ANSI Comments on the
U.S. Department of Agriculture's
Interim Final Rule on Establishment of a
Domestic Hemp Production Program
Docket No. AMS-SC-19-0042
January 28, 2020

The American National Standards Institute[1] (ANSI) welcomes the opportunity to provide input to the U.S. Department of Agriculture (USDA) on its interim final rule on the establishment of a domestic hemp production program. As the coordinator of the U.S. voluntary standardization system, ANSI works to advance standards-based solutions to national and global priorities.

About the U.S. Voluntary Standardization System

Market-driven and private-sector-led, the U.S. standardization system is dynamic and responsive because it thrives on the active participation and engagement of all affected stakeholders – including industry, government, standards developing organizations, academia, consumers, and others.

As one of the biggest users of standards, the U.S. government's active participation in standardization is of great importance. Through public-private partnership, the U.S. is able to respond most effectively to the strategic needs of the nation on both domestic and international fronts.

Reliance on private sector leadership, supplemented by Federal government contributions to standardization processes as outlined in OMB Circular A-119, *Federal Participation in the Development and use of Voluntary Consensus Standards and in Conformity Assessment Activities*, remains the primary strategy for government engagement in standards development. The circular has guided Federal agency implementation of the *National Technology Transfer and Advancement Act of 1995* for more than two decades.

About ANSI

ANSI is a federation whose members are government agencies, trade associations, standards developing organizations, professional societies, companies, academic and international bodies, and consumer organizations looking to harness the power of standards to position themselves for long-term success. ANSI represents the interests of more than 270,000 companies and 30 million professionals worldwide. As the voice of the U.S. standards and conformity assessment system, ANSI empowers its members and constituents to strengthen the U.S. marketplace position in the global economy while helping to assure the safety and health of consumers and the protection of the environment.

Voluntary consensus standards for products, processes, and services are at the foundation of the U.S. economy and society. The United States has a proud tradition of developing and using

[1] www.ansi.org

voluntary standards to support the needs of our citizens and the competitiveness of U.S. industry globally.

In its role, ANSI oversees the creation, promulgation, and use of thousands of norms and guidelines that directly affect businesses in nearly every sector. Through its wholly owned subsidiary, the ANSI National Accreditation Board (ANAB), ANSI is also actively engaged in accreditation of conformity assessment bodies – assessing the competence of organizations determining conformance to standards. And via its affiliate, Workcred, ANSI supports efforts to strengthen workforce quality by improving the credentialing system, ensuring its ongoing relevance, and preparing employers, workers, educators, and governments to use it effectively.

International Standardization

ANSI promotes the use of U.S. standards internationally, advocates U.S. policy and technical positions in international and regional standards organizations, and encourages the adoption of international standards as national standards where they meet the needs of the user community. The Institute is the sole U.S. representative and dues-paying member of the two major non-treaty international standards organizations, the International Organization for Standardization (ISO) and, via our U.S. National Committee (USNC), the International Electrotechnical Commission (IEC). As a founding member of ISO, ANSI plays a strong leadership role in its governing bodies while U.S. participation, via the USNC, is equally strong in the IEC.

To formulate and advance consensus U.S. positions with respect to ISO and IEC work, ANSI accredits U.S. Technical Advisory Groups (TAGs) to ISO and approves USNC TAGs to IEC. The primary purpose of these TAGs is to develop and transmit, via ANSI, U.S. positions on activities and ballots of ISO and/or IEC Technical Committees (and, as appropriate, subcommittees and policy committees). ANSI's *International Procedures* provide the due process-based framework within which U.S. TAGs develop and coordinate U.S. positions.

ANSI is a permanent member of both the ISO Council and Technical Management Board. ANSI and its members participate in nearly 80% of ISO Technical Committees (TCs) and Subcommittees (SCs) and administer 14% of TC and SC Secretariats. ANSI's USNC is a permanent member of the IEC Council Board, Standardization Management Board, and Conformity Assessment Board. The USNC participates in over 92% of IEC TCs and SCs, and administers 13% of TC and SC Secretariats.

American National Standards

Domestically, ANSI accredits standards developing organizations (SDOs) and approves standards from these organizations as ANS. To achieve the ANSI-Accredited Standards Developer (ASD) designation – the first step for developing ANS – SDOs must comply with ANSI's *Essential Requirements* and demonstrate commitment to a set of principles that includes openness, balance, due process, and consensus. The principles contained in the *Essential Requirements* are consistent with the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement principles for the development of international standards. Conformance to these principles means that the U.S. can set an example globally for what open and trusted standardization looks like.

ANSI's many checks and balances, including impartial audits, accreditation requirements, and an appeals process, underpin the integrity of the ANS process, regularly assuring adherence to the Institute's procedures and safeguarding the value of the ANS designation. This voluntary consensus standards process is time-tested, and has been relied on by many government agencies to the benefit of the public, government, industry and many other stakeholders. ASDs meet the definition in OMB Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,* of "voluntary consensus body."

ANSI National Accreditation Board (ANAB) Accreditation of Conformity Assessment

ANSI's work in the conformity assessment arena includes a complete portfolio of third-party accreditation programs under its wholly owned subsidiary, ANAB. These programs are conducted in accordance with widely accepted international standards and include accreditation of product and management system certification bodies, calibration and testing labs and forensic service providers, personnel credentialing organizations, inspection bodies, police crime units, greenhouse gas validation and verification bodies, reference material producers, and proficiency test providers.

Comments Specific to USDA's Hemp Regulation

ANAB representatives participated in the development of the American Council of Independent Laboratories (ACIL) comments on USDA's hemp regulation. ANAB comments are consistent with those of ACIL and are included below.

LAB APPROVAL

Drug Enforcement Agency Registration

While ANAB appreciates the intent of Drug Enforcement Agency 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 products 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.

As an alternative to DEA registration, we recommend accreditation to ISO/IEC 17025, *General Requirements for the Competence of Testing and Calibration Laboratories*, which is customary in many industries and provides all the measures and safeguards necessary to ensure lawful compliance with the Rule.

USDA Accreditation
The laboratory approval requirements should be tiered based on the use of International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (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, *Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies*, to demonstrate their competence. The ILAC MRA provides significant technical underpinning to the calibration, testing, medical testing, and inspection results, and provision of proficiency testing programs of the accredited conformity assessment bodies that in turn delivers confidence in the acceptance of results. . Accreditation by an ILAC MRA signatory should be a precursor to USDA registration. This tiered approach would give the government the ability to perform compliance activities, but give the routine assessment of the laboratory's competency to the recognized accreditation body.

SAMPLING

Defining Approved Sampling Agents
The Food Safety 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.

ANAB requests that USDA include sampler accreditation language to 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 Arrangement (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. ANAB recommends 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 sample collection report with the GPS coordinates for each of the subsamples; the name and address of the producer; name, address, and affiliation of the sampler; person accompanying the sampler; date and time of sampling, and other USDA requirements must accompany the samples. The sample collection report will 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, "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 third have significantly higher percentages of THC than the remainder of the plant. For comparison, the California Department of Food and 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 fewer issues for hemp shipped across state lines.

TESTING

Testing Standards
ANAB 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 developing organizations such as AOAC International and ASTM International should be relied upon to develop and maintain testing standards for the industry. Laboratories following the standards and protocols established via a voluntary consensus standards process could then be authorized by USDA 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. **ANAB offers ACIL's 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, ANAB recommends that **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 USDA Agricultural Marketing Service (AMS) testing guidelines stipulate, "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. Furthermore, 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 require only THC content to be reported and do not take into consideration 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.

PRODUCER VIOLATIONS

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 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 be very small*. The converse is also true: those laboratories whose processes do not produce accurate and precise results will have larger uncertainties for their analytical results. Larger uncertainties would allow the growers to be able to have potentially higher THC concentrations however, and still 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% within which to work.

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% within which to work.

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. Laboratory uncertainties 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.

We advocate that USDA establish 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.

For example: The maximum uncertainty cannot exceed 0.3 % ± 0.06 %. This 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 $\pm$ 0.05 % for low levels of THC in hemp.

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 preset**. 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.

ANAB 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, ANAB requests that USDA reach out to these programs to rely on their lessons learned, experience, and input to guide federal efforts. USDA should rely, where possible, on existing state regulatory programs to develop and regulate the hemp industry.

Conclusion

ANSI welcomes USDA's solicitation of input. We encourage USDA's reliance on voluntary consensus standards and accredited conformity assessment bodies to support regulatory activities. As the coordinator of the U.S. voluntary standardization system, we stand ready to

support USDA by helping to facilitate private-sector-led standardization solutions to advance public health and safety.

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