

Hemp Pre-Harvest Sampling and Testing Protocol for a Taxonomic Determination and Compliance

Publication Date: October 2, 2018 (revised June 2019)

Hemp or hemp is the *Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. In Vermont, hemp is considered an “agricultural product” when grown by an individual that is registered with Vermont Agency of Agriculture, Food & Markets (VAAFAM) as part of its Hemp Program.

VAAFAM through its Hemp Program, authorized under 6 VSA, Chapter 34, registers hemp growers and processor. The VAAFAM requires registrants to maintain sampling and testing records to indicate proof of compliance for potency and for contaminants. A registrant must maintain records for a period of three years for all harvest lots grown on Vermont or come into the possession of processor.

To be sufficient to meet the requirements for THC potency and contaminant sampling and testing under the Vermont Hemp Program Rules (VHPR) sampling and testing must be conducted as described in this protocol.

Section 1 Definitions

- 1.1. Acceptable potency level means a hemp crop that has a delta-9 concentration of 0.3 percent or less and a total theoretical tetrahydrocannabinol concentration of one percent or less.
- 1.2. Cannabinoid means any of a group of closely related chemical compounds which include THC (tetrahydrocannabinol), THCA (tetrahydrocannabinolic acid), CBD (cannabidiol), CBDA (cannabidiolic acid), CBN (cannabinol), CBG (cannabigerol), CBC (cannabichromene), CBL (cannabicyclol), CBV (cannabivarin), THCV (tetrahydrocannabivarin), CBDV (cannabidivarin), CBCV (cannabichromevarin), CBGV (cannabigerovarín), CBGM (cannabigerol monomethyl ether), CBE Vermont Hemp Program Rules 4/18/2019 3:06 PM 2 (cannabielsoin), CBT (cannabicitran), and other active constituents that are naturally occurring in a cannabis plant.
- 1.3. Certificate of analysis means a report prepared by a certified laboratory about the analytical testing it performed and the results of the testing.
- 1.4. Certified laboratory means a laboratory that is certified by the Agency under 6 V.S.A. § 567.
- 1.5. Chain of custody form means a record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; the collector; time of collection; preservation; and requested analyses.
- 1.6. Contaminant means any pesticide, solvent, heavy metal, mycotoxin, foreign material, and bacterial and fungal impurity introduced through cultivation or processing.
- 1.7. Delta-9 tetrahydrocannabinol, also referred to as “THC,” is the principal psychoactive cannabinoid found in cannabis.
- 1.8. Dry weight means the weight of plant material with no greater than 13% moisture content.
- 1.9. Harvest lot means a quantity of hemp harvested by the same Grower in a single growing season that is grown contiguously in the same cultivation area.
- 1.10. Harvest lot number means a unique numerical identifier that begins with the last five digits of a Grower’s registration number, followed by the year of harvest, and a unique number to identify the harvest lot.

- 1.11. Hemp means the plant *Cannabis sativa* L. whether growing or not and any part of that plant, including the seeds, all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, with the federally defined tetrahydrocannabinol concentration level, or is a type III or IV cannabis plant, as defined below.
- 1.12. Hemp crop means standing or harvested hemp that complies with the federal definition of hemp prior to processing.
- 1.13. Registrant means a person registered with the Hemp Program.
- 1.14. Taxonomic determination means a process of classification based on genetic testing of known cannabinoid ratios based on stable cultivars.
- 1.15. Type I means a cultivar of *Cannabis sativa* L. that is THC dominate.
- 1.16. Type II means a cultivar of *Cannabis sativa* L. ratio between CBD and THC vary, and where delta-9 THC is greater than 0.3 percent.
- 1.17. Type III means a cultivar of *Cannabis sativa* L. that is CBD dominate, at least 20:1.
- 1.18. Type IV means a cultivar of *Cannabis sativa* L. that is neither THC nor CBD dominate.

Section 2 Inspections:

- 2.1. The VAAFM will conduct random routine inspections of registered fields to verify that hemp is not produced in violation of state and federal law.
- 2.2. Any samples or information collected as part of a routine inspection may be used in research by the Agency.
- 2.3. The VAAFM may inspect a registrant's premises, machinery, equipment and facilities, any crop during any growth phase or any hemp product or hemp-infused product during processing or storage. This inspection may include the taking of samples, inspection of records, and inspection of equipment or vehicles used in the growing, processing or transport of hemp crops, hemp products or hemp-infused products.
- 2.4. The VAAFM may take samples of hemp crops as part of an inspection if crop is located in the field, and will use the following procedures when taking samples associated with an inspection.
- 2.5. The VAAFM may take composite samples of any crops after harvest, or if stored or present on the property. The VAAFM will use a post-harvest sampling protocol.

Section 3 Sampling Requirements

- 3.1. Harvest lots must be sampled separately and may not be combined with other harvest lots.
- 3.2. A new Hemp Pre-harvest Sampling Form and testing request form must be completed for each harvest lot.
 - (a) Testing request forms must at a minimum contain the following information for each harvest lot:
 - i. Requestor's name, business name and address, and registration number,
 - ii. Harvest lots, identified by harvest lot number,
 - iii. Type of hemp product or hemp-infused product (e.g. inhalable, ingestible, absorbable).
- 3.3. Sampling may be performed by the registered grower of the harvest lot; a registered processor to whom the harvest lot will transfer for processing; a laboratory certified by the VAAFM to conduct testing, pursuant to 6 V.S.A. §567; or VAAFM.
- 3.4. If sampling is conducted by someone other than the registered grower, the grower or their representative must be present during the sampling process.
- 3.5. A Hemp Pre-harvest Sampling Form must be completed at the time sampling is performed.

- 3.6. Samples shall be taken when the harvest lot is in flower and generally not more than 28 days before harvest.
- 3.7. Samples must be managed to avoid contamination from non-sampled material.
- 3.8. A Hemp Pre-harvest Sampling Form must be signed by the sampler and the grower.
- 3.9. A Pre-harvest sample to be tested must be accompanied by the completed Hemp Pre-harvest Sampling Form, completed testing request form, and a completed Chain of Custody Form to the certified laboratory.

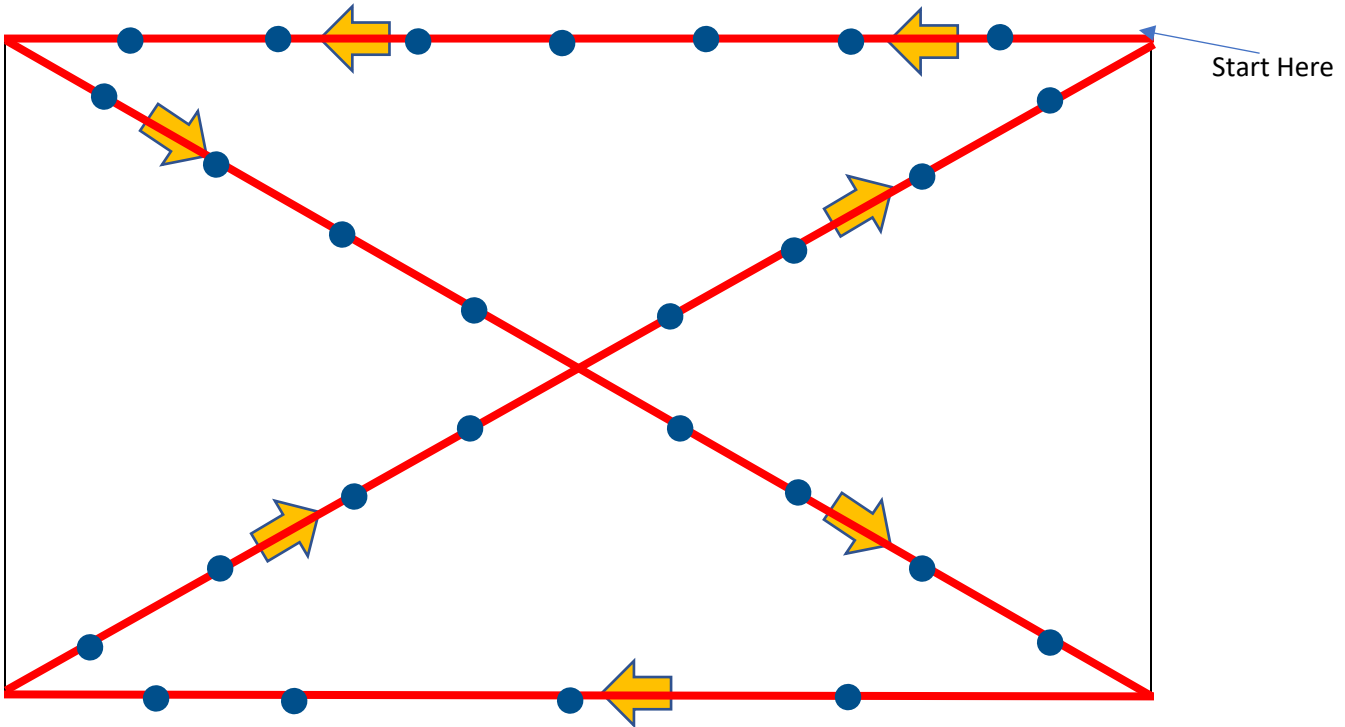
Section 4 Sampling Equipment

The sampler should bring the following equipment should be brought when sampling in the field

- Forms
- Garden shears -cleaned with alcohol wipes prior to and following each sample collection of a harvest lot
- Alcohol wipes
- Disposable rubber gloves
- Brown paper sample bags
- Marker
- Chain of custody form
- Sampling record form
- Aerial View Map(s)
- Cooler
- Ice packs

Section 5 Routine survey and sample collection

- 5.1. The sample pattern must ensure that all areas within the harvest lot are adequately and proportionately sampled.
- 5.2. The sampler must follow an “X” pattern when inspecting and sampling the harvest lot to the extent possible but may deviate from the pattern as necessary to account for the particular field conditions and to ensure that all areas are adequately and proportionately sampled to produce a representative sample of the harvest lot (See below).
- 5.3. Each sample shall be taken only when plants are in flower.
- (a) The sample shall be taken of a side arm flower, 8 inches in length.
 - (b) The sample shall not contain dead, diseased, pest infested, or injured plants.
 - (c) The sampler shall take one side arm flower per plant selected for sampling by the prescribed sampling pattern.
 - (d) Place each sampled flower in the paper sample bag.
- 5.4. Deviations from the “X” pattern based on field conditions or sampling procedures shall be documented in the Hemp Pre-harvest Sampling Form and with photographs.
- 5.5. Use the following procedure:
- (a) Starting in one corner, walk along one edge of the field, collecting seven (7) samples at approximately equidistant points along the transect.
 - (b) At the corner, continue the “X” pattern by walking diagonally through the field to the far corner. Again, at designated points along this transect, collect seven (7) flowering tops.
 - (c) Continue the “X” pattern by walking across the far side of the field to the opposite corner. At designated points along this transect, collect seven (7) flowering tops.
 - (d) Finish the “X” pattern by walking diagonally back to your original starting point. At designated points along this transect, collect seven (7) flowering tops.
- 5.6. At the conclusion of sampling and inspecting the harvest lot, the sampler should have approximately 30 side arm flowers in the representative sample, or as outlined in Table 1.



5.7. For small fields or greenhouses, or when sampling from a known number of plants, the attached Table 1 may be used.

5.8. In no instance shall a sample weigh less than 80 grams on a dry weight basis, which is the minimum amount necessary for laboratory tests and file samples.

Table 1

Total Number of Plants	Number of Plants to Randomly Sample
1-13	All
14-15	13
16-17	14
18-19	15
20-22	16
23-25	17
26-28	18
29-32	19
33-38	20
39-44	21
45-53	22
54-65	23
66-82	24
83-108	25
109-157	26
158-271	27
272-885	28
886-1,500 or one acre	29

5.9. The sample shall be securely contained in the paper bag and sealed (e.g. evidence tape or stapler) in a manner that would show or exhibit evidence of tampering. On the sample bag, record the harvest lot number, date of sampling, sampler’s signature, and registered grower’s registration number.

5.10. Label sample bags and place in cooler for transport to the lab or to a secure location.

- (a) samples should be immediately frozen, or
- (b) drying should begin within 12 hours of sampling.

Section 6 Transport of Samples

- 6.1. All samples must be provided to the certified laboratory in the sealed paper bag using an appropriate tamper-evident method (e.g. evidence tape or stapler).
- 6.2. Copies of the following forms shall accompany any sample submitting for testing:
 - (a) Hemp Pre-Harvest Sampling Form - Completed by sampling entity containing appropriate signatures;
 - (b) complete testing request form, grower signature; and
 - (c) Chain of Custody Form, containing appropriate signatures.

Section 7 Sampling for Genetic or Taxonomic Testing of Hemp for Compliance

- 7.1. Growers may request use of a genetic test to determine if a plant is a Type III or Type IV cultivar, and shall provide information required by the certified laboratory.
- 7.2., All samples must be provided to the certified laboratory in the sealed paper bag using an appropriate tamper-evident method (e.g. evidence tape or stapler), free from dead, diseased, pest infested, or injured material, and be accompanied by a Chain of Custody Form, and a testing request form containing appropriate signatures.
- 7.3. Testing to determine if contaminants are present shall be completed post harvest in compliance with post harvest composite testing requirements.

Section 8 General Requirements for Hemp Compliance Testing

- 8.1. Testing may only be performed by a laboratory certified by the Vermont Agency of Agriculture, Food and Markets to sample and test for tetrahydrocannabinol (THC) potency and contaminants in harvest lots.
- 8.2. All testing must be performed by personnel employed by a certified laboratory and in accordance with this protocol.
- 8.3. The certified laboratory must follow documented chain of custody procedures from time of sample receipt (accessioning) through, storage, testing and disposal.
- 8.4. Test request forms provided by the laboratory will contain customer name and location, hemp registration, lot numbers, requested tests for all samples received, condition that samples were received, and name and signature of sampler. This will begin the chain of custody at the laboratory.
- 8.5. The certified laboratory must store and perform testing in compliance with their Quality Management system as defined by their certification.
- 8.6. The laboratory shall maintain and provide Standard Operating Procedures for testing which document process for sample receipt, extraction, testing and reporting and shall include explicit procedures for:
 - (a) calibration;
 - (b) documentation of method and instrument detection limits,
 - (c) training documentation and competencies of analysts,
 - (d) rounding rules and significant figures,
 - (e) equations used to calculate concentrations;
 - (f) equations used to determine accuracy and precision measurements associated with samples;
 - (g) methods used to flag data and
 - (h) secondary review and reporting of data.
- 8.7. Data packages will be made available to the State that contain: sample information, chain of custody and other sample documentation, sample results and related data for calibration standards; surrogate and

standard recoveries, blank sample results, spike recoveries for control and matrix spike samples and duplicates, duplicate results, lab check samples, continuing calibration verification samples, area and retention time summaries, chromatograms and other raw data files.

- 8.8. Generic control limits of 70-130% may be used for calibration verification sample recoveries, surrogate and spike recoveries until performance based and statistically determined control limits can be developed. Quality control samples that are out of control will be flagged and all associated sample data. Out of control data may be rejected.
- 8.9. Method blank samples shall be free of all target compounds, and detection that is 1/10 the detection in any sample shall be flagged, and data may be rejected.
- 8.10. A minimum of five points shall be used for organic method calibration; no point shall be dropped from a calibration curve.
- 8.11. Secondary validation for all results shall be done by the laboratory.
- 8.12. The certified laboratory must store and perform testing in a manner that avoids contamination of the non-sampled material with sample containers that are free of analytes of interest and appropriate for the analyses requested.
- 8.13. The certified laboratory must report the percentage of delta-9 THC and total theoretical THC in the sample on a dry weight basis, as outlined in this protocol and the VHPR.

Section 9 Record keeping

- 9.1. A certified laboratory performing tests for a registrant must comply with the documentation requirements in this protocol must maintain the documentation for at least three years and provide that information to the VAAFMM upon request.
- 9.2. A certified laboratory must comply with record keeping requirements for samples outlined in the certified laboratory's policies and procedures, and at a minimum:
 - (a) review records accompanying each sample received to confirm the records contain the location of each sample taken, and
 - (b) the harvest lot number for each sample and have an unequivocal link to the certified laboratory analysis identification.
 - (c) The certified laboratory must have a documented system for uniquely identifying the samples.
 - (d) Place the certified laboratory identification code.
 - (e) Enter a unique identification number into the laboratory records. This number must be the link that associates the sample with related laboratory activities such as sample preparation. In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the unique identification number may be the same as the field identification code.

Section 10 Cannabinoid potency validation

- 10.1. When testing a sample for acceptable THC potency level and other cannabinoid concentrations a laboratory must comply with additional method validation as follows:
 - (a) Run a laboratory control standard within acceptance criteria of 70 percent to 130 percent recovery.

Section 11 Calculating total THC and total CBD.

11.1. Total theoretical THC must be calculated as follows, Total theoretical tetrahydrocannabinol or THC content is the maximum amount of possible delta-9 tetrahydrocannabinol in a hemp crop if total conversion were to occur and will be determined by the following calculation: the sum of the concentration of delta-9 tetrahydrocannabinol and its precursor, tetrahydrocannabinol-A, multiplied by 0.8777 on a dry weight basis and reported to two significant figures:

$$(a) \text{ Total theoretical THC} = ([\text{delta} - 9 \text{ THC}] + ([\text{THC} - \text{A}] * 0.877))$$

Section 12 Cannabinoid dry weight calculation

12.1. Report total THC and total CBD as Dry Weight. A laboratory must report total THC and Total CBD content by dry weight calculated as follows:

$$(a) \% \text{ total THC(dry)} = \% \text{ total THC(wet)} / [1-(13/100)]$$

$$(b) \% \text{ total CBD(dry)} = \% \text{ total CBD(wet)} / [1-(13/100)]$$

Section 13 Contents of a certificate of analysis for each harvest lot

13.1. All certificates of analysis for a harvest lot at the very least must contain the following information

- (a) Grower's name, business name, business address, and last five digits of registration number,
- (b) A copy of accompanying testing request form,
- (c) chain of custody form
- (d) sample ID number,
- (e) sample size by weight, specified on a dry weight basis and condition of the sample (e.g. flower-cured, flower wet)
- (f) percent moisture content at 13%,
- (g) testing date and method,
- (h) delta-9 THC concentration and total theoretical THC concentration,
- (i) other cannabinoids present and their potency, and
- (j) the certified laboratory's certification number, director's name and signature.

13.2. The certified laboratory shall report to the registrant and the VAAFm any compliance, and contaminant test result that shows pesticides, heavy metals, mycotoxins, and bacterial and fungal contaminants.

13.3. Data deliverables shall be provided in electronic format to the State in a standard csv file which contains sample information, results, data flags, associated quality control sample results and recoveries and limits of detection.

13.4. The VAAFm may, in its discretion, deviate from TNI Standards in order to comply with VHPR and based on its needs.

13.5. Non-compliance testing. A laboratory that conducts a quality control or research and development test for a registrant may use methods not approved by the VAAFm but the laboratory may not identify those test results as accredited results.