To Whom It May Concern:

Vote Hemp is the nation’s leading and longest serving advocacy organization for federal policy regarding hemp farming and hemp product manufacturing in the United States. At the request of the U.S. Department of Agriculture, Agricultural Marketing Service (“USDA” or “Agency”), we share the following comments regarding certain provisions of the Interim Final Rule on the Establishment of a Domestic Hemp Production Program (“IFR”), as the Agency continues to develop the regulatory framework mandated by The Agriculture Improvement Act of 2018 (the “2018 Farm Bill” or “Statute”).

Vote Hemp believes the USDA has taken steps in the right direction in drafting the IFR, however certain provisions do raise serious concerns for our stakeholders, hemp producers, processors and manufacturers that we discuss in detail below.

I. Measurement of Uncertainty

Vote Hemp appreciates the flexibility USDA provides in allowing an “acceptable hemp THC level” to fall within the range of a testing method’s measurement of uncertainty (“MU”). However, Vote Hemp is concerned that measuring of sampling uncertainty was not included in the IFR and hemp-testing laboratories will have insufficient insight into the crop sampling process to properly calculate total uncertainty resulting in potentially severe economic harm to hemp producers errantly found to have produced a non-compliant crop.

Per the IFR and the Sampling Guidelines for Hemp Growing Facilities (“Sampling Guidelines”), sampling of hemp material is to be performed by a USDA-approved sampling agent or law enforcement officer (“Sampling Agent”). Sampling Agents are not required to communicate any factors that may contribute to uncertainty which are caused by their specific sampling procedure or by variations within the crop being sampled. This bifurcation of the sampling and analysis process may leave laboratories with limited data as to the variation of THC within the crop or uncertainty due to the limited number of samples being taken, making any estimation of uncertainty due to sampling impossible.

For example, the Sampling Guidelines specify the use of a single plant sample when testing one acre or less. This is insufficient to provide an accurate representation of the average delta-9 THC level for the entire crop, given that a one acre hemp field can have anywhere from a few thousand to hundreds of thousands of plants. An inaccurate measurement of THC is bound to occur when the sample size is a tiny fraction of the plant population. Furthermore the lab will have no information on how many plants were in the sampled crop and what percentage of the crop was sampled.
Due to genetic instability of hemp cultivars, variations of cannabinoid concentrations among genetically identical plants not only occur when grown in different bioregions, but even within the same crop and field due to localized environmental factors (see Exhibit A attached). Indeed, the Agency itself acknowledged hemp’s genetic instability as the reason for not developing a federal seed certification program.

Although we agree with the Agency that quantifying uncertainty is necessary to verify the accuracy of test results, we do not agree with the limited scope of MU calculations under the IFR and the Testing Guidelines for Identifying Delta-9 Tetrahydrocannabinol (THC) Concentration in Hemp (“Testing Guidelines”).

MU under the IFR is an assessment of the various components related to a specific testing method, however, it fails to account for any uncertainty due to sampling. In other words, MU, under the Agency’s guidelines, calculates uncertainty arising from a specific testing procedure, but completely ignores the sampling procedure. Sampling uncertainty arises from the processes related to the collection and handling of the actual plant material to be tested as well as variations in the crop. The omission of a sampling measurement of uncertainty in the MU will certainly result in inaccurate, incomplete, and otherwise invalid test results due to the nature of the hemp sampling process.

The Agency relied on guidance from organizations such as the National Institute of Standards and Technology, the Joint Committee for Guides in Metrology (“JCGM”), and Eurachem/Coeperation on International Traceability in Analytical Chemistry (“Eurachem/CITAC”) in developing its concept of MU, stating the importance of having “a high degree of certainty that the THC concentration level is accurately measured and is in fact above 0.3 percent before requiring disposal of the crop,” due to the extreme economic burden posed to hemp producers who stand to lose the entirety of the value placed into their investment.

USDA’s apparent concern for the negative impact of inaccurate THC testing on hemp producers, while disregarding the need to measure sampling uncertainty, is a significant oversight, especially considering that the very authorities which the Agency cites recognize sampling uncertainty as particularly important in determining the accuracy of test results:

“Where taking field samples “forms part of the specified procedure, effects such as random variations between different samples and any potential for bias in the sampling procedure form components of uncertainty affecting the final result.”

“If the objective of the measurement is to estimate the value of the analyte concentration in a sampling target, then the uncertainty associated with the sampling process must inevitably contribute to the uncertainty associated with the reported result. It has become increasingly apparent that sampling is often the more important contribution to uncertainty and requires

1 J. Scott Lowman, Jack He, Mike Clark, and Mark Gignac, THC Distribution in Field Grown Hemp Prior to Harvest, The Institute for Advanced Learning and Research (2019).
equally careful management and control. The uncertainty arising from the sampling process should therefore be evaluated."\(^5\)

"[A] sample is only a tiny segment of the commodity being investigated and [] a contaminant level will actually vary in the marketplace. Sampling uncertainty is very important when judging compliance or developing monitoring programs... However, it is outside the scope of analytical uncertainty."\(^6\)

In light of this, we recommend that USDA amend the MU provision of the IFR to require the measurement and inclusion of sampling uncertainty. We recommend that USDA conduct or fund a study to develop a standard sampling measurement of uncertainty methodology for hemp THC testing. This measurement is critically important and necessary to know the total uncertainty of sampling and testing procedures, so that one can accurately and reliably define MU for hemp THC testing. The Agency must account for any inadequacy in the sample size, any sampling bias on the part of the Sampling Agent, and any other uncertainty components that would have arisen from the sampling process. The Agency must also account for genetic variations within the crop to determine MU for hemp genetics. Sampling and genetics measurements of uncertainty must reasonably be factored in to overall MU for a final determination on whether or not a crop falls within the acceptable hemp THC level range. Otherwise, hemp producers are left exposed to the extreme economic burden of losing their entire investment.

II. Sampling Procedure

The Sampling Guidelines require that Sampling Agents collect samples from only the top one-third of the plant. This upper portion of the plant is not the only part of the plant that is used in the manufacturing of hemp products. Moreover, the highest concentration of THC is found in this top portion of the plant which will result in an inaccurate measurement of THC in the plant. As the whole plant is utilized in the manufacturing of hemp products, including the lower two-thirds of the plant, which also happen to have lower THC concentrations, a far more accurate sample would logically include samples from the top ⅓, the middle ⅓, and the lower ⅓ of the plant. In order to get a more accurate reading of hemp THC concentration, all flowering portions of the selected plant must be sampled and homogenized.\(^7\) (See Exhibit A attached.)

Natural materials, such as plants, are inherently heterogeneous substances. That is, the chemical compounds that form their structure are unevenly distributed throughout the material. This heterogeneity in plant material is the reason the scientific method requires homogenization of a sample to accurately analyze the chemical makeup of a substance, and the calculation of additional uncertainty components arising from the sampling process.

"Unlike man-made materials, which may have proven homogeneity to a level beyond that required for the measurement, natural materials are often very inhomogeneous. This inhomogeneity leads to two additional uncertainty components. Evaluation of the first requires determining how adequately the sample selected represents the parent material being

\(^7\) J. Scott Lowman, Jack He, Mike Clark, and Mark Gignac, THC Distribution in Field Grown Hemp Prior to Harvest, The Institute for Advanced Learning and Research (2019).
analyzed. Evaluation of the second requires determining the extent to which the secondary (unanalyzed) constituents influence the measurement and how adequately they are treated by the measurement method. (Emphasis added). ⁸

Without all flowering portions of a hemp plant, the sampling is incomplete, would make the analysis of the sample fundamentally flawed, and will lead to harsh and burdensome penalties for hemp producers and the industry generally. We therefore recommend that Sampling Guidelines be amended to require samples taken and homogenized from the top 1/3, the middle 1/3, and lower 1/3 of the plant.

III. Sampling to Harvest Window

After extensive discussions with farmers, laboratories and state regulators, it is clear that allowing only 15 days between sampling and harvest is inadequate and unworkable due to labor constraints, weather, and the lack of DEA-registered laboratories.

A number of farmers we spoke with indicated that the harvesting process can continue for a month or more due to the use of labor-intensive hand harvesting methods. Existing mechanical harvesting methods are either unsuitable for hemp CBD plants or cost-prohibitive to average farmers. Weather can also impact the harvest process and result in delays because the crop must be dry prior to harvesting. When a field can contain hundreds of thousands of plants, 15 days between sampling and harvest are simply inadequate.

Moreover, there are logistical challenges making the 15-day window impossible. Only a limited number of laboratories exist that meet USDA requirements (44 are currently listed in the USDA/AMS site). Many states only have one acceptable testing facility, while some have none at all. The limited number of laboratories will be receiving a large number of samples over a short period of time, as harvest times will generally occur around the same time of the year. It is therefore impossible for the qualified laboratories to have the capacity and ability to process hemp samples and provide timely results within 15 days of collection.

Delays and backlogs at testing laboratories will result in hemp producers being unable to initiate harvest of their crop, as they will be unable to verify whether the crop is compliant. Farmers should not be compelled to incur the cost of a harvest prior to knowing whether the crop is within the acceptable hemp THC level or not. It makes no sense for a farmer to expend substantial funds on labor to harvest, only to find out that his crop must be destroyed. Far less expensive disposal methods can be employed, should a crop be deemed non-compliant, which would lessen the still significant economic burden on the farmer.

We recommend that USDA revise the regulations to allow for 45 days between sampling and harvest to take into account all these factors.

IV. Disposal of Non-Compliant Plants

The IFR requires all non-compliant plant material to be destroyed pursuant to DEA regulations. The complete destruction of a non-compliant hemp crop poses a great risk of economic hardship on hemp

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farmers, who may invest upwards of $35,000 per acre for planting. Under the IFR, hemp producers risk losing the entirety of their investment, and are subject to further liability for the costs associated with destruction of their crop.

The 2018 Farm Bill makes no mention of destruction; it only requires disposal of non-compliant plants or plant material. The Statute specifically states:

“(2) CONTENTS.—A State or Tribal plan referred to in paragraph (1)—
“(A) shall only be required to include—

“(iii) a procedure for the effective disposal of—
“(I) plants, whether growing or not, that are produced in violation of this subtitle; and “(II) products derived from those plants.”

Whereas the IFR states:

“plants exceeding the acceptable THC level, the material must be disposed of in accordance with 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.”

The USDA position that a non-compliant hemp crop is marijuana, a Schedule I substance, and as such must fall under the jurisdiction of the DEA is misguided. Following this logic, if non-compliant plants are a Schedule I controlled substance, and therefore must be subject to DEA regulations, the non-compliant producer is a “manufacturer” under the CSA, which must also require DEA registration as a controlled substance manufacturer. “Every person who manufactures... any controlled substance or who proposes to engage in the manufacture... of any controlled substance shall obtain a registration...” USDA correctly decided not to require this, and has thus acknowledged that non-compliant hemp producers are not producing Schedule I controlled substances, rather non-compliant or “hot” hemp.

Under DEA regulations, the unlawful manufacture of a Schedule I substance is subject to harsh criminal penalties, yet a hemp producer has immunity from criminal enforcement actions for technically producing marijuana, albeit inadvertently.

The intent of Congress is clear—crops grown pursuant to the 2018 Farm Bill, even if non-compliant, are not subject to the CSA or DEA regulations unless USDA or the States determine the hemp producer acted with a culpable mental state greater than negligence.

Congress did not intend for USDA to be bound by the CSA or DEA regulations for the disposal of a non-compliant crop which was not done intentionally or knowingly. Congress explicitly granted USDA sole authority to regulate all plants produced pursuant to the 2018 Farm Bill, including non-compliant hemp. The intent was clearly for USDA, States and tribes to oversee disposal of any non-compliant crops, not

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11 21 USC § 802(15).
12 21 CFR Part 1301.11(a).
the DEA. Non-compliant plants should be treated differently than the product of an unlawful marijuana grow operation. Just as it is not bound by DEA regulations that would classify non-compliant hemp producers as manufacturers of a Schedule I controlled substance, USDA is not beholden to the DEA to properly dispose of non-compliant crops.

We recommend that the Agency amend the disposal provisions of the IFR to regain the statutory authority it delegated to DEA. We further urge the Agency to allow states and tribes to implement the simplest and most cost-effective disposal methods, such that non-compliant leaf and flower biomass is rendered useless or non-consumable for humans, in an effort to limit the negative financial impact on hemp producers as much as possible.

V. DEA Registered Laboratories

The 2018 Farm Bill removed hemp from the definition of marijuana per the CSA, thereby removing DEA’s enforcement authority over hemp as well. Congress authorized USDA to regulate hemp production and promulgate rules to that effect. In the 2018 Farm Bill, Congress did not intend to provide DEA with a role in the testing process and, specifically, DEA-registered laboratories were not envisioned by Congress when it wrote:

“(2) CONTENTS.—A State or Tribal plan referred to in paragraph (1)—
“(A) shall only be required to include—
...
“(iii) a procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp produced in the State or territory of the Indian tribe,”

No mention of a DEA-registered laboratory was made or contemplated. The focus in this provision of the 2018 Farm Bill is implementation of a reliable method to test for delta-9 THC. DEA-registration does nothing to verify the reliability of the tests performed. Additionally, it creates a database of hemp producers at DEA never intended by Congress to be included in the 2018 Farm Bill which only authorized USDA to collect such data.

USDA was granted sole authority by Congress to enforce the 2018 Farm Bill, and was only required to “consult” with the Department of Justice (“DOJ”) in drafting of the IFR. The DEA’s involvement in the implementation of the IFR, however, borders on an impermissible re-delegation of statutory authority. In requiring a DEA-registered laboratory to make a final determination of compliance, USDA is essentially relinquishing its final decision-making authority to the DOJ, exceeding the mere consultative role expressly intended by Congress.

Aside from whether this action by USDA is an improper construction of the Statute, it is logistically impossible to accommodate the some 17,800 licensees under the 2014 Farm Bill, let alone all future licensees that are estimated to apply for hemp production licenses under the 2018 Farm Bill.

14 See U.S. Telecom Ass’n v. F.C.C., 359 F.3d 554 (D.C. Cir. 2004), .
USDA recently posted a list of all DEA-registered laboratories on its website—44 currently exist as of the date of this letter.\textsuperscript{15} Many states have only one registered lab, and some have none at all. For example, Tennessee had 3,200 hemp production licenses in 2019 (under the previous 2014 Farm Bill), but only one DEA-registered laboratory is currently listed for the whole state. It would be impossible for a single laboratory to properly analyze samples from each of these licensees within the time frame specified in the IFR.

Furthermore, in order to become registered with the DEA, a lab must be licensed by their state to handle the specific controlled substance for which it applies. This requirement conflicts with states where cannabis remains illegal and, absent an exemption from state-law, labs located in those jurisdictions would be unable to meet DEA requirements for registration. The registration process is also expensive and time consuming, potentially taking a year or more to complete. The high cost will be passed on to the producers increasing their financial burden.

In order to address this, USDA should create a streamlined process to certify laboratories to handle hemp sampling analyses. We recommend the removal of language requiring DEA registration and that USDA develops its own lab approval process specific to handling hemp. We further recommend that USDA create procedures for the reasonable and cost effective disposal of non-compliant hemp samples.

VI. Negligent Violation

The IFR defines negligence 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.”\textsuperscript{16} However, the IFR subsequently creates a bright-line rule where a THC measurement above 0.5% is considered negligent \textit{per se}. “Hemp producers do not commit a negligent violation under this paragraph if they make reasonable efforts to grow hemp and the cannabis (marijuana) does not have a delta-9 tetrahydrocannabinol concentration of more than 0.5 percent on a dry weight basis”.\textsuperscript{17} In drawing this arbitrary line, USDA contradicts its own definition of negligence as stated above due to the actual likelihood of producing non-compliant plants despite reasonably prudent behavior on the part of the hemp producer. This ambiguity exposes hemp producers to greater risk of enforcement actions and undue hardship.

Moreover, this construction is contrary to the plain text of the 2018 Farm Bill which does not contemplate a numeric threshold to negligence, rather it directs USDA, States, and tribal governments to make an independent determination that a hemp producer has “negligently violated the [USDA,] State or Tribal plan, including by negligently... producing Cannabis sativa L. with a delta-9 tetrahydrocannabinol concentration of more than 0.3 percent on a dry weight basis.”\textsuperscript{18}

The statutory language here demonstrates Congress’s intent for the applicable Agency to assess a hemp producer’s mental state at the time of an alleged violation in order to determine whether such individual had foresight of the prohibitive consequences and the desire to cause such consequences to

\textsuperscript{15} https://www.ams.usda.gov/rules-regulations/hemp/dea-laboratories
\textsuperscript{16} 84 Fed. Reg. 58,526 (Oct. 31, 2019)(codified at 8 CFR § 990)
\textsuperscript{17} 8 CFR § 990.29 (2019)
\textsuperscript{18} 84 Fed. Reg. 58,526 (Oct. 31, 2019) (codified at 8 CFR § 990)
occur. The intention of Congress was not to deem a violation negligent simply because of the existence of the violation itself.

In reading the full text of the Statute, an enumerated violation is a triggering event for the Agency to determine the degree of a producer's culpability, if any, and the appropriate remedy to seek. The only numerical value contemplated in the 2018 Farm Bill was 0.3 percent delta-9 THC. Congress understood the volatility of hemp genetics in drafting the 2018 Farm Bill and specifically did not create a strict liability for producers of plants exceeding 0.3 percent, but left it to the appropriate Agency to determine whether such a producer acted with either no fault, negligence, recklessness, knowledge, or intention in their violation of the Statute.

The IFR correctly refers to the genetic instability of hemp cultivars that result in variations of cannabinoid concentrations among genetically identical plants grown in different bioregions which was stated as the reason for not developing a federal seed certification program. In other words, seeds derived from the same parent plant may produce a compliant crop in one locale and a non-compliant crop in another. USDA erred however in creating a numerical threshold to determine a negligent violation, as it does not provide nearly enough of a margin for unintentional and non-negligent error.

Per the IFR, notwithstanding the exercise of the level of care of a reasonably prudent hemp producer, the mere fact that THC concentration exceeds 0.5 percent would deem a producer per se negligent for environmental factors that are outside of their control. If an individual were to use state-certified seed, seed that has consistently yielded compliant plants in other jurisdictions, implement best farming practices, and otherwise act reasonably as a hemp producer, they still cannot eliminate the real probability that genetic variations in the crop will occur causing heightened THC levels exceeding the 0.5 percent limit imposed by the IFR.

Further, this numerical limitation sets a dangerous example for states in drafting their own plans. As states are permitted to be more restrictive than the IFR, hemp producers would potentially have greater exposure to civil or possibly criminal liability for unintentionally producing plants with excessive THC levels that exceed what a particular state deems acceptable. In more restrictive jurisdictions, hemp producers may find themselves at the mercy of politically ambitious or prohibitionist prosecutors, who are more likely to find a hemp producer acted with a culpable mental state greater than negligence, creating a chargeable offense.

Although negligent violations are not criminally enforceable at any level of government under the 2018 Farm Bill provisions, the IFR tacitly permits civil action by law enforcement agencies. Hemp producers who commit a negligent violation could be subject to civil penalties or fines. Under federal law and the majority of state laws concerning civil asset forfeiture, it is not necessary for a property owner to be charged with a crime for assets to be seized, as long as a connection can be made between the seized assets and illegal drug activity. Along with any non-compliant crops, federal, state, or local law enforcement agencies can seize all property related to illegal drug activity including vehicles, farming equipment, cash, and any other personal property related to the activity. This is especially concerning for hemp producers located in cannabis-hostile jurisdictions who face a greater risk of such extreme consequences for unintentionally producing non-compliant crops. The risk of asset forfeiture must be addressed, and protections afforded to negligently non-compliant hemp producers.

At this nascent stage in the hemp industry, it is impossible to know with absolute certainty that a particular hemp cultivar will yield a non-compliant crop, a point noted by USDA in the IFR. It is illogical and unjust that a licensee who abides by all industry standards and best practices, but ultimately produces a crop measuring 0.51 percent THC would be considered negligent. Setting numerical limits on what is and is not "negligence" regardless of the relevant facts exposes hemp producers to an extreme and undue hardship.

The IFR 0.5 percent THC threshold is arbitrary and contradictory to the legislative intent in the 2018 Farm Bill, and as such, it is an improper statutory construction. We strongly recommend that this provision should be removed, and that the Agency determine the degree of culpability of a hemp producer by assessing the facts surrounding any violation of the Statute. In the alternative, should the Agency refuse to remove a numerical threshold, we recommend that it should be raised to at least 1 percent. Although still arbitrary, a 1 percent THC limit would give much needed flexibility to account for at least some of the various factors that can affect THC concentration that are outside of a hemp producer’s control.

Felony Ban

USDA has included a requirement for a report of the criminal history of “each key participant” of an applicant. We urge USDA to ensure this provision is limited to only to individual applicants or owners of a business entity when the applicant is a business entity. We recommend that USDA issue a clarification that this provision does not apply to any non-owner employees or vendors.

Updates to IFR

A number of states have decided to continue with 2014 Farm Bill programs for the 2020 growing season after a careful review of the IFR and receiving feedback from stakeholders. In its current form, the IFR is not a workable program and will do harm to farmers and the industry. State regulators face uncertainty about the future and need the Agency to make significant changes to hemp regulations as soon as possible to allow time to plan for the required submission to USDA for the 2021 growing season. We recommend that the Agency issue a new IFR adopting the changes we have requested as soon as possible rather than waiting. State and tribal regulators need certainty on how the IFR will regulate hemp so they can submit plans in time for the 2021 growing season. In some cases new legislation will need to be passed to make state law compliant. Therefore it is critical that the Agency act quickly to provide much needed assurances to states and tribes.

We appreciate that the Agency also wants to get feedback after the 2020 growing season. We recommend that the Agency holds another comment period in the 2nd half of 2021 and issue a final rule in the fall of 2021 after having more time to see how the new IFR has been working. We sincerely appreciate your consideration of these comments and look forward to working with the Agency to ensure a strong and successful hemp industry.

21 Id.
**Background:** Current hemp regulations set the legal limit of THC at 0.3 percent. However, where the plant is sampled and how many plants are sampled can generate significantly different values, leading to confusion as to whether the plant or field has exceeded the legal threshold. The primary purpose of this study was to determine the average levels of THC in the top, middle, and bottom sections of field grown hemp and to compare these results to the average. The secondary goal was to determine the variation of THC levels between plants.

**Methods:** Samples were collected from 10 hemp plants of one cultivar, grown from clones, in a field in Central Virginia. A sample was taken from the bottom, middle, and top of each plant, labeled, bagged separately and sent to IALR for immediate THC quantification using an ultra-performance liquid chromatograph (UPLC) coupled with a mass spectrometer (MS) detector.

**Results:** Figure 1. (Right) represents the average level of THC found in the top third, middle third, and bottom third of field grown hemp. Ten plants were included in the study and each were grown from genetically identical clones. The average THC of all samples was 0.14% percent. This number was only 63% of the THC value of samples taken from the top of the plant (0.22%), (Figure 1.). Figure 2. (Bottom) represents THC levels found in each plant sample. Significant variation was observed across all samples that cannot be explained by the expected variation in testing procedures.

**Conclusions:** Figure 1. (Right) illustrates that top only sampling, as prescribed in many state testing programs, leads to an overestimation of THC content by nearly 37%. To better represent total crop THC levels, samples should be taken from the top, middle, and bottom of plants in equal quantities. This approach would lead to overall lower THC values for growers, while also representing actual levels in the field.

Figure 2. (Bottom) illustrates the highly variable nature of THC production between plants, even from genetically identical material taken from the same field. This data indicates that a large number of plant samples need to be taken to gain an accurate representation of actual field value or a measurement of uncertainty for sampling must be calculated and provided to the lab for use in determining the acceptable THC level.