U.S. Hemp Roundtable

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September 15, 2020

Drug Enforcement Administration
Attn: DEA Federal Register Representative/DPW Diversion Control Division
8701 Morrissette Drive
Springfield, VA 22152

Re: RIN 1117-AB53/Docket No. DEA-500; Implementation of the Agriculture Improvement Act of 2018; Document Citation 85 FR 51639; Pages 51639-51645

To Whom it May Concern:

The U.S. Hemp Roundtable ("the Roundtable") appreciates the opportunity to provide comments to the U.S. Drug Enforcement Administration ("DEA") in response to the publication of its Interim Final Rule ("IFR") on the Implementation of the Agriculture Improvement Act of 2018 ("2018 Farm Bill").[1] The Roundtable is the hemp industry's leading national advocacy organization that represents over 80 firms from across the country—at each link of the hemp supply and sales chain—and includes the ex officio membership of the industry's major grassroots organizations.

In its summary of the impact of the IFR, the DEA claims that it "merely conforms DEA's regulations to the statutory amendments to the CSA that have already taken effect, and it does not add additional requirements to the regulations."[2] Indeed, in response to concerns raised by the industry about the IFR's import, a DEA official suggested that its enforcement focus would not be on hemp industry activities: "The United States is in the midst of an opioid epidemic fueled by fentanyl and is seeing a strong resurgence of methamphetamine. DEA is focusing its resources on disrupting and dismantling the Mexican cartels that are trafficking these deadly substances into and across the nation[.]"[3]

However, given the hemp industry's colored history with DEA and its reported involvement in the U.S. Department of Agriculture's ("USDA") recent rulemaking regarding hemp production,[4] we have significant concerns about the IFR's true impact and the displaced authority it gives to the DEA. Regardless of enforcement practices, farmers and businesses engaged in the hemp industry are not intended to be subject to DEA scrutiny. The 2018 Farm Bill carefully and deliberately amended the Controlled Substances Act by removing hemp and tetrahydrocannabinols derived from hemp from the schedules, thereby removing DEA's authority *entirely* over the hemp crop and hemp industry.[5] In fact, the DEA is not mentioned anywhere in the entirety of the 2018 Farm Bill.

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[1] U.S. Drug Enforcement Admin., Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51639 (Aug. 21, 2020).
[2] *Id.* at 51639.
[3] https://www.laweekly.com/the-dea-told-us-its-aware-of-the-cbd-industry-freaking-out-looking-at-policy-options/.
[4] https://www.marijuanamoment.net/usda-secretary-blames-dea-for-strict-hemp-rules/; https://youtu.be/eoTr2l9Dj48 at 3:00:25 (USDA Secretary Perdue testimony to Congress, March 4, 2020).
[5] *See also,* 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.").

Specifically, we are deeply concerned that the IFR could have far-reaching consequences for the hemp extract industry, creating a profound obstacle to the legal manufacture of most hemp extract finished products by criminalizing any in-process hemp extraction wherein the delta-9 tetrahydrocannabinol ("Δ^9-THC") concentration may temporarily exceed 0.3 percent. Furthermore, the Roundtable is also troubled by the IFR's discussion of "synthetically derived tetrahydrocannabinols" for purposes of implementing the 2018 Farm Bill's exemption for tetrahydrocannabinols derived from hemp under the Controlled Substances Act ("CSA").

We believe in both instances that the IFR impermissibly and unconstitutionally rewrites the 2018 Farm Bill in a way that defies Congressional intent. As outlined below, the IFR is an overtly significant regulatory action with serious commercial and economic implications that are also likely to create obstacles to legitimate product development as well as research and innovation, and therefore should be withdrawn. The Roundtable is confident that there are other means by which appropriate authorities are able to address concerns over consumer safety and distribution of active contaminants into the marketplace in a manner that does not threaten the hemp extract industry supply chain.

I. The IFR Creates Criminal Risk for Legitimate Hemp Processors Involved in the Production of Compliant and Lawfully-Sourced Finished Products

The Roundtable is concerned that the IFR could re-criminalize in-process hemp extract that may *temporarily* have a higher Δ^9-THC concentration than the legal hemp plant from which it was derived. The IFR clarifies that the definition of hemp "does not automatically exempt any product derived from a hemp plant, regardless of the Δ^9-THC content of the derivative. In order to meet the definition of 'hemp,' and thus qualify for the exemption from Schedule I, the derivative must not exceed the 0.3% Δ^9-THC limit."[6] This contradicts Congressional intent, the plain reading of the statute, the States' and Tribes' understanding of the statute, and the USDA General Counsel's legal opinion that both hemp extract and tetrahydrocannabinols derived from hemp are removed from Schedule I control.[7]

Consequently, the IFR purports to treat hemp extract as a Schedule I controlled substance during any point at which its Δ^9-THC concentration exceeds 0.3 percent. In effect, the IFR could criminalize the initial stages of hemp extract processing, which is wholly inconsistent with the intent of the 2018 Farm Bill hemp provisions—to encourage and support domestic hemp production *and* the production of products sourced from legally cultivated domestic hemp, *without* DEA interference. In direct contravention to this intent, the IFR would require processors engaged in the hemp extract industry to obtain a Schedule I controlled substance registration in order to conduct business, even if the raw or "in-process" hemp extracts are not in final form or intended to reach consumers.[8]

It is common knowledge—and it was known and understood by Congress in 2018 when the 2018 Farm Bill was being debated—that the initial stages of hemp extract processing cause most raw hemp extracts to temporarily exceed 0.3 percent Δ^9-THC concentration on a dry weight basis. By deliberately defining hemp, inclusive of its extracts and derivatives, based on its Δ^9-THC concentration on a *dry weight basis*, Congress made clear that hemp-derived substances are lawful so long as they do not contain more than 0.3 percent Δ^9-THC as starting plant material—when dry weight measurements are generally calculated and are necessary to ensure compliance with the 0.3 percent Δ^9-THC legal threshold—and in their finished form, when the product is distributed into interstate commerce or otherwise reaches the consumer.

The Roundtable agrees with the DEA's statements regarding finished hemp products, primarily that "a cannabis-derived product must itself contain 0.3% or less Δ^9-THC on a dry weight basis [and that] it is not enough that a product is labeled

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[6] *Id.* at 51641.

[7] *Memorandum for Sonny Perdue, Secretary of Agriculture; Subject: Legal Opinion on Certain Provisions of the Agriculture Improvement Act of 2018 Relating to Hemp*. U.S. Department of Agriculture, General Counsel Stephen Alexander Vaden, May 28, 2019, at pp. 5-6 and footnotes 8-9, https://www.ams.usda.gov/sites/default/files/HempExecSumandLegalOpinion.pdf. Accessed August 26, 2020.

[8] *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.

or advertised as 'hemp.'"[9] In order to protect consumers, the Roundtable supports testing of hemp-derived ***finished products*** to ensure the Δ^9-THC concentration in the product does not exceed the 0.3 percent threshold. In-process hemp extract is remediated to compliant concentrations 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. Additionally, many states already require hemp product manufacturers to provide a Certificate of Analysis for finished hemp products demonstrating that, among other things, the Δ^9-THC is consistent with the 2018 Farm Bill's definition of "hemp."

As many processors and extractors in the industry know, hemp extract almost invariably exceeds 0.3 percent Δ^9-THC concentration at some point during the extraction process, before that percentage is brought back into legal compliance for the final product. This is not unique to hemp; in fact, the extraction process for most if not all botanical ingredients leads to natural increases in the plant's active constituents and contaminants, and such increases are nearly impossible to avoid. Simply put, concentration is an inevitable outcome of the extraction process. However, like with any other botanical ingredient and contaminant, through proper formulation, testing and remediation practices, hemp extract processors and manufacturers can easily ensure that all finished products remain compliant with the legal limit for Δ^9-THC concentration and disposal of contaminants that have been rendered inert.[10]

Recognizing the challenges of working with botanicals that are affected by environmental stressors such as heat, water, or other varying climate conditions, the USDA in its Interim Final Rule on Domestic Hemp Production created a margin of error for hemp growers as well as means for addressing non-compliant hemp that does not automatically subject these growers to potential criminal prosecution.[11] For example, a hemp farmer that accidentally grows "hot hemp" that exceeds a 0.3 percent Δ^9-THC concentration has the opportunity to dispose of the product, and such violations would not necessarily result in a criminal penalty for the possession of marijuana, for example.

The vast majority of the industry is composed of legitimate hemp extract processors and manufacturers that are operating in compliance with relevant state laws, utilizing only legally cultivated hemp and consistently testing their hemp extracts and finished products, and that have the capabilities to correct anticipated increases in Δ^9-THC concentration during the normal hemp extraction process, like any other specification and contaminant. As evidenced by nearly two years of successful compliance with the 2018 Farm Bill and at least three full years of compliance with its predecessor Farm Bill, legitimate hemp processors and manufacturers have been able to manufacture and distribute safe and legal finished hemp products—without creating risk or concern over the illicit distribution of high- Δ^9-THC hemp extracts.

Therefore, the Roundtable believes that the IFR is both overreaching and overly restrictive for an industry that has successfully demonstrated its ability to comply with state and federal laws, and we urge the DEA to withdraw the IFR. To the extent that in-process hemp extract requires additional regulation, we believe this can be adequately addressed through state and tribal hemp programs, the FDA and/or USDA rulemaking.

II. The IFR Broadly Classifies Synthetically Derived Tetrahydrocannabinols Produced from Compliant Hemp as Controlled Substances

The Roundtable is also concerned with the IFR's treatment of synthetically derived tetrahydrocannabinols as Schedule I substances, regardless of the concentration of Δ^9-THC. The IFR broadly classifies all synthetically derived tetrahydrocannabinols as controlled substances, including those that are derived from hemp, regardless of concentration, structure, or intoxicating properties.

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[9] *Id*.

[10] This approach is consistent with FDA policy which 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: https://www.fda.gov/consumers/consumer-updates/what-you-should-know-about-using-cannabis-including-cbd-when-pregnant-or-breastfeeding#2.

[11] U.S. Dept. of Agriculture, Establishment of a Domestic Hemp Production Program, 84 Fed. Reg. 58522 (Oct. 31, 2019) (Creating an "acceptable hemp THC level" to account for uncertainty in test results).

The 2018 Farm Bill defined hemp to include all parts of the *Cannabis sativa L*. 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 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis (emphasis added)."[12] Therefore under the law, any and all hemp derivatives, including tetrahydrocannabinols that are derived from compliant hemp, are lawful provided they are within the federally defined limit for Δ^9-THC concentration. Congress did not place limits or restrictions on the processes used to obtain hemp derivatives. However, the IFR disregards this plain reading of the statute and states that "Δ^9-THC is not a determining factor in whether the material is a controlled substance."[13] The IFR goes on to conclude that "[a]ll synthetically derived tetrahydrocannabinols remain Schedule I controlled substances," while "tetrahydrocannabinols that are naturally occurring constituents" of the cannabis plant are not controlled provided the material contains 0.3 percent or less of Δ^9-THC by dry weight and is not controlled elsewhere under the Controlled Substances Act.

This interpretation not only contradicts the intent of the 2018 Farm Bill, but it also classifies tetrahydrocannabinols that are derived from lawful hemp material, for example, through the use of a catalyst or through chemical or biochemical synthesis, as Schedule I controlled substances. As a result, the IFR would unintentionally create a subset of controlled compounds that in no way possess the intoxicating properties nor resemble the structure of Δ^9-THC, and do not otherwise meet the criteria to be a controlled substance. Some of these compounds are important for research and innovation within the hemp industry, and such restrictions are not necessary to maintain public safety. Thus, we again urge the DEA to reconsider the IFR given its implications on legitimate commercial and research interests involving lawful tetrahydrocannabinols derived from hemp, in addition to the fact that it disregards the intent of Congress to legalize *all* hemp derivatives provided the Δ^9-THC concentration does not exceed 0.3 percent—regardless of the processes used to obtain these otherwise lawful derivatives.

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Again, the Roundtable appreciates the opportunity to provide comments and respectfully urges the DEA to consider the concerns outlined above and withdraw the IFR. We value the work of your agency in addressing dangerous drugs and crime, and we are hopeful that withdrawing this rule will free your officials to focus their attention on those critical matters.

We would be happy to discuss these recommendations with you at your convenience. Thank you for your consideration.

Sincerely,

Jonathan Miller
General Counsel

[12] 7 U.S.C. **§** 1639o (1).
[13] 85 Fed. Reg. at 51641.

2020 U.S. HEMP ROUNDTABLE

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