	manufacturing, processing, packing, or holding of the drug product?
	Has the responsibility for cleaning and maintaining equipment been assigned?
211.67 - Equipment cleaning and	Are there established maintenance and cleaning schedules, including where appropriate, sanitizing schedules?
maintenance	Is there a description in sufficient details of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of
	dissassembling and reassembling equipment as necessary to assure proper cleaning and maintenance?
	Are previous batch identifiers removed from all equipment?
	Is there protection for clean equipment to prevent contamination before its next use?
	Is there inspection criteria for equipment cleanliness immediately before use?
	Is there a system for recording all maintenance, cleaning, sanitizing, and inspecting as specified in 211.180 and 182?
	Is all automatic, mechanical, and electronic equipment routinely calibrated, inspected, or checked according to a written program designed to assure proper
	performance?
211.68 - Automatic, mechanical, and	Are there written records of calibration checks and inspections?
electronic equipment	Are there appropriate controls to assure that changes in master production and control records or other records are instituted by authorized personnel?
	Are inputs to and outputs from computers or related systems of formulas or other records or data double checked for accuracy?
	Are backup files maintained where data is entered into a computer or related system?
	Do any filters used for liquid filtration release fibers into the product?
211.72 - Filters	Are any fiber-releasing filters used in production?
	If there are fiber-releasing filters beign used, are the fibers subsequently removed by 0.22 micron filtration?

Equipment

Source: Orion GMP Solutions

### Definitions in Cannabis Manufacturing



# Mr. Darwin Millard Co-Founder and Partner, Plant Consulting Group

## Proposed Modernizing Terminology





**Drug Cultivar** 

**Nutritional Cultivar** 

Any cultivar of the cannabis plant that is Any cultivar of the cannabis plant that is Any cultivar of the cannabis plant that is cultivated first than purposes and ablied that is cultivated the purposes of the purposes of fiber, isolating or extracting the flowers. ... production or any other purposes biofuels, bio/phytoremediation or any essential birthesis, sapud, glanditional and/or supposes. Cannabis that is grown for human tricommensercial mapphications amay not be appropriate for human an animal consumption publications amay not be appropriate for human analyzanianal consumption publications. consumption of the contamination of the contaminati

### **Audience Participation**



What are the barriers to implementation?

Where are potential problems with project management for starting a Cannabis Manufacturing?

Where are there conflicts of interest between different segments of the cannabis industry?

How would standards limit opportunities for business?

#### Agricultural Standards for Cannabis



## Mr. Jeremy Applen Founder and CEO, Sprout Quality

### Agriculture Standards



#### **Existing Agriculture Practice Standards**

- World Health Organization Good Ag and Collection Practices
- Food and Agriculture Organization of the United Nations (FAO)
- USDA Good Agriculture Practices
- Food Safety Modernization Act

#### Elements of GAP

- Soil
- Water
- Animal/Wildlife Health and Welfare
- Healthcare and Public Health

#### **Social Equity**

- Cost of Compliance
- Economic Impact to Small Producers



#### Land Use Risk Assessment



Sample SOP: Land Use Risk Assessment

Revision: 3.0 Date: 7/2/2014

1—Purpose

Describes how to assess previous and nearby land use for risks to make sure that they are not a source of contamination to fresh fruit and vegetables.

2—Scope

**Applies to** people involved in deciding where crops are to be planted or those responsible for assessing produce fields prior to planting.

3—Responsibility

Prior to planting, farm owners/managers should evaluate previous and nearby land uses for possible sources of contamination and document the assessment. When necessary, actions should be taken to correct or reduce contamination risks that are identified to prevent contamination of the produce crop.

4—Materials

Land Use Risk Assessment Log

5—Procedure

Review and assess field risks including previous and adjacent land uses.

Check sewage treatment or septic systems on site (if present) to make sure they are properly maintained to prevent contamination to fields and water sources.

Review condition and location of sanitation units in the field to make sure they are properly located and have not leaked or spilled.

Assess wildlife activity by reviewing the Wildlife and Domestic Animal Activity logs. Determine whether actions need to be taken to minimize animal activity in produce fields.

Gather information related to application of chemicals to land or near your fields that may pose a food safety hazard.

Review your water sources including wells, open water sources, and municipal systems to ensure there are no potential sources of contamination nearby.

Assess impact from nearby land. Be sure to evaluate animal operations that are nearby your land, talk with neighbors about their current land uses, and gather information about previous land uses.

Choose fields for production based on where there is the least likelihood of contamination.
Source: Cornell University College of Agriculture and Life Sciences

#### Land Use Risk Assessment



Task	Yes or No	Observations	Corrective Actions	Date	Initials
Are there any current or previous land uses that may represent a risk of contamination to fruit and vegetable production?					
Have there been any significant changes to land use this year (e.g. addition of grazing animals, field location changes)?					
Has there been any runoff from compost and manure storage areas, animal pens, or grazing areas?					
Were there any flooding events this year or last year?					
Have you inspected your well head to make sure it is in good condition and not in need of any repair?					
Have you inspected your septic tank and leach field to make sure they do not lead to contamination of produce fields?					
Are portable toilets and handwashing stations used in the field functioning properly (i.e. no leaks or spills) and located away from produce growing and handling areas?					
Have there been any treatments or chemical applications to the land that may pose a risk to food safety?					
Has fecal contamination or damage to crops by wildlife or domestic animals been an issue in the past year? (Check Wildlife and Domestic Animal Activity Logs)					

Source: Cornell University College of Agriculture and Life Sciences



Management Area	Best Practice	Minor Adjustments Needed	Concerns Exist; Examine Practice	Needs Improvement: Prioritize Changes Here
Source of irrigation water for produce crops	Irrigation water is from a municipal, treated water source or from ground water obtained from a properly constructed, capped well, in good condition, that could be readily treated if indicator organisms were detected in annual water tests.	Irrigation water is sourced from an uncapped well.	Irrigation water is drawn from a surface water source with no knowledge of its microbial quality.	Irrigation water is sourced from a pond or other water source that has daily visits by livestock or wild animals <b>OR</b> little is known about irrigation water source.
Source of water for topical sprays	Spray water is from a municipal, treated water source or from ground water obtained from a properly constructed, capped well, in good condition, that could be readily treated if indicator organisms were detected in annual water tests.	Spray water is sourced from an uncapped well.	Spray water is drawn from a surface water source with no knowledge of its microbial quality.	Spray water is sourced from a pond or other water source that has daily visits by livestock or wild animals <b>OR</b> little is known about the water source.
Water Testing. See Water Use introduction for more specific recommendations	All water sources are tested for indictor organisms such as thermotolerant coliforms and generic E.coli AND these records are kept on file.	All water sources are tested <b>BUT</b> records are not maintained.	Water used for washing and cooling produce is tested <b>BUT</b> surface water used for irrigation is not tested. No records are kept.	No water tests are done and no attempt is made to get water test results from municipalities. No water records are kept.

Source: Cornell University College of Agriculture and Life Sciences



Management Area	Best Practice	Minor Adjustments Needed	Concerns Exist; Examine Practice	Needs Improvement: Prioritize Changes Here
Awareness of watershed concerns	The findings and efforts of local watershed committees are known. It is also known if water is drawn from a low, medium or high priority watershed.	General watershed issues are known but specific concerns with surface water quality, including indicator organisms, are not known.		Potential watershed or water quality concerns that affect surface water on the farm are unknown.
Monitoring of sediment levels in surface water used for irrigation	Water is not used for irrigation when water is cloudy (high turbidity). Settling ponds are used to reduce sediment content of irrigation water prior to application to crops. Records are kept.	Water turbidity is monitored prior to irrigation and occasionally water may have a high turbidity when drawn for irrigation. Records are kept.	Water applied to produce crops is often turbid or cloudy.	No effort is made to monitor the turbidity of surface water prior to application or to reduce sediment content of irrigation water prior to application to crops.
Irrigation method	Drip irrigation is used on produce crops <b>OR</b> furrow irrigation is used with no plant wetting.	Overhead or flood irrigation with ground water that is known to be free from pathogens is used on all produce crops.	Overhead or flood irrigation water is sourced from a surface water from source with no known upstream contamination points.	Overhead or flood irrigation with surface water that is known to have upstream practices that affect quality and increase microbial risks to water.
Backflow prevention	Anti-backflow or check valve devices are installed on all plumbing systems, and no cross connections exist between water supplies.	Anti-backflow devices are installed on some faucets with hose connections. Air gaps are maintained.		No anti-backflow devices are installed and cross connections may occur.

Source: Cornell University College of Agriculture and Life Sciences



Management	Best	Minor Adjustments	Concerns Exist;	Needs Improvement:
Area	Practice	Needed	Examine Practice	Prioritize Changes Here
Use of self-assessments (e.g. Farm-A-Syst¹) or consultants to reduce negative environmental impacts of farming practices	An assessment of farm environmental impacts has been conducted and changes have been made to farm practices to reduce risk of manure movement and soil erosion from fields or barnyards into water courses. These records are on file.	An assessment of environmental impacts has helped identify problem areas on the farm, and efforts are currently being made to reduce manure movement and soil erosion from fields or barnyards into water courses. These records are on file.	An assessment of farm impacts on water quality has identified problem areas on the farm, but no changes are being made to address these problems.	There has been no assessment of water quality impacts of current farm management practices.

Source: Cornell University College of Agriculture and Life Sciences



#### **Irrigation and Spray Water Quality Action Plan**

Date: Reviewer:					Field or Commodity:				
		=		Here	Your Plans to Reduce Risks				
Management Area	Best Practice	Minor Adjustment	Concerns Exist	Prioritize Changes	Action for Improvement	Person Responsible	Estimated Cost	Target Date	
Source of irrigation water for produce crops									
Source of water for topical sprays									
Water Testing See <i>Water Use</i> introduction for more specific recommendations									
Awareness of watershed concerns									
Monitoring of sediment levels in surface water used for irrigation									

Source: Cornell University College of Agriculture and Life Sciences



#### **Irrigation and Spray Water Quality**

Date:	Reviewer:	Field or Commodity:

Management Area		ŧ	Adjustment Concerns Exist	Here	Your Plans to Reduce Risks				
		Minor Adjustme		Prioritize Changes	Action for Improvement	Person Responsible	Estimated Cost	Target Date	
Irrigation method									
Backflow prevention									
Use of self-assessments (e.g. Farm-A-Syst¹) or consultants to reduce negative environmental impacts of farming practices									

<sup>1.</sup> Please see Farm-A-Syst web site for additional information: http://www.wisc.edu/farmasyst/.

Source: Cornell University College of Agriculture and Life Sciences

### Sanitizing Harvest Bins and Harvest Aids



Sample SOP: Cleaning and Sanitizing Harvest bins and Harvest Aids

Revision: 1.0 Date: 07/22/2014 1—Purpose

**Describes how food contact** surfaces, tools, and equipment are to be cleaned and sanitized.

#### 2—Scope

**Applies to** farm and packinghouse personnel including farm owners and workers.

#### 3—Responsibility

Worker's are responsible for **following the SOPs** to properly clean and sanitize food contact surfaces.

Farm owners and food safety managers are responsible for training the workers on proper technique, providing necessary resources such as tools, detergents and sanitizers, and making sure the cleaning and sanitizing steps are followed correctly.

4—Materials

**Detergent** name, brand, and concentration (labeled for use on food contact surfaces) [Provide name here]

Sanitizer name, brand, and concentration [Provide name here]

Container(s) as needed for mixing and using detergent(s) and sanitizer(s) or for washing tools

Brushes, sponges, or towels for scrubbing tools and equipment

Clean water (microbial equivalent to drinking water)

#### 5— Procedure

**Step 1.** Rinse all loose soil and debris from the harvest container or harvest aid with potable water.

**Step 2.** Wash harvest containers or harvest aids with soap and warm to hot potable water.

**Step 3.** Before adding a sanitizer such as bleach, determine the water pH using a pH test strip or a pH meter. The water pH should be between 6 and 7.5.

**Step 4.** Place 1-2 tablespoons of common household bleach (5.25-6 percent active ingredient, nonscented and splashless) per gallon of potable water into a pail, bucket or sink. This equals a 100-200 parts per million concentration. Use a test strip to determine ppm.

**Step 5.** Dip the nonporous harvest container or harvest aid into the sanitizing solution for 2 minutes. Porous containers will require a higher concentration of household bleach (600 ppm).

**Step 6.** For porous surfaces, rinse with potable water.

Step 7. Allow bins and harvest aids to air dry before using.

Step 8. Store sanitized containers appropriately. (See guidelines listed under "Harvest Bins, Knives, Pruners and Other Harvest Aids.")

Source: Cornell University College of Agriculture and Life Sciences

## Sanitizing Harvest Bins and Harvest Aids



		Cleanii	ng List (chec	k each)			Cleaned
Date	Knives	Buckets	Gloves/ Aprons	Packaging Containers	Other	Treatment	by (initials):
9-17-13	C/S	С		C/S		Washed with dishwashing soap, rinse with tap water, sanitized with 100 ppm chlorine solution dip for 20 seconds.	GLW

Source: Cornell University College of Agriculture and Life Sciences

## **Processing Cannabis Raw Materials**



# Mr. Darwin Millard Co-Founder and Partner, Plant Consulting Group

## D37.04 on Processing and Handling



#### **Current Work Items**

- 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 (classifications and specifications)
- WK60434 \* Cannabis Extraction Equipment (classifications and specifications)
- WK60435 \* Solvent Based Cannabis Extraction Equipment (classifications and specifications)
- WK60446 \* Standard Practice for labeling and packaging of cannabis product for consumer use (i.e., recreational/adult and medical use)



#### **ASTM INTERNATIONAL**

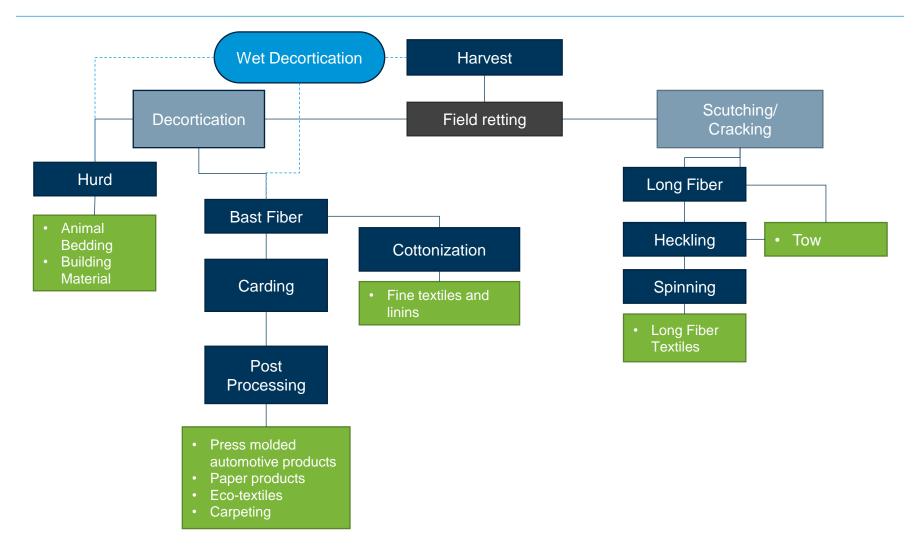
Helping our world work better

## Introduction to Fiber Processing

Traditional Field Retting, Wet Decortication & Potential Standards

### Cannabis Fiber Manufacturing Processing





### **Natural Fiber Processing**



#### Retting

- 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 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.)



- Chemical properties
- Physical properties
- Structural properties
- Test Methods for validating specifications
  - Limits of detection
  - Analytical equipment
- 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









#### **ASTM INTERNATIONAL**

Helping our world work better

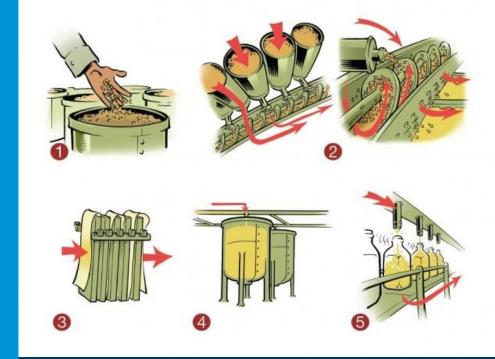
## Introduction to Seed Oil Production

Overview, Process Description & Potential Standards



## Overview Of The Seed Oil Manufacturing Process

- Seeds are separated from the flowers and then cleaned and graded
- Seeds appropriate for pressing are segregated from those intended for shelling (commercial scale)
- Seeds are cold pressed using expeller presses to extract the oils
- Raw oil is filtered to remove any contaminants (e.g. seed parts)
- Oil can then be further processed to improve flavor, color and consistency
- Oil is then stored until packaged



- 1. Source high quality seed
- 2. Cold pressing (below 50°C)
- 3. Filtering
- 4. Refinement & Storage
- 5. Nitrogen Packaging\*

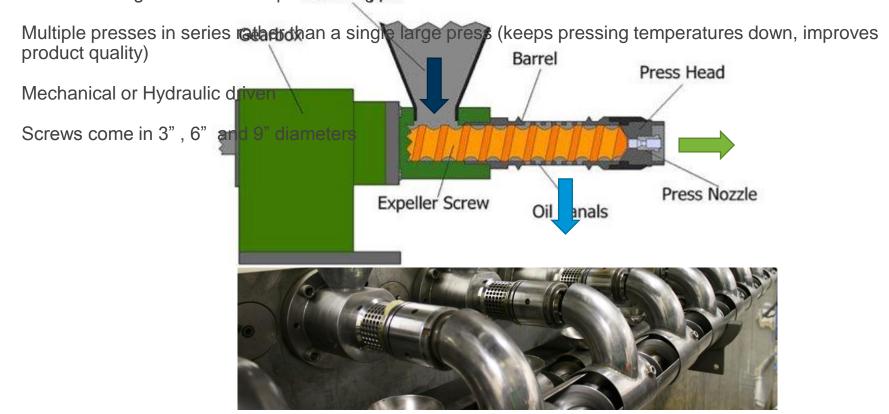
10/20/2017 31

## The Cold Pressing Process



Process Efficiency: 60% - 80% of available oil is extracted on the first pass – Cake can be further extracted to get the remaining oil

"Cold Pressing" below 50°C to prevent dropped ation of the volatile EFAs



## Cold Pressing Hemp Seed





Hemp Oil Canada's \$50M Processing Facility <a href="https://www.youtube.com/watch?v=lhEen\_oA4Bo">https://www.youtube.com/watch?v=lhEen\_oA4Bo</a>

#### Potential Standards for Seed Oils



- 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 seed oils (THC content, Omega-3 & Omega-6 content)
  - Chemical properties
  - Physical properties
- Test Methods for validating specifications
  - Limits of detection
  - Analytical equipment
- Guides and Practices for growing, harvesting, processing, material handling, testing, disposal, etc.

## Commoditizing the Cannabis Plant







Areas where standards would aid in acceptance:

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









#### **ASTM INTERNATIONAL**

Helping our world work better

## Introduction to Phytocannabinoid extraction

Extraction Process, Solvents Used & Potential Standards



#### Phytocannabinoid Extracts



#### Whole Plant

- Multiple synergistic constituents
- Ensemble Effect
- Considered more effective than synthetic cannabinoids and single molecule preparations
- Varying composition
- Concentration: 40% 80% w/w



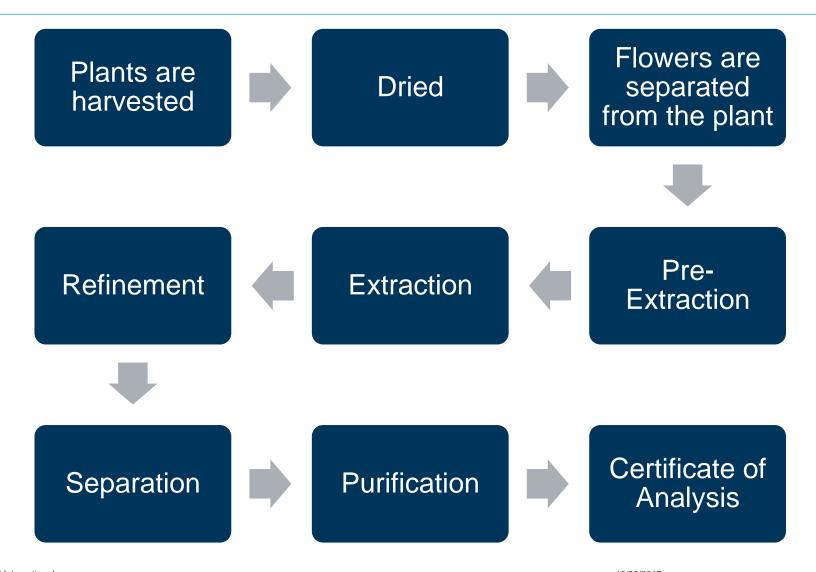
#### Mono-cannabinoid

- Single cannabinoid
- Known composition
- Ideal for formulation
- Concentration: 98+% w/w



## Overview of the Phytocannabinoid Extraction Process





# **Designing Extraction Trains**





- Whole Plant Extract
- Acid/Neutral Form
- Analytically Pure Extract



- Polar or Non-Polar
- Melting Point
- Vapor Pressure



Solvent

- Polar or Non-Polar
- Selectivity
- Refinement



- Bench Top, Pilot, or Commercial
- Validation
- Equipment Availability

Economic & Environmental Impact

- Solvent Choice
- Scale of Operation
- Waste

# Solvents Used in Industry



Organic Liquid Solvents – traditional solvents used for centuries, inexpensive, some waste, 90+% recycling efficiency

- Methanol, Ethanol, Hexane & Cyclohexane, Chloroform
- Some are known carcinogens and poisons, unfit for human consumption, requiring strict safety and handling as well as mandatory residual solvent analysis

CO2 – standard in pharmaceutical industry, inexpensive, carbon neutral, high batch to batch reproducibility, 90+% recycling efficiency

Highly selective

Propane & Butane – used in no other industry to produce extract intended for human consumption

 Extremely flammable, appropriate HVAC, VOC, and explosion precautions required when operating in an enclosed space

# Phytocannabinoid Extraction Considerations



#### Compliance is key

Stay on top of globally changing regulations – Single Convention

#### Know your building, electrical and fire codes

- Mistakes will lead to costly downtimes or worse
- Class 1 Division 1 Requirements (intrinsically safe, explosion proof, spark-less environments) ATEX Zone 0, I and II and IECEx equivalence

#### VOC ventilation is critical

- CO2 is a dense gas that sinks to the ground, and expands rapidly causing asphyxiation and death
  - Complete air exchange in under 60 seconds
- Propane < Butane < Air

### Not all equipment is the same

 Stamped and Certified pressure vessels and connecting lines are critical (ASME VIII Boiler and Pressure Vessels)

#### Reclamation of Used Solvent

- Environmental impact
- May contain contaminants
- Must be redistilled prior to reuse

# Potential Standards for Phytocannabinoid Extracts



- Terminology
  - Extract vs Concentrate
  - Cannabinoid vs Phytocannabinoid
- Classification of flower type (medical, recreational)
  - Grades (A, B, etc.)
- Classification of extract type (medical, recreational)
  - Grades
- Specifications for extracts (cannabinoid & contaminant content)
  - Chemical properties
  - Physical properties
- Test Methods for validating specifications
  - Limits of detection
  - Analytical equipment
- Guides and Practices for growing, harvesting, processing, material handling, testing, disposal, etc.

# Commoditizing the Cannabis Plant







#### **DRUG PRODUCTS**

Areas where standards would aid in acceptance:

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





© ASTM International 20 October 2017 4



#### **ASTM INTERNATIONAL**

Helping our world work better

# Introduction to Quality Management System Elements



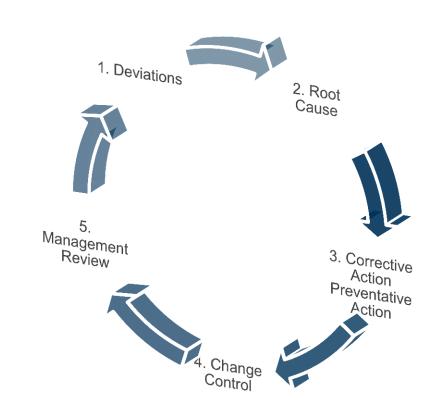
# **Quality Management System Elements**



Quality Management Systems are used by manufacturers of almost every industry.

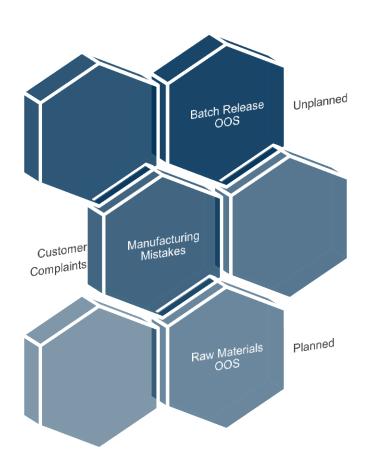
The elements of Quality
Management Systems varies, but
all such systems function to
captures process related
deviations, correct them, and
make sure that they don't happen
again through documented change
control.

Management Review ultimately puts all quality related issues in front of leadership.



## **Deviations**





Deviations are when documented processes are not executed as per the organization's policies.

Deviations are primarily concerned with manufacturing, however, Quality Control units utilize these systems as well.

All personnel in manufacturing, QC, or QA have the responsibility to initiate deviations when a process does not go as planned.

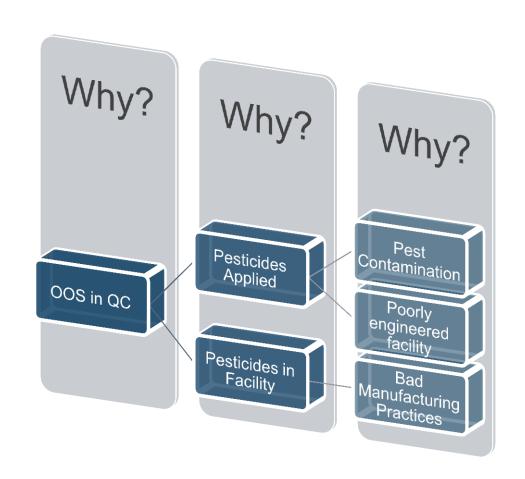
# **Root Cause Analysis**



Root cause analysis is an essential component of any Quality Management System.

It is the method used to clearly define where problems in manufacturing exist, and ensure that problems are fully characterized and understood.

Typical methods include the "Five Why's."

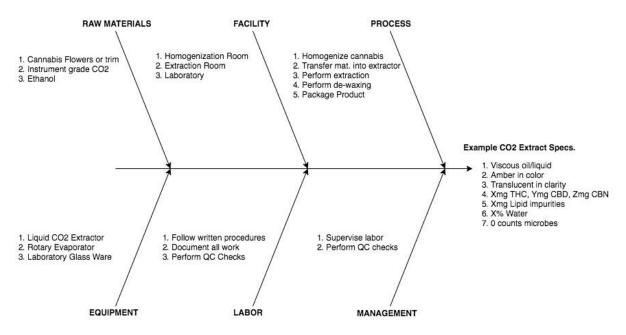


## Corrective Action – Preventative Action



CAPA is a process that ensures problems are immediately corrected, then prevented from occurring again.

Where has the manufacturing process failed? How can we be sure the failure never happens again?



Source: Orion GMP Solutions

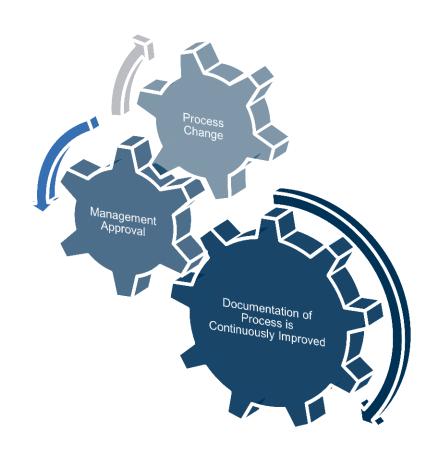
# Change Management



Change Management is the institutionalization of changing process in manufacturing.

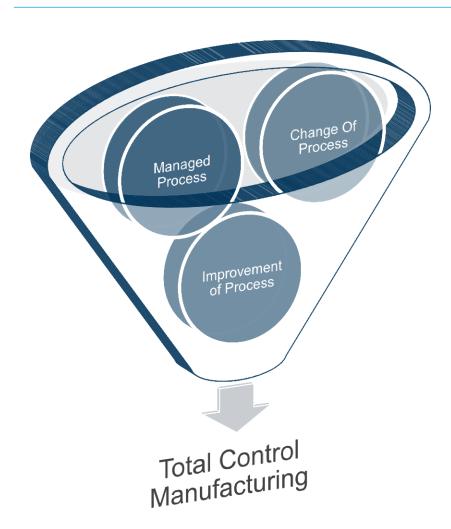
It is an indispensable tool for ensuring that documentation of all process changes are sent through the appropriate leadership and management channels.

The approval of such changes is dependent on management approval, and ultimately is the ultimate tool of continuous improvement.



# **Management Review**





Leadership and Management is responsible for all failures and success of an organization.

Management Review is understanding the process, identifying opportunities for improvement of process, and ensuring the process is executed according to Standard Operating Procedures.



ASTM INTERNATIONAL Helping our world work better

# Early Engagement Standardization

Christine DeJong
Director, Business Development
D37 Hemp and Cannabis Workshop

11 October 2017 Berlin, Germany www.astm.org

### Considerations



### Where does the marketplace look like?

- Do you know your industry needs standards?
- Does your industry have or anticipate regulatory or codes oversight?
- Is there a market demand for 3<sup>rd</sup> party oversight?
- Is there a baseline of products that is in the market or will be in the next 1-3 years?
- Is there widespread, or even diverse, R&D entities active?
- Is there a lack of trust or perception of reliability by users/consumers in the marketplace?
- Is the cost of getting product to market higher than manufacturers believe is reasonable?

When? Why? How?

# Research and Development



### It's early, but products are in demand?

- Innovation is evolution
  - Products aren't stagnant, neither are standards
- ASTM standards & committees evolve with industry
  - What baselines can be achieved to establish safety, quality and reliability for consumers?

- Regulations take longer to revise
  - Hinder innovation
  - Too prescriptive drives cost up!
- Proactive engagement increases trust in consumers
  - Marketability and accountability



© ASTM International 20 October 2017

# Research and Development



### Exchange of knowledge but not divulgence of secrets

- Technical Workshops
  - Sharing of knowledge with standards in mind
- Industry Strategy Development
  - Exploration of standards needs and program development
- Parallel Development
  - Earlier stage development => earlier to market
  - What's the needed solution, write standards for primary program needs
- Start Small
  - Task group 1 draft
  - Subcommittee small compilation
  - New Committee Industry wide solution



© ASTM International 20 October 2017 4

# Early Engagement with Peers



### Partnerships and Alliances

- New industries, young strategies
- Engagement in ASTM increases opportunities
  - Networking
  - Supply Chain representation
  - Education on innovation
- Save resources
  - Divide and conquer
  - ASTM platform and experience



© ASTM International 20 October 2017

# **ASTM Business Development Team**



#### A Resource for You

#### Explore, Plan, Organize and Launch Standardization Needs

- Get Stakeholders to the Table
- Standards training and impact awareness
- Strategize and draft roadmaps

#### Explore and strategize new programs and services

- Ensure standards integrate into desired solutions
- Training and eLearning
- Certification (personnel and product)
- Proficiency Testing Programs
- Alternative Deliverables (databases, apps, checklists, etc)

#### Foster and Establish Relationships and Partnerships

- Leveraging organizational strengths
- Increasing awareness
- Collaborating towards solutions

© ASTM International 20 October 2017 6