

Waganakising Odawak

Little Traverse Bay Bands of Odawa Indians Office of Tribal Chairperson

7500 Odawa Circle, Harbor Springs, Michigan 49740 Phone 231-242-1401 • Fax 231-242-1411

HEMP REGULATORY COMMISSION REGULATIONS FOR HEMP SAMPLING AND THC TESTING REG-WOS 2020-015-060220-004

I. Definitions. These Regulations incorporate the definitions set forth in the Tribe's Hemp Authorization and Regulatory Commission Statute.

II. Random and Federally Mandated Inspections.

- A. The Commission shall have authority to conduct random inspections of Hemp Growers and all Licensed Locations or Land Areas, and federally-mandated sampling and testing requirements, to verify compliance with all requirements of the license issued and all federal laws. Random inspections shall be conducted on at least an annual basis. Inspection shall include sampling and testing in accordance with Sections III, IV and V of these Regulations.
- B. Inspection visits may be conducted at any time during regular business hours. Inspectors shall be granted unrestricted access to the Licensed Location or Land Area.
- C. All samples collected by the Commission shall become the property of the Commission and no compensation shall be owed by the Commission for such samples.
- D. The Commission shall keep test results for all Hemp and Hemp Products tested for a minimum of three (3) calendar years.

III. Sampling Timeline and Grower Responsibilities

A. Responsibility of a Licensed Producer Prior to Harvest of Hemp Plots.

1. Within 15 days prior to the anticipated harvest of cannabis plants, a producer shall have an approved Federal, State, local law enforcement agency or other USDA designated person collect samples from the flower material of such cannabis material for delta-9 tetrahydrocannabinol concentration level testing.

- 2. The method used for sampling from the flower material of the cannabis plant must be sufficient at a confidence level of 95 percent that no more than one percent (1%) of the plants in the lot would exceed the acceptable hemp THC level. The method used for sampling must ensure that a representative sample is collected that represents a homogeneous composition of the lot.
- **3.** During a scheduled sample collection, the producer or an authorized representative of the producer shall be present at the growing site.
- 4. Representatives of the sampling agency shall be provided with complete and unrestricted access during business hours to all hemp and other cannabis plants, whether growing or harvested, and all land, buildings, and other structures used for the cultivation, handling, and storage of all hemp and other cannabis plants, and all locations listed in the producer license.
- **5.** A producer shall not harvest the cannabis crop prior to samples being taken, and shall harvest the crop not more than fifteen (15) days following the date of sample collection.

IV. Sampling Procedures

A. Purpose

- 1. Samples are taken to obtain specimens for the measurement of tetrahydrocannabinol (THC) content, which determine whether the specimens are hemp or marijuana.
- 2. The measurements are intended to be representative of the THC content in a "lot" of hemp crop acreage as identified by the Producer.
- 3. Hemp Producers may not harvest hemp prior to the hemp being sampled and tested for THC concentration.

B. Scope

- 1. Samples collected under this procedure are acceptable for submission to a qualified, DEA-registered laboratory for determination of THC in hemp.
- 2. Since the THC content of hemp generally peaks as the plant ripens, the timing of when sampling occurs is important to accurately measure THC concentration and monitor compliance with the USDA hemp production program.
- 3. Samples must be collected by a USDA approved sampling agent, or a Federal, State or Tribal law enforcement agent authorized by USDA to collect samples. It is the responsibility of the licensed Producer to pay any fees associated with sampling.

C. Summary of Practice

- 1. This practice provides procedures for entering a growing area and collecting the minimum number of plant specimens necessary to represent a homogeneous composition of the "lot" that is to be sampled. An authorized representative enters a growing area, strategically examines the growing area, establishes an approach for navigating the growing area, and collects individual specimens of plants in order to obtain a representative sample of hemp in the designated lot.
- 2. Cuttings from each "lot" of hemp crop acreage, as identified by the Producer, and submitted to and uniquely identified by the Farm Service Agency per the requirements of the USDA hemp production program, shall be organized as composite samples. For the purposes of these procedures, a "lot" is a contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of cannabis throughout. In addition, "lot" refers to the batch of contiguous, homogeneous whole of a product being sold to a single buyer at a single time. "Lot" is to be defined by the Producer in terms of farm location, field acreage, and to be reported as such to the FSA.

D. Equipment and Supplies

- 1. Garden pruners/shears (Cleaned prior to and following each composite sample. Some examples of appropriate cleaning agents and supplies to use on garden pruners/shears are bleach, rubbing alcohol, steel wool, and/or sandpaper.)
- 2. Sample bags, paper.
 - i. The size of the bags will depend upon the number of clippings collected per lot.
 - ii. The bags should be made from material known to be free from THC.
- 3. Security tape
- 4. Permanent markers
- 5. Sample collection forms
- 6. GPS Unit
- 7. Disposable gloves Nitrile

E. Sampling Guidelines

- 1. The licensee or designated employee shall accompany the sampling agent throughout the sampling process.
- 2. Surveillance of the growing area.
 - i. The inspector shall verify the GPS coordinates of the growing area as compared with the GPS coordinates submitted by the licensee to USDA.
 - ii. The inspector shall estimate the average height, appearance, approximate density, condition of the plants, and degree of maturity of the flowering material, meaning inflorescences

(flowers/buds).

iii. The inspector shall visually establish the homogeneity of the stand to establish that the growing area is of like variety.

3. Time of Sampling:

i. Within 15 days prior to the anticipated harvest of cannabis plants, an approved Federal or Tribal law enforcement agency or other Tribal designated person shall collect representative samples from such cannabis plants for THC concentration level testing.

4. Field Sampling:

- i. For purposes of determining the number of individual plants to select for sampling, the size of the growing area shall be considered. For sampling purposes, samples from separate "lots" must be kept separate and not be comingled.
- ii. For lots of less than one acre, including greenhouses, select a minimum of 1 plant, then take a cutting from the plant to form a sample. For lots of 2 to 10 acres, including greenhouses, select a minimum of one plant per acre, then take cuttings of each plant, then combine to form a composite sample.
- iii. For growing areas larger than ten (10) acres, including greenhouses, the number of plants that will be selected to form a composite sample is based upon the Codex Alimentarius Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLS CAC/GL 33-1999.
 - a) The sample size is estimated in a two-step process. The first step is to estimate the number of primary plants to be sampled. The second step is to adjust the estimate of primary plants by the acreage under cultivation.
 - b) The initial number of primary plants is estimated using

$$n_o = \frac{\ln(1-p)}{\ln(1-i)}$$

where p is the confidence level to detect hemp plants having THC content greater than the Acceptable Hemp THC Level and i is the proportion of hemp plants having THC content greater than the Acceptable Hemp THC Level. The values for i are based on past experience in the same or similar growing areas.

c) The initial primary plants estimate is adjusted by the number of acres to calculate the minimum number of primary plants for composting as follows:

$$n = \frac{n_o}{1 + \frac{(n_o - 1)}{N}}$$

where n is the minimum number of primary plants to be selected for forming a composite sample, n_0 is the initial number of primary plants, and N is the number of acres under cultivation.

d) Example 1: The initial primary plant sample size is 299 with a confidence level of 95% to detect hemp plants having THC content greater than the Acceptable Hemp THC Level and a proportion of hemp plants having THC content of greater than the Acceptable Hemp THC Level equal to 0.01 is considered appropriate. The adjusted primary plant sample sizes for fields from 11 to 173 acres in size are shown in the following table:

Number	Sample	Number	Sample		Number	Sample		Number	Sample
of acres	Size "n"	of acres	Size "n"		of acres	Size "n"		of acres	Size "n"
11	11	40	36		75-76	61		119-120	86
12	12	41-42	37		77	62		121-122	87
13	13	43	38		78-79	63		123-124	88
14	14	44	39		80-81	64		125-126	89
15	15	45-46	40	domestic.	82	65		127-128	90
16	16	47	41		83-84	66		129-130	91
17	17	48	42		85-86	67		131-132	92
18-19	18	49-50	43		87	68		133-134	93
20	19	51	44		88-89	69		135-136	94
21	20	52	45		90-91	70		137-138	95
22	21	53-54	46		92	71		139-140	96
23	22	55	47		93-94	72		141-143	97
24	23	56	48		95-96	73		144-145	98
25-26	24	57-58	49		97-98	74		146-147	99
27	25	59	50		99	75		148-149	100
28	26	60-61	51		100-101	76		150152	101
29	· 27	62	52		102-103	77		153-154	102
30	28	63-64	53		104-105	78		155-156	103
31-32	29	65	54		106-107	79		157-157	104
33	30	66-67	55		108	80	****	159-161	105
34	31	68	56		109-110	81		162-163	106
35	32	69-70	57		111-112	82		164-166	107
36	33	71	58		113-114	83		167-168	108
37-38	34	72-73	59		115-116	84		169-170	109
39	35	74	60		117-118	85		171-173	110

e) Example 2: The adjusted primary plant sample sizes for fields from less than 1 to 10 acres in size are shown in the following table:

Number of	Sample		
Acres "N"	Size "n"		
Less than 1	1		
1	1		
2	2		
3	3		
4	4		
5	5		
6	6		
7	7		
8	8		
9	9		
10	10		

5. Collecting Samples from each lot:

- i. Sampling agents shall always walk at right angles to the rows of plants, beginning at one point of the lot and walking towards another point on the opposite side of the lot.
- ii. While walking through the growing area, the inspector shall cut at least "n" flowering material, meaning inflorescences (the flower or bud of a plant) at random but convenient distances. Avoid collecting too many specimens from the borders of the field/greenhouse.
- iii. The cut shall be made just underneath a flowering material, meaning inflorescence (the flower or bud of a plant), located at the top one-third (1/3) of the plant. (See figure below.) The sample size must be of adequate volume to accommodate laboratory tests.



iv. Utilize a paper sample bag for collecting sample cuttings. Ensure that each bag has the HEMP REGULATORY COMMISSION REGULATIONS FOR SAMPLING, THC TESTING, AND POST-TESTING ACTIONS AND DISPOSAL OF NONCOMPLIANT PLANTS AND PRODUCTS. REG-WOS 2020-015-060220-004

minimum number of cuttings, n, as calculated by 4.3.3, or in the Example Tables 1 and 2.

v. Seal each bag and record the sample number.

6. Sample identification:

- i. The inspector shall seal each bag and record the sample identification number. The sample shall also be identified with the following information:
 - a) The sample ID shall include:
 - 1) Sampling agent contact information;
 - 2) name and contact information of the Producer;
 - 3) Producer hemp license or authorization number;
 - 4) date of sample;
 - 5) "lot" ID as provided by the USDA Farm Service Agency; and
 - 6) any other information that may be required by the Commission, Law Enforcement Authorities, mail delivery services, customers or groups of customers.

V. PROCEDURES FOR TESTING

A. Purpose

- Standard testing procedures are specified for samples taken in accordance with the Sampling Procedures for the USDA Hemp Program to measure the delta-9 tetrahydrocannabinol (THC) concentration levels of those samples on a dry weight basis. Hemp testing laboratories are not required to be ISO accredited, although the Commission strongly encourages adherence to the ISO 17025 standard.
- 2. The results are intended to measure the THC content of composite hemp samples collected from a designated "lot" of hemp crop acreage designated by a hemp Producer and as reported to the USDA Farm Service Agency as required under the USDA hemp production program. The purpose of the measurements is to determine whether the THC concentration of the tested material is within the Acceptable Hemp THC Level.
- 3. As required under USDA hemp production program regulation, laboratories conducting testing of hemp must conduct analytical testing for purposes of detecting the concentration

levels of delta-9 tetrahydrocannabinol THC and shall meet the following standards:

- i. Laboratory quality assurance must ensure the validity and reliability of the test results;
- ii. Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing;
- iii. The demonstration of testing validity must ensure consistent, accurate analytical performance; and
- iv. Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this Section.
- v. At a minimum, analytical testing of samples for delta-9 tetrahydrocannabinol concentration levels must use post-decarboxylation or other similarly reliable methods approved by the Secretary. The testing methodology must consider the potential conversion of delta-9 tetrahydrocannabinolic acid (THCA) in hemp into delta-9 tetrahydrocannabinol (THC) and the test result reflect the total available THC derived from the sum of the THC and THC-A content. Testing methodologies meeting these requirements include, but are not limited to, gas chromatography and high-performance liquid chromatography.
- vi. The total delta-9 tetrahydrocannabinol concentration level shall be determined and reported on a dry weight basis.
- vii. Sample test results shall be at least 95% confidence that the THC content of the sample is higher than the Acceptable Hemp THC Level shall be conclusive evidence that the lot represented by the sample is not in compliance with this Section.
- 4. Laboratories approved for THC testing must also be registered with DEA to handle controlled substances under the Controlled Substances Act (CSA), 21 CFR part 1301.13.

5. Lots tested and not certified by the DEA-registered laboratory at or below the acceptable hemp THC level may *not* be further handled, processed or enter the stream of commerce and the producer shall ensure the lot is disposed of in accordance with Section 20 " Procedures for Disposal/Destruction of Non-compliant cannabis plants."

B. General Sampling and Testing Procedures

- 1. Laboratory receives sample.
- 2. Dry sample to remove the majority of water.
- 3. Mill and "manicure" sample though a wire screen no larger than 1.5 x 1.5mm to discard mature seeds and larger twigs and stems.
- 4. Separate sample into a test and retain specimens.
 - i. Test specimen: go to step 5
 - ii. Retain specimen: package and store until needed. When needed go to step 5.
- 5. Determine moisture content or dry to a consistent weight (meeting criteria).
- 6. Perform chemical analysis.
- 7. Calculate total THC on a dry weight basis. Test results should be determined and reported on a dry weight basis.
- 8. Samples shall be received and prepared for testing in a DEA registered laboratory as follows:
 - i. Once the composite sample is received by the laboratory, the laboratory shall dry all of the leaf and flower (not obvious stem and seeds) of the composite sample until brittle in a manner that maintains the THC level of sample. Samples are to be dried to a consistent loss (typically 5- 12% moisture content) so that the test can be performed on a dry weight basis, meaning the percentage of THC, by weight, in a cannabis sample, after excluding moisture from the sample. The moisture content is expressed as the ratio of the amount of moisture in the sample to the amount of dry solid in the sample.
 - ii. The laboratory shall mill and manicure samples though a wire screen no larger than 1.5x 1.5mm to discard mature seeds and larger twigs and stems.
- iii. The laboratory shall form sieve a "Test Specimen" and a "Retain Specimen." One

- sample part shall be selected for analysis and labeled "Test Specimen". The other sample part shall be marked "Retain Specimen" and shall be packaged and stored in a secured place.
- iv. The laboratory shall then determine moisture content or dry to a consistent weight.
- v. The laboratory will then perform chemical analysis on the sample using post-decarboxylation or other similarly reliable methods where the total THC concentration level considers the potential to convert delta-9-tetrahydrocannabinolic *acid* (THCA) into THC.
- vi. Testing methodologies meeting these requirements include those using gas chromatography and high-pressure liquid chromatography. *High-performance liquid chromatography*. High- performance liquid chromatography (HPLC) or (LC) is a scientific method (specifically, a type of chromatography) used in analytical chemistry used to separate, identify, and quantify each component in a mixture. It relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid adsorbent material to separate and analyze compounds. Under the terms of this part, HPLC is one of the valid methods by which laboratories may test for THC concentration levels. Ultra-Performance Liquid Chromatography (UPLC) is an additional method that may also be used as well as other liquid or gas chromatography with detection.
- vii. The laboratory will then calculate total THC on a dry weight basis.
- 9. **Testing Methods** The total available THC, derived from the sum of the THC and THCA content, shall be determined and reported on a dry weight basis.
 - i. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty. Laboratories shall meet the AOAC International standard method performance requirements (SMPR) for selecting an appropriate method. The range of estimated uncertainty is reported as a ± value and is the same unit as the hemp THC threshold (0.3% THC), following best practices for significant figures and rounding. Measurement of uncertainty (MU) must be estimated and reported with test results.
- ii. There are resources available for defining, guiding, and calculating measurement uncertainty. They include the GUM, ISO, and Eurachem. It is necessary for the HEMP REGULATORY COMMISSION REGULATIONS FOR SAMPLING, THC TESTING, AND POST-TESTING

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laboratory to determine the uncertainty of accuracy (u_{bias}), repeatability (u_r), and reproducibility (u_R) for each validated method. Once the expanded measurement uncertainty (U) is determined, then the confidence interval can be calculated around a designated threshold such as the hemp THC threshold (0.3% THC).

iii. Based on the aforementioned resources, the following equation is recommended:

Equation:

 $U = k \times u_c$

Where,

 $u_c = \sqrt{u_r^2 + u_R^2 + u_{bias}^2}$

And:

u = standard uncertainty (standard deviation)

 $u_r = uncertainty due to repeatability$

u_R = uncertainty due to reproducibility

ubias = uncertainty due to accuracy (bias)

 $u_c = combined standard uncertainty$

U = Expanded uncertainty = $\frac{u}{Mean} * k_{95\% confidence level}$, k = 2

k = coverage factor, use 2 for a 95% confidence level

- 10. **Test results exceeding 0.3% THC.** Sample test results shall be 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. If the results of a test conclude that the THC levels of a sample are conclusively higher than the Acceptable Hemp THC Level, the laboratory will promptly notify the Producer, the Commission and USDA or its authorized agent.
- 11. **Retest Procedures**. Any licensed Producer may request that the laboratory retest samples if it is believed the original THC concentration level test results were in error. If this occurs, the laboratory shall follow the same procedures as described in paragraphs (A)-(C) above that were followed to conduct the initial test. The licensee requesting the retest of the second sample will pay the cost of the test. The retest results shall be issued to the licensee requesting the retest and a copy shall be provided to the Commission, the USDA or its

12. Information Sharing with USDA. Laboratories performing THC testing for hemp produced under this program are required to share test results with the licensed Producer, the Commission, and USDA. USDA will provide instructions to all approved labs on how to electronically submit test results to USDA. Laboratories may provide test results to the Commission and licensed Producers in whatever manner best aligns with their business practices, but the Commission and Producers must be able to produce a copy of test results. For this reason, providing test results to the Commission and Producers through a web portal or through electronic mail, so the Commission and the Producer will have ready access to print the results when needed, is preferred.

CERTIFICATION

As Tribal Chairperson, I approve these Hemp Regulatory Commission Regulations.

	Date: <u>U</u> 22020	Regina Gasco Bentley, Tribal Chairperson
Receiv	ved by the Tribal Council Office	
approv Poll of	yed by the Tribal Council of the I	ouncil Secretary, we certify that these regulations were Little Traverse Bay Bands of Odawa Indians by Phone 25,2220, by a vote of in favor, opposed,
Date:	67.2020	Emily Broctor, Legislative Leader
Date:	6.7.2020	Julie Shananaquet, Secretary