

U.S. Hemp Roundtable

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September 15, 2020

Docket Clerk
Marketing Order and Agreement Division, Specialty Crops Program
Agriculture Market Service, U.S. Department of Agriculture (“USDA”)
1400 Independence Avenue, SW, STOP 0237
Washington, DC 20250-0237

Re: Doc. No. AMS-SC-19-0042 SC19-990-2 IR; Establishment of a Domestic Hemp Production Program; Document Citation 85 FR 55363; Pages 55363-55366

To whom it may concern:

On behalf of the U.S Hemp Roundtable, the hemp industry’s leading national business advocacy organization, we write to express our gratitude for your continued commitment to the U.S. hemp industry as evidenced by your willingness to reopen the docket for comments to the interim final rule you published on October 31, 2019 at 84 FR 58522 (“IFR”).¹

As the IFR relates to the technical aspects of farming hemp, we defer to our partners with the U.S. Hemp Growers Association and individual hemp farmers whom we have encouraged to submit detailed commentary concerning the impact of the IFR on the 2020 and 2021 planting seasons.

We instead want to use this opportunity to submit further comments that elaborate on a simple, but important point: When Congress passed the 2018 Farm Bill, it clearly intended to vest full and final regulatory authority on the production of hemp in your agency, the USDA. President Trump’s signing of the legislation ended the era of hemp’s regulation by the Drug Enforcement Administration (“DEA”). Since hemp and tetrahydrocannabinols derived from hemp are no longer controlled substances, the DEA can instead focus exclusively on its critical mission, which the DEA has repeatedly confirmed to be fighting the opioid epidemic and the illicit sale of dangerous drugs like methamphetamines.²

Unfortunately, as reported by USDA Secretary Sonny Perdue’s testimony before Congress, the DEA provided considerable influence over the development of the agency’s IFR. The Secretary noted that the DEA was “not excited about the crop as a whole anyway,” and provided “pretty serious constraints” over USDA’s regulatory process, specifically making “a lot of impact” with testing and farming limitations.³

We know that the USDA passionately supports American farmers. That is why we ask you to let farmers farm and encourage the DEA – once and for all – to remove itself from the hemp business.

Fundamentally, DEA has staked out a position that it has authority to assert its jurisdiction throughout the hemp processing supply chain at any point during which the tetrahydrocannabinol (“THC”) concentration exceeds 0.3%,

¹ We reiterate the comments we shared last November, which can be found at <https://hempsupporter.com/assets/uploads/USHR-Comments-to-USDA-Interim-Final-Rule.pdf>

² <https://www.laweekly.com/dea-doesnt-want-you-to-worry-about-its-new-hemp-rule-dont-take-the-bait/>

³ <https://youtu.be/eoTr2l9Dj48> at 3:00:25 (USDA Secretary Perdue testimony to Congress, March 4, 2020).

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defining “THC” as broadly as possible.⁴ That was not what Congress intended at all. Policymakers were well aware that it is quite normal for THC levels in hemp to naturally fluctuate during cultivation and the extraction process. Concentration is germane to extraction. For example, by defining hemp inclusive of its derivatives based on its delta-9 (“ Δ^9 ”) THC concentration on a “dry weight basis,” Congress made clear that hemp derivatives are lawful so long as they do not exceed that concentration as starting plant material and in finished form – when dry weight measurements are generally calculated and are necessary to ensure compliance with the threshold.

Further, Δ^9 -THC concentrations that are temporarily elevated above 0.3% pose no threat of harm to the general public. Consensus scientific opinion holds that cannabis does not begin to display intoxicating characteristics until it features concentrations of 1.0% Δ^9 -THC or more.⁵ It is improper for the DEA to impose displaced and burdensome oversight outside of its jurisdiction, particularly oversight that results in significant regulatory consequences⁶ that were clearly not intended by Congress, for processes that are easily and quickly remedied to ensure compliant levels of Δ^9 -THC in final hemp extract products.⁷

As the IFR transitions into a Final Rule, it is critical that the USDA reflect Congress’ intent. The 2018 Farm Bill carefully and deliberately amends the Controlled Substances Act to remove DEA’s authority *entirely* over the hemp crop and hemp industry.⁸ Indeed, the DEA is not mentioned anywhere in the entirety of the 2018 Farm Bill. Farmers should not be treated as criminal suspects, and the hemp industry should be given flexibility to comply with broadly-written federal laws without undue regulatory and law enforcement burdens.

With respect to these concerns, we first and foremost ask that USDA align with the recommendations of U.S. Senators Chuck Schumer, Cory Gardner, Ron Wyden and Jeff Merkley and Cory Gardner⁹ and delay implementation of the Final Rule until 2022, allowing those states that are operating programs under the provisions of the 2014 Farm Bill to continue to do so. This will provide critical certainty for farmers in those states to grow hemp crops efficiently and sustainably while the Final Rule is being ironed out.

With regard to specific provisions of the IFR, we make the following recommendations.

- We appreciate that you have delayed implementation of the original requirement that only DEA-registered laboratories can be qualified to conduct Δ^9 -THC testing. We strongly urge you to eliminate this requirement permanently from the Final Rule. The rationale for such a restriction – that only DEA labs can handle controlled substances – does not reflect the comprehensive expertise in the non-DEA lab marketplace, and again grants displaced authority to the DEA, while exaggerating the fear of slightly and temporarily elevated levels of Δ^9 -THC. More significantly, this limitation would place an undue strain on labs, delay Δ^9 -THC testing, and create long bottlenecks that would not only inevitably disrupt the hemp industry supply chain but also force crops to remain

⁴ U.S. Drug Enforcement Admin., Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51639 (Aug. 21, 2020).

⁵ See e.g., <https://www.winnipegfreepress.com/arts-and-life/life/cannabis/the-order-of-cannabis-468097053.html>; <https://www.agriculture.com/news/business/largest-us-farm-group-supports-higher-thc-limit-for-industrial-hemp>.

⁶ See e.g., https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_13.htm; https://www.deadiversion.usdoj.gov/21cfr/cfr/1305/1305_04.htm.

⁷ The U.S. Food & Drug Administration (“FDA”) simply considers Δ^9 -THC to be a contaminant in the same manner it considers pesticides and heavy metals to be contaminants, and the FDA requires contaminants to be remediated to acceptable levels. In-process hemp extract is remediated to compliant levels of Δ^9 -THC for final products before those products reach consumers, and any remaining Δ^9 -THC is easily rendered inert in the same manner excess mercury, for example, is rendered inert. See <https://www.fda.gov/consumers/consumer-updates/what-you-should-know-about-using-cannabis-including-cbd-when-pregnant-or-breastfeeding#2>.

⁸ See e.g., <https://www.rollcall.com/2018/12/11/mitch-mcconnell-touting-victory-with-hemp-legalization-on-farm-bill/> (Senate Majority Leader Mitch McConnell: The Farm Bill moves hemp regulation “out of the Justice Department, over to the Department of Agriculture.”).

⁹ <https://hempindustrydaily.com/us-sen-chuck-schumer-urges-usda-to-delay-interim-final-rules-due-to-coronavirus/>; <https://westernagnetwork.com/colorado-senator-cory-gardner-calls-on-usda-to-protect-hemp-industry>; <https://www.wyden.senate.gov/imo/media/doc/Hemp%20letter.pdf>.

growing in the field after their optimal time to harvest, causing financial losses to farmers at a time when they are already struggling mightily due to plummeting biomass prices and COVID-19 disruptions.¹⁰

- We disagree with the conclusion that a testing measurement of 0.5% THC or higher should automatically be considered “negligence” – triggering potentially severe penalties. The 0.5% standard does not allow enough room for unintentional error. In some cases, farmers would be deemed negligent when in fact they were deceived in a seed transaction, or subject to unpredictable environmental conditions. It is unjust to deem a farmer negligent when they have acted in a completely reasonable manner with no intent to violate the law. We believe Congress intended “negligence” to be consistent with traditional legal interpretations of that term; to involve lack of specific intent, not an arbitrary number. If there must be a number in the Final Rule, 1.0% is much more appropriate, given that it is the established scientific benchmark for intoxication.
- The IFR improperly measures THC concentration levels by calculating “total THC.” That is in direct contrast with what the 2018 Farm Bill requires: determining the “delta-9 tetrahydrocannabinol concentration” on a dry weight basis using post-decarboxylation “or other similarly reliable methods.” There are methods similarly reliable to post-decarboxylation that will provide an accurate Δ^9 -THC concentration result, and farmers should not be endangered by the significant consequences of unnecessary false excessive readings caused by the regulatory mandate of testing “total THC.” This dangerous and unnecessary risk is compounded by the fact that the IFR mandates independently of the statute that the plant sample composition be solely “from the flower material,” which is nonrepresentative of the entire plant’s cannabinoid profile. While the resins containing hemp’s cannabinoids are concentrated in the plant’s “flower material,” those resins are found throughout the entire hemp plant. A majority of farmers are harvesting the entire plant, and therefore such a “flower material” sample composition is not a representative sample of the actual harvested material. Rather, a homogenized blend of the entire plant, inclusive of stalk, stems and any seeds would be an accurate representation of the harvested material. These USDA policies would create unnecessary “false positives” and require farmers to lose significant money on crops that slightly exceed the mandated Δ^9 -THC concentration level. We urge you to both remove the total THC requirement in the Final Rule by using the Δ^9 -THC standard that Congress made explicit in the 2018 Farm Bill, and to amend the plant sample composition to be a homogenized blend of the whole plant, inclusive of stalk, stems and any seeds.
- The IFR requires all non-compliant plant material to be destroyed. However, Congress directed no such destruction in the 2018 Farm Bill and, in fact, specifically directs *disposal* as follows, “(iii) a procedure for the effective disposal of—(I) plants, whether growing or not, that are produced in violation of this subtitle.” We recommend that non-compliant parts of the plant be permitted for use in farming or fuel, with a prohibition on it entering commerce with some exceptions. Particularly in light of the tremendous value of hemp biomass and cellulose in the fuel, battery, energy, composite resin, air and space, and carbon block industries, and for research and development purposes, we specifically suggest clarifying in the Final Rule that pyrolysis is an acceptable means of effective disposal and that the resulting valuable products may enter into commerce.¹¹
- The IFR’s requirement of a 15-day sampling period is also problematic. Not only does such a short period exacerbate the lab scarcity issue mentioned above, it impairs state programs that currently have longer sampling periods. It is also inconsistent with the framework established in the 2018 Farm Bill, which allows state programs approved by the USDA to assume absolute regulatory authority over the production of hemp,

¹⁰ See e.g., <https://hempsupporter.com/assets/uploads/USHRHempPricingData.pdf>; <https://wfpl.org/hemp-prices-crash-leaving-ohio-valley-farmers-feeling-burned/>; <https://www.barrons.com/articles/hemp-cbd-demand-is-poor-prices-are-falling-in-a-blow-to-farmers-51580482811>; <https://www.reporterherald.com/2020/05/18/enthusiasm-leads-to-oversupply-of-hemp-in-colorado/>; <https://www.cnbc.com/2019/11/02/trade-wars-climate-change-plunge-the-family-farm-into-crisis.html>; <https://www.regulations.gov/document?D=FSA-2020-0004-0171>.

¹¹ The USDA is engaged and investing in pyrolysis research. See, <https://www.ars.usda.gov/northeast-area/wyndmoor-pa/eastern-regional-research-center/docs/biomass-pyrolysis-research-1/what-is-pyrolysis/>

including sampling and testing. Instead, we recommend a sampling period of at least 30 days in the Final Rule, which is the baseline of many state programs.

- We appreciate the USDA's openness to considering alternative sampling and testing methods, and we urge the USDA to soon approve appropriate methods other than gas or liquid chromatography as they become available.
- While we appreciate that THC testing will be reported with a measurement of uncertainty, there is some risk that a measurement of uncertainty could be abused. We understand from USDA that a measurement of uncertainty is scientifically defined and limited and that qualified laboratories are familiar with the parameters, but the parameters are not stated in the IFR. Labs use a variety of analytical methodologies, and we ask that the Final Rule outline parameters for the measurement of uncertainty that laboratories must follow to ensure uniformity.

We appreciate your attention to these critical matters. We look forward to our continued partnership with the USDA, advancing the interests of American farmers.

Sincerely,



Jonathan Miller
General Counsel

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