

January 2, 2020

Bill Richmond, Chief, U.S. Domestic Hemp Production Program
United States Department of Agriculture
1400 Independence Avenue SW, Stop 0237
Washington, D.C. 20250-0237

Re: Comments on USDA Interim Rule 84 FR 58522 Establishment of a Domestic Hemp Production Program

Mr. Richmond,

The Minnesota Department of Agriculture (MDA) has administered the Minnesota Industrial Hemp Pilot Program since 2016. After completion of the fourth year of hemp production in Minnesota, we are pleased to report we have seen exponential growth licensees of both hemp growers and hemp processors. In 2019 there were 343 licensed hemp growers and 206 licensed hemp processors in Minnesota. Hemp was grown on over 8,000 acres and over 400,000 indoor square feet across the state. As we watched the industry develop and grow throughout our pilot phase, we have found that industrial hemp is a critical market that could help diversify our agricultural economy and bring economic opportunity to communities in Minnesota.

We are pleased that industrial hemp is now considered an agricultural crop, and we are thankful for the work the USDA has put into issuing the Interim Rule on Establishment of a Domestic Hemp Production Program. Shortly after its release, the MDA held listening sessions across the state and heard from hemp farmers and industry leaders at a series of meetings to determine if the proposed interim rule was feasible to implement in Minnesota. It concerns me that there are parts of the interim rule that would make implementation of the hemp program extremely difficult in our state, putting our promising hemp industry in jeopardy.

Below are formal comments from the MDA concerning the interim rule and associated guidance documents, including our concerns about sampling and testing, Drug Enforcement Administration (DEA) laboratory approval, enforcement, and the 2020 growing season. As we move forward in this process, I would like to extend the offer to continue informal conversations with our industrial hemp staff. They have been operating the pilot program in Minnesota for four years and have set up a successful regulatory framework that works for our hemp farmers. Their expertise could certainly inform and improve the proposed interim rules.

Sampling and Testing

The required 15- day timeframe between testing and harvest and the required testing of every licensed field is unworkable for both licensed hemp farmers and the MDA Industrial Hemp Program.

The requirement of sampling and testing each field 15 days prior to harvest is not feasible to implement and will put incredible stress on the developing hemp industry in Minnesota. MDA hemp inspectors have been sampling fields within 30 days of harvest for the past four years of the pilot program. The proposed 15-day timeframe between testing and harvesting is far too narrow and would condense all outdoor hemp field testing into a very short window of time. For outdoor growers in Minnesota, hemp fields generally reach optimal sampling dates between September 1- October 1. Projecting to the 2020 growing season, there will be over 1,000 fields that would be required to be sampled and tested in approximately 20 business days. MDA cannot practically employ enough qualified staff to sample every field at the optimal and correct time. In addition, there are not sufficient laboratory testing services available to process this number of samples in a reasonable timeframe.

In order to implement these requirements, MDA would need to stagger sampling over a wider period to physically get to each grow location and to allow adequate time for laboratory testing. If hemp farmers are forced to harvest within 15 days of sampling and testing, it is inevitable they will be harvesting crops that have not reached peak condition or when weather is unfavorable. This will impact producers of hemp grain, fiber, and CBD. Farmers that would need to harvest early due to a condensed inspection schedule risk harvesting a crop that is not at peak condition, significantly impacting its value. CBD producers may have lower CBD levels than would normally be achieved, diminishing yield and earnings. Farmers that would need to harvest late due to a condensed inspection schedule risk their crop going over the THC limit. There are examples of this happening in other states where sampling could not be completed until after the farmer's declared anticipated date of harvest, which resulted in many fields failing and destruction of crops at no fault of the farmer.

Weather will always be the unknown factor for farmers, and in Minnesota weather plays a major role in the success of our crops. In 2019 Minnesota farmers faced extremely wet spring conditions and an early freeze. Harvest was drug out due to continued wet conditions and the inability to get into fields. All farmers need to have the ability to harvest when crop and weather conditions are right, including hemp farmers. It is not practical to have a farmer's hemp harvest dictated by our ability to sample and test a field. It is imperative that sampling and testing requirements are practical while still ensuring the industry is meeting requirements of the law.

According to the Agriculture Improvement Act of 2018, "a state or tribal plan... shall only be required to include... a procedure for conducting annual inspections of, *at a minimum, a random sample of hemp producers* to verify that hemp is not produced in violation of this subtitle." This clearly states that random sampling of hemp fields for THC testing would meet the requirements set forth in the Farm Bill.

MDA hemp inspectors have tested every hemp lot produced in Minnesota in the past four years. The test results show that hemp grown for grain and fiber production has never tested above the 0.3% total THC limit. The grain varieties that have been grown in Minnesota are certified varieties found either on the Health Canada List of Approved Cultivars or the European Union's Organisation for Economic Co-operation and Development List of Varieties Eligible for Seed Certification. MDA recommends that certified seed varieties should be sampled and tested from a random selection of hemp grain and fiber fields 30 days prior to harvest.

Varieties grown for CBD production are more likely to test over the 0.3% THC limit. There are currently no certified varieties of hemp for CBD production. In 2019, about 13% of the hemp samples taken tested over the 0.3% THC limit, all of which were CBD varieties. Resources should be focused to concentrate sampling testing of the crops most at risk of violating the requirements. For uncertified varieties, MDA recommends requiring a post-harvest test, as well as a pre-harvest test of a random selection of fields within 30 days of harvest.

Sampling procedures of hemp fields and grow locations should be uniform across states and tribal governments to ensure that the same part and amount of each individual plant is being tested.

The sampling protocol that was released by USDA is substantially different from what most states have been doing under their respective pilot programs. In Minnesota, cuttings are taken from 30 different plants at each grow location, unless it is very small and then the number of plants sampled is adjusted to a proportional level. The USDA protocol subscribes that we would sample only one plant from a grow location that was one acre or less. This would not be considered a scientifically representative sample. Plants within a hemp population can

vary substantially beyond the normal variability that occurs within populations. In addition, many varieties being grown are highly variable and not uniform. Due to the high genetic variability found within hemp CBD varieties, more samples should be taken to try to capture a snapshot of the total field THC levels. MDA recommends the number of plants sampled be higher, especially in the grow locations of 30 acres or less and less than 1 acre. MDA also recommends that USDA define a specific sampling procedure, developed with those operating under existing pilot programs, to ensure that sampling protocols across states and tribal governments are consistent.

Measurement of uncertainty alone is not an accurate determination on whether a test result meets the requirements of the THC limit.

The use of measurement uncertainty to determine whether a test result complies with the 0.3% total THC is not accurate because it does not incorporate the largest source of variability in any testing process: variability due to sampling. This requirement will cause a significant negative impact on hemp farmers producing hemp for CBD as those varieties show the most phenotypic variability and lack of uniformity in the field. The sampling variability for these varieties is expected to be high. MDA recommends the acceptance criteria for determining compliance of a test result to include *both* sampling variability and measurement of uncertainty.

Post-harvest testing should be utilized for CBD varieties rather than strictly field testing.

As production of hemp for CBD extraction has become more common, it has been found that the varieties grown for this type of production are not stable and are highly variable. The best way to ensure any non-certified variety of hemp does not exceed the total THC limit is to develop a sampling plan for harvested hemp flower or to consider testing the crop after the cannabinoids have been extracted and refined into products. CBD production can result in passing a pre-harvest test, only to find THC levels have spiked later. In this case, it is likely some processors would not accept the crop. Allowing for post-harvest testing ensures the harvested material complies with federal and state law. MDA recommends that states and tribal governments have the option to submit in their plans protocols for post-harvest testing of plant material where appropriate.

States and tribal governments should be allowed to develop a regulatory process for remediation of fields that test above the 0.3% total THC limit.

Minnesota has worked closely with state and local law enforcement to develop regulatory processes that prevent production of marijuana or allow any other illegal activities. In Minnesota, law enforcement authorities have expressed they do not consider negligible amounts of THC (1%-3%) worth investigation. Hemp crops that test above the 0.3% total THC limit but under negligible levels should be allowed to enter commerce under a regulatory scheme that requires remediation and testing after remediation to ensure final products meet the definition of industrial hemp.

MDA recommends that states and tribal governments overseeing industrial hemp should be allowed to develop a regulatory process for remediation of cannabis plants that were grown for the intent of producing hemp but tested above the 0.30% total d-9 THC threshold. This could be done by:

- Dilution during processing by removing and destroying THC or diluting the final product under 0.3% total THC by dry weight.

- Dilution by blending plant material testing over 0.3% total THC with plant material testing lower to achieve levels below the requirement.
- Allow for use of stalks or seed of plant material testing over 0.3% total THC as those materials are exempt from the definition of marijuana per the Controlled Substances Act.

The rule should address the potential for genetic testing to be used in the future.

Genetic testing will be cheaper and more efficient than field testing and will help hemp farmers reduce risk prior to planting. Genetic variation at a single gene, CBDA Synthase, appears to determine whether THC or CBD is predominantly produced. In addition, other genetic loci and candidate genes have been identified that determine the level of expression and total amount of CBD and THC. This genetic research presents an opportunity for plant breeders to leverage markers in their breeding programs to get better uniformity in THC production, ensuring new germplasm meets the definition of hemp. Because the use of genetic markers in the production of agricultural seed is quite routine in current plant breeding programs, it is expected that genetic markers will also be used for hemp breeding and seed production. When these markers are used, they will provide a quality assurance tool that allows seed to be tested for varietal purity as well as for specific traits such as THC production. While knowledge of these markers and their use is limited today, as these marker sets are developed and deployed genetic testing could augment or replace THC testing of plant material at harvest. MDA recommends that the scope of testing is broadened in the rule to allow for the transition to a more robust testing strategy as new technologies come online that ensures all seed entering the marketplace meets the definition of hemp.

Licensees should not be required to be present for sample collection.

The sampling protocol that was released requires that the producer or an authorized representative of the producer must be present when sampling grow locations occurs. The process of coordinating all the hemp inspections in a very short time frame is already a challenge, and ensuring the schedule is also coordinated with the producer or a representative would make it nearly impossible. In order to keep sampling efficient, in Minnesota we schedule sampling for hemp farmers located near each other on the same day. Adding this complication to the schedule could cause delay in collecting samples, getting results back, and pushing back a harvest date. The MDA hemp inspectors work with all hemp farmers to schedule sampling when it is most convenient, and they are certainly welcome to be present if they so choose. However, some hemp farmers grow in multiple locations across the state. Those farmers usually meet an inspector at the first location and ask any questions they may have. All subsequent sampling done at other locations has been done independently by the sampling agent. MDA recommends that the language is changed from stating that the producer or authorized representative “must” be present to “may” be present.

Laboratory Approval

DEA laboratory approval is unnecessary to comply with hemp regulations, and further adds cost to implementation.

Oversite by local law enforcement is preferable to DEA approval of laboratories. Minnesota’s pilot program has been in operation for over four years and has worked closely with state and local law enforcement on issues involving destruction of hemp testing over the 0.3% THC limit. The state is confident in its ability to maintain

adequate procedures, training, and destruction records to meet the needs of law enforcement regarding any laboratory samples that test above the threshold. DEA involvement also places undue restraints on state Cannabis programs, for example medical marijuana. Medical marijuana is legal in Minnesota and the Minnesota Department of Health and MDA use the same third-party, accredited laboratory to conduct testing for both medical marijuana and industrial hemp. This laboratory may not be able to obtain DEA approval because of its work on medical marijuana. This illustrates the need for local oversight.

Currently MDA and law enforcement share information regularly. There is a work group of state agencies developing a regulatory structure for how to handle destruction of hemp and hemp samples that test over the 0.3% THC limit. The involvement of DEA in registration of laboratories is not necessary or practical and will be an added cost to both the MDA state laboratory and any third-party laboratories used for hemp testing. This cost will need to be recovered on the backs of hemp farmers through license fees. MDA recommends that the rules allow for state or tribal governments to develop regulatory requirements for laboratories handling hemp testing to dispose of any material testing over the THC limit with state and local law enforcement.

Enforcement

The requirements in the rule outlining negligent violations are too strict and will result in law-abiding hemp farmers being pushed out of the industry.

In Minnesota, 13% of the hemp samples taken in 2019 tested over the THC limit. The average THC level in those failures was 1.07% delta-9 THC post-decarboxylation, which is clearly well above the 0.3% limit. Most of these cases show that hemp farmers are doing the best they can to select good seed with predictable genetics, and at times have been misled by seed companies. Until hemp genetics and regulation of the hemp seed industry improve, this entirely puts the burden of testing high on the farmers.

The 0.5% THC level is far too low to be considered “negligent.” This could inadvertently push farmers out of eligibility for small infractions that are already being addressed by crop destruction. This low threshold also discourages experimentation and research. During the pilot program, hemp farmers grew multiple varieties to see which ones performed best. If farmers are worried about receiving three negligent violations in five years, they will not risk growing new varieties, stifling innovation in this new industry. Each individual field, grow location, or lot test should not be considered a negligent violation. This could result in hemp farmers growing multiple varieties receiving all three negligent violations in one growing season.

MDA recommends the level defined for negligence is moved to 1% THC, rather than 0.5% THC, and that farmers growing multiple varieties only receive one negligence violation if any of their tests are above 1% THC. MDA also recommends that if hemp farmers can show they attempted to purchase legal hemp seed or clones in good faith, they should not be punished with a negligent violation.

USDA should allow states and tribal governments submitting plans to work with their state and local law enforcement in-place of DEA.

Throughout the duration of Minnesota’s pilot program, MDA has worked closely with local law enforcement. Local drug and gang task forces have been made aware of any hemp grow locations that test over the THC limit

and have observed and documented destruction of such crops. County sheriffs have assisted in site visits. MDA is currently working with the state departments of Public Safety and Health to develop guidance on how to regulate hemp processing, including proper destruction of THC. MDA recommends that states and tribal governments overseeing industrial hemp production should be allowed to work with local law enforcement leadership to determine a process for how hemp is destroyed and by whom.

USDA should clearly define who is a key participant and who needs to have a background check to be licensed.

In the interim rule the definition of a key participant is a person or persons who have a direct or indirect financial interest in the entity producing hemp, such as an owner or partner in a partnership. A key participant also includes persons in a corporate entity at executive levels including chief executive officer, chief operating officer and chief financial officer. This does not include such management as farm, field or shift managers. The definition is vague and does not state all position titles that need to pass the background check requirement. The language in Minnesota's state hemp statute grants MDA permission to conduct background checks on the primary applicant or licensee. Better defining who is expected to receive a background check would give clarity to licensees and provide uniformity across state and tribal government hemp plans.

Oversight of industrial hemp seed and clone producers and vendors is critical to ensure success of the industry and to protect hemp farmers.

It is concerning that USDA is not considering a certified seed program at this time stating, "the same seeds grown in different geographical locations and growing conditions can react differently." This is exactly why oversight is needed. Hemp farmers are shouldering all the risk and financial burden of unstable varieties in the marketplace. MDA recommends that USDA sets a timeline to establish certification requirements that drives the creation of a stable hemp seed and clone industry, just as the industries that have developed for other agricultural crops.

2020 Growing Season

The October 31, 2020 date to change over from pilot programs to approved USDA plans is not practical.

Minnesota plans to remain in operation under the pilot program for the 2020 growing season while a plan is developed to submit to USDA. Minnesota's state hemp statute aligns the hemp licensure period with the calendar year. The two-month gap to fill in licensing will lead to confusion for growers, as well as be out of conformance with state law. Harvest will also be happening during this time. MDA staff will be fully focused on sampling hemp fields, and will not be able to manage applications, supporting documents, and licensing coming in to be processed prior to November 1. Hemp farmers would also be inconvenienced by this timing of changing over during harvest. MDA recommends that USDA grant an extension to state pilot programs until December 31, 2020.

Thank you for your consideration of these comments. If you have any questions or concerns, please reach out to MDA Assistant Commissioner Whitney Place at whitney.place@state.mn.us or 651-201-6480. MDA looks forward to our continued work together to ensure that we can put forth the best framework for regulation of industrial hemp production in Minnesota.

Sincerely,

A handwritten signature in cursive script that reads "Thom Petersen". The signature is written in black ink and is positioned below the word "Sincerely,".

Thom Petersen
Commissioner