

Complex Hemp Processes Need Nimble Regulatory Approach

By **David Kouba** (August 8, 2023)

The 2018 Farm Bill[1] legalized hemp and products derived from hemp so long as they contain less than 0.3% Delta-9 THC.

On the surface, this 0.3% limit seems simple. But cannabis and cannabis products take many forms. And the processes that grow seeds into plants, convert plants into in-process extracts and derivatives, and incorporate those in-process materials into end products are multifaceted and complex.

As a result, the 0.3% standard has presented, and continues to present, different issues at the time of harvest, during processing and when products enter commerce.

The following discusses each stage, the issues they raise, and potential legal approaches that embrace flexibility, continued adjustment and reasonableness.

The 2023 Farm Bill, likely to be deliberated later this year, presents an opportunity for Congress to address these issues.

THC Limits at the Time of Harvest

The 2018 Farm Bill amended the Controlled Substances Act's definition of "marihuana" to exclude both hemp plants and

the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant.[2]

Congress defined "hemp" as

the plant *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 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.[3]

It further directed the U.S. Department of Agriculture to enact regulations to ensure compliance with this standard.[4]

The USDA subsequently enacted regulations that, among other things, require that the Delta-9 content in cannabis be tested no more than 30 days before harvest and set forth how those tests should take place.[5]

The regulations further describe the permissible range of results that will satisfy the 0.3% standard.[6] If THC content falls within that range, the cannabis qualifies as hemp under the statute at the time of harvest.

When applied to plants at the time of harvest, the 0.3% limit has raised criticism. One



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significant concern is that the standard is too low and harms hemp farmers.

According to a Congressional Research Service report, the USDA estimates that around 20% of hemp plants each year exceed the limit — and must be destroyed — often for reasons beyond a farmer's control, such as weather.[7]

The same report notes that some farmer and hemp advocacy groups have advocated for raising the limit on THC content for hemp plants to "provide flexibility to growers and avoid crop destruction." [8]

Congress, it appears, might answer those calls in the near future and increase the current 0.3% standard that applies to hemp in the field.[9]

Last year, for example, Rep. Chellie Pingree, D-Maine, introduced the Hemp Advancement Act that included a 1.0% limit at the time of harvest.[10] The limit, however, would apply not only to Delta-9; it would limit the total THC concentration, which would include the aggregate concentration of Delta-8, Delta-9 and Delta-10 THC, and other cannabinoids.[11]

A question remains as to whether an increased limit that applies more broadly to total THC concentration would be more challenging for hemp farmers or present issues for downstream producers of nonintoxicating CBD products.

Congress will need to engage in additional fact-finding from hemp farmers and other relevant stakeholders to ensure that any new standard is reasonably achievable, does not unduly burden hemp cultivation and production, and yet still ensures that hemp and hemp products fall within a category of nonpsychoactive substances.

A THC limit more onerous than necessary risks undercutting Congress' original goals in legalizing hemp in 2018.

THC Limits on In-Process Extracts and Derivatives

The 0.3% standard applies beyond harvest. It also applies to "all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not." [12]

This definition has led to a practical question: Must every derivative, extract or byproduct of hemp meet this standard, even if it only exists temporarily while the hemp is processed — i.e., an in-process substance — or does the 0.3% standard apply only after processing to products that will be introduced into commerce?

Two senators who authored the 2018 Farm Bill, Sens. Jeff Merkley, D-Ore., and Ron Wyden, D-Ore., have answered this question and made clear that Congress did not intend for the 0.3% standard to apply to in-process materials, stating that "when Congress passed the 2018 Farm Bill, [it] understood that intermediate stages of hemp processing can cause hemp extracts to temporarily exceed 0.3% THC." [13]

Merkley and Wyden also explained that the Farm Bill uses dry weight measurements and that "dry weight measurements are commonly taken from the initial hemp plant and final hemp-derived product." [14]

The U.S. House of Representatives Committee on Appropriations subsequently endorsed this approach, explaining that "in-process hemp extract may temporarily exceed the delta-9 THC concentration of 0.3 percent before being packaged and sold as a finished product for

consumption."[15]

This approach makes sense from a policy perspective. There is little reason to impose strict limits on derivatives, extracts and byproducts that exist only during processing and that will be diluted prior to introduction into commerce.

Limits on THC content are intended to protect the public, and restrictions on materials that do not actually reach the public would therefore be misplaced.

In addition, federal law does not typically treat in-process materials that are used to produce food, drug or cosmetics the same as a final product sold to consumers. There is no reason to treat hemp-derived products differently.

Instead, when it comes to in-process materials, the 0.3% limit in the 2018 Farm Bill should continue to apply as Congress intended — which is to say, it should not apply to in-process materials at all.

THC Limits on End Products Derived From Hemp

The 2018 Farm Bill limits the amount of Delta-9 in hemp-derived products but does not limit other cannabinoids such as Delta-8 and Delta-10.[16] The statute instead states that hemp-derived products are treated as hemp regardless of the concentration of other cannabinoids, so long as Delta-9 content is within limits.

The U.S. Court of Appeals for the Ninth Circuit reached this conclusion as well.[17] In its decision last May in *AK Futures LLC v. Boyd St. Distro LLC*, the court found that products containing Delta-8 are lawful under the Farm Bill, as "delta-8 THC in the e-cigarette liquid is properly understood as a derivative, extract, or cannabinoid originating from the cannabis plant and containing 'not more than 0.3 percent' delta-9 THC." [18]

The court concluded further that the Delta-8 in the product at issue was not synthetically derived merely because it had been "extracted from the cannabis plant and refined through a manufacturing process." [19]

As the court explained, the unambiguous definition of hemp in the Farm Bill does not depend on

the manner by which "derivatives, extracts, [and] cannabinoids" are produced. Rather, it expressly applies to "all" such downstream products so long as they do not cross the 0.3 percent delta-9 THC threshold.[20]

Under this interpretation, companies can sell products derived from hemp that contain Delta-8 and Delta-10 without violating the federal Controlled Substances Act, as long as the amount of Delta-9 does not exceed 0.3%. And companies have sold such products since the 2018 Farm Bill became law.

Delta-8 and Delta-10 products, however, are not without critics.

Ethics counsel to the U.S. Hemp Roundtable Russell Coleman, who previously served as senior adviser and legal counsel to Senate Minority Leader Mitch McConnell, R-Ky., has stated that treating intoxicating Delta-8 products as legal hemp is inconsistent with congressional intent when enacting the 2018 Farm Bill, and that it "undermines the integrity of the legal hemp industry" and "threatens the livelihoods of farmers themselves." [21]

Moreover, actions at the federal and state levels to regulate and limit the sales of these products have accelerated recently.

In April, the Cannabis Regulators Association, a nonpartisan association representing cannabis and hemp regulatory agencies from over 40 member states and territories, recently sent a letter to Congress asking that it amend the Farm Bill to "provide a regulatory framework for hemp-derived cannabinoid products." [22]

And Rep. James Comer, R-Ky., recently asked the U.S. Food and Drug Administration to regulate these products. [23]

In addition, in May, the U.S. Drug Enforcement Administration indicated that it is considering proposed changes to federal drug laws to address Delta-8 and other intoxicating cannabinoids derived from hemp. [24]

During this same time, certain states have amended or proposed amendments to their own laws that would restrict or limit the sale of products that include Delta-8 and Delta-10, regardless of whether they are derived from hemp or marijuana. [25]

It remains to be seen whether Congress or a federal agency will address these products or instead leave it to states to enact their own laws and regulations.

States appear more nimble than Congress in regulating cannabis and likely will step in to fill the federal void before Congress acts.

We may see another patchwork of state regulations for Delta-8, Delta-10 and other cannabinoids, similar to the varying state laws governing standards for hemp products.

At a minimum, the flurry of recent activity suggests that the regulatory landscape for consumer goods containing Delta-8 and Delta-10 is in a state of flux that will continue to evolve and that, in at least some jurisdictions, new restrictions will be placed on hemp-derived products containing Delta-8 or Delta-10.

Conclusion

The 2018 Farm Bill took a significant step when legalizing hemp and certain hemp-derived products. Because the processes involved in growing and producing hemp and hemp-derived products are complex, the need for continued adjustments and flexibility when regulating them — whether they take place via the 2023 Farm Bill or state law — is paramount.

This includes taking reasonable approaches toward limits on the amount of THC they contain. As reflected by developments since 2018 and efforts continuing today, such an approach depends significantly on the hemp or hemp product in question, its purpose, and where in the process any THC limit applies.

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[1] Agricultural Improvement Act of 2018, Pub. L. 115-334.

[2] 21 U.S.C. § 802(16)(A).

[3] 7 U.S.C. § 1639o.

[4] 7 U.S.C. § 1639r(a)(1)(A).

[5] 7 C.F.R. §§ 990.20, 990.24-25.

[6] 7 C.F.R. § 990.1.

[7] Congressional Research Service, Farm Bill Primer: Selected Hemp Industry Issues (Dec. 12, 2022) (<https://crsreports.congress.gov/product/pdf/IF/IF12278>).

[8] *Id.*

[9] Cannabis Business Times, Industry Associations Weigh In on 2023 Farm Bill: What's to Come for Hemp? (Jan. 18, 2023) (<https://www.cannabisbusinesstimes.com/news/industry-associations-weigh-in-2023-farm-bill-whats-to-come-for-hemp-growers/>) (quoting executive director of National Hemp Association as "anticipating a big push to raise the THC limit for hemp to 1% in the 2023 Farm Bill).

[10] Congresswoman Chellie Pingree, Press Release: Pingree Unveils Bill to Unburden Hemp Industry (Feb. 8, 2022) (<https://pingree.house.gov/news/documentsingle.aspx?DocumentID=3970>).

[11] *Id.*

[12] 21 U.S.C. § 802(16)(A).

[13] Jeff Merkley, United States Senator for Oregon, Wyden, Merkley To DEA: Interim Rule On Hemp Contradicts Congressional Intent By Criminalizing Intermediate Steps In Hemp Processing. (Oct. 23, 2020) (<https://www.merkley.senate.gov/news/press-releases>), <https://www.wyden.senate.gov/imo/media/doc/102320%20Wyden%20Merkley%20Hemp%20DEA%20Letter.pdf>.

[14] *Id.* (explaining further that the 2018 Farm Bill removed hemp, including all derivatives and extracts, from purview of the DEA and gave USDA sole authority to promulgate federal regulations and guidelines).

[15] House Report 6645, Agriculture, Rural Development, Food & Drug Administration, & Related Agencies Appropriations Bill, 2023 (Feb. 8, 2022) (<https://docs.house.gov/meetings/AP/AP00/20220623/114947/HMKP-117-AP00-20220623-SD002.pdf>), <https://www.marijuanamoment.net/congress-tackles-hemp-industry-challenges-cbd-marketing-marijuana-research-and-psychedelics-in-spending-legislation/>.

[16] 7 U.S.C. § 1639o.

[17] *AK Futures LLC v. Boyd Street Distro, LLC*, 35 F.4th 682, 691 (9th Cir. 2022).

[18] *Id.* at 691-92.

[19] *Id.* at 692.

[20] *Id.* at 692 (citing 7 U.S.C. § 1639o(1)). The court also referenced DEA's position, as set forth in an agency letter, that "'synthetic' delta-8 THC is produced 'from non-cannabismaterials.'" *Id.*

[21] Russell Coleman, Ethics Counsel to U.S. Hemp Roundtable, former U.S. Attorney for the Western District of Kentucky (2017-2021), former Senior Advisor & Legal Counsel to Senator Mitch McConnell (2010-2015) (<https://hempsupporter.com/news/u-s-hemp-roundtable-statement-on-the-marketing-of-intoxicating-products-under-the-guise-of-hemp/>).

[22] Letter from Cannabis Regulators Association to Hon. Kevin McCarthy, et al. (April 17, 2023). Representative Pingree's proposal would place a 0.3 percent limit on "total tetrahydrocannabinol concentration," including delta-8, rather than banning it. See *supra*.

[23] Letter from James Comer, Chairman, Committee on Oversight and Accountability, to Dr. Robert M. Califf, Commissioner, U.S. Food & Drug Administration (April 17, 2023).

[24] DEA Official Says New Rules Are Coming for Synthetic Cannabinoids, Including CBD and Delta-8 THC, *Marijuana Moment* (May 17, 2023) (<https://www.marijuanamoment.net/dea-official-says-new-rules-are-coming-for-synthetic-cannabinoids-including-cbd-and-delta-8-thc/>).

[25] See, e.g., Ark. Act 629 (Apr. 11, 2023) (<https://www.arkleg.state.ar.us/Bills/Detail?id=sb358&ddBienniumSession=2023%2F2023R>); Tenn. Senate Bill 378 (May 11, 2023) (<https://legiscan.com/TN/text/SB0378/2023/>); Va. Sen. Bill 903 (Apr. 12, 2023) (<https://lis.virginia.gov/cgi-bin/legp604.exe?231+sum+SB903>); Ala. Sen. Bill 66 (Mar. 21, 2023) (<https://whnt.com/news/alabama-news/new-alabama-law-aims-to-ban-underage-sale-of-delta-8-products/>); Colo. Senate Bill 23-271 (Jun. 7, 2023) (<https://leg.colorado.gov/bills/sb23-271>); Missouri House Bill 1328 (Mar. 29, 2023) (<https://www.patientsmagazine.com/2023/03/29/missouris-first-pass-at-delta-8-regulation-would-remove-a-bulk-of-hemp-derived-products-from-store-shelves/>).