



January 28, 2020

Re: AMS-SC-29-0041

The Association of Public Health Laboratories (APHL) appreciates the opportunity to comment on the interim final rule (IFR) *Establishment of a Domestic Hemp Production Program*. Our member laboratories often are the first to provide testing services in response to new federal and state regulations and have developed significant expertise working at the forefront of testing cannabis, both hemp and marijuana.

Laboratory accreditation

APHL recognizes that ISO/IEC 17205 accreditation is one element to ensure a robust quality management system under which the laboratory produces defensible data. While additional requirements may be needed to establish competency for hemp testing, a separate approval and audit by USDA would be redundant to the accreditation audit and neither cost nor resource effective to laboratory programs. APHL recommends that USDA create a checklist of any additional requirements to the ISO/IEC 17025 standard to fulfill hemp testing for THC and provide these standards to the accrediting bodies and laboratory community for monitoring and auditing purposes. This is similar to the AOAC International *Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals* (also known as ALACC Guidelines) and the Association of American Feed Control Officials *Quality Assurance/Quality Control Guidelines for Feed Laboratories*, where the accrediting body is able to assess the laboratory to these additional requirements during their ISO/IEC 17025 external assessment

However, ISO/IEC 17025 accreditation does not necessarily ensure that the laboratory is technically competent and it would be helpful to discuss with USDA how the AMS Laboratory Accreditation Service (AMS LAS) assesses this. Additionally, APHL recognizes the importance of proficiency testing as an element to ensure technical competence and recommends that participation in hemp proficiency testing programs be mandatory for laboratories, along with adequate safety measures for the testing being performed.

Controlled Substance Requirements

APHL member laboratories would appreciate guidance on whether laboratories testing only for substances other than THC, such as other cannabinoids (CBD) or contaminants (microbes/pesticides), will be required to have DEA registration and whether laboratories can provide marijuana testing services in the same facility as hemp testing. Excluding marijuana testing laboratories from the program, when hemp is likely of low regulatory priority for the DEA, would place a much higher burden of testing on public health laboratories.

APHL requests enforcement discretion as the domestic hemp production program begins, allowing laboratories with pending DEA licensure to take part, and consideration that appropriately accredited cannabis testing laboratories be allowed to take part, helping prevent a laboratory capacity bottleneck in the nascent program.

Components Other Than THC

Although the IFR focuses exclusively on THC, there are many other components of hemp for which laboratories may need to test. APHL requests USDA publishes a recommended testing list for contaminants, developed in coordination with stakeholders. While APHL recognizes FDA's regulatory authority over CBD in hemp, we encourage interagency coordination on testing to provide appropriate, consistent regulatory oversight.

Testing Capacity

The high volume of seasonal testing expected through the sampling requirements in the IFR will likely prove problematic for some public health laboratories. During hemp harvest season, laboratories will have a surge in testing, potentially taking staff away from other important programs, or requiring the hiring of temporary staff, purchase additional costly testing equipment for this program, and use already limited laboratory space.

While APHL appreciates the provided fee for service authority, state and local public health laboratories may not have mechanisms to bill, receive funds, or manage accounts payable from private parties. Given the already high capital costs of investing in advanced equipment and trained and certified staff that will be required to satisfy the requirements of this IFR, problematic reimbursement for services will likely be an untenable strain on governmental laboratory resources.

Due to the capacity issues described above, some laboratories may not be able to consistently return final test results within the required 15-day window for harvesting. To allow laboratories sufficient time for testing, APHL suggests clarification that producers be allowed to harvest prior to the return of laboratory results, but may not release product until results are obtained.

Retesting

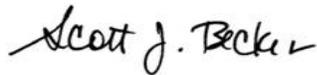
The IFR allows for a retest if the licensee believes the initial test to be inaccurate. However, the IFR does not state how long the licensee has to request a retest. APHL requests guidance on how long samples should be stored for any additional testing needs, especially as appropriate storage space is likely to be limited at many laboratories. Further guidance should be provided on procedures to be followed given discrepant retest result.

Laboratory Test Results Report

The IFR requires laboratories submit test results via the "Laboratory Test Results Report" to USDA and also to the licensee. APHL encourages USDA to develop a reporting system that integrates with current Laboratory Information Management Systems (LIMS) to reduce the chance of errors and the need for time consuming duplicative data entry. Many LIMS systems are not designed for reporting of results directly to a private party. APHL requests clear flexibility in the final rule to allow for provision of results via a third party such as a state Department of Agriculture.

APHL would appreciate being able to discuss some of the immediate concerns described above with USDA in the near future. Please contact Kuki Hansen, Manager of Regulatory and Public Policy (kuki.hansen@aphl.org) for any follow up. We hope to be able to work more closely with USDA and other stakeholders as the domestic hemp production program gets underway.

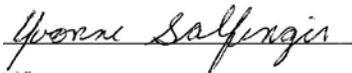
Sincerely,



Scott Becker
Executive Director



Paul Moyer
Chair, Environmental Health Committee



Yvonne Salfinger
Co-Chair, Human and Animal Food Subcommittee

The Association of Public Health Laboratories (APHL) represents state and local governmental health laboratories that monitor and detect public health threats.