



Association of Western Hemp Professionals

January 29, 2020

The Honorable Greg Ibach
Under Secretary,
Marketing and Regulatory Programs
U.S. Department of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250

Re: Comments on USDA AMS Interim Final Rule Establishing a Domestic Hemp Production Program; Submitted by the Association of Western Hemp Professionals

Docket ID: AMS-SC-19-0042

Dear Under Secretary Ibach,

On behalf of the Association of Western Hemp Professionals (AWHP), an association of small and medium hemp producing, harvesting, extracting and ancillary hemp-derived product businesses located in the Western states, we would like to take this opportunity to comment on USDA's Interim Final Rule (IFR) establishing a domestic hemp production program published in the Federal Register on October 31, 2019 with comments due January 29, 2020. We have been operating in a robust manner pursuant to state law for longer than most other regions of the country and thus have a unique, highly informed and pragmatic perspective to share with USDA.

Our submissions echoes and supports the submissions of the many national, regional and state hemp and hemp-derived products organizations calling on USDA to implement the 2018 Farm Bill in a flexible and pragmatic manner. **We also have a unique and important proposal regarding sampling and testing that we hope USDA will consider and implement before the 2020 growing season.**

In summary, we ask that USDA move to a "whole plant" science-based sampling and testing protocol; we also urge that USDA allow additional flexibility for lab results turnaround and reconsider the DEA lab registration requirement; and finally, we would compel USDA to

consider allowing for crops to be harvested and moved once they are sampled. Such adjustments would allow the industry to flourish and continue to create new jobs in the agriculture sector.

We appreciate that USDA issued the rule as an interim final rule, going into effect immediately; however, we are concerned about the lack of input from stakeholders before the rule is effective for the 2020 and 2021 growing seasons. The IFR states: “USDA is committed to issuing the final rule expeditiously after reviewing public comments and obtaining additional information during the initial implementation. This interim final rule will be effective for two years and then be replaced with a final rule.” While we appreciate that USDA will apparently accept comments for a two-year period, it makes sense for USDA to also incorporate important suggested improvements on a rolling basis. We strongly request that USDA account for stakeholder comments on the IFR prior to the 2020 growing season and not wait for a two-year period.

I. Over Regulation will Destroy the Positive Hemp Economy Trajectory

We appreciate all that USDA has done to assist the US hemp industry to get started and to continue a positive trend. USDA was instrumental in moving forward and implementing the 2014 and 2018 Farm Bills that have allowed hemp production to again begin to thrive in the United States. At a time when some regions of the country are looking for new and more profitable crops, hemp has been a welcome alternative to U.S. farmers.

A recent survey found that once fully realized, the hemp industry is poised to become the fourth major crop and a foundation to agriculture in the United States. The survey also concluded that, in its first year, even if only a small fraction of the biomass produced during the 2019 season makes it to market, hemp has the potential to become the third largest agricultural crop in the United States by revenue, second only to corn and soy. If hemp supply chain issues are resolved and the full value of the acreage is realized, the total value of the hemp biomass is an estimated \$11.3 billion or roughly 6% of the total value of the entire U.S. cash crops.

In the Western states, we have developed a strong economic ecosystem surrounding hemp including partnerships with universities for research and development. In Oregon, the new Global Hemp Innovation Center, which combines 40 scientists from 19 disciplines at 10 research centers statewide, is setting the course for vigorous investigation of the crop from genetic analysis to harvest techniques and beyond. The industry has worked in collaboration with one another and closely with state departments of agriculture to establish the appropriate labs and training programs since research hemp pilot programs were installed as early as 2014.

While the IFR, following on the numerous stakeholder meetings conducted by USDA, indicates USDA’s sincere and largely successful effort to provide the regulatory structure needed to move

the industry to the next national level, we believe that there are some elements that are misguided and which we fear would hinder or even destroy the industry if implemented without change. We understand that hemp is a unique crop in that certain THC levels trigger DEA oversight. However, if the right balance is not found and the industry is too tightly regulated, the hemp industry will suffer serious economic harm.

In summary, this balance requires that USDA develop a program with the following three critical elements:

- 1. A sampling program based on using a homogenized sample that consists of 25% -30% flower and the remainder being made up of stem/leaf and stalk.*
- 2. A testing program that is at least 30 days before harvest or a post-harvest test.*
- 3. A phase in period for DEA lab registration.*
- 4. Allowance to move a crop from field to drying facility prior to testing results even if that entails moving the crop between independent license holders.*

It is with this important concern about the fate of this important industry for our region that we provide the following comments.

II. The Proposed Sampling and Testing Guideline Would Seriously Harm the Industry

The proposed sampling and testing guidelines accompanying the IFR is not in accord with current practice in the western region and would seriously harm the industry if implemented as proposed. Attached we have provided a “redline” version of the sampling and testing guidance for your consideration (ref. Appendices A, B and C). We have also prepared a proposed approach to methods and procedures for the preparation of THC-compliant hemp biomass for extraction (Appendix E).

“Whole Plant” Testing

In the state of Washington--which currently stands as the third-largest agricultural state--THC concentration testing for harvest samples is performed by creating a test sample via random sampling which is homogenized and decidedly representative. Derived from a statistically significant set of data, the Washington Department of Agriculture (WSDA) Industrial Hemp Research Program (IHRP) determined a sample representative of hemp entering commerce consists of approximately 25-30% flower and 70-75% stem, leaf and stalk.

It is our experience that sampling the top third of the plant, as proposed in the USDA sampling guidance, would be a drastic change from WSDA determination and is neither derived from scientific substantiation nor based on good policy. Sampling from the top third of the plant is not

representative of the whole plant and selecting only from the flowering and leaf material of the hemp plant is also not representative of the nature of the crop entering commerce. To change the approach to that of the USDA sampling guideline would be devastating to our industry.

We appreciate that the sampling protocol is in the USDA guidance and not the IFR itself. On this basis, we maintain that our state authorities could choose to continue their current practice. However, we recommend USDA model their guidance according to WSDA precedent and use protocol outlining the analysis of a whole-plant, homogenized, representative sample of 25-30% flower and 70-75% with stem, leaf and stalk.

The USDA sampling guidance also contemplates that field inspectors would be responsible for gauging the maturity of plants in terms of flowering, which differs according to different genetics, varieties and growing environments. We therefore stress the importance of stout training of sampling officials for accurate assessment of sampling viability.

Proposed 15-Day Period is Too Short

In our many years of experience and considering current factors, the turnaround time can vary from twelve to beyond twenty-five days for sampling to lab result. Farmers need the flexibility to plan for harvest according to compliance results. In our region, the period is twenty-eight days for Oregon and thirty days for Washington. We respectfully submit that fifteen days is simply too restrictive. In a realistic scenario, to sample material from every lot from a field, prepare said material to the degree that the sample can be tested on a dry weight basis, conduct compliance testing and release results will require more than fifteen days.

Another approach that is science-based, representative and administrable is to move to a postharvest test. Washington state passed hemp legislation in 2019 for a postharvest test based on a whole plant representative sample as the official sampling method before the official publication of the IFR. Under this program, the harvested crop would have been ground into biomass and tested, rendering results representative of the identity of the crop as it would exist entering the marketplace. Since the IFR does not cover a postharvest test and requires an in-field, preharvest test instead, this method was unfortunately abandoned.

The period from sampling to test results ranges greatly depending on location of farm, how wet or dry the sample and time of harvest. An important factor that we would like to bring to USDA's attention is the drying process as it relates to moisture content of samples for accurate THC testing. At different seasons, and regions, etc. the drying process can either be a non-issue or it can be seriously time-consuming. When setting standards, the USDA should be careful in putting undue burdens on hemp farmers in regions such as the Willamette Valley in Oregon

whose acreage experience more rainfall per year than many other areas of the country. The samples received from the Willamette Valley, for example, will potentially arrive to testing labs wetter than most and will require significantly more time, processes, or overall effort to render them fit for accurate analysis, making the fifteen-day testing window that much harder to stay within.

On average, the timeline for us in Oregon and Washington is typically:

1. Samples taken from the farm. They arrive at the lab one to five days from "sampling" by an agency inspector.
2. Samples are dried at the lab. It takes up to ten to fourteen days to dry each sample before extraction and analysis. (When samples are too wet you don't get a reliable extraction efficiency.)
3. Samples are analyzed. Depending on the testing platform used and sample volume, testing typically takes a minimum of three business days.

In overview, we would be able to support either a postharvest THC concentration analysis in lieu of a preharvest test; a thirty day preharvest test with a "whole-plant," representative sample in lieu of a fifteen day preharvest test; or a choice between the two options. We would also like to suggest that perhaps USDA utilize sampling procedures according to market i.e. employ a sampling of flowering material for flower producers and a whole-plant, representative sample for biomass producers.

A redline of the Washington State Department of Agriculture (WSDA) procedure is as attached (Appendix D) which outlines our ideal sampling and testing guideline.

DEA Lab Registration Requirement is Potential Bottleneck

While we understand the role of the Drug Enforcement Agency (DEA) in light of the failure to remove THC from the CSA as proposed by numerous bills pending in Congress, we are concerned that there will not be adequate lab capacity as the result of the DEA analytical lab registration requirement.

It is our understanding that DEA is considering not allowing analytic labs that currently test for medical and recreational marijuana pursuant to state laws to register as hemp analytic labs. We urge USDA to work with DEA to allow these labs to be registered as analytic labs for testing hemp. The existing state-regulated cannabis labs already have the method development and validation techniques for the cannabis plant and can ramp up quickly.

There is a strong argument that DEA involvement is not necessary. Hemp is an agricultural commodity and therefore should not be categorized otherwise. Beyond this fact, testing labs will only be providing compliance testing and will not have a significant amount of THC on hand. DEA registration and overreaching requirements would be a deterrent to testing laboratories entering this market.

If DEA will not allow existing state regulated cannabis labs, then there must be a three- to five-year period during which unregistered analytic labs will be allowed to phase into the program.

Farmers May Need to Move Their Crops to be Dried Before Test Results are Received

The IFR does not address moving hemp crops to be dried after harvesting while awaiting test results. Hemp farmers face significant obstacles when it comes to drying their crops, the two main considerations being space to dry and/or access to drying facilities. If hemp crops are not able to be moved, farmers will have no choice but to have to wait to harvest until test results are received with plants sitting in the field for days or weeks after being tested before harvesting. In order to avoid mold, degradation and silage fire concerns as result of, a vast majority of crops will need to be moved from fields to properties to start the drying process within six hours of harvesting. Some farmers may have drying capabilities but not all farmers will have proper storage on site and may also have to move off premises to be stored.

Again, this is another instance by which a postharvest test would mitigate some of the struggles that face hemp producers to date. But, in the absence of a postharvest test, USDA must allow hemp crops to be moved to a drying area or facility off the premises as soon as tests are taken and then stored until test results are released, even if this means a change in custody. Drying areas and facilities as well as storage spaces, could be documented as needed to follow the movement of the crop until determined legal hemp. After moved, dried and placed in storage, crops determined to be over 0.3% THC will then be returned to the premises and dealt with for use on the farm or destruction.

The timing of harvesting and drying are an integral part of producing hemp and without allowances for this in a timely manner, compliant crops could be lost in total.

Conclusion

The shared goal of the industry and USDA is to allow the promising U.S. hemp industry to continue to flourish and create good rural agriculture jobs for our nation. To achieve this goal, we must work together to balance the key factors of: 1) definition of the sample; 2) timing of

taking of sample and test results; 3) lab qualification; and, 4) drying considerations of hemp pending test results. USDA should approach these four key decisions against the backdrop of an already thriving and established industry pursuant to state laws in the western U.S. states. USDA should not disrupt this ongoing job creation and agriculture success story unnecessarily. In addition, USDA should consider that the testing level of 0.3% total THC is arbitrary, let alone extremely difficult to obtain in accord with nature, i.e. the living and growing hemp crop. Adding additional restrictions in this already difficult industry will most likely seriously harm the economic viability of the crop nationally.

Sincerely,



Dylan Summers

President, Association of Western Hemp Professionals

On Behalf of the Association of Western Hemp Professionals

Cc: Steve Censky

Bill Summer

Sonia Jimenez

Bill Richmond

Patty Bennett

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Attachments:

Appendix A - "Proposed Redline of Sampling Guidance (Pre-harvest)"

Appendix B - "Proposed Redline of Sampling Guidance (Postharvest)"

Appendix C - "Proposed Redline of Testing Guidance"

Appendix D - "Trace Analytics Hemp Cannabinoid Testing Protocol"

Appendix E - "Method and Procedures for the Preparation of THC Compliant Hemp Biomass for Extraction."

Appendix F (attached for reference not mentioned in comment) - Washington State Senate Letter

Sampling guidelines for hemp growing facilities - Pre-harvest

Purpose:

1. Standard sampling guidelines are specified for field and greenhouse sampling of hemp.
2. Samples are taken to obtain specimens for the measurement of tetrahydrocannabinol (THC) content, which determine whether the specimens are hemp or marijuana. The measurements are intended to be representative of the THC content in a “lot” of hemp crop acreage as identified by the producer. Hemp producers may not harvest hemp prior to the hemp being sampled and tested for THC concentration. Testing procedures are provided in a separate document.

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.

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.

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.
 - 2.1. The size of the bags will depend upon the number of clippings collected per lot.
 - 2.2. 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

Sampling Guidelines:

1. The licensee or designated employee shall accompany the sampling agent throughout the sampling process.
2. Surveillance of the growing area.
 - 2.1. The inspector shall verify the GPS coordinates of the growing area as compared with the GPS coordinates submitted by the licensee to USDA.
 - 2.2. 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).
 - 2.3. The inspector shall visually establish the homogeneity of the stand to establish that the growing area is of like variety.
3. Time of Sampling:
 - 3.1. Within ~~15~~ 30 days prior to the anticipated harvest of cannabis plants, an approved Federal, State, local, or Tribal law enforcement agency or other State or Tribal designated person shall collect representative samples from such cannabis plants for THC concentration level testing. (15 days is an unacceptable turnaround time from farm to laboratory and then back to the agency. Samples should be dried and processed as soon as possible without a constricted of timeline. t least 30 days is more realistic then 15 days. The producer shall be allowed to quarantine their harvested product while waiting laboratory results once dried on or off premises.)
4. Field Sampling:
 - 4.1. 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.
 - 4.2. For lots of less than one acre, including greenhouses, select a minimum of ~~1~~ 3 plant, then take a cutting from the plant to form a sample. The cutting must consider the representative differences in the phenotype of the biomass. It is generally accepted that in any given hemp plant that approximately 25-30% is flower, the rest is stem, leaf and stalk. Those three samplings per plant shall indicate one “sample” For lots of 2 to 10 acres, including greenhouses, select a minimum of ~~one~~ 3 plant per acre, then take cuttings of each plant, then combine to form a composite sample. Every sample taken shall conform to the sampling

technique that employs taking a representative sample from three points on the plant.

4.3. For growing areas larger than ten (10) acres, including greenhouses, the number of plants that will be selected to form a **representative** composite sample of is based upon the Codex Alimentarius Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLS CAC/GL 33-1999.

4.3.1. 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.

4.3.2. The initial number of primary plants is estimated using...

...6. Collecting Samples from each lot:

6.1. 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 **in a zig-zag pattern.**

6.2. 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.

6.3. ~~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. **The cuts must be made to take a representative sample from all three major areas of the plant: flower, leaf and stem, and stalk. There needs to a focus on whole plant “representative” sampling.**

6.4. Utilize a paper sample bag for collecting sample cuttings. Ensure that each bag has the minimum number of cuttings, n, as calculated by 4.3.3, or in the Example Tables 1 and 2.

6.5. Seal each bag and record the sample number.

7. Sample identification:

7.1 The inspector shall seal each bag and record the sample identification number. The sample shall also be identified with the following information:

(1) The sample ID shall include: Sampling agent contact information ; name and contact information of the producer; producer hemp license or authorization number ; date of sample; and “lot” ID as provided by the USDA Farm Service Agency; any other information that may be required by States, Tribes, Law Enforcement Authorities, mail delivery services, customers or groups of customers.

Sampling guidelines for hemp growing facilities - Postharvest

Purpose:

1. Standard sampling guidelines are specified for field and greenhouse sampling of hemp.
1. 2. Samples are taken to obtain specimens for the measurement of **delta 9** tetrahydrocannabinol (THC) content **postharvest**, which determine whether the specimens are hemp or marijuana. The measurements are intended to be representative of the THC content in a “lot” of hemp crop acreage as identified by the producer. Hemp producers may not **harvest remove hemp from a listed location once dried to transfer to a buyer** prior to the hemp being sampled and tested for THC concentration. Testing procedures are provided in a separate document.

Scope:

1. Samples collected under this procedure are acceptable for submission to a qualified, ~~DEA~~-registered **state or USDA** laboratory for determination of THC in hemp.
1. 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. **Postharvest representative sampling and testing of the hemp plant will give the most accurate THC concentration of material entering the market.**
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.

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 **representative** 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~~ **hemp** 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.

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.

2.1. The size of the bags will depend upon the number of clippings collected per lot.

2.2. 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

Sampling Guidelines:

1. The licensee or designated employee shall accompany the sampling agent throughout the sampling process.

2. Surveillance of the growing area.

2.1. The inspector shall verify the GPS coordinates of the growing area as compared with the GPS coordinates submitted by the licensee to USDA.

2.2. ~~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).~~

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

3. Time of Sampling:

3.1. ~~Within 15 days prior the anticipated harvest of cannabis plants~~ **After harvest of licensed hemp lots**, an approved Federal, State, local, or Tribal law enforcement agency or other State or Tribal designated person shall collect representative samples from such ~~cannabis~~ **homogenized hemp** plants for THC concentration level testing. **The producer shall be allowed to quarantine their harvested product while waiting laboratory results. The cutting must consider the representative differences in the phenotype of the biomass. It is generally accepted that in any given hemp plant that approximately 25-30% is flower, the rest is stem leaf and stalk. These three samplings per plant shall indicate one sample. Samples will be processed as soon as possible without a constricted timeline.**

4. ~~Field Sampling:~~

4.1. ~~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.~~

4.2. ~~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 3 cuttings of each plant, then combine to form a composite sample.~~

4.3. ~~For growing areas larger than ten 10 acres, including greenhouses, the number of plants that will be selected to form a~~ **representative** ~~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.~~

4.3.1. ~~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.

4.3.2. The initial number of primary plants is estimated using

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.

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

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.

4.3.4. 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:

Appendix B

Number of acres	Sample Size "n"	Number of acres	Sample Size "n"	Number of acres	Sample Size "n"	Number of acres	Sample 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	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	150-152	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

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 Acres "N"	Sample 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

6. Collecting Samples from each lot:

6.1. — ~~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.~~

6.2. — ~~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.~~

6.3. — ~~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. Samplers will take a representation of all three major areas of the plant: flower, leaf, stem, and stalk to focus on whole plant. A 1/4 cup of a ground representative sample will be taken randomly from each 1000lbs of dried homogenized hemp material.~~

6.4. Utilize a paper sample bag for collecting sample cuttings. Ensure that each bag has the minimum number of cuttings, n, as calculated by 4.3.3, or in the Example Tables 1 and 2.

6.5. Seal each bag and record the sample number.

7. Sample identification:

7.1 The inspector shall seal each bag and record the sample identification number. The sample shall also be identified with the following information:

(1) The sample ID shall include: Sampling agent contact information ; name and contact information of the producer; producer hemp license or authorization number ; date of sample; and "lot" ID as provided by the USDA Farm Service Agency; any other information that may be required by States, Tribes, Law Enforcement Authorities, mail delivery services, customers or groups of customers.

Testing Guidelines for Identifying Delta-9 Tetrahydrocannabinol (THC) Concentration in Hemp

Purpose:

1. 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 and assess the moisture content of the sample**. Hemp testing laboratories are not required to be ISO accredited, although USDA 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 **are 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:
 - (a) Laboratory quality assurance must ensure the validity and reliability of test results;
 - (b) 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;
 - (c) The demonstration of testing validity must ensure consistent, accurate analytical performance; and
 - (d) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part.
 - (e) 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.
 - (f) The total delta-9 tetrahydrocannabinol concentration level shall be determined and reported **on a dry weight basis along with the moisture content of the sample**.
 - (g) Any 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 the lot

represented by the sample is not in compliance with this part 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. In order to provide flexibility to States and Tribes in administering their own hemp production programs, alternative testing protocols will be considered if they are comparable and similarly reliable to the baseline mandated by section 297B(a)(2)(ii) of the Agricultural Marketing Act of 1946 and established under the USDA plan and procedures. Alternative testing protocols must be requested of USDA in writing and approved in writing by USDA, provided they meet the requirements of this guidance.

General Sample Preparation and Testing Procedures are as follows:

1. Laboratory receives sample.
2. ~~Dry sample to remove the majority of water.~~ The moisture content of the sample material is assessed using a moisture balance or other acceptable instrument.
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.~~ The sample is then homogenized taking representative samples of the biomass to reflect the weight of all parts of the sampled material.
4. Separate sample into a test and retain specimens.
 - a. Test specimen: go to step 5
 - b. 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.~~

(A) Samples shall be received and prepared for testing in a DEA registered laboratory as follows:

(1) 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.~~

(2) ~~The laboratory shall mill and manicure samples though a wire screen no larger than 1.5 x 1.5mm to discard mature seeds and larger twigs and stems.~~

(3) 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.

(4) ~~The laboratory shall then determine moisture content or dry to a consistent~~

~~weight.~~

(5) 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.

~~Total THC is calculated using the following formula: Total THC= (THCa * .877) + THC).~~

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.

~~(6) The laboratory will then calculate total THC on a dry weight basis.~~

References:

E. Small and H. D. Beckstead. 1973. Common Cannabinoid Phenotypes in 350 stocks of Cannabis. *J. of Natural Products*. 36(2): 144-165.

United Nations Office on Drugs and Crime: Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products. ISBN 978-92-1-148242-3.

Appendix D

Trace Analytics Hemp Cannabinoid Testing- Fall 2019 Method

Trace was tasked with method development for the Industrial Hemp Pilot Program (IHPP).

Overview:

Obvious phenotypic biomass differences exist throughout the hemp plant. The challenge was to submit a “representative” plant biomass sample for cannabinoid testing. Trace scientists assessed the biological differences in plant matter and assessed the relative differences in mass type by percentage of mass.





The plant is made up of stems, stalk, leaves and flower material.



The samples were manually separated by biomass classification.



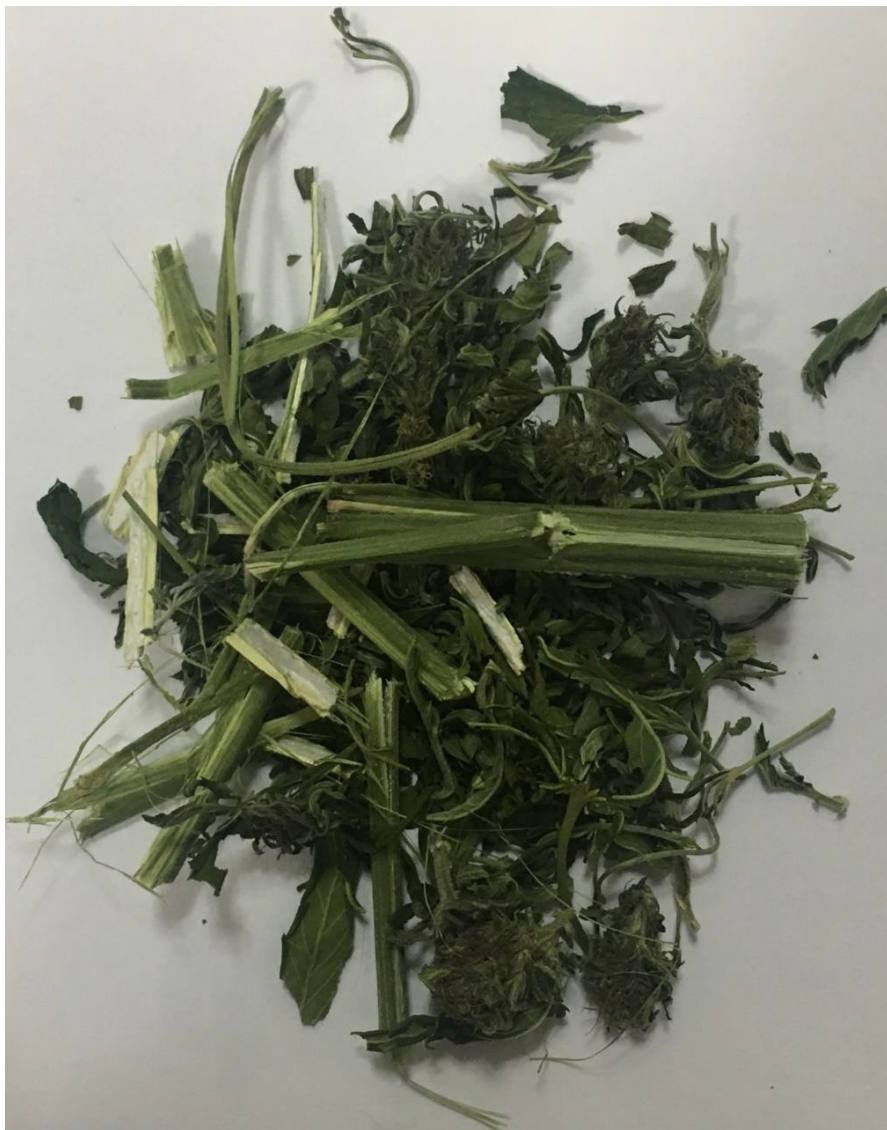
**Stalk Stems Stems Leaves Flower
(Leaf) (branches)**

After sample analysis it was evident that stalk, stems and flower make up the following percentages after the biomass was divided. (in % by weight of sample)

- Flower: 30%
- Medium Stems: 17%
- Leaf Stems: 3%
- Stalk: 13%
- Leaves: 37%

Appendix D

A representative biomass sampling:



Analysis based on sample is following the algorithm in which samples are subsampled based of the biomass differences across the plant. The following percentages are applied to the analytical testing to interpret true cannabinoid percentages across each industrial hemp plant sample.

Stalk and Stems: 33%
Leaves: 37%
Flower 30%

Method and Procedures for the Preparation of THC Compliant Hemp Biomass for Extraction.

Interstate Shipment of Biomass for extraction:

Growers responsibility is to grow, harvest, dry and bulk package for sale bulk Hemp material that is Federally compliant (.3% on a dry weight basis).

Solution: Homogenization of Biomass into a Homogenous blend of whole or partial plant material. Post homogenization Potency test for compliance. An optional last step is to further process the homogenous material into pellets for a second option for safe transportation. A postproduction potency test to verify Federal compliance.

Critical Items: Testing pre harvest and post-harvest. Hemp plant material homogenization with a post homogenization potency analysis for Total THC.

THC compliance to the Federal Level. Maximum THC d9 .3% Dry Weight.

- **TESTING ACCURACY.** Throughout the Hemp Supply Chain, sample cross contamination issues (THC vs CBD) will occur if Marijuana THC Laboratories are designated as Hemp Testing Labs. Multiple areas of cross contamination. Accuracy of Laboratory testing is a requirement throughout the Hemp Supply Chain. It begins with the farmers' preharvest test, an inaccurate test can potentially cost the grower his crop. Shimatzu, a leading manufacturer of HPLC's for the Marijuana Industry, just released for sale a Hemp Potency Analyzer (HPLC) that will test for a broad range of Cannabinoids with ultra-high resolution and far greater accuracy.
- **HOMOGENIZATION OF EXTRACTION BIOMASS:** Step #1: A grower produces Hemp for **CBD Extraction**. In Oregon, the Dept of Agriculture requires a pre harvest test for THC Potency. We will assume that the Hemp passes this first Lab test. This pre harvest test can be done up to 3-4 weeks prior to harvest. This pre harvest test needs to be for the exclusive use of the Oregon Department of Agriculture. The ODA pre harvest test cannot be used for THC compliance when the Hemp is sold. Step #2: Based on the grower's method of harvest (ground, chopped, shucked, etc.) the grower will need to create a Standard Operating Procedures (SOP's) for Biomass sold to extractors. The grower will need to consider the following: [1] the method of harvest for the farms Biomass for extraction; [2] based on the grower's method of harvest and the size of the harvest lot(s), the grower would then collect plants (# of plants TBD) from the harvest lot(s) to be harvested. The grower needs to replicate the harvest method (chopping, grinding or stripping etc). Step #3: the grower is to set up one or more composite tests for potency based on the size of the harvest lot i.e. the number of plants sampled. The final step in the preparation of the Composite samples is to grind and homogenize the material to be lab tested. The composite test(s) or "current" pre harvest test for Cannabinoids needs to be submitted to an approved lab 7 days prior to harvest.
- **DETERMINE THE OPTIMUM HARVEST METHOD & HOMOGENIZATION:** Evaluate the "C" pre harvest Lab test results for Federal compliance. Adjust Harvest method to meet Federal THC limits. Chopping, homogenizing and packaging the Harvested Hemp can now be done with confidence.

- **PREFERRED METHOD OF PACKAGING FOR INTERSTATE COMMERCE:** Ag Bags or Super Sac's is the preferred method of packaging for delivery to customer. Each Bag will be weighed and tagged with a Gross Weight and a Tare Weight. Each Bag will have a sequentially numbered heavy-duty zip-tie. This will be considered the specific Batch or Lot number with Chain of Custody to the specific Harvest Lot and the specific Genetics and the related details. Suggested procedure: chop harvested material and load into Ag Bags to a specific weight.
- **FINAL PACKAGED PRODUCT LAB TEST PRIOR TO SHIPPING:** Make a Composite sample every four bags of chopped hemp biomass. Track the four bags that make up the Composite Lab test by assigning a specific numbered zip-tie to each bag and record the bag numbers on the Composite Potency test to the Lab. As each bag is sampled, the zip-tie is sealed and recorded on the Bill of Lading. The Lab test results will be detailed on a Certificate of Analysis (COA). Each COA will list each of the four, individual zip-tie with the corresponding numbers. A COA will be attached to the corresponding Bag in a transparent plastic sheet cover. Ship the Load.



Legislative Building
Olympia, WA 98504-0482

Washington State Senate

Phone: (360) 786-7550
FAX: (360) 786-1999

December 18, 2019

The Honorable Sonny Perdue
Secretary, United States Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20250

Re: Washington State Elected Officials' Comments on the New USDA Hemp Program

Dear Secretary Perdue:

On behalf of a group of Washington state elected officials and businesses, we would like to share with you our appreciation for the new United State Department of Agriculture (USDA) hemp program and also highlight several proposals for improvements to the Interim Final Rule that implements the new program.

As we know you agree, the passage of the 2018 Farm Bill was a momentous occasion for agricultural businesses in the state of Washington and the United States, and we appreciate all that you did to make this new program a reality.

In issuing the Interim Final Rule (IFR) implementing the 2018 Farm Bill, the United States Department of Agriculture has helped further the federal hemp production program and we appreciate your efforts to give new business opportunities to farmers and other industry professionals in our state.

As sponsors and supporters of our Washington Hemp Legislation, WA SB 5276, we are considering points raised by hemp researchers, cultivators and regulators in our state. There are a few issues with the IFR that we believe deserve careful attention from USDA. Highlighted below are key areas of concern along with proposed solutions we believe to be well-aligned with the 2018 Farm Bill and the goal of creating a thriving American hemp economy.

The most pervasive concern heard from across nearly all phases of the hemp cultivation industry surround the fifteen-day period for preharvest compliance testing. Additionally, there are warranted concerns regarding what constitutes a significant "representative" sample when assessing compliance.

The Washington Department of Agriculture Industrial Hemp Pilot program found that in a statistically significant number of "representative" samples that approximately 25-30% was flower and 70-75% was stem, leaf and stalk. Sampling from the top third of the plant is not representative of the whole plant and selecting only from the flowering and leaf material of the hemp plant is also not representative. The hemp grown in Washington this year was mainly for biomass.

Solution: A whole plant homogenized representative sample of 25-30% flower and 70-75% with stem, leaf and stalk.

USDA must understand that fifteen days is too restrictive. In a perfect scenario, to sample material from every lot from a field, prepare said material to the degree that the sample can be tested on a dry

weight basis, conduct compliance testing and release results will require more than fifteen days. Our state's Hemp Legislation included a postharvest test for the 2020 season with a whole plant homogenized representative sample. Under the 2019 IHRP, we had a 30 day preharvest with a whole plant homogenized representative sample which proved a reasonable time frame.

Solution: To accurately ensure compliance with the 0.3% THC testing requirement, a postharvest test is most appropriate. However, a secondary choice is to simply extend the fifteen-day sampling period to thirty days using a whole plant homogenized representative sample. This gives hemp growers a more reasonable amount of time to plan for harvest according to compliance test results. States should have the option to choose between a pre or postharvest test.

There is a general concern about the role of the Drug Enforcement Agency and that requiring that testing facilities register with the DEA will cause an undue industry bottleneck which would slow commerce. Testing labs will only be providing compliance testing and will not have a significant amount of THC on hand. Also, labs entering this industrial hemp testing market will have to develop and validate analytical methods which can take a year or more. A DEA registration and overreaching requirements would be a deterrent to testing laboratories entering this market. Since testing labs would only have minute amounts of THC extracted for chemical analysis, there is likely no need to have labs register with the DEA.

Solution: Remove registration under the purview of the Drug Enforcement Agency.

We look forward to your careful consideration of our recommendations.

Sincerely,



Senator Doug Ericksen
42nd Legislative District



Senator Judy Warnick
13th Legislative District