USDA (Agricultural Marketing Service) 7 CFR Part 990 [Doc. No. AMS-SC-19-0042; SC19-990-2 IR]
Establishment of a Domestic Hemp Production Program
AMERICAN COUNCIL OF INDEPENDENT LABORATORIES COMMENTS

Referenced throughout: Cannabis Laboratory Accreditation Program (CanNaLAP) requirements published by the American Council of Independent Laboratories and the Independent Laboratories Institute and included in Attachments #3 and #4 of these comments.

LAB APPROVAL

Drug Enforcement Agency Registration
While ACIL appreciates the intent of Drug Enforcement Agency (DEA) registration for testing laboratories, the practical impact of registration for hemp testing presents a number of issues:

- DEA registered laboratories are **only** permitted to receive samples from other DEA registered facilities. Hemp producers would thus have to acquire DEA registration in order to send product for testing – a requirement **that is not mandated through the USDA program**.
- Acquiring and holding DEA registration would raise the cost of compliance for producers, as there are a number of additional business requirements that would need to be met in order to register.
- Requiring DEA registration would not allow laboratories currently engaged in cannabis and hemp testing to participate, since they receive THC items through State sanctioned programs from non-DEA registered holders.

Our member laboratories have contacted DEA offices in their respective areas and were advised that the DEA is **unaware of the registration requirement and do not have any program set up specifically for the hemp industry.** With the compliance issues presented by this requirement at present, **ACIL encourages USDA to drop the registration requirement with DEA until such time as the rules and policies are aligned with regard to the hemp industry between the two Agencies.**

As an alternative to DEA registration, we recommend an International Organization for Standardizations (ISO) 17025 Accreditation requirement, which is customary in many industries and provides all the measures and safeguards necessary to ensure lawful compliance with the Rule. This Accreditation requirement is included our CanNaLAP guidelines for cannabis testing laboratories.

USDA Lab Approval
Laboratory approval requirements should be based on the use of International Laboratory Accreditation Cooperation Mutual Recognition Agreement (ILAC MRA). The accreditation bodies that are signatories to the ILAC MRA have been peer evaluated in accordance with the requirements of ISO/IEC 17011 to demonstrate their competence. This system has been adopted not just nationally but internationally. This global recognition for laboratories is used to attest to the quality, integrity, assessment of risk, and scope of abilities around the world to global

standards. There are currently over 100 signatories to the ILAC MRA and the agreement follows **ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories**.

While accreditation to ISO/IEC 17025:2017 by an accrediting body recognized by the ILAC MRA is an important first step in showing the laboratory's competence, it does not specifically address the unique qualities of hemp. For this reason, additional criteria must be considered. ACIL has developed its CanNaLAP criteria to complement the ISO/IEC 17025:2017 standard specifically with considerations specifically related to cannabis. This set of criteria was developed with the participation of over 15 independent entities consisting of large and small contract laboratories, industry representatives and related stakeholders. These criteria are based upon solid scientific technique with a focus on sampling and method validation.

We recommend the use of the CanNaLAP criteria by USDA to give the government the ability to perform cannabis-specific compliance activities while assigning the routine assessment of the laboratory's competency to recognized laboratory accreditation bodies with required ISO 17025 compliance.

SAMPLING

Defining Approved Sampling Agents
The Food Safety and Modernization Act (FSMA) program for approved food samplers provides the best federal example for the accreditation of hemp samplers. The existing program offers an already implemented and approved process that can be modeled to regulate and ensure the quality of hemp sampling.

Sampling is always the most error prone portion of any analytical task. If the samples taken are not representative of the harvest, the risks are twofold: a false positive THC failure, resulting in unnecessary destruction of the harvest; or a false negative, resulting in the inappropriate release of the harvest to market. In order to mitigate these risks, sampling organizations should be required to show competence to develop and execute sampling plans that will meet the goals of the USDA program. **The best way to accomplish this is for sampling organizations to be part of an accredited program where they demonstrate their abilities to meet these requirements to an accreditation body.** Furthermore, to best serve the industry, impartiality should be maintained by the sampling organization.

ACIL requests that USDA include sampler accreditation language with the following effect: **"Sampling organizations are to be independent of the grow operation. These organizations shall be accredited for sampling to ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories by an International Laboratory Accreditation Cooperation Mutual Recognition Agreement (ILAC MRA) signatory accreditation body."** The standard itself has both general technical requirements related to sampling and requirements for impartiality.

Chain of Custody

The current USDA IFR for a Domestic Hemp Production Program lacks a process for chain of custody to track samples from sampling to testing laboratories. ACIL requests the following industry best practices be formalized:

- Samples must be sealed with a tamper-proof seal appropriate for the sample container. Seals must be uniquely numbered and when possible identify the sampler, individual or entity. Additional tags would correspond to the location of sampling, date and time.
- Sample collection reports must be placed in a moisture barrier bag and sealed with the sample. An original copy of the sample collection report with the GPS coordinates for each of the subsamples; the name and address of the producer; the name address and affiliation of the sampler; the person accompanying the sampler; the date and time of sampling and other USDA requirements must accompany the samples. The sample collection report must have a space where the receiving laboratory will acknowledge condition, date, time and person receiving the sample.
- Sample containers must be appropriate to protect the integrity, condition and security of the sealed samples. Samples must remain under the control of the sampler until received at the lab.

Sampling Procedures

The Agricultural Marketing Service (AMS) sampling guidelines stipulate that a "cut shall be made just underneath a flowering material, meaning inflorescence (the flower or bud of a plant), located at the top one-third {⅓} of the plant". The testing guidelines further stipulate that "the laboratory shall dry all of the leaf and flower (not obvious stem and seeds) of the composite sample".

The result will be an analysis of material that is **not representative of the entire plant or batch**, since leaves and flowers taken from the top 3rd have significantly higher percentages of THC than the remainder of the plant. For comparison, California Department of Food & Agriculture (CDFA) stipulates in their Regulations for Industrial Hemp Cultivation that "Each primary sample shall include all parts of the plant, including stems, stalks, flowers, leaves, seeds, and buds from... the terminal 18 inches of the top lateral branch… and the terminal 18 inches of one lateral branch from the lower one-third of the plant" (if containing multiple branches). If the plant contains only one branch, then the sample is to be taken of the "terminal 18 inches from the terminal bud at the top of the plant… [or] if the plant is less than 18 inches tall, the whole plant shall be taken."

Since hemp cultivators use all parts of the plant, and not just flowers and leaves taken from the top third, we encourage USDA to adopt CDFA Regulations regarding whole plant sampling of hemp material. These sampling requirements would result in more representative samples, fewer false positives for excessive THC content, and less issues for hemp shipped across state lines.

Testing Standards
ACIL does not believe that government entities should be rewriting standards, procedures and methodologies for cannabis testing. The legalization of cannabis in many states has led to the development of regulatory frameworks for laboratory testing and accreditation. Established consensus standards development organizations such as AOAC and ASTM should be relied upon to provide testing standards for the industry. Laboratories following the protocols established by these non-governmental organizations could then be authorized by the Federal government to conduct analytical testing activities with cannabis in accordance with the Rule.

The Canadian government gives a valuable example in this regard, authorizing laboratories to conduct analytical testing under their Cannabis Act but not accrediting the testing procedures or methods. **ACIL offers its CanNaLAP requirements for Laboratories as a model for domestic cannabis testing. CanNaLAP relies on the industry testing standards described above to set out uniform requirements for laboratories in the cannabis sector.**

Testing instrumentation
Because of the decarboxylation of THCA in a heated Gas Chromatography (GC) inlet during sample injection and analysis which converts THCA to THC thereby adding another variable to the analysis of Hemp, the ACIL Laboratory community **prefers high performance liquid chromatography (HPLC) be required as the preferred analytical instrument** since it does not alter the concentration of active ingredients contained in samples through the analytical process.

Conversion factor to delta 9 not defined in IFR
The AMS Testing guidelines stipulate that "The testing methodology must consider the potential conversion of delta-9 tetrahydrocannabinolic acid (THCA) in hemp into delta-9 tetrahydrocannabinol (THC)" but does not define the conversion factor for the conversion of THCA to THC. **We believe a conversion factor of 0.877 should be utilized** per the molecular weight of each compound. This is the conversion factor adopted by the California Bureau of Cannabis Control (BCC), Washington State Liquor and Cannabis Board (WSLCB), Code of Colorado Regulations, and a number of other state, national, and non-governmental entities.

Full Range Testing
Current AMS Testing guidelines requiring only THC content to be reported does not consider a number of other harmful materials that could be absorbed by hemp. Cannabis safety testing often includes screenings for heavy metals and pesticides, as well as other toxins and pathogens. **USDA should consider the wide range of potential contaminants that may be present in the composition of the plant** as processing post-harvest can result in the further concentration of these contaminants and there are currently no requirements for finished goods testing. This poses a risk to public health.

Measurement of Uncertainty (MU)
According to National Institute of Standards and Technology guidance, assigned uncertainty should be small relative to the total uncertainty targeted for test samples. **As a rule of thumb, assigned uncertainties should be about one-third or less of the target uncertainty** to ensure that uncertainty in the certified value will have negligible influence on the results of measurements. Current USDA AMS IFR language would allow for producers to use laboratories with poor uncertainty determination. The wider the uncertainty, the more product that can be approved potentially inappropriately.

The current Rule allows for the lowest accepted level of THC, 0.3%, to be *within the testing laboratory's method uncertainty*. If the laboratory has all of their processes developed to provide the most accurate and precise result, *their uncertainty will very small*. The contrast is also true that those laboratories who are not accurate and precise will have larger uncertainties for their analytical results. This would allow the growers to be able to have potentially higher THC concentrations, however, be within the laboratory uncertainty limits.

For example:
Lab A: Accurate and precise data (i.e.: higher quality data) would provide the below results:

0.32 % THC +/- 0.06% This gives the grower with the upper analytical range of 0.36% to work within.

Lab B: Much less accurate and precise data (i.e.: Lower quality data) would provide the below results:

0.38% THC +/- 0.12% This gives the grower with the upper analytical range of 0.42% to work within.

The issue is that the grower may be passing off out of control crops that may have unacceptable levels of THC only because the laboratory has poor analytical technique, and this is reinforced by the marketplace with a preferred commercial standing. The uncertainties of the laboratories must also be reviewed and evaluated independently to be comparable and statistically valid. This can be accomplished using proficiency testing studies with thorough and rigorous laboratory assessments.

If, for example, the maximum uncertainty cannot exceed 0.3 % ± 0.06 %, the requirement would drive method development and adoption of better technology such as liquid chromatography–mass spectrometry (LC-MS). Unofficial member laboratory polling revealed uncertainty averaging at ± 0.05 % for low levels of THC in hemp.

We advocate that the USDA Final Rule provides an uncertainty range that cannot be exceeded by a participating laboratory, therefore not giving the producer the ability to

shop for the widest uncertainty. This will also result in improved data comparability across the hemp industry.

COST ANALYSIS

Sampling of hemp is a complex logistical problem, because of the geography and scope of sampling on farms. USDA has grossly underestimated the sampling time and cost in IFR language. We understand that it is required that USDA estimate and publish the economic impact of the rule. **Our concern is that by publishing this cost data, producers will assume that the sampling and testing fees are pre-set**. The process of sampling is much more involved than arriving at a farm to start sampling hemp. For example, the field might be an extraordinary distance from the sampling facility. Arrangements must be made for introductions, coordination and operation of the necessary supplies and personnel for the sampling effort and, because the owner must accompany the sampler(s) in the field, the work is at the pace of the owner - not the sampler.

ACIL encourages USDA to calculate anticipated sampling costs with a minimum number of hours for each step in the sampling process versus a set metric that does not take into account the variables outlined above.

STATE PREEMPTION

As many states have established regulatory programs for marijuana and hemp, ACIL requests that USDA reach out to these programs to rely on their lessons learned, experience, and input to guide efforts. USDA should rely on existing state regulatory programs to develop and regulate the hemp industry.

ACIL supports the principles outlined in the Strengthening the Tenth Amendment Through Entrusting States (STATES) Act (S. 1028) introduced in the United States Senate on April 4, 2019. This Act ensures that each State has the right to determine for itself the best approach to marijuana within its borders. The bill also extends these protections to Washington D.C, U.S. territories, and federally recognized tribes, and contains common-sense guardrails to ensure that states, territories, and tribes regulating marijuana do so in a manner that is safe and respectful of the impacts on their neighbors.