

# Hemp Testing and Lab Certification for Compliance with the Vermont Hemp Program



# Today's webinar

- Pre-Harvest Sampling, Inspections, Investigations
- Background- creation of the Cannabis Quality Control Program
- Overview- required testing and status of Certified Labs
- Testing- now in effect
  - Table 2 required testing
  - Tables 3-8 parameters and action limits
- Process for becoming a certified laboratory
  - Overview - knowledge of rules
  - Requirements- accredited or applying for ISO/ using validated methods
  - Documentation/ reporting
  - Updated industry standards for storage, preparation, extraction and analysis

# 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 research purposes
- ▶ Sample results collected from an inspection are not considered official results for compliance purposes. Results can be shared with the registrant
- ▶ VAAFM will inspect growing areas, processing facilities, machinery, equipment, records etc.
- ▶ Registrants should have copy of their registration, certificates of analysis, pre-harvest sampling forms, seed / clone purchase receipts, and required records found in hemp rules
- ▶ Inspections will be documented with photographs and notes

# Hemp Investigations

VAAFM conducts investigations as well as inspections

- ▶ Responding to complaints:
- ▶ Seed / nursery stock complaints
- ▶ Product complaints
- ▶ Unregistered locations and incorrect registrations
- ▶ Suspected registrants or hemp products in violation



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

# Start Pre-Harvest Sampling Now

- Most crops are close to 28 days from harvest
- Review the pre-harvest sampling protocol
- Review the pre-harvest sampling form and required maps
- Identify your harvest lots
- Start communicating with a laboratory
- Take samples!
- Must harvest by Oct 31, 2020 to fall under the Vermont Hemp Rules pilot program

# Cannabis Quality Control Program

## Introductory Background

The Vermont Hemp Program is required to establish a cannabis quality control program under 6 V.S.A. § 567 for the following purposes:

- to develop potency and contaminant testing protocols for hemp and hemp-infused products,
- to verify cannabinoid label guarantees of hemp and hemp-infused products,
- to test for pesticides, solvents, heavy metals, mycotoxins, and bacterial and fungal contaminants in hemp and hemp-infused products, and
- to certify testing laboratories that can offer the services for cannabinoid label guarantees and contaminant testing.

**GOAL:** protecting consumers and ensuring the quality of the Vermont brand

# Cannabis Quality Control Program

## Background

The program will review lab procedures and protocols *to verify* that a laboratory seeking certification from the Agency of Agriculture, Food & Markets *meets the certification requirements and the following standards:*

- has reviewed the Vermont Hemp Rules,
- understands the testing requirements on hemp crops, hemp concentrates, hemp products, and hemp-infused products,
- has knowledge of the action levels of contaminants and potency requirements for regulatory compliance,
- maintains required documentation,
- participates in 3<sup>rd</sup> party proficiency testing and with the Agency if provided, and
- reports required information to the Hemp Program.

**A person must register as a certified laboratory to test hemp or hemp products under 6 V.S.A. § 564, for compliance testing.**

# OVERVIEW

## Required Testing for Fall Harvest 2020 (and current processing lots) for compliance in the Hemp Program

- Required testing for hemp crops, hemp concentrates, and hemp products and hemp infused products is listed on Table 2 of the Cannabis Quality Control Program document (and online).
- Table 3 through 8 list the testing parameters with the associated action limits. Includes potency, moisture, microbiological, heavy metals, pesticides and residual solvents.
- Any test result above an action limit indicates a failure for that process/harvest lot. Results must be at or below an action limit.
- Trimmed Flower is considered a process lot.

# OVERVIEW

## Certification of Laboratories

- The Hemp Program will begin certifying laboratories once the Cannabis Quality Control Program has been finalized.
- Testing samples for compliance with the Hemp Program will require a certified laboratory, once certified laboratories are in place.

# Table 2 Testing Requirements (Vermont Cannabis Quality Control Program)

	Potency	Moisture or Water Activity	Microbiological (mycotoxins, total aerobic microbial, total combined yeast & mold)	Heavy Metals	Pesticides	Residual solvents
<b>Harvest lot</b>						
	Each lot	Each lot	N/A	Note 5	Each Lot Note 6	N/A
<b>Plant material</b>						
<b>Trim flower</b>	Note 1	Each process lot	Each process lot	Note 1	Note 1	N/A
<b>Concentrates</b>						
<b>Liquids</b>	Each process lot	N/A	Each process lot	Each process lot	Each process lot	Note 3
<b>Solids</b>	Each process lot	N/A	Each process lot	Each process lot	Each process lot	Note 3
<b>Products and Infused products</b>						
<b>Liquids, including infused products (tinctures, and water based)</b>	Note 4	N/A	Note 2	Note 1 or Note 2	Note 2	Note 2 or Note 3
<b>Solids, including infused edibles, tablets</b>	Note 4	N/A	Note 2	Note 1 or Note 2	Note 2	Note 2 or Note 3

# Table 2 Notes

- **Note 1:** Harvest lot testing is sufficient to show compliance.
- **Note 2:** Trim flower or hemp concentrate testing is sufficient to show compliance.
- **Note 3:** Residual solvents are tested whenever solvent based extraction techniques are used.
- **Note 4:** Please apply Vermont Hemp Program Rule Section 8.3 (a) for potency. (Summarized, a hemp product or hemp-infused product process lot complies when a CoA demonstrates that the product meets the acceptable potency level or the processor's formulation demonstrates compliance with the acceptable potency level.) Please apply Vermont Hemp Program Rule Section 6 for processors. (Summarized: all claims of a specific quantity of any cannabinoid must be analyzed at least once to confirm formulation).
- **Note 5:** Testing for heavy metals is required whenever the hemp crop land was used for orchard crops or any land use other than farming as defined in the Required Agricultural Practices Rule, unless a recent soils test demonstrates that the heavy metals are within the authorized action limits for soils.
- **Note 6:** No pesticide testing required if crop is certified organic.
- **Note 7:** Testing for other contaminants is necessary when the Agency of Natural Resources has approved biosolids applications to the hemp crop land.

# Testing Parameters and Action Levels

(Vermont Cannabis Quality Control Program)

**Table 3. Potency parameters and limits**

parameter	Action limits (%)	Product labeling
d9-THC	0.3	
Total THC	1.0	Within 10% of label value
CBD, and CBD-A	none	Within 10% of label value
Other cannabinoids	none	Within 10% of label value

**Table 4. Moisture parameters and limits (either analysis)**

Parameter	Action limits for trim flower
Moisture content	13 %
Water activity	0.65

# Testing Parameters and Action Levels

(Vermont Cannabis Quality Control Program)

**Table 5. Microbiological parameters and action limits**

Parameter	Action limits dried cannabis bud/ biomass	Action limits for concentrates	Action limits for random sampled capsules, tinctures, topicals, etc
Total Aerobic Microbial Count (CFU per gram or ml) *	100,000	10,000	1000
Total Combined Yeast and Mold count (CFU per gram or ml) *	10,000	1000	100
Mycotoxin: the total of Aflatoxin B1, B2, G1, and G2	20 ppb	20ppb	20ppb
Mycotoxin- Ochratoxin A	20 ppb	20ppb	20ppb

**Table 6. Metal parameters and action limits**

parameter	Trim flower and dried biomass action limits (ppm, mg/kg)	Concentrate action limits (ppm)	Soil action limits (ppm, mg/kg) for agricultural use (additional levels for Cr, Cu, Ni, and Zn) Note 1.
Arsenic	0.200	1.500	---
Cadmium	0.200	0.500	0.43
Lead	0.500	1.000	200
Mercury	0.100	1.500	---

# Testing Parameters and Action Levels

(Vermont Cannabis Quality Control Program)

**Table 7. Pesticide parameters and action limits**

parameter	Action limits (ppm, mg/kg, mg/l)
Acephate	10
Acequinocyl	0.5
Avermectin	0.01
Azoxystrobin	0.2
Bifenazate	1
Bifenthrin	0.2
Carbaryl	0.2
Chlorothalonil	1.0
Chlorpyrifos	0.2
Cypermethrin (zeta) sum of isomers	1.0
Diazinon	0.2
Ethephon	2
Etoxazole	0.5
Imazalil	0.1
Imidaclobutanil	0.05
Myclobutanil	0.03
Pyrethrins (sum of 3 isomers)	0.5
Spinosyn (each for spinosad A & D)	0.01

**Table 8. Residual solvent parameters and action limits (only lipid, Ethanol, CO2 or mechanical extractions allowed)**

parameter	Action limits (ppm, mg/kg, mg/l) concentrates
Acetone	5000
Acetonitrile	410
Benzene	2
Chloroform	60
Ethanol	5000
Heptanes (total)	5000
Hexanes (total)	290
Isopropyl alcohol	5000
Methanol	3000
Methylene Chloride	600
Toluene	890
Xylenes (total)	2170
Any solvent not permitted for extraction in the hemp rule (butane, propane, or other hydrocarbons) each	5000

# Lab certification/accreditation



- ▶ VAAFM will evaluate labs for Certification of Hemp Analysis
- ▶ (USDA recommends ISO 17025 adherence)
  - ▶ IFR Requires ISO 17025 (and DEA registration)
- ▶ What is ISO/IEC 17025? General requirements for the competence of testing and calibration laboratories
- ▶ ISO based Accreditations are required for Certification:
  - ▶ Specific accreditation programs with or without hemp
    - ▶ NELAC, ANAB, A2LA, Perry Johnson, +
  - ▶ Specific cannabis accreditation programs (CANNALAP, +)
  - ▶ Or a lab is working towards/ have applied for accreditation
    - ▶ ISO based format followed
    - ▶ (Certification limited to Potency, Moisture, Pesticide analysis)

# Specific requirements to become a certified laboratory

- ▶ The laboratory must also use appropriately validated or verified methods for each hemp analysis, and those approved methods and related guidelines (for validations and methods) must be derived from recognized industry sources.
- ▶ Recognized agencies for sources include (but are not limited to) AOAC International, FDA, USDA, EPA, ISO, AHP, USP, ASTM, and APHL. (A manufacturer's validation is acceptable when following these recognized sources.)
- ▶ All validated and verified methods shall have written Standard Operating Procedures (SOPs).
- ▶ Certified laboratories must participate in proficiency testing for potency and other parameters as proficiency tests become available
- ▶ Laboratories will be required to register with the Drug Enforcement Administration (DEA) in accordance with federal law (see 7 C.F.R §§ 990.3(a)(3)(i)).

# QA Program Requirements towards VAAFM Certification



- ▶ Quality Management System (QA program)
- ▶ 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)
  - ▶ Example: Total THC  $0.31\% \pm 0.02\%$

# Additional requirements for certification

(Vermont Cannabis Quality Control Program, sections 6 & 7)

- ▶ Laboratories must be certified by the Cannabis Quality Control Program to issue Certificates of Analysis (CoAs) for proof of compliance with the Vermont Hemp Rules. A test result from a laboratory not properly certified in the specific testing area at issue shall not be considered a certified result nor accepted as proof to establish compliance with the Vermont Hemp Rules
- ▶ CoA requirements: information (dates, lot #s, etc), when dry weight results are required, concentration units must utilize the same units in the Tables, Measurement Uncertainty (MU)
- ▶ Submission of samples requirements
- ▶ Documentation requirements including pre-harvest sample forms, CoAs, Chain of Custody
- ▶ Required methods for dry weight and decarboxylation determination
- ▶ Reporting to the Agency
  - ▶ If a harvest lot exceeds the acceptable potency level or action limits as outlined in Tables 3 thru 7 then the following conditions apply :  
The certified laboratory shall send the certificate of analysis containing the result and the testing request form within 24 hours of completing the harvest lot test to:  
the Agency and the registrant who requested the testing.



# Cannabis Quality Control Program

## Looking at the Basic Potency Test

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

# Certificate of Analysis (CoA) for Potency (see Agency's website: Interpreting a CoA)

Cannabinoids listed

Cannabinoid Profile	%	mg/g
Tetrahydrocannabinolic Acid (THCa)	0.561	5.61
Tetrahydrocannabinol ( $\Delta$ 9-THC)	ND	ND
Tetrahydrocannabinol ( $\Delta$ 8-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)

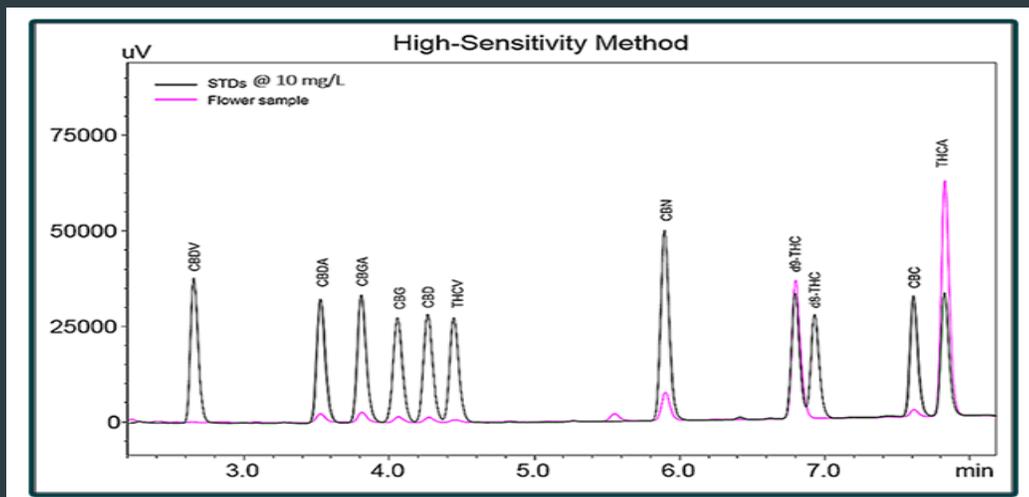
Formula for calculations

$$\begin{aligned} \text{Total THC} &= \text{THCa} * 0.877 + \Delta 9\text{-THC} \\ \text{Total CBD} &= \text{CBDa} * 0.877 + \text{CBD} \end{aligned}$$

# Stay updated with industry standards



- ▶ Continued improvement in recovery of target compounds
  - ▶ Cannabinoids
  - ▶ Contaminants
- ▶ Consider all stages
  - ▶ Storage , preparation
  - ▶ Extraction
  - ▶ Analysis
- ▶ Reference an accepted protocol
- ▶ Verify/validate methods
- ▶ Document in Standard Operating Procedures (SOPs)



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Covid-19 relief for hemp farmers

<https://agriculture.vermont.gov/agency-agriculture-food-markets-news/covid-19-impacts-hemp-farmers-too-vcaap-can-help>

