Docket No. AMS-SC-19-0042-0983

USDA is considering requiring all laboratories testing hemp to have ISO 17025 accreditation. We are requesting comment on this requirement as well and are interested to learn about the number of labs that already have this accreditation, the associated burden, and the potential benefits of such a requirement.

Laboratory accreditation is required by most state standards and is included in their cannabis rules and regulations. Typically, this accreditation is to the ISO 17025[1] standard, which is an accreditation offered by a number of different organizations. While Americans for Safe Access (ASA) acknowledges the value in ISO 17025 accreditation, it is not the only standard that exists to evaluate laboratory operations. ASA would recommend to implement a laboratory accreditation requirement, but not limit the accreditation to only ISO 17025, but to those accreditations offered through other services that would be vetted and approved by the USDA.

The ISO 17065 standard applies to certifying bodies and ASA would recommend that all accrediting and certifying bodies that are evaluating cannabis laboratories be accredited to this standard. This standard is more stringent than its counterpart, ISO 17020, and is more appropriate to those organizations that are evaluating cannabis businesses. These certifying bodies should also be allowed to review and certify cultivation operations that fall under the jurisdiction of the USDA. Should the USDA approve State or Tribal Plans, the certifying bodies would be encouraged to work with their state organizations to implement hemp cultivation and laboratory operation standards.

We are requesting comments and information regarding the 15-day sampling and harvest timeline.

Americans for Safe Access is in favor of a minimum 30-day sampling and harvest timeline. Because some cultivators will have large lots, and because hemp flowers being cultivated for cannabidiol (CBD) content may require harvesting by hand, it is unreasonable to expect that all cultivators will be able to arrange for samples to be taken, wait for test results, and completely harvest their crop within a 15-day window.

It should be noted that the requirement that testing be conducted by DEA-certified labs may lead to a bottleneck. According to the USDA's website, there are only 42 such laboratories, and they can be found within only 22 states. (Table 1). At this time, laboratories have indicated an application process that can take up to, and even exceed, 2 years to receive DEA certification. Because of the lack of DEA certified labs, and the potential to not add new labs before the first harvest season next fall, ASA encourages USDA to allow states to adopt regulations outlining

[1] Disclaimer: The Americans for Safe Access Foundation's PFC certification program offers a dual PFC ISO/IEC 17025:2017 accreditation through a partnership with the American Association for Laboratory Accreditation (A2LA).

requirements short of DEA certification that licensed cannabis-testing laboratories could adhere to in order to provide analytical services to hemp producers.

Additionally, cannabis testing laboratories may not receive DEA Schedule I chemical analysis licenses. In January 2010, Full Spectrum Laboratories, a then-state-licensed cannabis testing lab in Colorado, had all of its cannabis testing samples seized by the DEA when agents inspected the facility as part of the DEA license application process. The laboratory lost all client samples, was shut down for almost a week, and lost a month of revenue. Despite the laboratory being authorized to test cannabis under Colorado's medical cannabis program, their samples were seized due to the federal status of cannabis. Because of this incident, no other cannabis testing labs have applied for DEA licensure.

Table 1: States with USDA Approved Hemp Testing Laboratories

State	# Labs
Arizona	1
California	7
Colorado	2
Florida	4
Georgia	1
Indiana	1
Kansas	1
Kentucky	3
Michigan	2
Minnesota	1
New Jersey	1
New York	1
North Carolina	2
North Dakota	1
Ohio	1
Pennsylvania	1
Tennessee	1
Texas	4
Utah	3
Virginia	1
Washington	1
Wisconsin	2

THC Testing

While the USDA does not specifically ask any questions regarding the methods used to quantitatively determine the total amount of THC, Americans for Safe Access would like to address the sampling and harvest timeline as it relates to testing. Freshly harvested hemp flowers contain a high amount of water, which can cause problems with certain sample

preparation techniques that are in use by cannabis testing laboratories. While laboratories have developed protocols to handle high-moisture samples so that there is no interference with the analysis, the issue arises when the testing results are reported.

USDA is requiring results be reported on a dry-weight basis. When a flower sample is analyzed that has a high water content, the overall results are that the cannabinoid content appears to be lower than it would be were it tested at a lower moisture level. When the samples are analyzed at a reasonable moisture level that more closely matches the moisture content of hemp floral material made available for sale or used in processing, the results are more accurately reported, particularly with regard to reporting on a dry-weight basis. While formulas exist for converting wet-weight results into dry-weight results, a more accurate method would be to report the potency and moisture level of the sample as tested and require the sample to meet specifications. Should a sample's moisture content fall outside of the specifications, it would need to be resampled after further drying.

Table 2 shows how samples may vary if results are adjusted for moisture content and reported based on that adjustment. The red boxes indicate samples that would fail for THC based on adjusting the moisture content after testing freshly harvested plant material. The orange boxes are samples that could potentially pass, if samples that are exactly 0.3% Total THC are acceptable based on the measurement of uncertainty. All flowers that tested at 0.3% THC wet weight would fail testing unless they had a measurement of uncertainty that could keep the actual result to 0.33 or less. Flower samples at 0.2% THC would need to have a moisture content of 10% or less in order to pass the requirements. At 0.1% THC, freshly harvested flowers with 75% moisture would fail after adjusting total THC to account for moisture.

As results are reported on a dry-weight basis, ASA recommends that testing be done when the product's moisture content matches industry standards to ensure the most accurate results reporting. The Bureau of Cannabis Control in California requires that finished flower have a moisture content of 5-13% by weight (see Appendix I). ASA would recommend that flowers intended for cannabinoid extraction be tested within a similar moisture range to ensure more accurate results reporting. Cultivators who are processing hemp for their cannabinoids already dry their flowers prior to the extraction process, so this requirement would ensure that test results more faithfully reflect the THC content of the hemp floral material being used toward this end.

Table 2: Potential Adjusted Results Outcomes for Hemp

% THC Wet Weight	% Moisture	% THC Adjusted Dry Weight	Rounding for Significant Figures
0.3	75	1.20	1.2
0.3	50	0.60	0.6
0.3	25	0.40	0.4
0.3	10	0.33	0.3
0.3	5	0.32	0.3
0.2	75	0.80	0.8
0.2	50	0.40	0.4
0.2	25	0.27	0.3
0.2	10	0.22	0.2
0.2	5	0.21	0.2
0.1	75	0.40	0.4
0.1	50	0.20	0.2
0.1	25	0.13	0.1
0.1	10	0.11	0.1
0.1	5	0.11	0.1

ASA supports the USDA's requirement that all results must be reported as Total THC by adding both the acidic and neutral forms of tetrahydrocannabinol together using the scientifically valid equation Total THC = THC + 0.877(THCA). However, ASA does not support the use of a gas chromatography (GC) method to determine cannabinoid content. At this time there are no published methods for gas chromatography that effectively show a 100% conversion of THCA to THC, thereby resulting in a potential loss of analytes. When samples are injected into the sample port of a GC system they are heated, which causes decarboxylation of the naturally occurring acidic cannabinoids. This decarboxylation is not always effective and there can be a loss of analytes, which could cause a batch to pass when it would be failing. ASA supports the use of liquid chromatography (LC) in the analysis. Liquid chromatography does not heat samples, so the results are more accurate and representative.

ASA also supports USDA's requirement that laboratory analyses be reported with a measurement of uncertainty. This measurement provides a more accurate depiction of what the cannabinoid content of the hemp plant is and encourages downstream producers to use accurate testing numbers when preparing manufactured products.

Sampling

Americans for Safe Access supports the USDA requirement that all samples be collected by a USDA-approved sampling agent or a federal, state, or local law enforcement agent authorized by USDA to collect samples. Experience has shown that allowing businesses to submit their own samples to laboratories for analysis provides opportunities for unscrupulous actors who prioritize profit over safety to adulterate samples in order to pass testing. By requiring that

samples be collected according to a scientifically valid sampling scheme and collected by independent samplers, operators will not be able to adulterate samples to pass testing.

ASA encourages USDA to allow for cultivators to be able to test their products post-drying, specifically for those producers who are growing hemp for its cannabinoid content. Cultivators who are producing hemp for cannabinoids must remove much of the moisture in the floral material prior to processing it. The high water content can disrupt the testing process by potentially reducing the total THC content when reported on a dry-weight basis, thereby leading to higher total THC upon drying. By requiring CBD producers to test their products post-drying, a more accurate value for total THC may be calculated. This is currently the standard practice for cannabis testing within the states that require potency analysis.

Hemp Waste and By-Products

The environmental impact of the growing desire for CBD products should not be ignored when putting these groundbreaking regulations into place. It is possible to produce hemp in a manner that is environmentally friendly and reduces the carbon footprint of large operations. ASA would encourage waste provisions for cultivation and manufacturing operations that allow for roots, stems, stalks, and other waste generated during cultivation be allowed to be composted, used as animal feed, or other approved green methods.

Disposal of Non-Compliant Plants

Per the 31 October 2019 Federal Register notice, “If a producer has produced cannabis exceeding the acceptable hemp THC level, the material must be disposed of in accordance with the CSA and DEA regulations because such material constitutes marijuana, a schedule I controlled substance under the CSA. Consequently, the material must be collected for destruction by a person authorized under the CSA to handle marijuana, such as a DEA-registered reverse distributor, or a duly authorized Federal, State, or local law enforcement officer.” This would seem to foreclose the possibility of remediating a crop that tests above 0.3% THC after accounting for the measure of uncertainty.

ASA urges that measures be implemented to allow cultivators to attempt to bring the level of THC down to or under the legal limit if it exceeds 0.3% (e.g., by adding vegetal material presumed to be devoid of THC, such as stems and stalks, to the vegetal material that tested at above 0.3% THC and then mulching and mixing the vegetal material to ensure that plant material that exceeds 0.3% THC cannot be separated out from the mixture.) Once retesting of the remediated mixture confirms that THC does not exceed 0.3% by dry weight, the mixture could be sent on for processing. This would help producers avoid potentially catastrophic financial losses when THC levels slightly exceed the legal limit for hemp and would help ensure sufficient availability of hemp and hemp-derived cannabinoids throughout the manufacturing sector. If remediation of a particular crop is impractical or impossible, producers should have the opportunity to turn the hemp into biochar. The THC (and other constituents) would be destroyed through pyrolysis, but the carbon could be used in farming or gardening and the producer would not have to take a total loss on the crop.

Compliance With Enforcement Procedures Including Annual Inspection of Hemp Producers

The Federal Register notice states:

> In the context of this part, negligence is defined as a failure to exercise the level of care that a reasonably prudent person would exercise in complying with the regulations set forth under this part. [...] This rule specifies that hemp producers do not commit a negligent violation if they produce plants that exceed the acceptable hemp THC level and use reasonable efforts to grow hemp and the plant does not have a THC concentration of more than 0.5 percent on a dry weight basis. USDA recognizes that hemp producers may take the necessary steps and precautions to produce hemp, such as using certified seed, using other seed that has reliably grown compliant plants in other parts of the country, or engaging in other best practices, yet still produce plants that exceed the acceptable hemp THC level. USDA seeks comments whether there are other reasonable efforts to be considered. We believe that a hemp producer in that scenario has exercised a level of care that a reasonably prudent person would exercise if the plant does not have a THC concentration of more than 0.5 percent on a dry weight basis.

ASA's position is that tying negligence to THC levels is inappropriate. In the framework proposed by the USDA, two producers could have identical mental states and take identical actions when producing their crops, but one could be found to have committed a negligent violation if their crop happens to test at over 0.5% THC. As USDA acknowledges, factors beyond the producer's control can influence a crop's THC content. It does not logically follow that a producer who used seed that had reliably grown compliant plants in other parts of the country and who had engaged in other best practices failed to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation simply because the THC level in that producer's crop exceeded 0.5%.

USDA Hemp Producer License

Per the Federal Register notice, "For the first year after USDA begins to accept applications, applications can be submitted any time. For all subsequent years, license applications and license renewal applications must be submitted between August 1 and October 31. [...] USDA requests comments on whether this application period is sufficient." ASA urges that applications be accepted and reviewed on a rolling basis to maximize hemp's economic potential. Obtaining a license is a key step in launching commercial hemp activities; limiting the application period to three months per year will make it harder to plan and raise funds for cultivation activities, thereby limiting business opportunities.