

Hemp Extracts: The Dry Weight Problem

By Griffen Thorne¹

In 2018, President Donald Trump signed the Agriculture Improvement Act (“2018 Farm Bill”)² into law, removing hemp from the definition of “marihuana” in the federal Controlled Substances Act (“CSA”) and thereby legalizing hemp. Today, the only meaningful *legal* distinction between hemp and “marihuana”, both of which are members of the cannabis genus, is the presence of the cannabinoid delta-9 tetrahydrocannabinol (“THC”). Cannabis with a THC concentration of more than .3% on a “dry weight basis” is deemed “marihuana” and is illegal,³ and cannabis with .3% THC or less on a dry weight basis is deemed hemp and is generally legal.⁴

The federal THC standard is of paramount importance to every participant in the hemp industry. Even unintentional crossing of the threshold can render a hemp plant or extract unlawful⁵ and lead to confiscation, arrest, or other serious penalties.⁶ An interim final rule published by the United States Drug Enforcement Administration (“DEA”) in August 2020 emphasizes that even extracts of lawfully cultivated hemp that contain excessive THC concentrations will be deemed federally illegal controlled substances.⁷ Therefore, precise calculation of THC content is crucial to operating compliant hemp businesses.

Despite the need for precision in testing, hemp extracts can be challenging to test and the pertinent federal laws fail to clearly provide such a mechanism. Much of the chaos stems from the 2018 Farm Bill and CSA’s definitions of hemp and marihuana, which each call for measurement of THC content by “dry weight”—essentially meaning without moisture. Federal hemp law fails to account for extract products that are by definition liquid and cannot be easily dried. States often employ different requirements. Consequently, compliant hemp extract in one state may potentially be deemed unlawful under federal law or under the law of other states. Even if that does not happen, it may be

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² Publ. Law. 115-334 (Dec. 20, 2018).

³ 21 U.S.C. § 802(16)(A) (2020); *see id.* § 812 Sched. I(c)(10) (2020) (placing “marihuana” on Schedule I).

⁴ *See id.* § 802(16)(B) (exempting “hemp” as defined in 7 U.S.C. § 1639o from the CSA’s definition of “marihuana”); *see also* 7 U.S.C. § 1639o(1) (defining 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.”); 21 U.S.C. § 812 Sched. I(c)(17) (placing tetrahydrocannabinols—except those in “hemp”—on Schedule I of the CSA).

⁵ *See, e.g.*, 7 C.F.R. § 990.6 (establishing criteria for “negligent” and “culpable” violations, pursuant to which hemp in excess of the .3% THC threshold is considered unlawful). Additionally, *see infra* for a discussion of the DEA’s interim final rule on hemp extracts.

⁶ While regulations issued pursuant to the 2018 Farm Bill set culpability standards for *cultivation* of hemp, transporting, processing, or selling hemp that exceeds the federal threshold and is therefore “marihuana” is not protected in any sense and can subject to the participant to federal and state criminal liability.

⁷ *See generally* 85 Fed. Reg. 51639, 51641 (Aug. 1, 2020) (discussed *infra*).

difficult for hemp extract makers or sellers to determine what the appropriate THC level is if different testing methods would yield different results.

This article examines problems with the dry weight standard and proposes a volume or percentage based standard to lower the risk of non-compliant hemp extract products and provide certainty to hemp industry participants.

The Legalization of Hemp

Prior to the enactment of the 2018 Farm Bill, the CSA made no reference to THC levels and failed to distinguish hemp from “marihuana”. Consequently, both plants were Schedule I narcotics and were deemed by the federal government to be as illegal as heroin:

The term “marihuana” means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include 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 which is incapable of germination.⁸

In 2014, President Barack Obama signed the Agricultural Act of 2014 (or “2014 Farm Bill”) into law,⁹ kicking off the modern hemp industry. The 2014 Farm Bill clarified that notwithstanding the CSA’s blanket prohibition of hemp, “industrial hemp” could be cultivated and researched by certain institutions of higher education or under pilot programs implemented by state departments of agriculture.¹⁰ The 2014 Farm Bill defined “industrial hemp” as “the plant *Cannabis sativa* L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”¹¹

The result of the 2014 Farm Bill was that for a number of years, hemp was federally illegal yet could be grown and even sold by certain public and private actors so long it was grown for vaguely defined “research” purposes. Notably too, the 2014 Farm Bill required very little, if any, federal oversight into the cultivation of what was then deemed a Schedule I narcotic. In that sense, the 2014 Farm Bill was among the most—if not the most—progressive federal controlled substance laws to date.

The 2018 Farm Bill went several steps further and completely removed hemp from the CSA’s definition of “marihuana”, officially legalizing hemp. Rather than rely on the 2014 Farm Bill’s definition of “industrial hemp”, which was limited to just the hemp plant and parts of the hemp plant, the drafters of the 2018 Farm Bill chose to broadly legalize the entire plant *and* virtually all extracts of the plant by adopting the following broad definition of “hemp”:

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

⁸ 21 U.S.C. § 802(16) (2018).

⁹ Publ. L. No. 113-79 (Feb. 7, 2014).

¹⁰ *Id.* § 7606(a).

¹¹ *Id.* § 7606(b)(2).

growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.¹²

Following the passage of the 2018 Farm Bill, the question of whether hemp-derived cannabinoids and extracts were lawful seemed to have been settled. The only limiting threshold seemed to be the difference between the plants based on the federal .3% threshold. Problematically, however, neither law explicitly defined what “dry weight” meant.

Defining Dry Weight

On October 31, 2019, the United States Department of Agriculture (“USDA”) issued interim final rules to carry out the 2018 Farm Bill’s mandate to create a regulated hemp industry.¹³ Pursuant to the USDA’s interim final rules, the federal government adopted a definition of the term “dry weight” as follows:

Dry weight basis. The ratio of the amount of moisture in a sample to the amount of dry solid in a sample. A basis for expressing the percentage of a chemical in a substance after removing the moisture from the substance. Percentage of THC on a dry weight basis means the percentage of THC, by weight, in a cannabis item (plant, extract, or other derivative), after excluding moisture from the item.¹⁴

Notably, the USDA interim final rules’ testing provisions (and the rules themselves) are generally only directed to hemp *cultivators*, and not extract manufacturers, as the 2018 Farm Bill generally was intended to regulate only hemp cultivation and ostensibly left the manufacture of hemp products to the United States Food and Drug Administration (“FDA”)¹⁵ and states. In fact, there are no provisions in the 2018 Farm Bill or USDA interim final rules that explicitly require testing of hemp extract or products containing hemp extract¹⁶—over the years, a number of U.S. states have imposed such requirements, but federal law did not.

Nevertheless, the federal definitions of hemp, in combination with the USDA’s incorporation of the terms “extract” and “other derivative” into the definition of “dry weight” hammer home that any derivative of hemp must be tested on a dry weight basis. The federal government simply failed to explain when and how that testing was required.

Things came to a head on August 21, 2020, when the DEA issued an interim final rule on hemp and hemp-derived substances. In a preamble to the DEA’s interim final rule, the DEA noted that:

Pursuant to the [2018 Farm Bill], unless specifically controlled elsewhere under the CSA, any material previously controlled under Controlled Substance Code Number 7360 (marihuana) or under Controlled Substance Code Number 7350 (marihuana extract), that contains 0.3% or less of Δ^9 -THC on a dry weight basis—*i.e.*, “hemp” as that term defined

¹² Publ. Law. 115-334 § 297A(1) (codified at 7 U.S.C. § 16390(1)).

¹³ 84 Fed. Reg. 58522 (Oct. 31, 2019).

¹⁴ 7 C.F.R. § 990.1 (2019).

¹⁵ The 2018 Farm Bill made clear that the FDA retained jurisdiction over many consumer products derived from hemp because the 2018 Farm Bill expressly preserves the authority of the FDA to regulate hemp products under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and section 351 of the Public Health Service Act. 7 U.S.C. § 1639r(c). Nevertheless, the FDA quickly clarified that it viewed the majority of consumer products containing hemp-derived cannabidiol (“CBD”) to be illegal. See U.S. Food & Drug Administration, Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency’s regulation of products containing cannabis and cannabis-derived compounds (Dec. 20, 2018), available at <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scottgottlieb-md-signing-agriculture-improvement-act-and-agencys>.

¹⁶ Note, however, that there are references to extracts and derivatives in the reference to “Dry weight basis” cited above. This does not necessarily impose testing obligations on hemp processors, though, as they fall outside the USDA’s jurisdiction.

under the [2018 Farm Bill]—is not controlled. Conversely, any such material that contains greater than 0.3% of Δ^9 -THC on a dry weight basis remains controlled in schedule I.¹⁷

The DEA then went on to create a new definition for the term “marihuana extract” as follows:

Marihuana Extract7350 Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus *Cannabis*, containing greater than 0.3% delta-9-tetrahydrocannabinol on a dry weight basis, other than the separated resin (whether crude or purified) obtained from the plant.¹⁸

The DEA’s modified definition of “marihuana extract” makes clear that any derivative of the hemp plant that contains more than .3% THC on a dry weight basis is considered a federally illegal controlled substance, *even if* it was derived from legal hemp.¹⁹ This DEA rule drove home the fact that even in the absence of federal testing requirements for hemp extracts, extract makers and sellers *need* to ensure that their products do not contain impermissible levels of THC. No longer was it simply sufficient to rely on certificates of analysis from testing of underlying plant material—hemp extract makers and sellers need to ensure that higher THC concentrations were not achieved during processing, otherwise they could face criminal liability.

Of course, the USDA and DEA interim final rules offer no guidance for how hemp extract makers can achieve dry weight for measuring liquids.²⁰ The only noteworthy federal guidance on point is a draft, non-binding guidance document prepared by the FDA and directed to certain drug makers wishing to incorporate cannabis derivatives into drugs (the “FDA Draft Guidance”).²¹ Pursuant to the FDA Draft Guidance, companies working with “solution-based material (intermediate, in-process material, or final drug product)” would need to achieve dry weight for testing purposes as follows:

1. Determine the density of the liquid formulation and convert 1 mL of the formulation to mass units (mg).
2. Calculate water content (in mg) of each active and excipient component present in 1 mL of the formulation.
3. Sum the water content (in mg) for all components present in 1 mL of the liquid formulation and subtract this amount from the total mass of 1 mL (from step 1). This is the water-adjusted total mass of 1 mL of the formulation.
4. Calculate the mass, or mg amount, of delta-9 THC present in 1 mL of the liquid formulation.
5. Calculate the percentage delta-9 THC by dividing the mass of delta-9 THC from step 4 by the total water-adjusted mass in step 3 and multiplying by 100.²²

¹⁷ 85 Fed. Reg. 51639, 51641 (Aug. 1, 2020).

¹⁸ *Id.* at 51645 (codified at 21 C.F.R. § 1308.11(d)(58)).

¹⁹ For a discussion of the shaky legal grounds on which the DEA’s interim final rule is based, see Griffen Thorne, *The 2018 Farm Bill Does Not Support the DEA Interim Rule*, Canna Law Blog (Sept. 16, 2020), <https://harrisbricken.com/cannalawblog/the-2018-farm-bill-does-not-support-the-dea-interim-rule/>

²⁰ See Kamran Aryah & Rod Kight, “Hot” Hemp Extract-New Lawsuit Underlines Need For Clarity, Kight on Cannabis (June 8, 2020), available at <https://cannabusiness.law/hot-hemp-extract-new-lawsuit-underlines-need-for-clarity/> (noting that a dry-weight measurement “cannot rationally apply to hemp extract, which takes the form of a ‘wet’ oil or other liquid” and that “extracts are not ‘dry’”).

²¹ Food & Drug Admin., Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research, Draft Guidance (July 2020), available at <https://www.fda.gov/media/140319/download> (the “FDA Draft Guidance”).

²² *Id.* at 8. To reiterate, the FDA Draft Guidance is non-binding and was directed to a very limited audience.

In other words, the FDA’s guidelines do not require hemp extract makers to “dry” liquid extracts. Rather, they use a calculation to determine the percentage of water is in a liquid substance and derive from that the percentage THC level by determining the mass of THC present in the liquid. Volume or percentage testing seems to have also been applied by various states, although using differently expressed calculations. For example, Oregon regulations require measuring THC on a dry weight basis as follows: “A laboratory must report total THC and Total CBD content by dry weight calculated as follows: $P \text{ total THC(dry)} = P \text{ total THC(wet)} / [1-(P \text{ moisture}/100)]$ ”.²³

The Dry Weight Problem and Solutions

The federal .3% THC threshold is an immovable standard for determining whether a plant material constitutes hemp. The DEA’s interim final rule hammers home that this standard applies to all hemp extract products, regardless of whether they were derived from legal hemp and regardless of whether they are liquid or solid products. Notwithstanding these clear lines in the sand, the federal government has not clearly defined how hemp companies should measure THC content on a dry weight basis for liquid hemp extract products.

To the extent that states adopt different approaches to measuring dry weight in extract products—or more likely, fail to even account for this problem²⁴—hemp extract that is deemed lawful in one state may have excessive THC content in the next. This makes interstate hemp extract transport extremely dangerous.

The only solution is for the federal government to adopt a clear standard by which THC content in hemp extract can be measured. The federal government can adopt percentage or volume based testing methods similar to those put forth by the FDA or states.²⁵ The FDA already apparently believes that this is an effective standard for measuring THC and the FDA is the agency with primary authority of many types of consumer products derived from hemp. These standards may not require any modification of the statutory definition of the THC standard and may conceptually mesh with the concept of “dry weight”.

Conclusion

The United States must adopt a uniform testing standard for hemp extracts that is based on rational application of scientific standards. Testing methods that have already been adopted by some states and proposed by the FDA may be an effective way to do that. Absent federal guidance, hemp industry participants will continue to face discriminatory penalties, federal scrutiny, and arrests.

²³ Oregon Admin. Code § 333-064-0100(5).

²⁴ Many states, such as California, lack clear guidelines for the processing of hemp and measuring of THC content in processed hemp as opposed to hemp flower.

²⁵ A volume-based testing solution was proposed by hemp attorneys Kamran Aryah and Rod Kight. *See* Aryah & Kight, *supra* note 20 (“the best unit of measurement would be a percentage by volume, not dry weight, since extracts are not ‘dry’”).