VERMONT

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VIA ELECTRONIC FILING
Bill Richmond, Chief
U.S. Domestic Hemp Production Program
Agricultural Marketing Service
United States Department of Agriculture
c/o E-Docket ID No. AMS_FRDOC_0001-1919
1400 Independence Ave. SW
Washington, DC 20250-0237

Re: *Comments of the Vermont Agency of Agriculture, Food & Markets related to the Federal Program Requirements for the Establishment of a Domestic Hemp Production Program; Interim Final Rule, 84 Fed. Reg. 58523 (Oct. 31, 2019) Docket # AMS_FRDOC_0001-1919, 7 CFR part 990.*

Dear Mr. Richmond,

The Vermont Agency of Agriculture, Food & Markets (VAAFM) welcomes this opportunity to comment on the USDA's Interim Final Rule (IFR) on the Establishment of a Domestic Hemp Program. VAAFM appreciates USDA's efforts to expedite its process and supports a regulatory framework for domestic hemp production that complies with the 2018 Farm Bill. VAAFM is concerned that portions of the USDA's IFR exceed the statutory mandate.

The 2018 Farm Bill authorized USDA to establish a regulatory framework for domestic hemp production. Congress expressly stated that State plans could exclusively address the following seven requirements:

- record keeping identifying where hemp is grown;
- testing procedures for delta-9 tetrahydrocannabinol (THC), including the ability to use similarly reliable methods that do not include decarboxylation;

- procedures for the disposal of crops and products produced in violation of the statute;
- procedures to comply with enforcement provisions;
- procedures for conducting annual inspections;
- procedures for promptly sharing information with USDA; and
- the State's certification that it is capable of carrying out its plan.

The USDA's IFR creates a State plan framework that regulates activities that lie outside its statutory rulemaking grant. The IFR also includes unnecessary restrictions that will significantly prejudice producers.

Specifically, VAAFM believes the IFR's negligence standard conflicts with the statute, that its sampling protocol is unreasonably restrictive, that its testing procedures will unfairly result in widespread crop failure, that lab procedures are too onerous, that it should not require farmers to report to both the State and Federal governments, and that good faith producers should be eligible for crop insurance.

VAAFM is particularly concerned about the IFR's detrimental impact for small-scale producers. The IFR's requirements favor large producers with deeper pockets and will create an uncertain agricultural commodity market for hemp. While large producers may have the resources to absorb the significant risk of producing noncompliant crops, small producers have little to no ability to endure the crop failures the IFR is likely to mandate. And, the lack of opportunity to remediate THC levels or salvage the compliant portions of a crop compound the risks. Vermont, like much of New England, has many small producers. VAAFM believes the proposed framework will disrupt small farmers who are successfully producing hemp under Vermont's pilot program authorized by the 2014 Farm Bill. *See* 7 U.S.C. § 5940.

VAAFM respectfully requests revisions to the IFR so USDA does not hinder Vermont's many small producers or interfere with the success and/or growth of Vermont's hemp industry. VAAFM

supports consumer protection and quality control through reasonable regulation and asks USDA to ensure that Vermont and other States with small producers can benefit from this important economic opportunity. State agencies have the local knowledge to facilitate industry growth and understand how regulatory clarity promotes the infrastructure necessary to achieve success. VAAFM solicits a regulatory framework that protects the public while permitting the creation of high-paying jobs. VAAFM wants to encourage responsible hemp production for its farmers and facilitate job growth in laboratories and facilities that process grain, fiber, and resinous hemp.

It is often easier to criticize than compliment. VAAFM truly appreciates USDA's efforts to provide clarity and consistency for States and Tribal authorities. VAAFM requests changes, because the IFR appears to block States from establishing appropriate protocols and standards to address the conditions within each State's agricultural industry. The 2018 Farm Bill did not authorize USDA to exceed the Congressional mandate. Federal agencies may only preempt State authority in accordance with the governing federal law. VAAFM believes federal agencies should implement policy by encouraging States to develop local practices that meet a program's objectives, by deferring to States for appropriate standards, and by consulting with States about national standards and/or about whether to preserve a State's authority to regulate its local community. Federalism works best with a strong federal mandate coupled with technical and financial support, while States retain the latitude to operate state-specific plans that account for local variables and necessities.

- IFR § 990.6. Explanation of negligent violations.

The IFR defines negligence as a "[f]ailure to exercise the level of care that a reasonably prudent person would exercise in complying with the regulations set forth under this part." The definition is intended to interpret section 297B (e)(2) of the 2018 Farm Bill describing a negligent violation. The statute states, "A hemp producer in a State...shall be subject to subparagraph (B) of this paragraph if the State department of agriculture...determines that the hemp producer has *negligently* violated the

State...plan, including by *negligently* (i) failing to provide a legal description of land on which the producer produces hemp; (ii) failing to obtain a license or other required authorization from the State department of agriculture...; or (iii) producing Cannabis sativa L. with a delta-9 tetrahydrocannabinol concentration of more than 0.3 percent on a dry weight basis." (*Emphasis added.*)

Importantly, Congress defined a "negligent violation" as a producer action that is performed *negligently* and violates the plan. Accordingly, a hemp producer only commits a negligent violation by *negligently* producing *Cannabis sativa* L. that exceeds the 0.3 percent THC threshold. Perhaps in an effort to provide clarity, the IFR exceeds the statutory mandate by appearing to explicitly define some actions as "negligent violations" irrespective of whether the producer acted negligently. Specifically, the IFR as drafted may mandate a finding that any failure to provide a legal description of land, to obtain a license, or to produce cannabis under the proscribed 0.5 percent THC threshold constitutes a negligent violation. Troublingly, the IFR describes negligent violations without specifying that a producer must act negligently to commit a violation.

VAAFM respectfully contends that defining a negligent act without evaluating whether a producer failed to act in a reasonably prudent manner overrides Congressional intent. In our view, a producer only commits a negligent violation when the producer negligently violates the plan. There is no need to define negligent violations beyond Congress's directive, and equating a crop that exceeds 0.5 percent THC to negligence exceeds the statutory mandate, contradicts the statute's express language, and is unfair to producers.[1] The question of negligence should be determined by the producer's actions and/or omissions, not by a chemical test that may be entirely unrelated to a producer's reasonable prudence. VAAFM believes Congress directed the USDA to adopt a standard of compliance that

[1] If the intent was to exclude crops under the 0.5 percent threshold from a negligence finding rather than to equate crops exceeding that threshold to producer negligence, VAAFM believes the IFR should be revised to better reflect that objective. Regardless, the IFR should be clear that a negligent violation requires producer negligence and is not exclusively premised on THC levels.

evaluates the expectations of a reasonable, prudent person under similar circumstances—not to establish negligent violations by exclusive reliance on THC test results.

The 0.3 percent THC concentration referenced in Section 297B (e)(2)(iii) establishes whether a crop is hemp. Congress expressly stated that a "negligent violation" includes instances where a producer *negligently* exceeds the THC limit. States should be allowed to determine negligence by evaluating whether a hemp producer acted as a reasonably prudent person would act under similar circumstances when securing seed and growing and harvesting a crop.

USDA's Hemp Program should recognize that producers want to be able to sell their crops and are putting their trust and resources into seeds with reliable genetics. Nevertheless, weather, geography, and other factors beyond the producer's control may play a role in whether plants ultimately exceed the 0.3 percent THC limit. While the IFR alludes to this reality by establishing an apparent 0.5 percent THC floor for 'negligence,' it also relies on plant chemistry instead of producer behavior to determine negligence.

Even if a test result alone could permissibly establish negligence, the THC limit would have to be much higher. If the USDA believes it has the authority to further define negligence by equating it to a specific THC level, VAAFM respectfully requests that the level be raised to at least 1 percent. In VAAFM's experience, it is challenging to grow hemp that has a total THC concentration following complete decarboxylation that does not exceed 0.3 percent. Producers in northern States—who have fewer hours of daylight at the end of the season and different weather extremes than the current seed-producing States—will struggle to grow consistently saleable crops until the breeding stock achieves market certainty and maturity. A producer acting as a reasonably prudent person may produce crops that exceed the current 0.5 percent "negligence" threshold. That non-negligent producer should not be penalized or charged with a negligent violation. A producer should only be penalized under a State plan when a State evaluates the pertinent facts and determines that a producer negligently violated the plan.

Recommendation: A THC test result should not automatically establish a producer's negligence. State plans should enforce negligent violations consistent with the statutory mandate and States should determine negligence by evaluating whether a producer violated a State plan by failing to exercise the level of care that a reasonably prudent person would exercise. Absent negligence, the loss of a producer's crop is a more than sufficient penalty for any good faith failure to satisfy the 0.3 percent THC limit.

- IFR § 990.3 (a)(2). Required sampling protocol.

The IFR requires sampling within 15 days of harvest and exclusively specifies that samples be taken from hemp's flower material by a designated person. Congress did not impose such a time-limited or rigorous standard, and USDA's rule will create an unsustainable bottleneck that will seriously disrupt crop production and harvest.

Vermont is a rural State with small farms, a short growing season, and limited laboratory capacity. The requirement that all crops—which will mature during the same time period—be sampled by a State-designated person within 15 days of harvest creates a logistical impossibility. Moreover, the short timeframe will make it extremely difficult to obtain test results prior to harvest. Vermont has hundreds of hemp growers dispersed on mostly small plots around the State and a limited number of qualified regional laboratories capable of meeting the IFR's demanding testing standards.

It will not be possible for the limited number of designated individuals to sample and test the disperse hemp crops in accordance with the identified standards within 15 days, nor to know whether a crop is compliant prior to harvest. Accordingly, crops will either be lost to an unreasonable bureaucratic process or harvested for destruction instead of sale. Neither situation is tenable, nor warranted by Congress's much more limited requirement for THC testing procedures. In addition, the limited available resources may drive up the cost of sampling during the harvest window and make the expense prohibitive for small growers. VAAFM respectfully asks USDA to—at minimum—expand the pre-harvest sampling time period to 45 days.

In addition, the apparent requirement to exclusively test flower material is not required and is unreasonable. As VAAFM understands it, the 0.3 percent THC threshold stems from a 1976 study by

Canadian horticulturists. In that study, the horticulturists apparently sampled young leaves of relatively mature plants and, in their own words, "arbitrarily" adopted the 0.3 percent delta-9 THC demarcation line for hemp. VAAFM understands that Congress requires hemp to meet this threshold, but Congress did not specify that producers could only test hemp flowers or that producers would be required to dispose of their entire crop if one test result representing complete decarboxylation exceeded the total THC limit.

Instead of dictating an unforgiving standard that is likely to result in widespread crop failure, the USDA should either permit States to utilize their expertise to determine proper sampling procedures within the Congressional mandate, or develop a more balanced sampling process that evaluates the entire crop instead of exclusively focusing on its flower material.

Recommendation: Either remove the IFR's sampling requirements and permit States to submit their own plans, or significantly expand the sampling timeframe and specify a much broader sampling protocol that assesses a plant's overall THC level instead of exclusively testing its flower material.

- IFR § 990.3 (a)(3). Testing Procedures.

The IFR's testing procedures—coupled with its flower-material-only sampling requirement—is unduly restrictive. The procedures also ignore the research into determining high-THC cannabis varieties, and VAAFM believes the testing methodology will render most crops useless. VAAFM applauds the federal government's legalization of hemp, but the IFR makes the legal farming of it impracticable and potentially disastrous for small-scale producers. The USDA—by adopting a flower material testing protocol that fully converts THC-A into THC and requires a "total available THC" calculation—combined the most restrictive possible interpretations and processes to endanger small farmers who cannot absorb the significant risks inherent to USDA's rule. The USDA should allow sampling procedures that identify the THC level of a more homogenous collection of hemp samples instead of evaluating the entire crop by exclusively testing the total THC level of its flowers. Congress did not mandate such a restrictive testing protocol.

In addition, the IFR's apparent requirement that one positive test requires the destruction of an entire lot is an unduly burdensome interpretation of USDA's authority to regulate hemp. USDA should balance its testing protocol to measure the overall THC level of a plant and/or permit crop remediation to salvage crops. The USDA could also allow producers to extract and destroy THC prior to selling hemp. It could also limit destruction to those specific portions of the plant that exceed the THC threshold. Finally, in partnership with the Drug Enforcement Agency, USDA could permit crops that exceed 0.3 percent THC—perhaps up to 1 percent—to be destroyed in a manner that would allow farmers to retain some crop value, like for use as animal bedding, compost, or fuel.

The IFR's exclusive endorsement of gas or liquid chromatography also ignores the statutory flexibility envisioned by permissible *similarly reliable methods*. Vermont law, 6 V.S.A. § 566 (a)(2), authorizes VAAFM's Secretary to adopt rules "to specify the method or methods of testing hemp, including, where appropriate, the ratio of cannabidiol to tetrahydrocannabinol levels or a taxonomic determination using genetic testing[.]" VAAFM continues to research the viability of genetic testing as a *similarly reliable method* to potency testing for the determination that a plant is hemp. Genetic research demonstrates taxonomic differences between high-THC cannabis and hemp. Early genetic testing could reduce costs for producers and support a seed certification program, which would mitigate the production risks. Possible benefits to genetic testing could include testing the seed or early plant growth cycles (including at the leaf stage) before planting or maturation, and identifying "hemp" plant varieties genetically instead of through chemical analyses that may fluctuate based on unpredictable growing conditions, the time of sampling, or the specific part of the plant that is sampled. Genetic testing could also produce less subjective results (like 0.3 percent is hemp and 0.31 percent is marijuana) and increase flexibility for combining testing and harvesting.

Ideally, valid genetic testing could eliminate the risk of growing high-THC cannabis instead of hemp. Our State of Vermont Agriculture and Environmental Lab (VAEL) is pursuing genetic research and

its exciting potential benefits on two fronts. The first is verification of our Tru-Hemp™ analyzer, a bench testing kit that uses a molecular DNA-based assay referenced in scientific research. *See Application of a Simple Genetic Assay to Discriminate Hemp from Drug-Type Cannabis*, Cannabis Science and Technology (CST, V2, No.6). Second, VAEL biologists are exploring the feasibility of the qPCR type testing referenced in distinct research. *See Gene Duplication and Divergence Affecting Drug Content in Cannabis Sativa*, Weiblen, et al., New Phytologist (2015) 208:1241-1250. If hemp could be dispositively identified through genetic testing, the industry benefits could be significant.

Alternatively, if the USDA does not believe it can refrain from adopting such a restrictive—and impracticable—testing procedure, it should work with the Drug Enforcement Agency and Department of Justice to revise its Rule and allow for a broader sampling protocol that evaluates the entire hemp plant and determines its overall THC level, that permits THC mitigation, and/or that preserves the portions of any crop that do not exceed the THC limit. Finally, if USDA does not believe it can permit the necessary flexibility to allow for sustainable hemp production within the current statutory framework, it should propose legislative changes that will allow farmers to produce and market this new and potentially valuable crop. As written, VAAFM believes the IFR may place small farms with limited resources on the brink of failure.

Recommendation: Amend IFR § 990.3(a)(3) to permit testing for the average THC level of the entire hemp plant, to expressly endorse alternative testing methods like genetic testing, to permit THC mitigation and destruction, and to limit crop losses stemming from flower-level THC potency tests.

- IFR § 990.3 (a)(3)(iii). Analytical testing requirements.

VAAFM appreciates USDA's effort to provide laboratory testing standards and agrees that laboratory integrity is important. That said, VAAFM believes some of the requirements exceed the statutory mandate and are unduly onerous. VAAFM contends that States should be allowed to propose testing standards for USDA review. If USDA feels compelled to specify standards, then VAAFM requests that some standards be relaxed to allow reasonable compliance.

First, DEA licensure for testing and destruction should not be required for low-level THC testing or destruction. The IFR's mandate creates unnecessary expenses and burdens for low-level THC Hemp testing and destruction. VAAFM requests that USDA work with DEA to permit more efficient and less expensive testing and destruction protocols—at least unless a plant is positive for a much higher level of THC.

Second, the required quality controls are too stringent for evaluating a new crop. The measurement of uncertainty (MU) is good practice, but laboratories may need time to review documents, run tests, gather enough data points, perform MU calculations, and apply the reported values. MU Standard Operating Procedures (SOPs) should be allowed to develop and be implemented before MU reporting is required.

Third, USDA proposed that "laboratories should meet the AOAC International method performance requirements for selecting an appropriate method." Laboratories may have validated methods under another ISO 17025 format that is similarly rigorous to the AOAC International Standard Method Performance (SMPRs) protocols. Moreover, the new AOAC protocols may not have been available when existing laboratories developed their current good practices, and requiring their use could require extensive revalidation. Laboratory compliance should not be restricted to AOAC SMPRs.

Finally, USDA solicited comment on the possibility of establishing a fee-for-service hemp laboratory approval process through the AMS Lab Approval Program (LAP). VAAFM does not support requiring USDA laboratory approval. Accreditation and certification are time consuming and expensive, and creating new requirements for State certified laboratories would be unnecessarily burdensome. Alternatively, USDA is considering requiring all hemp laboratories to have ISO 17025 accreditation. VAAFM supports accreditation, but existing hemp laboratories may have different forms of accreditation or be working toward that goal. Rather than specifically requiring the ISO 17025 format, VAAFM prefers

that the USDA continue to encourage laboratory adherence to the ISO 17025 standard or ISO accreditation, while allowing laboratories and States to adopt additional best practices.

- IFR § 990.3 (a)(9) Information sharing and reporting requirements.

The IFR requires individual producers operating under a State plan to separately submit information to the Farm Service Agency (FSA). This requirement is not statutorily mandated and could require unnecessary duplication. USDA should permit States to collect producer information and share it with USDA. If a State does not want to collect and share the information, USDA could require producers to report directly to the FSA. In Vermont, VAAFM requires growers—under its pilot program—to include the location and acreage of all hemp parcels. VAAFM also requests a legal description of the land and a map of the location for each hemp field. Registered growers use Google Maps or a similar online service to find the geospatial location of their cultivation areas, and VAAFM reserves the right to request more information as needed. Although the IFR suggests that most growers report land use data to FSA for other crops, most Vermont farmers are not currently working with FSA. The requirement to submit information to both a State plan and FSA seems unnecessarily duplicative. A more streamlined approach for all parties would authorize State plans to collect the pertinent information and share it with USDA.

Recommendation: Amend the IFR to permit States with approved plans to submit the data in section 990.3 (a)(9) to USDA instead of requiring registered producers to report separately to the State and Federal governments.

Additional Observations

As VAAFM understands USDA's interpretation, a hemp crop that exceeds the 0.3 percent THC limit is not considered a covered loss under Whole-Farm Revenue Protection (WFRP). The ineligibility of crop coverage for hemp that marginally exceeds the 0.3 percent THC threshold is untenable for small farmers who may not be capable of assuming the risk without insurance. Weather-related events are the principal basis for crop insurance, and weather can play a substantial role in how hemp grows and in

the determination of its THC content. At least until this burgeoning industry can better evaluate how to grow compliant crops in divergent geographic regions, small producers should have USDA's support to protect their investment.

Recommendation: USDA should permit hemp growers to purchase crop insurance. USDA could exclude coverage for growers who exceed the THC limit with a mental state greater than negligence.

Conclusion

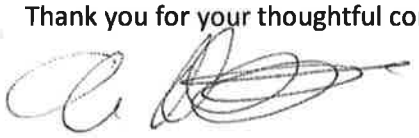
VAAFM appreciates the complexity of crafting a federal rule for industrial hemp. However, the IFR does not always correctly interpret Congressional intent and is overly restrictive in some of its mandated procedures. Congress enumerated seven requirements for State plans and specified that they are the *only* permissible requirements.

VAAFM respectfully contends that—in certain limited instances—the IFR either exceeds the statutory mandate or implements overly restrictive requirements that will adversely impact farmers who are acting in good faith and using the best available methods within their means. In VAAFM's view, portions of the IFR prioritize enforcement and crop destruction over the important goal of facilitating legal hemp production. VAAFM proffers several comments on distinct issues, but most importantly, urges USDA to create and facilitate a sustainable hemp program that incorporates the requisite flexibility to allow the program to develop and flourish.

As written, VAAFM is extremely concerned that the IFR will disrupt established hemp production and retail markets and increase the costs and risks to hemp producers. While large growers may be equipped to absorb some of this loss, small farmers cannot lose a substantial portion of their annual crop value and remain viable. As with any new industry, the learning curve is steep and farmers have much to discover. Farmers continue to study which seeds are successful depending upon location and weather, what equipment to use, and what specialized care may be required for hemp. As the industry continues to mature, VAAFM believes USDA's IFR may harm small-scale producers and squeeze them out of the industry. Establishing negligence and/or requiring crop destruction based solely on the total

THC level of hemp flowers may make sense in time, but the industry should be allowed to develop before producers are punished and/or financially devastated for circumstances beyond their control.

Thank you for your thoughtful consideration of these important issues.



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