Vermont Regulatory Requirements for Hemp Sampling, Inspections, and Testing

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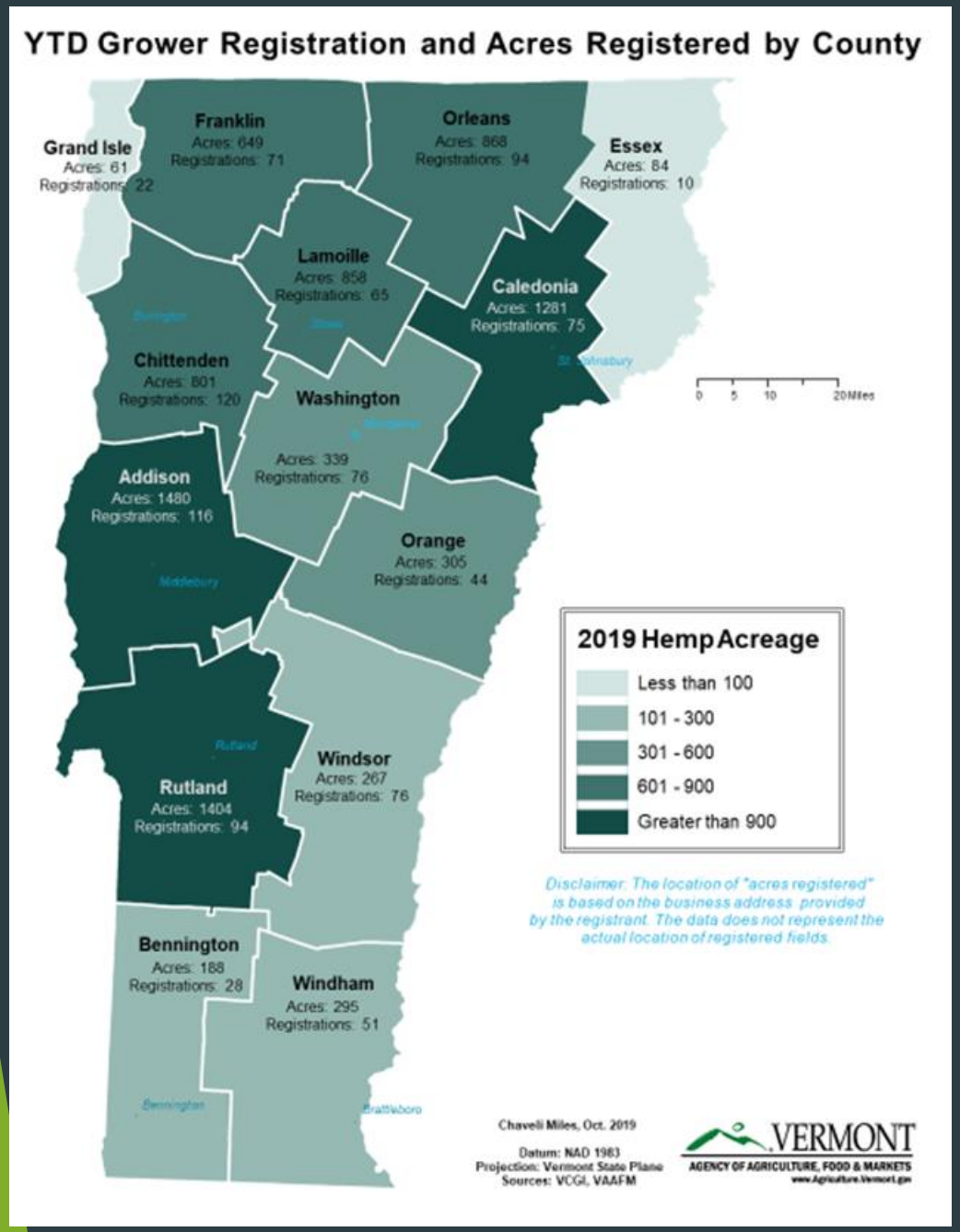
Robert Shipman and Mike DiTomasso



2019 Hemp production by Vermont County

- Just under 1,000 registered growers
- Just under 300 registered processors
- Over 9,000 acres registered

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Vermont Hemp Program and Rules

- Establishing the requirements for the registration of growers, processors of hemp and hemp-infused products, and certified labs
- Establishing an inspectional program for hemp registrants, and setting parameters for sampling requirements
- Communication with Law Enforcement
- Creating a Cannabis Quality Control Program
  - Consumer protection
  - Support the industry

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2020 New Registration Fees

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- $25 - For personal use grower registration.
- $100 - for food oil, grain and fiber production regardless of acres planted
- $100 - Less than 0.5 acres planted or less than 500 pounds processed
- $500 - 0.5 to 9.9 acres planted or less than 10,000 pounds processed
- $1,000 - 10 to 50 acres planted or less than 50,000 pounds processed
- $3,000 - Greater than 50 acres or greater than 50,000 pounds

Indoor cultivation (bringing crops to flower under lights)

- $1,000 - 500 Sq. ft or less; $2,000 - Greater than 500 Sq. Ft
- One fee for registering as a grower and a processor
- The fee to grow exclusively indoors is separate from the outdoor hemp grower fee that is based on acreage.

Lab Certification $1500

Who is a Grower?

- Growing includes all aspects of cultivating and harvesting hemp
- Growing also includes drying hemp that a registrant grows, in a facility owned, operated, or leased by the registrant
- Pruning, bucking, and any other methods involved in plant maintenance or harvesting is considered growing

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Who is a Processor?

* Processing does not include making a finished product from a hemp extract or isolate that is already compliant with Vermont's acceptable potency level

- Trimming hemp that you grow for a finished product requires that you register as a processor
- Drying a hemp crop that you did not grow requires that you register as a processor
- Processing also includes transporting, handling, or packaging hemp from a single or multiple growers if taking ownership of the hemp

Pre-Harvest Sampling for Potency Compliance

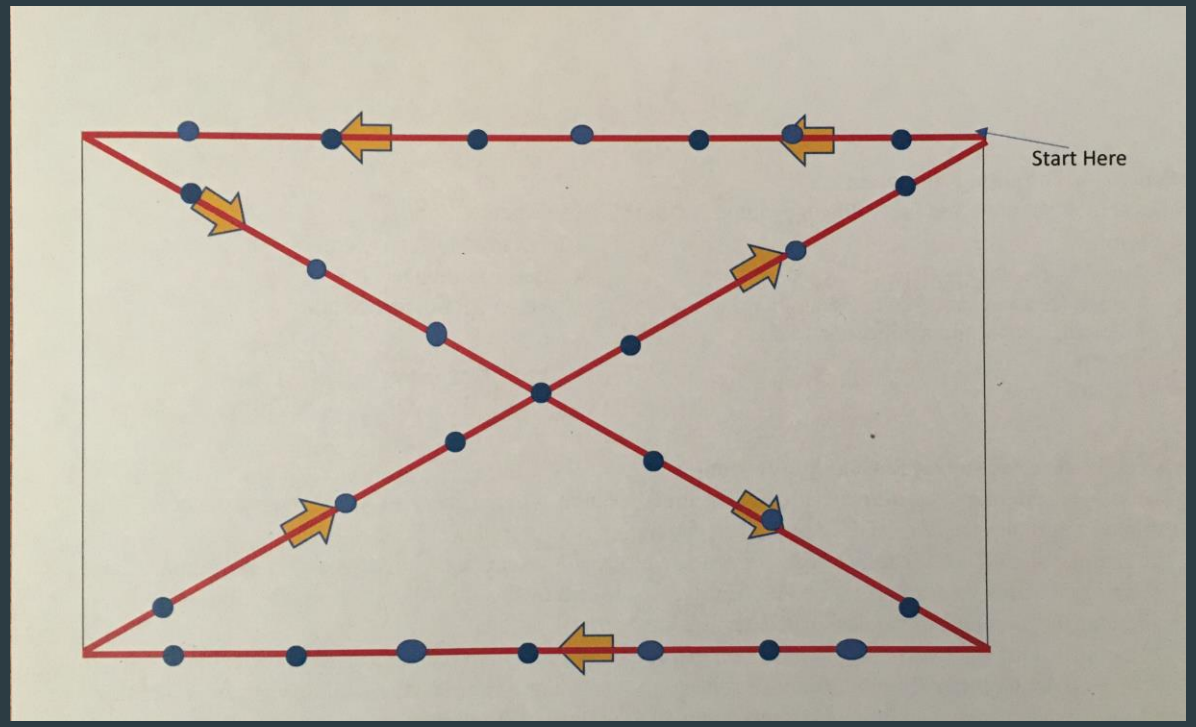
- Harvest Lot - Means a contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or cultivar of the Cannabis Sativa L. plant throughout the area

- Sampling of harvest lots must be taken prior to harvesting, and completed separately for each harvest lot
- Samples must represent a homogenous composition of each harvest lot, and must not be comingled with other lots
- A hemp pre-harvest sampling form must be completed at the time sampling is performed
- All samples taken for potency compliance must be submitted to a certified laboratory

Harvest Lot Sampling Protocols and Procedures

- Samples for a determination of compliance must be taken during flower and not more than 28 days before harvest
- Sampling must be completed by the registrant, or if completed by someone else, the registrant must be present
- The sampler shall take 2 inches of floral material from side arm flowers
- The sample shall not contain dead, diseased, or pest infested material
- The sampler shall select plants to be sampled based on the prescribed sampling pattern

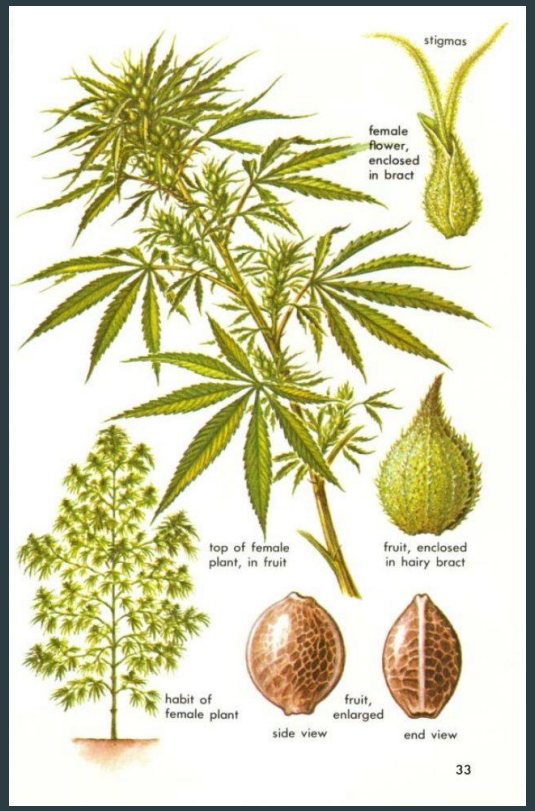
Prescribed Sampling Pattern



- The sampler must follow this X pattern to the extent possible. Any deviations must be recorded in the pre harvest sampling form
- At the conclusion of sampling, the sampler should have 29 cuttings, unless the harvest lot is smaller than 29 plants
- The sampler must take a minimum of seven samples per row of each harvest lot
- No more than 29 cuttings are required when the harvest lot exceeds one acre.

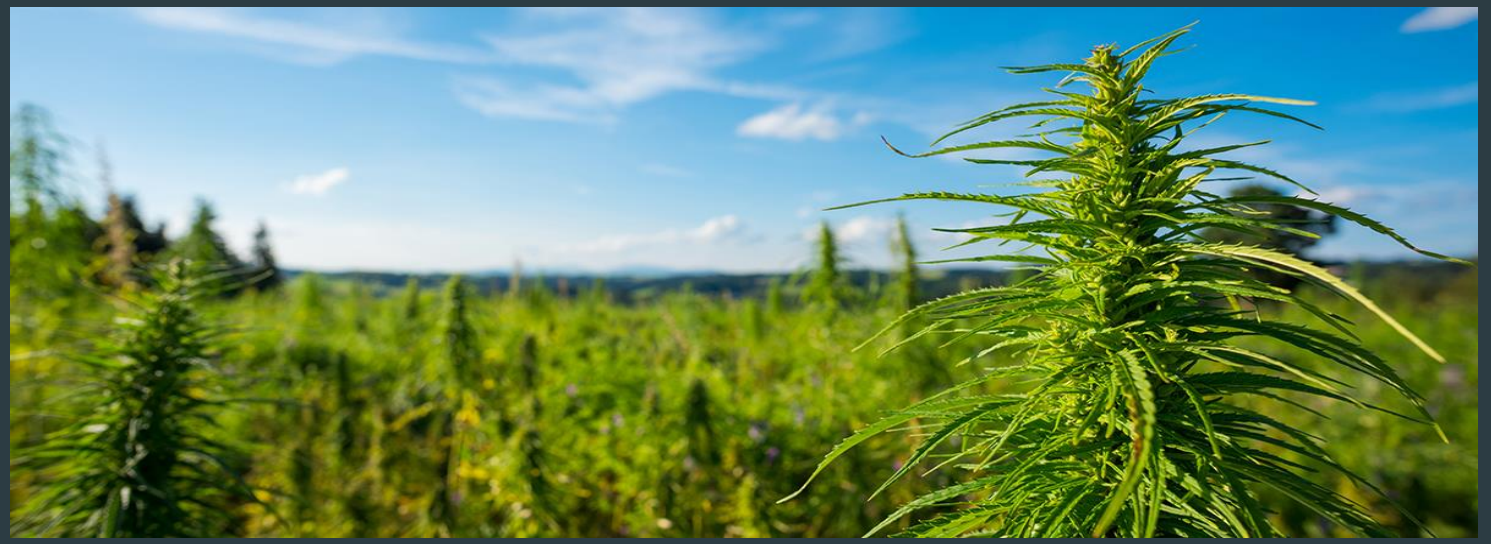
Hemp Pre-Harvest Sampling Form

- A hemp pre-harvest sampling form must be filled out after each harvest lot is sampled
- The sampler must outline their sampling pattern using an aerial map of each harvest lot



- The sampler must record the date, time, cultivar sampled, and assign each harvest lot a harvest lot number.
- The sampler must bring when submitting samples to the certified laboratory.

What to Expect During an Inspection



- VAAFM will be conducting routine inspections of all hemp registrants throughout the year
- Inspectors will take samples of hemp crops and hemp products for monitoring and research purposes
- VAAFM will inspect growing areas, processing facilities, machinery, equipment and records
- Registrants should have copy of their registration, certificates of analysis (CoA), pre-harvest sampling form, seed / clone purchase receipts, and other required records
- Inspections will be documented with pictures and notes

Hemp Investigations

VAAFM will be conducting investigations as well as inspections

- Responding to complaints:
- Seed / nursery stock complaints
- Odor complaints
- Product complaints
- Concerns over potency

- Investigations related to incorrect registration information
- Suspected registrants or hemp products in violation

- Investigations will include taking samples
- Review of records such as registration, sales receipts and invoices, certificates of analysis
- Investigation of facilities, fields, equipment and more
- Pictures and other forms of documentation will be used

CBD is everywhere

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Proposed Testing Requirements

FROM: Vermont Hemp Rule and the Cannabis QC Program (currently being drafted)

- Pre-harvested crops- Potency (for THC, CBD, etc)
- Trim flower- potency, moisture content, microbiological
- Concentrated oils/ solids from extraction-
  - potency, microbiological, heavy metals, pesticides
- Consumer infused products- edibles, tinctures
  - Similar testing to concentrated products or verification of concentrate testing

Vermont Hemp Rules
Cannabis Quality Control Program

- Testing for potency (including product labeling)
  - HPLC (most common test) - identifies acids
    - Total theoretical THC = (Delta-9 THC) + (THC-A x 0.877)
  - GC analysis will yield total values for CBD and THC
  - Genetic testing- researching with VAEL

Grinding Hemp Samples

Cannabis Potency Analysis using HPLC

Standard Compound List	
d9-THC	d9-Tetrahydrocannabinoid
d8-THC	d8-Tetrahydrocannabinoid
THCA	d9-Tetrahydrocannabinolic acid
THCV	Tetrahydrocannabivarin
CBD	Cannabidiol
CBDA	Cannabidiolic acid
CBDV	Cannabidivarin
CBG	Cannabigerol
CBGA	Cannabigerolic acid
CBN	Cannabinol
CBC	Cannabichromene
Click to view the Cannabis Alkaloids	

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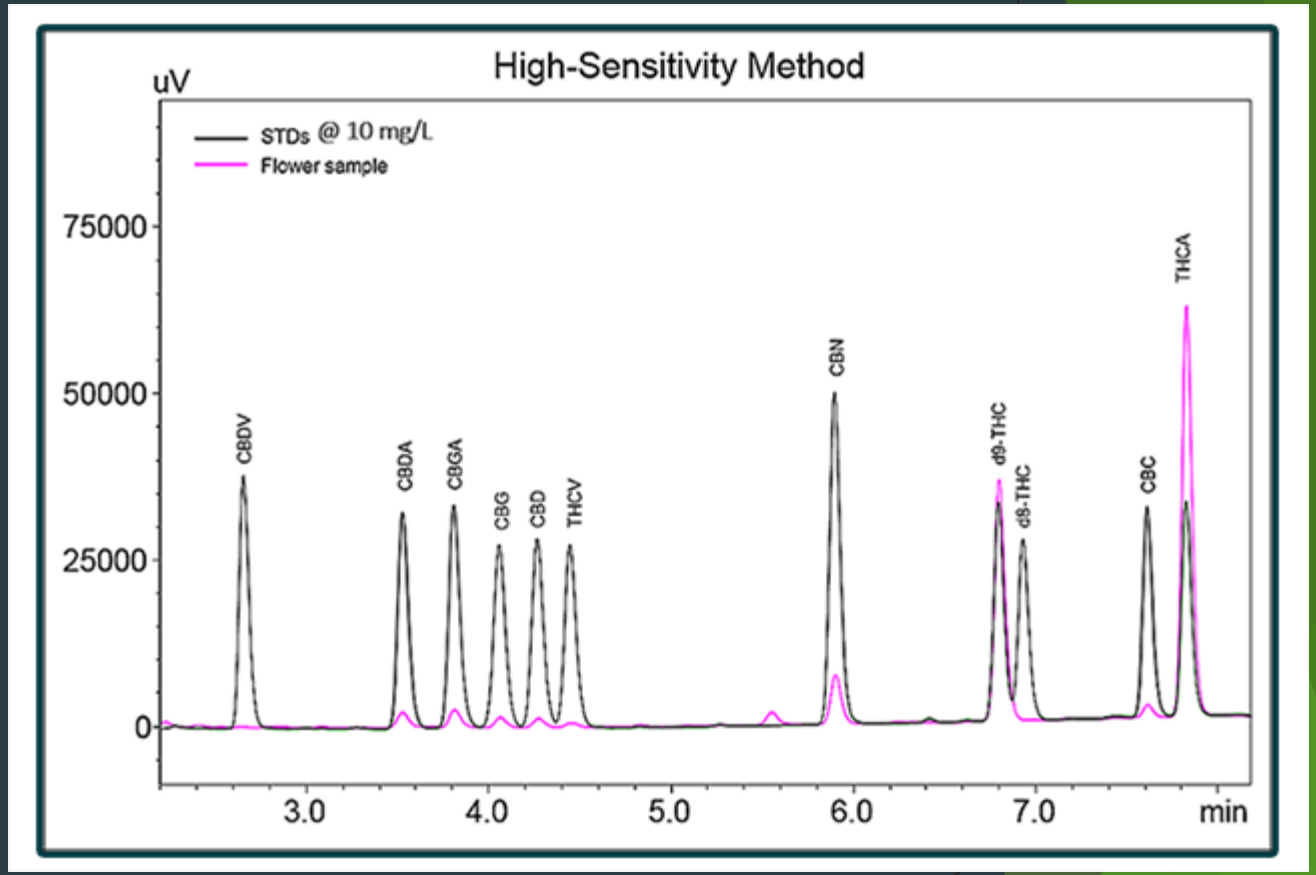
Cannabis Potency Analysis using HPLC

- Chromatogram
  - Standard (in black)
  - Cannabis sample (purple)
  - UV detection



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Certificate of Analysis (CoA) for Potency

Cannabinoids listed

Cannabinoid Profile	%	mg/g
Tetrahydrocannabinolic Acid (THCa)	0.561	5.61
Tetrahydrocannabinol (Δ9-THC)	ND	ND
Tetrahydrocannabinol (Δ8-THC)	ND	ND
Tetrahydrocannabivarin (THCv)	ND	ND
Cannabidiolic Acid (CBDa)	14.650	146.50
Cannabidiol (CBD)	0.196	1.96
Cannabidivarin (CBDv)	ND	ND
Cannabinol (CBN)	ND	ND
Cannabigerolic Acid (CBGa)	0.646	6.46
Cannabigerol (CBG)	ND	ND
Cannabichromene (CBC)	0.060	0.60
Total THC	**0.492%**	**4.923 mg/g**
Total CBD	**13.044**	**130.443**

Total THC and CBD reported (Hemp sample)

Formula for calculations

Total THC = THCa * 0.877 + Δ9-THC
Total CBD = CBDa * 0.877 + CBD

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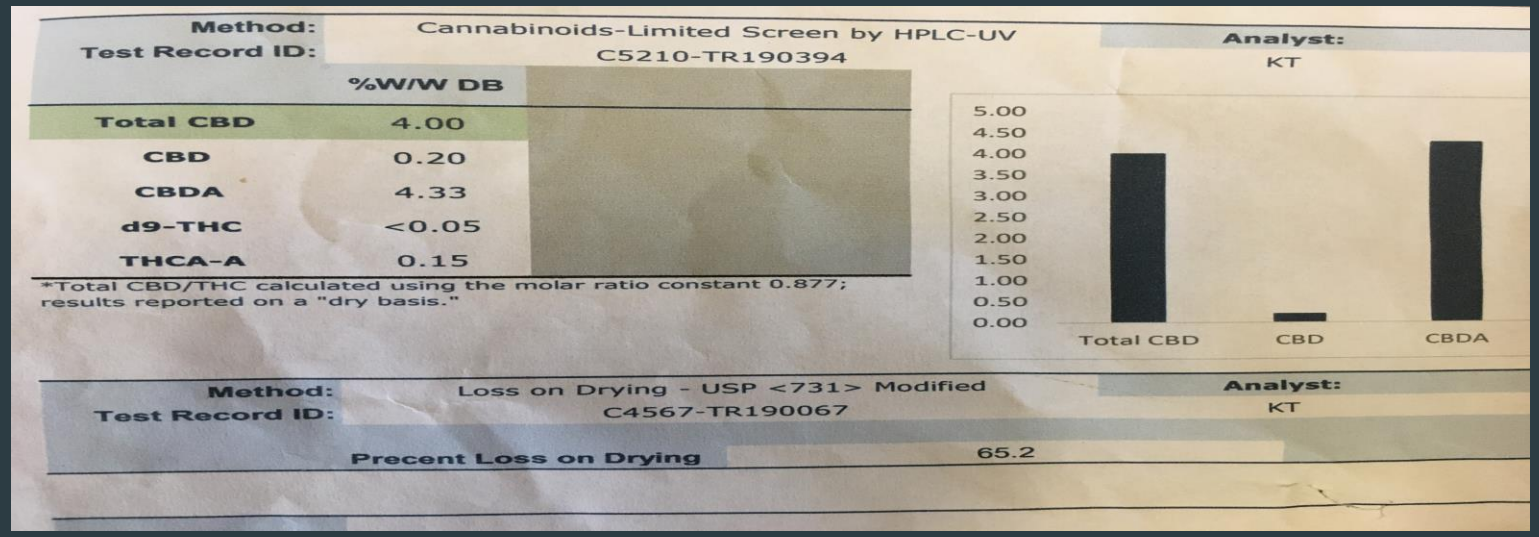
Vermont Hemp Rules Interpreting a COA
When total THC is not reported- calculating total THC



Method: Cannabinoids-Limited Screen by HPLC-UV
Test Record ID: C5210-TR190394
Analyst: KT

	%W/W DB
Total CBD	4.00
CBD	0.20
CBDA	4.33
d9-THC	<0.05
THCA-A	0.15

*Total CBD/THC calculated using the molar ratio constant 0.877; results reported on a "dry basis."

Method: Loss on Drying - USP <731> Modified
Test Record ID: C4567-TR190067
Analyst: KT

Precent Loss on Drying	65.2

- Total (theoretical) THC = (<0.05% or 0%) + (0.15% x 0.877) = 0.13%
- This is a compliant hemp harvest lot
  - the delta-9 THC concentration is < 0.05% or (< 0.3%)
  - Additional limitation: the total THC concentration is 0.13% (< 1%)
- Make sure the results are reported in dry weight!

Cannabis Extractions (Processing)

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Vermont Hemp Rules
Cannabis Quality Control Program

- Testing for contaminants
  - Microbial- mold, fungus, bacteria, mycotoxins
  - Heavy Metals
  - Pesticides
  - Residual Solvents

  The program is currently designing the criteria:
    - When to test/ which tests/ parameters/ “action” levels

Hemp Plants Contaminated with Mold

- Hemp plants with obvious signs of mold must not enter commerce

Lab certification/accreditation

- USDA recommends ISO 17025 adherence
  - (IFR Requires ISO 17025, and DEA registration)
- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
- Accreditations- several ISO based programs
  - (Hemp/Cannabis testing is a new area)
  - NELAC, ANAB, A2LA, +
  - Specific cannabis programs
    - CANNALAP, Cannabis Testing LAP, +
- AAFM will certify laboratories (ISO formats)

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Considering ISO 17025 Requirements

- Quality Management System (QA program)
- Validated methods
  - AOAC and ASTM have working methods and methods in development- may allow verification
  - AOAC has standard method performance requirements (SMPRs) for hemp analysis
- Standard Operating Procedures (SOPs)
- Personnel training/education
- Proficiency testing
- Sample handling and storage
- Calibration and QC procedures
- Measurement and standard traceability
- USDA IFR: Measurement Uncertainty (MU) 0.31% ± 0.02%

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Using a Certified Laboratory

- For a Certificate of Analysis (COA) to be official, it must be issued by a lab certified by the Vermont AAFM Hemp Program

- All other Certificates or Lab Reports are only reports. These reports are good for :
  - Monitoring crop CBD and THC levels
  - Estimation of potency or contaminant levels

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Research: Genetic Testing- alternative to Potency?

New Phytologist (2015) 208: 1241-1250 U MN

Cannabis Science and Tech (nov/dec 2019) V2, No 6, 42-46 Digipath, Inc

New Phytologist

Research

Gene duplication and divergence affecting drug content in *Cannabis sativa*

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Key words: cannabidiol (CBD), cannabinoids, domestication, hemp, marijuana, tetrahydrocannabinol (THC).

Summary

- *Cannabis sativa* is an economically important source of durable fibers, nutritious seeds, and psychoactive drugs but few economic plants are so poorly understood genetically.
- Marijuana and hemp were crossed to evaluate competing models of cannabinoid inheritance and to explain the predominance of tetrahydrocannabinolic acid (THCA) in marijuana compared with cannabidiolic acid (CBDA) in hemp. Individuals in the resulting F_2 population were assessed for differential expression of cannabinoid synthase genes and were used in linkage mapping. Genetic markers associated with divergent cannabinoid phenotypes were identified.
- Although phenotypic segregation and a major quantitative trait locus (QTL) for the THCA/CBDA ratio were consistent with a simple model of codominant alleles at a single locus, the diversity of THCA and CBDA synthase sequences observed in the mapping population, the position of enzyme coding loci on the map, and patterns of expression suggest multiple linked loci. Phylogenetic analysis further suggests a history of duplication and divergence affecting drug content.
- Marijuana is distinguished from hemp by a nonfunctional CBDA synthase that appears to have been positively selected to enhance psychoactivity. An unlinked QTL for cannabinoid quantity may also have played a role in the recent escalation of drug potency.

Application of a Simple Genetic Assay to Discriminate Hemp from Drug-Type Cannabis

The explosion in the hemp industry within the United States has created confusion for state regulators and hemp farmers. The passage of the 2018 Farm Bill provides for the widespread planting of hemp containing less than 0.3% tetrahydrocannabinol (THC). While some hemp is being grown for fiber and seed, most of the 2019 hemp harvest is intended for extraction of cannabidiol (CBD). Therein lies the anxiety, since resinous hemp is often above that 0.3% THC threshold. An alternative to relying on THC content alone is to distinguish the categories of fiber hemp, resin hemp, and THC cannabis based on genetics. Here we report on the findings from the initial field evaluation of one such molecular DNA-based assay. The assay ID markers correctly identified 420 out of 420 individual seed, leaf, and flower cannabis samples. Correlation with a subset of available cannabinoid data shows that while low in THC content, 72% of these resin hemp samples fall outside of the 2018 Farm Bill's definition of hemp of less than 0.3% THC

A. Hilyard, S. Lewin, S. Johnson, P. Henry, and C. Orser

The Agriculture Improvement Act of 2018, otherwise known as the 2018 Farm Bill, was signed into law on December 20, 2018. The 2018 Farm Bill legalized the ...

Genetic differences between Hemp and MJ Cannabis

Application of Single Nucleotide Polymorphisms to Identify Hemp from CBD and THC Producing Cannabis

AAFM unit at VT Agriculture and Environmental Lab (VAEL)

Industrial hemp | Resin hemp | THC cannabis

Figure 1: Phenotypes of *Cannabis sativa* L.

Table I: Distinction by single nucleotide polymorphisms

Category	Mito_318'683	THCAS_8'374
Fiber hemp Fiber, seed, and by-product production	A/A	A/A
Resin hemp Oil production - CBD most abundant	C/C	A/A
THC cannabis Oil production - THC most abundant	C/C	G/G or G/A

Digipath beta research with NC, NV, and VT plants

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Table III: Analytical cannabinoid data for Tru-Hemp ID categorized samples

	Samples	Samples with Analytical Data	Avg. Total THC%	Avg. Total CBD%	Samples Above 0.3% THC	Sample % Above 0.3% THC
Fiber hemp	10	0	n/a	n/a	n/a	n/a
Resin hemp	100	47	0.40	9.16	34	72
THC cannabis	310	110	20.92	0.14	110	n/a

- Fiber hemp
- Resin (CBD) Hemp
  - 0.4% avg THC
  - 9.16% avg CBD
- THC Cannabis
  - 20.92% avg THC
  - 0.14% CBD

- 72% of resin hemp > 0.3%

Possible advantages to genetic testing (proposed to USDA as a similarly reliable method to potency)

Can test seeds to determine genetic make up

(Potency requires a mature plant)

Clones /transplants can be tested before planting

Leaf testing

Sample field crop before flowering

Leaf testing

More flexibility in 15-28 day harvesting schedule?

Avoids the 0.3% pitfall - Grow for max CBD!!!

DISADVANTAGE- less representative sampling (DNA overload of analysis)

High Seed $

VAEL is currently evaluating the Tru-Hemp using seeds and crops from 2019

A genetic qualitative test is not a potency quantitation
Biological vrs Chemical testing

Existing Regulatory Programs

- Seed Dealer /Nursery Dealer Programs
- Fire Safety Division- Processing activities
- Pesticide Program
- Seed Dealer Registration Program, S. 194
- Water Quality Program- Required Agricultural Practices
- Vermont Agricultural and Environmental Lab
- Water and Wastewater, Dept. of Environmental Conservation

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