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Cannabis Testing Labyrinth

Navigating the Regulatory Pitfalls of Cannabis Lab Testing



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Webinar Topics

- How state and federal regulatory agencies regulate cannabis lab testing.
- Economic and legal risks facing industry from the hemp farm through retail.
- Tips and Strategies to enhance the likelihood of success.



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State and Federal Regulation of Cannabis Lab Testing





Regulatory Cannabis Lab Testing

- Cannabinoids
- Terpene Content
- Mycotoxins
- Heavy Metals
- Moisture Content,
- Residual Solvents,
- Pesticides
- Microbial Impurities



**BUREAU OF
CANNABIS
CONTROL**
CALIFORNIA

ALL CANNABIS HARVESTED ON OR AFTER 1/1/2018 AND ALL CANNABIS PRODUCTS MANUFACTURED ON OR AFTER 1/1/2018, SHALL BE TESTED ACCORDING TO TITLE 16 OF THE CALIFORNIA CODE OF REGULATIONS, SECTION 5715, AND THE REGULATIONS THAT FOLLOW.

PHASE-IN OF REQUIRED LABORATORY TESTING	INHALABLE CANNABIS	INHALABLE CANNABIS PRODUCTS	OTHER CANNABIS & CANNABIS PRODUCTS
JANUARY 1, 2018			
Cannabinoids Testing	✓	✓	✓
Moisture Content Testing	✓		
Category II Residual Solvents and Processing Chemicals Testing		✓	✓
Category I Residual Pesticides Testing	✓	✓	✓
Microbial Impurities Testing (A. fumigatus, A. flavus, A. niger, A. terreus)	✓	✓	
Microbial Impurities Testing (Escherichia coli and Salmonella spp.)	✓	✓	✓
Homogeneity Testing of Edible Cannabis Products			✓
JULY 1, 2018			
Category I Residual Solvents and Processing Chemicals Testing		✓	✓
Category II Residual Pesticides Testing	✓	✓	✓
Foreign Material Testing	✓	✓	✓
DECEMBER 31, 2018			
Terpenoids Testing	✓	✓	✓
Mycotoxins Testing	✓	✓	✓
Heavy Metals Testing	✓	✓	✓
Water Activity Testing of Solid or Semi-Solid Edibles	✓		✓



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Regulatory Cannabis Lab Testing

Illinois: Immediately prior to manufacturing or processing, each batch shall have a random sample collected and tested:

1. microbiological contaminants;
2. mycotoxins;
3. pesticide active ingredients;
4. residual solvent; and
5. purposes of conducting an active ingredient analysis.



State Level Cannabis Lab Testing



Delaware has one of the **least** comprehensive statutory frameworks

- **Pesticides:** Use of pesticides is statutorily prohibited.
- **Potency:** The total milligrams of active cannabinoids and terpenoids in the product must be available upon request.
- **No Heavy Metals Requirement:** There are no **heavy metals** testing requirements in the Delaware statutes.



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Federal Level Cannabis Lab Testing



THC Testing



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Hemp & Marijuana – 2018 Farm Bill

Hemp is defined under the 2018 Farm Bill to include any cannabis plant, or derivative thereof, that contains not more than 0.3 percent delta-9 tetrahydrocannabinol ("THC") on a dry-weight basis.



The 2018 Farm Bill directs the USDA to issue regulations and guidance to implement a program for the commercial production of industrial hemp in the United States.

THC Concentration

A “sample test result showing with at least 95% confidence that the THC content of the sample is higher than the acceptable hemp THC level shall be conclusive evidence that one or more cannabis plants or plant products from the lot represented by the sample contain a THC concentration in excess of that allowed under the Act.”

Hot Lots must be **DESTROYED**



Enforcement Discretion



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Disposal Options



Enforcement Discretion

1. Plowing Under
2. Mulching/Composting
3. Disking
4. Bush Mower/Chopper
5. Deep Burial
6. Burning



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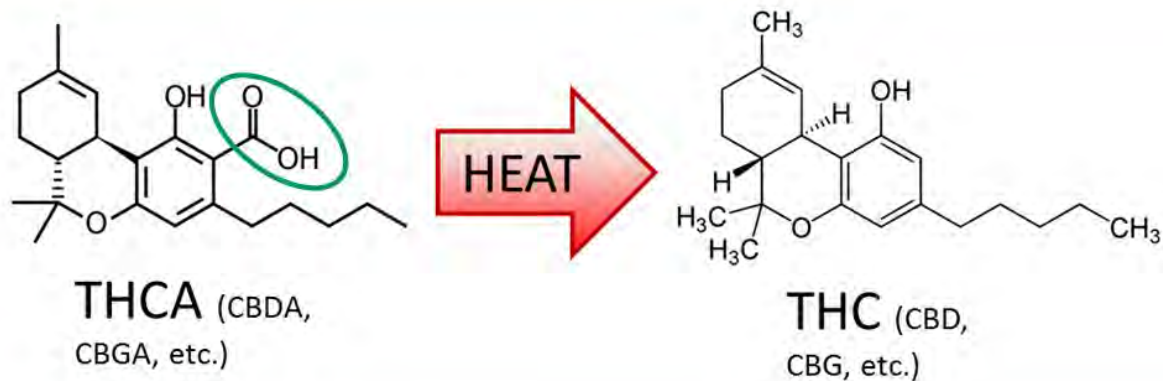


Why THC Testing Protocols are So Problematic.



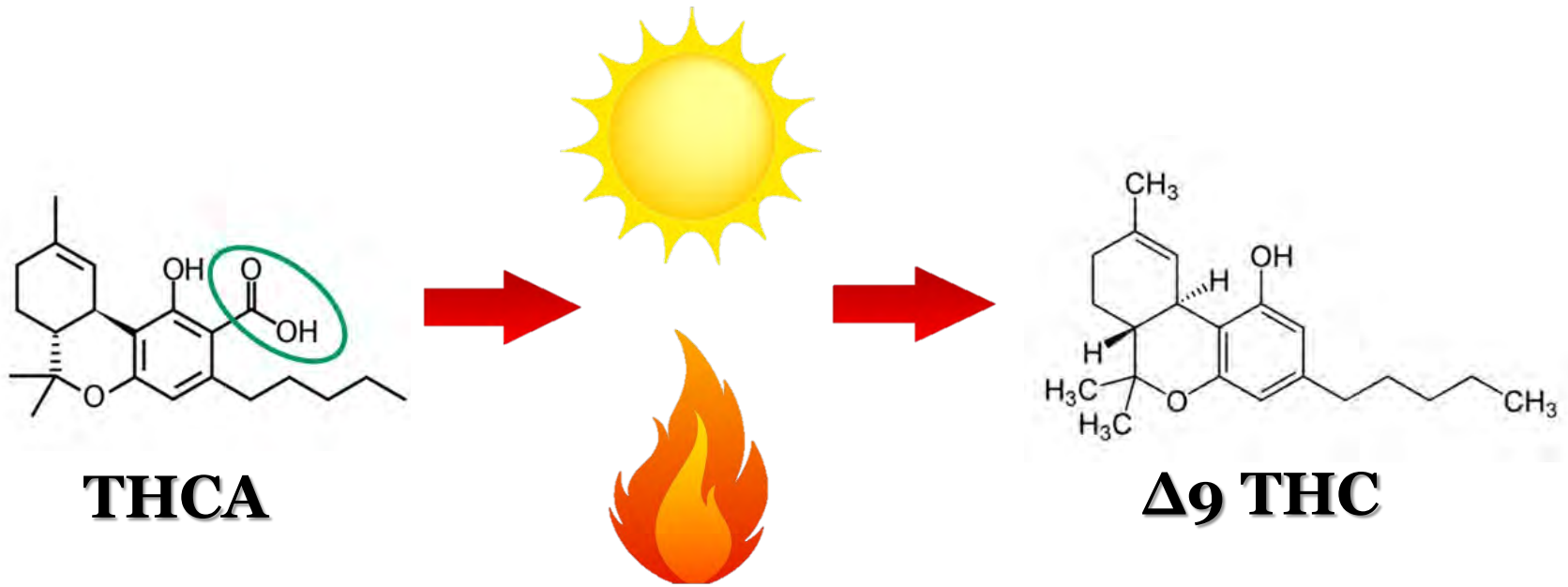
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THCA vs. THC



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DECARBOXYLATION PROCESS



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THC & THCA

Total THC = ($\Delta 9$ THC) + (87.7% THCA)

MOU: USDA requires the uncertainty in test results be accounted for through the “measurement of uncertainty”

AMBIGUITY: Statute specifically references $\Delta 9$ THC.



Certificate of Analysis			
Client:	Anandia Sample ID: V1908_0908-001		
Strain: Ambition (Blue Dream)			
Lot #: 19-318			
Authorized By:			
CoA Prepared: 17-Aug-19	Said Zeinab Senior Manager, Quality Control		
Potency		wt %	mg/g
Total THC equivalents	($\Delta 9$ -THC + $\Delta 9$ -THCA x 0.877)	20.98%	209.82
Total CBD equivalents	(CBD + CBDA x 0.877)	BLQ	BLQ
Most abundant minor			
CBGA		wt %	
CBCA		0.09%	
		0.07%	
Terpenes			
Most abundant of the			
alpha-Pinene		wt %	
beta-Myrcene		0.050	
beta-Pinene		0.047	
Limonene		0.041	
trans-Caryophyllene	0.133	trans-Verololol	0.039
	0.087	alpha-Humulene	0.034
Loss on Drying		7.3%	
Contaminant Analysis			
Microbial Quality			
Total aerobic microbial counts		pass	
Total yeast and mold counts		pass	
Bile-tolerant gram-negative bacteria		pass	
E coli		absent	
Salmonella spp		absent	
Aflatoxins	Aflatoxin B1, B2, G1, G2	pass	
Heavy Metals	Arsenic, Cadmium, Lead, Mercury	pass	
Pesticides		None detected	



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THC Testing Regulations



At a minimum, analytical testing for THC concentration levels must use post-decarboxylation or ***other similarly reliable methods.***

Interim Rule: The testing methodology must consider the potential conversion of THCA in hemp into THC and the test result reflect the total available THC derived from the **sum of the THC and THC-A content.**



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Lab Testing Methodologies

Most Common Testing Methodologies

1. High-Performance Liquid Chromatography (HPLC)
2. Liquid Chromatography Mass Spectrometry (LC-MS)
3. Gas Chromatography Mass Spectrometry (GC-MS)



Mitigating Economic and Legal Risks

1. Test Your Laboratory
2. Contract Away the Risk
3. Weigh Cost vs. Risk
4. Do the Right Thing



What's Next?



THANK YOU!

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