Ryan F. Quarles
Commissioner

Kentucky Department of Agriculture

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January 29, 2020

Hon. Greg Ibach
Under Secretary for Marketing and Regulatory Programs
Agricultural Marketing Service
United States Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20250-0237

Re: Comments on Interim Final Rule titled "Establishment of a Domestic Hemp Production Program" (Doc. No. AMS-SC-19-0042), published October 31, 2019

Dear Under Secretary Ibach:

As Kentucky's Agriculture Commissioner, it is my honor and privilege to be an advocate for the interests of the 75,000 farm families who make the Commonwealth's agricultural economy work. I want to begin by thanking you and your team for your courtesy and professionalism these past several months.

This spring, Kentucky's growing community of hemp farmers and processors will embark upon our seventh season of hemp production in the modern era. As you know, Kentucky was one of the very first states in the nation to take advantage of the pilot-program provision that Congress included in the 2014 Farm Bill.

When I took office as Commissioner in January 2016, I recognized that Kentucky's hemp program, which was then in its infancy, represented a major economic development opportunity. In short, my goal was to position Kentucky as an epicenter for American hemp production. To achieve that goal, I set out to build the best hemp program in the country, figuring that a well-designed, free-market-oriented hemp program would attract interested farmers, entrepreneurs, and investors from across the country and around the world. If Kentucky could build a critical mass during these early years, we would be well-positioned to win the race to establish our Commonwealth as a hemp epicenter.

We are well on our way to making that vision into a reality. With critical assistance from the members of Kentucky's General Assembly, we have worked hard over the past several years to design and implement the best hemp program in the nation. Other states have used Kentucky's hemp laws and regulations as a model to emulate, and we regularly receive phone calls from counterparts in other states who are seeking to build successful hemp programs like ours.

Having built what we believe is the best hemp program in the nation, the members of Kentucky's hemp community are beginning to see the fruit of our labors. In 2019, we saw more than 26,000 acres planted here in Kentucky, a dramatic increase from the 922 acres that were

planted the year before I took office. We expect that our state's licensed processors' reported gross product sales will exceed $100,000,000, with significant room for growth in future years.

While we are proud of these achievements and optimistic about continued growth in the years to come, we also recognize that Kentucky's growing hemp community faces some significant challenges on the horizon: declining market prices, access to credit challenges, and a business climate hindered by bureaucratic inaction at the federal agency level, particularly in the U.S. Food and Drug Administration and the U.S. Drug Enforcement Administration.

I want to thank you and your colleagues at USDA for your demonstrated interest in Kentucky's hemp program's structure and operations. Last year it was an honor to welcome you, Secretary Sonny Perdue, and a number of other USDA officials who visited Kentucky to learn about our hemp program. I want to express my genuine appreciation for your team's willingness to engage in a meaningful give-and-take as we attempted to negotiate the terms of a State Plan for Kentucky. I am confident that we will be in a position to submit a quality State Plan in advance of the 2021 growing season, and I look forward to substantive and respectful interactions between our offices in the years to come.

The focus of my letter today is to provide my office's comments and suggestions for revisions to the Interim Final Rule (IFR) that USDA published in the Federal Register on October 31, 2019. I hope you will take these comments into account as you consider options for improving the IFR at the end of the 2020 growing season and subsequently.

As you will see, we have compiled ten comments for your agency's consideration: three that pertain to practices that occur on the farm when a sample is being collected; three that focus on laboratory practices, and four about the IFR's enforcement mechanisms.

On the Farm: Simplify and standardize the part of the plant to be cut for sampling.

The IFR does not specify which part of the hemp plant should be cut and collected for sampling. In Kentucky, we cut the top 20 centimeters (approximately eight inches) from the main stem of the female plant. We believe that this standard strikes an appropriate balance between the need to collect a sufficiently large portion of the female plant's flower (where THC and other cannabinoids are at their most concentrated), on the one hand, and the need to avoid cutting a portion that is so large that it would logistically difficult to transport, dry, and grind up the sample for lab testing.

Adopting this 20-centimeter standard on a nationwide basis would put everyone on a level playing field. And it would have the additional benefit of being easier to understand and follow than the guidance set forth in USDA's 10/31/2019 *Sampling guidelines for hemp growing procedures*, Section 6.3, which mandates that "[t]he cut shall be made just underneath a flowering material, meaning inflorescence (the flower or bud of a plant), located at the top one-third (1/3) of the plant."

On the Farm: Simplify and standardize the number of plants to be sampled from each lot.

The IFR does not state a fixed number of plants that should be sampled from each lot; instead, Section 990.3 provides that a State Plan's method "must be sufficient at a confidence level of 95% that no more than one percent (1%) of the plants in the lot would exceed the acceptable hemp THC level." In Kentucky, we require five (5) plants to be selected for cutting samples. We believe this standard provides a reasonably representative sampling of the plants present in a particular lot.

By contrast, the guidance set forth in USDA's 10/31/2019 *Sampling guidelines for hemp growing procedures* calls for State Plans to use a sliding scale which requires an escalating number of plants to be sampled as the size of the lot increases. This approach is problematic for at least three reasons.

First, the sliding-scale calculation relies upon a decades-old pesticide residue sampling regime which may or may not be appropriate for the purposes of calculating confidence levels in a hemp plant's THC content.

Second, the sliding-scale formula is likely to create state-to-state variations in the number of samples that must be collected from fields of the same size. The formula uses, for its denominator, a value representing "the proportion of hemp plants having THC content greater than the acceptable hemp THC level," but this "value" is almost certain to vary widely from one state to another—and from one year to the next in the same state. Moreover, a formula using this denominator value would have the perverse effect of "rewarding" states whose historical testing data showed higher rates of non-compliant THC test results. Increasing the workload required of agency employees in a state with higher compliance rates (or USDA's own employees, in the case of a state whose farmers grow hemp under the USDA Plan) seems illogical and unnecessary.

Third, the USDA's sliding-scale calculation, as applied to a 170-acre field, could require the sampling of as many as 110 plants from that field. Such a burden would be impossible for a state department of agriculture to meet. It is no exaggeration to say that a team of agency employees could spend a full day selecting samples from a single field, could require multiple vehicles to transport the accumulated sampled material off the farm, and could create an impossible workload for the THC testing lab employees to grind up all of that material prior to testing.

There is a simpler path that the IFR could take: fixing a single number of plants to be sampled from every lot, without regard to its size, would be the simplest and most direct approach. In the alternative, USDA could publish its own table that provides a fixed sliding scale (for example, a lot of less than 10 acres requires 5 plants; a lot between 10 acres and 20 acres requires 6 plants; and so on) rather than leaving those calculations to each state.

In the Lab: Instead of creating a new laboratory approval program inside USDA, take advantage of the Hemp Proficiency Testing Program already serving dozens of laboratories across the nation.

The IFR's supplementary information advises that "USDA is considering establishing a fee-for-service hemp laboratory approval process for labs that wish to offer THC testing services," such that USDA-approved laboratories would need to comply with the requirements of the Laboratory Approval Program. The IFR explains that the purpose of this requirement would be to

develop "an individual program for hemp . . . with a set of documented requirements to capture specific regulatory, legal, quality assurance and quality control, and analytical testing elements."

We believe that the aims of this potential requirement could be better achieved by a different means. As you may know, currently there are 67 laboratories across the nation participating an a Hemp Proficiency Testing Program ("HPT Program") that is being led by Dr. Frank Sikora at the University of Kentucky's College of Agriculture, Food and Environment, Division of Regulatory Services ("UK DRS"). The purpose of this collaborative effort is to enable participating laboratories to develop reliable testing capabilities and protocols. Benefits for participating labs include greater quality assurance, access to reliable reference materials, method validation, method standardization for industry, and a means for evaluating inter-laboratory variability.[1] We are very proud and appreciative of Dr. Sikora and his colleagues at UK DRS for taking the initiative to organize and lead this nationwide effort.

Given the promising efforts that are already underway here in Kentucky and across the nation, we do not believe it is necessary for USDA AMS's Laboratory Approval Service to undertake a similar effort. Instead of building from scratch a new hemp laboratory approval service to be headquartered in Washington, D.C., we believe it would make more sense for the IFR simply to mandate that every lab providing THC compliance testing services in the nation must participate in the HPT Program being led by Dr. Sikora and his colleagues at UK DRS.

In the Lab: Do not mandate the removal of seeds, twigs, and stems before grinding the sample.

The IFR does not require the removal of seeds and stem material from a collected sample prior to grinding, but the guidance set forth in USDA's 10/31/2019 *Testing Guidelines for Identifying Delta-9 Tetrahydrocannabinol (THC) Concentration in Hemp* states that the laboratory personnel should "[m]ill and 'manicure' sample through a wire screen no later than 1.5 x. 1.5 mm to discard mature seeds and larger twigs and stems." There are at least three problems with this approach.

First, it is impossible to mill a sample at the same time that the seeds, twigs, and stems are being removed. If seeds, twigs, and stems are to be removed, they must be removed before the remaining material can pass through an initial 1.5 mm screen (let alone through the 1.0 mm screen which is the acceptable particle size for analysis according to AOAC Official Method 2018.11).

Second, the process of removing seeds, twigs, and stems adds variability. No two laboratory personnel will perform the task in exactly the same way, regardless of whether they attempt to take them out "by hand" or by passing the material through an initial 1.5 mm screen. To reduce this variability, the better practice would be to grind up for testing the entire sample that arrives at the lab.

Third, the process of removing seeds, twigs, and stems before grinding takes more time than would otherwise be necessary to prepare a sample for testing.

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[1] Information about the HPT Program, which enables participating laboratories to pursue ISO 17025 accreditation, is available at: re.uky.edu/regulatory/hpt/index.php.

For all of these reasons, we believe it would be appropriate to revise the 10/31/2019 Testing Guidelines to conform more closely to the practices recommended by AOAC, particularly those methods pertaining to grinding specifications (2018.11) and moisture content (930.04). We also recommend that you consider the protocols developed by the Division of Regulatory Services within the University of Kentucky's College of Agriculture, Food and Environment, specifically these two:

- UK DRS SOP#HMP-LB-001 (Procedures for Receiving, Preparing and Releasing Hemp Samples), and
- UK DRS SOP#HMP-LB-002 (Procedures for Measuring Delta-9 THC Content in Industrial Hemp by Gas Chromotography with Flame Ionization Detection).

In the Lab: There should be a single, nationwide, and comprehensive measurement of uncertainty that also takes into account variability in the steps that occur before a sample reaches the laboratory.

Section 990.3(a)(3)(F) requires state departments of agriculture to calculate a "measurement of uncertainty" that will be reported with THC testing results. We believe that USDA's decision to mandate a "measurement of uncertainty" was appropriate in light of the inherent limitations in quantitative testing which the National Institute of Standards and Technology (NIST) *Reference on Constants, Units, and Uncertainty* explained this way: "measurement result is complete only when accompanied by a quantitative statement of its uncertainty." Or as the IFR's Supplementary Information put it, "knowing the measurement of uncertainty is necessary to evaluate the accuracy of test results."

We agree. In recent years our experience has been that the variation in testing results could be as great as 0.1%, which is why Kentucky's existing hemp program deems a THC result of up to 0.3999% to be compliant with the 0.3% definition that was adopted in statute by the Congress and the Kentucky General Assembly.

In time, we expect that advances in technology and improvements in methodologies should cause a decline in these variation rates. And some laboratories, especially those with the benefit of several years of experience, will achieve a tighter variation rate faster than others.

We believe that instead of requiring each laboratory to determine and apply its own measurement of uncertainty, the IFR should mandate the calculation of a single, nationally-uniform measurement that will be applied to all. We believe this is appropriate for at least three reasons.

First, there is no guarantee that an individual laboratory will correctly calculate its own measurement of uncertainty because the mathematical principles involved are complicated. Hemp farmers should not be exposed to risks of economic loss that are created, but concealed from view, by mathematical errors within an individual laboratory's computations.

Second, there is no universally accepted way to calculate a measurement of uncertainty, which makes it very likely that the inter-laboratory variation in announced measurements of uncertainty will be attributable as much to differences in calculation method as to differences in precision and instrument quality.

Third, a farmer whose harvest's fate hangs in the balance may be tempted to "shop around" for a laboratory whose announced measurement of uncertainty is greater than those of its competitors. Even assuming that every laboratory's announced measurement is accurate (which is not a safe assumption, for the two reasons set forth above), this "shopping around" dynamic could create an economic incentive for laboratories to refrain from embracing innovations that would improve the quality of its testing services because doing so would require a downward revision of its measurement of uncertainty. The IFR should not create a perverse incentive for a laboratory to slow down its efforts to innovate and improve.

For these reasons, we believe it is desirable for there to be a single, nationwide measurement of uncertainty that will be applied uniformly. The Hemp Proficiency Testing Program's participating laboratories could be tasked with calculating and announcing a measurement of uncertainty that will be used for compliance testing purposes on a nationwide basis. As methods and instruments improve over time, the announced measurement of uncertainty could narrow, such that the nationwide acceptable hemp THC level could converge in the direction of the 0.3% statutory definition.

This approach would create a level playing field for hemp producers across the country, eliminate the requirement for each individual laboratory to calculate and announce its own measurement of uncertainty, and foreclose the possibility of laboratory-shopping on the part of farmers in search of a more forgiving acceptable hemp THC limit.

There is one more factor that bears emphasis: a true measurement of uncertainty must take into account variability in the steps that occur before the samples reach a laboratory. We cannot assume that there will be uniformity in all of those steps: cutting, bagging, sealing, transporting, handling, and so on. In addition, there will be variation in the length of time between when a sample is cut and when it is received by a laboratory. To account for this variation, it is necessary to build in an additional measurement of uncertainty for pre-laboratory activities (*a*), in addition to the measurement of uncertainty for in-laboratory activities (*b*), such that a total measurement of uncertainty (*c*) can be calculated as the square root of the sum of those squared values (*a* squared plus *b* squared = *c* squared). This will require an upward revision of the total measurement of uncertainty. For example, if the in-laboratory measurement of uncertainty (*b*) is calculated as 0.0300%, and the pre-laboratory measurement of uncertainty (*a*) is estimated to be 0.0400%, then the total measurement of uncertainty (*c*) would be 0.0500%.

Enforcement: THC testing results should be reported to USDA by the state department of agriculture, not by the testing laboratory.

Section 990.70(d) of the IFR requires producers to "ensure that the DEA-registered laboratory that conducts the test of the sample(s) from its lots reports the test results for all samples tested to USDA." We do not dispute the propriety of a requirement for USDA to receive copies of test results, but we believe that the obligation to furnish it should rest with the state department of agriculture, not the laboratory itself. We believe this for at least two reasons.

First, the state department of agriculture should be receiving this testing data from its affiliated laboratories already, so there is no additional burden in requiring the department to transmit it to USDA.

Second, here in Kentucky we do not provide grower-identifying information to our affiliated laboratory so that there is no possibility of bias or favoritism. Our laboratory partners do not know whose samples they are testing at any given moment, and we understand that they prefer it that way. If there is a need for a farmer to receive unfortunate news about his or her harvest's non-compliant test results, we believe that he or she should receive that information from the state department of agriculture, not the laboratory.

For that reason, it may prove difficult to require the testing laboratory to disclose the grower's identifying information (name, address, and lot identification number) in connection with test result reports to USDA. We believe it makes more sense for the state department of agriculture to be responsible for this task.

Enforcement: The IFR should allow post-harvest retests.

In Kentucky, we have developed a two-part strategy for keeping non-compliant strains and varieties out of the Commonwealth. On the front end, so to speak, we maintain a Summary of Varieties List that gives notice to farmers about the THC testing history of every variety or strain that has been introduced in past years. In our annual end-of-season review of our THC testing data, we designate those varieties that have consistently yielded plants with excessive THC levels as "prohibited varieties." (We designate varieties with some non-compliant tests as "varieties of concern"; a farmer is authorized to plant a variety of concern in an upcoming year, but he or she is on notice of the heightened risk of a non-compliant harvest that may require disposal and a resulting economic loss.) We use this tool to curate the genetics that are allowed to remain in the Commonwealth from one year to the next, and to prevent farmers from bringing into the state varieties or strains that consistently yield cannabis that does not meet the legal definition of hemp.

The second aspect of our strategy is to give farmers an opportunity to realize a financial return on his harvest by giving them a second chance to achieve a compliant THC test result. For plots with a THC measurement between 0.4% and 1.0%, the farmer is given an option: either agree to the immediate destruction of the leaf and floral material of the crop, without additional testing, or elect to pay the $250 fee for a "post-harvest retest." (A plot with a THC measurement in excess of 1.0% is not eligible for a post-harvest retest; destruction is the only option.)

We believe that offering post-harvest retests is good policy because the material to be tested is typically in a ground-up state. If the farmer's harvest is being transferred to a licensed processor in that ground-up state—that is, in a state whose THC concentration may be diluted as compared to the concentration found in the top 20 centimeters that were cut, weeks before, for the pre-harvest sample—then we believe it is fair to allow the farmer to allow his harvest's THC content to be measured in the state in which it will leave his or her possession.

Offering post-harvest retests for eligible plots has proven to be a very successful tool for helping our farmers avoid a devastating financial loss. To take the 2018 growing season as an example, 29 of the pre-harvest samples that were collected that year returned a THC measurement between 0.4% and 1.0%.[2] Of the 29 plots with such a measurement, the farmer elected to pay for

[2] In the 2019 growing season, 493 of the 3,231 pre-harvest samples that were collected returned a THC measurement between 0.4% and 1.0%. As of today, the post-harvest sample

a post-harvest retest in 22 instances.[3] Of those 22 post-harvest retests, none returned a second measurement that was above 0.3999%, which meant that the farmer was able to realize an economic return on his investment. And as a result, approximately 1% of the total acreage grown in 2018 (6,700 acres) ultimately had to be destroyed—just a fraction of what the percentage would have been if KDA did not offer our farmers an option for a post-harvest retest.

Enforcement: A 0.5% THC measurement is too low a threshold to necessitate a "negligent violation."

Section 990.6(b)(3) of the IFR states that "[h]emp producers do not commit a negligent violation under this paragraph (b)(3) if they make reasonable efforts to grow hemp and the cannabis (marijuana) does not have a delta-9 THC tetrahydrocannabinol concentration of more than 0.5 percent on a dry weight basis." The implication of this paragraph appears to be that a farmer whose harvested lot is measured to have THC content in excess of 0.5% must be deemed to be a "negligent violation," even if there is no information to suggest an improper motive or carelessness on the farmer's part.

Simply put, 0.5% is too low of a threshold. For instance, in the 2019 growing season, more than 5.5% of the pre-harvest samples collected by KDA were measured to have a THC content greater than 0.5%.[4] There are any number of reasons why a particular lot might receive such a high measurement: using a variety or strain with THC-producing propensities that the farmer did not fully appreciate; year-specific stressors such as unusual rainfall patterns; land-specific variables such as soil quality; and a lack of experience on the part of a farmer who may be working with hemp for the first time in his or her career.

We believe that USDA should give state departments of agriculture the flexibility and discretion they need to determine when a particular non-compliant test result should be deemed to be evidence of a negligent violation on the farmer's part. In the alternative, if USDA believes it is necessary to fix a quantitative threshold for deeming a noncompliant test result as a "negligent violation," then we believe that the threshold should be greater than 0.5%—and in no event below 1.0%.

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testing has not yet been completed; for that reason my letter is focusing on our experience in 2018 for the purpose of this illustration.

[3] In the other seven cases, the farmer elected to destroy the leaf and floral material. Five of those cases (representing 33 acres) resulted in a total destruction. The remaining two cases (representing 46 acres) were fiber varieties, which meant that the stalks could be salvaged even though the leaf and floral material was destroyed.

Thus, in 2019 a total of 79 acres were voluntarily destroyed, representing approximately 1% of the total acreage.

[4] This figure accounts for 121 different licensed growers, representing 14% of the total grower population.

Enforcement: Make clear that only one "negligent violation" can be assessed each year.

Section 990.6(c)(4) of the IFR states that "[a] producer that negligently violates a USDA-approved State or Tribal plan three times in a 5-year period shall be ineligible to produce hemp for a period of 5 years beginning on the date of the third violation." We understand this provision to mean that if a farmer negligently produces non-compliant harvests in three different years within a five-year period, he or she shall then be deemed ineligible to participate for the next five years. We believe it would promote clarity, and reduce confusion among the public, for the IFR to make explicit that a farmer who produces three non-compliant lots in a single growing season (for example, by planting multiple lots with a seed variety with genetic propensities which create a higher-than-normal risk of generating a non-compliant plants) will not be deemed to have committed three violations at the same time. A farmer, in other words, can only commit one negligent violation in each growing season. [Of course, if a state department of agriculture finds that a farmer has violated some other program rule (for instance, by failing to provide accurate location data for a specific field where hemp was planted), in addition to producing a non-compliant harvest, then it could be appropriate for the farmer to receive more than one negligent violation in a given year.]

Enforcement: Allow disposal of non-compliant harvests by on-farm destruction methods.

Section 990.3(a)(3)(E) of the IFR states that non-compliant harvests must be disposed of "in accordance with DEA reverse distributor regulations found at 21 CFR 1317.15." That regulation, in turn, contemplates that a reverse distributor shall take possession "of a controlled substance by delivery or pick-up" so that it may be stored or destroyed at an authorized location. Nowhere in this regulation does there appear any consideration of the reality that the most efficient, cost-effective method of disposal for non-compliant hemp harvests are on-farm methods—either by incineration or by grinding it up and disking it under the soil. In past years KDA has used both of these on-farm disposal methods, under the direct supervision of a KDA employee, to effectuate the disposal of non-compliant harvests by rendering the material into a non-retrievable state.

The time and expense of transporting a noncompliant harvest from a farm to another location for its disposal would be much greater than allowing state departments of agriculture to choose one of these two proven on-farm disposal methods. To that end, we suggest revising the IFR so that it does goes beyond simply incorporating by reference a DEA regulation that was likely crafted to effectuate the effective disposal of other kinds of controlled substances, and instead identify acceptable methods of disposal that are tailored to the specific circumstances of a harvested lot that needs to be rendered into a non-retrievable state in the most time- and cost-effective method available.

Thank you for the opportunity to provide these comments. If you would like to discuss these comments further, or any matters relating to hemp policy, please do not hesitate to contact me and my staff. We realize that many issues exist and new ones are certain to emerge in the future. We appreciate USDA's leadership in helping to grow our nation's hemp industry, and we hope we can be a resource for you in the future.

Respectfully,

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October 8, 2020

Hon. Greg Ibach
Under Secretary for Marketing and Regulatory Programs
Agricultural Marketing Service
United States Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20250-0237

Re: Second Set of Comments from the Kentucky Department of Agriculture Regarding the Interim Final Rule titled "Establishment of a Domestic Hemp Production Program" (Doc. No. AMS-SC-19-0042), published October 31, 2019

Dear Under Secretary Ibach:

As Kentucky's Agriculture Commissioner, it is my honor and privilege to be an advocate for the 75,000 farm families who make the Commonwealth's agricultural economy work. Earlier this year I submitted to your office a letter, dated January 29, with comments on ten specific aspects of the Interim Final Rule (IFR) that USDA published in the Federal Register on October 31, 2019. I hope you will take those comments into account as you consider options for improving the IFR in the months ahead.

In addition, your agency recently reopened the comment period with a request for comments on several specific topics. To that end, with the remainder of this letter I will offer comments on those topics, and I would welcome the opportunity to discuss them further at your convenience.

Sampling: Which part of the plant should be cut for sampling and testing purposes.

The IFR does not specify which part of the hemp plant should be cut and collected for sampling. In Kentucky, we cut the top 20 centimeters (approximately eight inches) from the main flower of the female plant. (This sampling standard was adapted from the United Nations Office on Drugs and Crime's *Recommended methods for the identification and analysis of cannabis and cannabis products*, UN document ID number ST/NAR/40.) We believe that Kentucky's standard strikes an appropriate balance between the need to collect a sufficiently large portion of the female plant's flower (where THC and other cannabinoids are at their most concentrated), on the one hand, and the need to avoid cutting a portion (or harvesting an entire plant, for that matter) that is so large that it would be logistically difficult to transport, dry, and grind up the sample for lab testing.

Adopting this 20-centimeter standard on a nationwide basis would put everyone on a level playing field. And it would have the additional benefit of being easier to understand and follow

than the guidance set forth in USDA's 10/31/2019 *Sampling guidelines for hemp growing procedures*, Section 6.3, which mandates that "[t]he cut shall be made just underneath a flowering material, meaning inflorescence (the flower or bud of a plant), located at the top one-third (1/3) of the plant."

Sampling: The 15-day harvest window.

Section 990.3(a)(2)(i) of the IFR states that "[w]ithin 15 days prior to the anticipated harvest of cannabis plants, a Federal, State, local, or Tribal law enforcement agency or other Federal, State, or Tribal designated person shall collect samples from the flower material from such cannabis plants for delta-9 tetrahydrocannabinol concentration level testing." Your agency's rationale for this rule—which is consistent with the 15-day window in KDA's existing program rules, per 302 KAR 50:020, Section 17—was that "[i]f producers delay harvest beyond 15 days, the plant will likely have a higher THC level at harvest than the sample that is being tested. This requirement will yield the truest measurement of the THC level at the point of harvest. Accepting that a pre-harvest inspection is best to identify suspicious plants and activities, and that the sample should be taken as close to harvest as possible, the time was selected based on what would be a reasonable time for a farmer to harvest an entire field."

If USDA is considering whether it would be appropriate to expand the 15-day window (for example, by replacing it with a 30-day period), then we urge you to examine the body of research (including ongoing research that is being conducted here in Kentucky, a summary of which Dr. Bob Pearce and his colleagues at the University of Kentucky plan to submit to USDA in advance of today's deadline) that investigates how cannabinoids proliferate, week over week, as a hemp plant matures.

Sampling: Who should be allowed to select and cut samples for THC testing.

In Kentucky, the only personnel who are permitted to select and cut samples are KDA's employees. We take this approach for three reasons. First, we train our personnel to ensure that the plants are being selected, cut, and handled in a uniform manner; this would be virtually impossible to ensure if farmers were directed to select, cut, and send in their own samples. Second, we believe it is important, for the integrity of the program, for samples to be selected and cut by someone (a KDA employee) who does not have a personal financial stake in the results of the THC test. Third, there would be chain-of-custody problems that could cast doubt on the accuracy of a testing laboratory's THC measurements if a sample were selected and cut by someone other than an employee of the state department of agriculture.

Because of the seasonal nature of this work—with the majority of samples being collected during the months of August, September, and October—we have found it helpful to use temporary workers, hired on a seasonable basis, to meet the additional workload. With appropriate training, temporary workers can perform these tasks with the same level of proficiency and professionalism as our full-time employees. We recommend that USDA should consider incorporating temporary seasonal workers in its approach to sampling.

Sampling: The number of plants needed for a homogenous, representative sample.

The IFR does not state a fixed number of plants that should be sampled from each lot; instead, Section 990.3 provides that a State Plan's method "must be sufficient at a confidence level

of 95% that no more than one percent (1%) of the plants in the lot would exceed the acceptable hemp THC level." In Kentucky, we require five (5) plants to be selected for cutting samples. We believe this standard provides a reasonably representative sampling of the plants present in a particular lot.

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Second, the sliding-scale formula is likely to create state-to-state variations in the number of samples that must be collected from fields of the same size. The formula uses, for its denominator, a value representing "the proportion of hemp plants having THC content greater than the acceptable hemp THC level," but this "value" is almost certain to vary widely from one state to another—and from one year to the next in the same state. Moreover, a formula using this denominator value would have the perverse effect of "rewarding" states whose historical testing data showed higher rates of non-compliant THC test results. Increasing the workload required of agency employees in a state with higher compliance rates (or USDA's own employees, in the case of a state whose farmers grow hemp under the USDA Plan) seems illogical and unnecessary.

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There is a simpler path that the IFR could take: fixing a single number of plants to be sampled from every lot, without regard to its size, would be the simplest and most direct approach. In the alternative, USDA could publish its own table that provides a fixed sliding scale (for example, a lot of less than 10 acres requires 5 plants; a lot between 10 acres and 20 acres requires 6 plants; and so on) rather than leaving those calculations to each state.

Sampling: Do not mandate removal of seeds, twigs, and stems before grinding the sample.

The IFR does not require the removal of seeds and stem material from a collected sample prior to grinding, but the guidance set forth in USDA's 10/31/2019 *Testing Guidelines for Identifying Delta-9 Tetrahydrocannabinol (THC) Concentration in Hemp* states that the laboratory personnel should "[m]ill and 'manicure' sample through a wire screen no later than 1.5 x. 1.5 mm to discard mature seeds and larger twigs and stems." There are at least two problems with this approach.

First, the process of removing seeds, twigs, and stems adds variability. No two laboratory personnel will perform the task in exactly the same way, regardless of whether they attempt to take them out "by hand" or by passing the material through an initial 1.5 mm screen. To reduce this

variability, the better practice would be to grind up for testing the entire sample that arrives at the lab. Second, the process of removing seeds, twigs, and stems before grinding takes more time than would otherwise be necessary to prepare a sample for testing. For these reasons, we believe it would be appropriate to revise the 10/31/2019 *Testing Guidelines* to conform more closely to the practices recommended by AOAC, particularly those methods pertaining to grinding specifications (2018.11) and moisture content (930.04).

Sampling: Mandating sample collection and testing from immature plants would not be a good use of agency time and resources.

We are aware that some have suggested that the IFR should require the collection of samples, for THC testing purposes, from seedlings, microgreens, and immature clones. We believe that such a requirement would create an additional workload on the part of regulatory agencies and testing laboratories that is not warranted. The reason is simple: the cannabinoids within an immature hemp are simply too low—or nonexistent, in the case of very young plants—to be measured. The laboratory results from such samples would almost certainly be zero (or near-zero). In addition, because the IFR also requires each lot to be sampled at a later stage (at maturity and shortly before harvesting), an additional requirement for them to be sampled during their immaturity would effectively create a redundant system with duplicated testing loads.

If USDA is seriously considering such a requirement, then we urge you to take time to examine the body of research (including research being conducted here in Kentucky) that examines how cannabinoids proliferate, week over week, as a hemp plant matures. We believe that the findings from such research will persuade you that mandating sampling and testing from immature plants would not be a wise allocation of time and resources.

Testing: The "Measurement of Uncertainty" should be uniform nationwide <u>and</u> take into account the variability occurring in steps that occur before a sample reaches the laboratory.

Section 990.3(a)(3)(F) requires laboratories to calculate a "measurement of uncertainty" that will be reported with THC testing results. We believe that USDA's decision to mandate a "measurement of uncertainty" was appropriate in light of the inherent limitations in quantitative testing which the National Institute of Standards and Technology (NIST) *Reference on Constants, Units, and Uncertainty* explained this way: "measurement result is complete only when accompanied by a quantitative statement of its uncertainty." Or as the IFR's Supplementary Information put it, "knowing the measurement of uncertainty is necessary to evaluate the accuracy of test results."

We agree. In recent years our experience has been that the variation in testing results could be as great as 0.1%, which is why Kentucky's existing hemp program deems a THC result of up to 0.3999% to be compliant with the 0.3% definition that was adopted in statute by the Congress and the Kentucky General Assembly.

In time, we expect that advances in technology and improvements in methodologies should cause a decline in these variation rates. And some laboratories, especially those with the benefit of several years of experience, will achieve a tighter variation rate faster than others.

We believe that instead of requiring each laboratory to determine and apply its own measurement of uncertainty, the IFR should mandate the calculation of a single, nationally-

uniform measurement that will be applied to all. We believe this is appropriate for at least three reasons.

First, there is no guarantee that an individual laboratory will correctly calculate its own measurement of uncertainty because the mathematical principles involved are complicated. Hemp farmers should not be exposed to risks of economic loss that are created, but concealed from view, by mathematical errors within an individual laboratory's computations.

Second, there is no universally accepted way to calculate a measurement of uncertainty, which makes it very likely that the inter-laboratory variation in announced measurements of uncertainty will be attributable as much to differences in calculation method as to differences in precision and instrument quality.

Third, a farmer whose harvest hangs in the balance may be tempted to "shop around" for a laboratory whose announced measurement of uncertainty is greater than those of its competitors. Even assuming that every laboratory's announced measurement is accurate (which is not a safe assumption, for the two reasons set forth above), this "shopping around" dynamic could create an economic incentive for laboratories to refrain from embracing innovations that would improve the quality of its testing services because doing so would require a downward revision of its measurement of uncertainty. The IFR should not create a perverse incentive for a laboratory to slow down its efforts to innovate and improve.

For these reasons, we believe it is desirable for there to be a single, nationwide measurement of uncertainty that will be applied uniformly. The Hemp Proficiency Testing Program's participating laboratories could be tasked with calculating and announcing a measurement of uncertainty that will be used for compliance testing purposes on a nationwide basis. As methods and instruments improve over time, the announced measurement of uncertainty could narrow, such that the nationwide acceptable hemp THC level could converge in the direction of the 0.3% statutory definition. There are currently more than 80 labs from across the country participating in the Hemp Proficiency Testing Program.

This approach would create a level playing field for hemp producers across the country, eliminate the requirement for each individual laboratory to calculate and announce its own measurement of uncertainty, and foreclose the possibility of laboratory-shopping on the part of farmers in search of a more forgiving acceptable hemp THC limit.

There is one more factor that bears emphasis: a true measurement of uncertainty must take into account variability in the steps that occur before the samples reach a laboratory. We cannot assume that there will be uniformity in all of those steps: cutting, bagging, sealing, transporting, handling, and so on. In addition, there will be variation in the length of time between when a sample is cut and when it is received by a laboratory. To account for this variation, it is necessary to build in an additional measurement of uncertainty for pre-laboratory activities (a), in addition to the measurement of uncertainty for in-laboratory activities (b), such that a total measurement of uncertainty (c) can be calculated as the square root of the sum of those squared values (a squared plus b squared = c squared). This will require an upward revision of the total measurement of uncertainty. For example, if the in-laboratory measurement of uncertainty (b) is calculated as 0.0300%, and the pre-laboratory measurement of uncertainty (a) is estimated to be 0.0400%, then the total measurement of uncertainty (c) would be 0.0500%.

THC Testing and Remediation: Post-harvest retests should be permitted.

In Kentucky, we have developed a two-part strategy for keeping non-compliant strains and varieties out of the Commonwealth. On the front end, so to speak, we maintain a *Summary of Varieties List* that gives notice to farmers about the THC testing history of every variety or strain that has been grown in Kentucky in past years. In our annual end-of-season review of our THC testing data, we designate those varieties that have consistently yielded plants with excessive THC levels as "prohibited varieties" and remove all planting materials associated with those varieties from our program. We also designate varieties with some non-compliant tests as "varieties of concern"; a farmer is authorized to plant a variety of concern in an upcoming year, but he or she is on notice of the heightened risk of a non-compliant harvest that may require disposal and a resulting economic loss. We use this tool to curate the genetics that are allowed to remain in the Commonwealth from one year to the next, and to prevent farmers from bringing into the state varieties or strains that consistently yield cannabis that does not meet the legal definition of hemp.

In 2019, when circumstances made it impossible for us to sample 100% of the lots that were grown that year, we used the *Summary of Varieties List* as a tool to guide targeted, risk-based sampling and testing in this manner:

- Samples were collected and tested from 5% of lots that were produced from certified seed;
- Samples were collected and tested from 50% of lots that were produced from varieties that had been tested and proven compliant in previous years;
- Samples were collected and tested from 100% of lots that were produced from varieties designated as a "variety of concern."

The targeted, risk-based approach we used in 2019 allowed for cost and time savings while also providing sufficient incentive for all growers to do their best to grow crops within compliance limits. We urge USDA to consider developing a nationwide list of compliant varieties that could be grown by farmers with a greater degree of confidence of compliance and would also require less rigorous sampling and testing.

The second aspect of our strategy—the part that comes into play "on the back end" so to speak—is to give farmers an opportunity to realize a financial return on their harvests by giving them a second chance to achieve a compliant THC test result. For plots with a pre-harvest THC measurement between 0.4% and 1.0%, the farmer is given an option: either agree to the immediate destruction of the leaf and floral material of the crop, without additional testing, or elect to pay the $250 fee for a "post-harvest retest." (A plot with a THC measurement in excess of 1.0% is not eligible for a post-harvest retest; destruction is the only option.)

We believe that offering post-harvest retests is good policy because it minimizes the loss to the farmer while ensuring that only compliant material enters commerce. The material to be tested post-harvest is typically in a ground-up state. If the farmer's harvest is being transferred to a licensed processor in that ground-up state—that is, in a state whose THC concentration may be diluted as compared to the concentration found in the top 20 centimeters that were cut, weeks before, for the pre-harvest sample—then we believe it is fair to allow the farmer to allow his harvest's THC content to be measured in the state in which it will leave his or her possession.

Offering post-harvest retests for eligible plots has proven to be a successful tool for helping our farmers avoid a devastating financial loss. To take the 2019 growing season as an example, 493 of the pre-harvest samples that were collected that year returned a THC measurement between 0.4% and 1.0%.[1] Of the 493 plots with such a measurement, the farmer elected to pay for a post-harvest retest in 441 instances. Of those 441 post-harvest retests, only 46 returned a second measurement that was above 0.399% (which resulted in destruction), which meant that the farmer was able to realize an economic return on his investment for remaining 395 lots. And as a result, approximately 5.7% of the total acreage grown in 2019 (which totaled 26,500 acres) ultimately had to be destroyed—less than a third of the 17.1% that would have been destroyed if KDA did not offer our farmers an option for a post-harvest retest.

Testing: DEA laboratory registration is desirable but should not be required.

KDA relies upon two laboratories for its THC testing services: the Division of Regulatory Services within the College of Agriculture, Food, and Environment at the University of Kentucky in Lexington; and the Breathitt Veterinary Center at the Murray State University in Hopkinsville. Both of these laboratories have attained a laboratory registration from DEA, as is currently required by the IFR. We are also aware of several privately-owned laboratories in Kentucky that have obtained a laboratory registration. While we believe that laboratory operators may find it desirable to obtain such a registration from DEA—not least because a DEA registration may assuage concerns among law enforcement agency representatives, and the general public, about the lawfulness of their business—we do not believe the IFR needs to mandate it.

Negligence: The 0.5% threshold is too low.

Section 990.6(b)(3) of the IFR states that "[h]emp producers do not commit a negligent violation under this paragraph (b)(3) if they make reasonable efforts to grow hemp and the cannabis (marijuana) does not have a delta-9 THC tetrahydrocannabinol concentration of more than 0.5 percent on a dry weight basis." The implication of this paragraph appears to be that a farmer whose harvested lot is measured to have THC content in excess of 0.5% must be deemed to be a "negligent violation," even if there is no information to suggest an improper motive or carelessness on the farmer's part.

Simply put, 0.5% is too low of a threshold. For instance, in the 2019 growing season, more than 5.5% of the pre-harvest samples collected by KDA were measured to have a THC content greater than 0.5%.[2] There are any number of reasons why a particular lot might receive such a high measurement: using a variety or strain with THC-producing propensities that the farmer did not fully appreciate; year-specific stressors such as unusual rainfall patterns; land-specific

[1] In the 2019 growing season, 493 of the 3,231 pre-harvest samples (15.3%) that were collected returned a THC measurement between 0.4% and 1.0%. These 493 samples represented 3,749 acres of hemp crops. Among those 493 samples, 52 lots were chosen for destruction by the farmer instead of paying for the retest. The retested lots yielded 395 compliant results (representing 3,529 acres) and 46 results (representing 181 acres) above the acceptable THC level resulting in ordered destruction.

[2] This figure accounts for 121 different licensed growers, representing 14% of the total grower population.

variables such as soil quality; and a lack of experience on the part of a farmer who may be working with hemp for the first time in his or her career.

We believe that USDA should give state departments of agriculture the flexibility and discretion they need to determine when a particular non-compliant test result should be deemed to be evidence of a negligent violation on the farmer's part. In the alternative, if USDA believes it is necessary to fix a quantitative threshold for deeming a noncompliant test result as a "negligent violation," then we believe that the threshold should be greater than 0.5%—and in no event below 1.0%.

Disposal: Allow disposal of non-compliant harvests by on-farm destruction methods.

Section 990.3(a)(3)(E) of the IFR states that non-compliant harvests must be disposed of "in accordance with DEA reverse distributor regulations found at 21 CFR 1317.15." That regulation, in turn, contemplates that a reverse distributor shall take possession "of a controlled substance by delivery or pick-up" so that it may be stored or destroyed at an authorized location. Nowhere in this regulation does there appear any consideration of the reality that the most efficient, cost-effective method of disposal for non-compliant hemp harvests are on-farm methods—incineration, grinding it up and disking it under the soil, or spreading it across a field's surface so it can decompose and be incorporated into the soil through natural processes. In past years KDA has used both of these on-farm disposal methods, under the direct supervision of a KDA employee, to effectuate the disposal of non-compliant harvests by rendering the material into a non-retrievable state.

The time and expense of transporting a noncompliant harvest from a farm to another location for its disposal would be much greater than allowing state departments of agriculture to choose one of these two proven on-farm disposal methods. To that end, we suggest revising the IFR so that it goes beyond simply incorporating by reference a DEA regulation that was likely crafted to effectuate the effective disposal of other kinds of controlled substances, and instead identify acceptable methods of disposal that are tailored to the specific circumstances of a harvested lot that needs to be rendered into a non-retrievable state in the most time- and cost-effective method available.

Thank you for the opportunity to provide these comments. If you would like to discuss these comments further, or any matters relating to hemp policy, please do not hesitate to contact me and my staff. We realize that many issues exist and new ones are certain to emerge in the future. We appreciate USDA's leadership in helping to grow our nation's hemp industry, and we hope we can be a resource for you in the future.

Finally, I want to thank you and your colleagues at USDA for your demonstrated interest in Kentucky's hemp program's structure and operations. Last year it was an honor to welcome you, Secretary Perdue, and a number of other USDA officials who visited Kentucky to learn about our hemp program. I look forward to substantive and respectful interactions between our offices in the years to come.

Respectfully,

Ryan F. Quarles
Commissioner