Global Alliance for Cannabis Commerce

January 29, 2020

Submitted via Federal eRulemaking Portal

The Honorable Greg Ibach
Under Secretary of Agriculture for Marketing and Regulatory Programs
U.S. Department of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250

Re: Establishing a Domestic Hemp Production Program: Acceptable Hemp THC Levels for Hemp Production
Docket ID: AMS-SC-19-0042
84 Federal Register 58522 (October 31, 2019)

Dear Undersecretary Ibach:

On behalf of the Global Alliance for Cannabis Commerce (GACC), we are submitting these comments on the above referenced interim rule.

GACC is a California-based 501(c)(6) trade organization representing over a billion dollars of legal global cannabis businesses. GACC advocates in front of government policymakers and legislators to support legalizing and regulating the cultivation, manufacture, distribution, and use of medical and adult-use cannabis products globally. Additionally, GACC has taken the step toward being the industry leader in nationwide private voluntary safety certification. GACC Certified™ is a nationwide voluntary private industry safety standard for cannabis products of all kinds. "Blue Leaf" certification gives licensed sellers and consumers confidence that the legal products that are approved under this program meet accepted safety and purity standards and are genuine. "Safe" means a safe product that is safe and responsible medical and adult use. All current GACC members have pledged to support the development of this standards setting protocol and to adopt and implement it as well when it is effective.

As the nation moves toward the legalization of cannabis generally, development of regulatory programs addressing hemp provide some indication and a base of experience that no doubt will impact future cannabis regulation. Accordingly we support sound, scientifically based regulation

of hemp and applaud the Department's efforts in this regard. In that spirit, we offer the following comments.

Legal Standards Applicable to this Rulemaking

USDA must comply with the Administrative Procedure Act, which requires it to provide interested parties with notice of the rule, and an opportunity to comment on it. 5 U.S.C. §§ 553(b), (c). In addition, the Administrative Procedure Act requires that the Commission's decision be "the product of reasoned decision-making," and requires that a court vacate any rule that is determined to be arbitrary and capricious, or otherwise inconsistent with law. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983).

With respect to facts and data relied upon during the course of a rulemaking, "an agency's decision [need not] be a model of analytic precision to survive a challenge." *Frizelle v. Slater*, 111 F.3d 172, 176-177 (D.C. Cir. 1997) (internal quotation marks omitted). Instead, "[a] reviewing court will uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Id.* (internal quotation marks omitted). As a result, "[a]ll that is required is that the [ ] decision minimally contain a rational connection between the facts found and the choice made." *Id.* (internal quotation marks omitted). "[T]he ultimate standard is not whether the agency's analysis is impeccable, but whether it is reasonable; not whether most of the evidence supports the agency's position but whether enough of it does; not whether the agency's policy choices are wise but whether they are rational." *Small Refiner Lead Phase-Down Task Force v. United States*, 705 F.2d 506, 541 (D.C. Cir. 1983). The Commission's consideration of the proposed rule, and decision to adopt it after considering all relevant comments, more than satisfies this standard.

Moreover, a court may vacate a rule upon a finding that the agency: (1) "has relied on factors which Congress has not intended it to consider," (2) "entirely failed to consider an important aspect of the problem," (3) "offered an explanation for its decision that runs counter to the evidence before the agency," or (4) "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id*. The court must sustain the agency action unless it determines that the agency committed a "clear error in judgment." *Marsh v. Oregon Nat'l Res. Council*, 490 U.S. 360, 378 (1989) (internal quotation marks omitted).

It is within the context of this legal standard that we ask that our comments be considered.

Total THC Testing (THC + THC-A)

Under the 2018 Farm Bill, a cannabis plant must contain a delta-9 tetrahydrocannabinol ("Delta-9 THC") concentration of less than 0.3 percent on a dry weight basis to be considered legal hemp.[1]

[1] As defined in the 2018 Farm Bill, the term "hemp" means the plant species *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9

Under the IFR, a cannabis plant may not exceed 0.3 percent of total THC, which includes both Delta-9 THC (the psychoactive chemical in marijuana) and tetrahydrocannabinolic acid ("THC-A"). THC-A is the precursor of Delta-9 THC. THC-A itself is *not psychoactive*; rather it can be converted into Delta-9 THC through a chemical reaction. We are concerned that many hemp plants that do not have a concentration of Delta-9 THC in excess of 0.3 percent will "test hot," meaning their total THC levels may exceed 0.3 percent on a dry weight basis. Because the IFR requires the disposal of plants whose THC concentration is 0.3 percent or higher, the unfortunate result will be a significant and unnecessary loss of hemp production, which in turn, will reduce economic development and job growth in many rural communities.

This problem is further compounded because the IFR requires post-decarboxylation testing of hemp plants. This type of testing was not required under the 2014 Farm Bill. One result may be that a cannabis plant tested pursuant to the requirements of the 2014 Farm Bill would qualify as hemp, whereas the same plant would fall within the Controlled Substances Act when tested pursuant to the under the 2018 bill. The former would be legal and the latter illegal. While we recognize the differences between the regimes implemented under the two bills and that the program under the 2014 bill will end next year, this disparate treatment is still problematic.

Carefully calibrating the THC testing standard is important because it directly affects the value of the hemp market. Generally, hemp cultivators want to cultivate the highest cannabinoid level as possible because a significant portion of the market demand for hemp is for hemp-derived cannabinoids. Lowering the authorized total THC concentration lowers the overall potency of a hemp plant's cannabinoids, affecting the ability to produce hemp products efficiently. Moreover, the current threshold limits the types of strains and seeds farmers can use for the next growing season due to the lack of genetic availability. We are aware of at least one hemp farmer[2] who has advised the USDA of this point:

> We have genetics that can grow over 25% cannabinoid content while staying under 0.3% Delta-9 THC; however genetics that must grow under the proposed 0.3% total THC rule will be under 15% and perhaps even under 10% ... A farmer will have to grow approximately twice as much acreage under the proposed 0.3% total THC threshold to get the same amount of end product as he would under the 0.3% delta-9 THC threshold.

Prior to the publication of the IFR, several States and tribal jurisdictions established different testing requirements with respect to whether THC or THC-A concentrations must be tested . As the IFR was made effective immediately, it has placed farmers who were preparing for an imminent harvest with little time to comply, putting their crop at risk of testing "hot."

Finally, there is no requirement in the statute that only post-decarboxylation be used. The law provides that a state plan may include a procedure for testing that uses post decarboxylation "or

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tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Delta-9 tetrahydrocannabinol, or THC, is the primary intoxicating component of cannabis. Cannabis with a THC level exceeding 0.3 percent is considered marijuana, which remains classified as a Schedule I controlled substance regulated by the DEA under the Controlled Substances Act.

[2] See November 8, 2019 comment of Josh Briggs of Back40 Organics.

other similarly reliable methods" for testing delta-9 tetrahydrocannabinol concentration levels. " Section 297B(a)(2)(A)(ii). We believe it would be unreasonable and without foundation for USDA to require that THC-A concentrations be tested for. This constituent is not psychoactive, and the only result will be to vastly undermine the efficient production of hemp.

This issue also directly impacts the cost benefit analysis of the rule. It is entirely possible that it could completely undermine the industry and its growth given the potential that this testing methodology would result in significant amounts of the market being impacted.

DEA-Certified Labs

We have significant concerns about the requirement that only laboratories registered with the Drug Enforcement Administration (DEA) can be qualified to conduct THC testing. The limitation, in addition to the possibility that all labs must be LAP or ISO 17025 certified[3], places a strain on the availability of certified labs and could significantly delay THC testing.

In addition, since only DEA-registered labs may conduct testing, this raises the possibility that if hemp is sent out of a state or jurisdiction for testing and fails to meet the THC level, the sender could potentially be subjected to criminal prosecution for sending its product across state lines.

There is no rational reason to limit testing to DEA approved labs, since hemp is no longer a CSA regulated substance. If a supplier in good faith is producing hemp and records demonstrate that the product does meet these tests, those producers should be permitted to use other laboratories.

Sampling Timeline and Procedures

The sampling time frame of 15 days is too soon before harvest. Thirty to forty-five days before harvest is more appropriate. Also, as there are not enough DEA-certified labs, the 15 day window between THC testing and crop harvest may not occur seamlessly in certain parts of the country.

Clarity regarding the process of sampling the flowers is also needed. The IFR does not clarify which part of the flower must be sampled, and more guidance from the USDA will prevent samples from falsely testing "hot."

Destruction of Non-Compliant Plants

The IFR requires all non-compliant plant material to be destroyed. Congress has not specified destruction of such plants, only disposal,[4] in the Farm Bill. There is no reason that non-compliant parts of the plant be permitted for use on farms with feedstock or fuel. This is consistent with

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[3] LAP or ISO 17025 - general requirements for lab competence to carry out tests and calibrations, including sampling; it covers testing and calibration quality systems using standard methods and laboratory-developed or modified methods.

[4] The Farm Bill directs disposal, not destruction, in Section 297B (2)(A)(iii) - "a procedure for the effective *disposal* of products that are produced in violation of this subtitle" (emphasis added).

Congress' findings in the Resource Conservation and Recovery Act which promotes reuse rather than disposal when possible, feasible and environmentally responsible.

> (c) Congress finds with respect to materials, that—
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> (1) millions of tons of recoverable material which could be used are needlessly buried each year;
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> (2) methods are available to separate usable materials from solid waste; and
>
> (3) the recovery and conservation of such materials can reduce the dependence of the United States on foreign resources and reduce the deficit in its balance of payments.

42 U.S.C.§ 6901(c)

The U.S. Hemp Roundtable, a business advocacy organization for hemp, stresses the value of hemp biochar as a soil amendment and for research and development purposes. It also specifically suggests pyrolysis as an acceptable means of effective disposal to allow the resulting char to enter into commerce.[5]

Thank you for your consideration.

Randal John Meyer

Executive Director
Global Alliance for Cannabis Commerce

[5] *See* the U.S. Hemp Roundtable November 12, 2019 comment.