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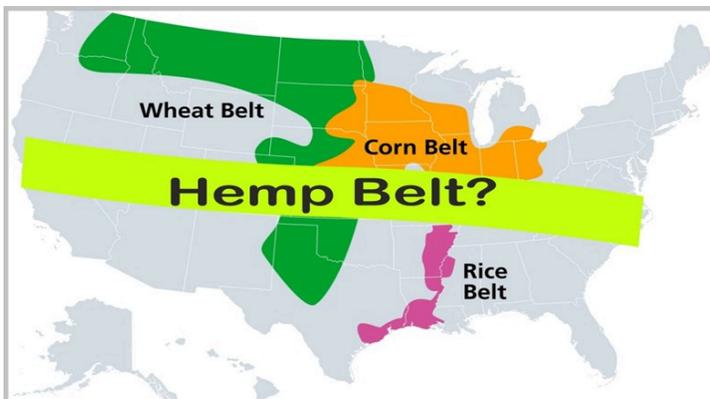
Proliferation Of Intoxicating Hemp Ingredients Prompts Request For Federal Regulatory Pathway

11 Apr 2024 | **NEWS**

by **Malcolm Spicer** | @TheTanSheet | malcolm.spicer@citeline.com

Executive Summary

US Cannabis Council says farm bill reauthorization is “key opportunity to tackle the national crisis caused by unregulated intoxicating hemp products” by limiting the variety of hemp derivatives which qualify as de-scheduled.



Source: Shutterstock

The de-scheduling of hemp as a controlled substance in the US has allowed a “statutory loophole which has allowed unregulated intoxicating hemp products to proliferate across the United States,” says a cannabis trade association.

The regulation also isn’t helping the hemp industry as states are setting their own rules. But neither retail sales of intoxicating hemp ingredients nor regulatory difficulty for the industry appear likely to prompt Congress to

act.

The US Cannabis Council, in a 10 April letter to the ranking members of the House and Senate Agriculture Committees, says reauthorization of the farm bill is “a key opportunity to tackle the national crisis caused by unregulated intoxicating hemp products” by limiting the variety of hemp derivatives which qualify as de-scheduled by containing no more than 0.3% delta-9 tetrahydrocannabinol concentration by dry weight. (Also see “FDA Road To Decision On Expanding CBD Uses Starts With Weighing Impact On Existing And Future Use As Drug” - HBW Insight, 2 Jun, 2019.)

“This has resulted in the widespread availability of unsafe consumer products, often produced using unregulated industrial-scale chemical processes that fail to meet the fundamental product safety standards that Americans have come to expect in consumer-packaged goods,” the Washington-based USCC added.

Maybe In Farm Bill Reauthorization ...

Congress in December 2023, after failing to pass a five-year reauthorization of the farm bill, extended the current bill another year.

In its letter to the committees, the USCC suggests adding this language to the definition of hemp under the federal regulation:

“ADDITIONAL DEFINITION: Products in final form intended for human or animal consumption which are:”

“a. Made or derived from hemp or hemp bi-products; and”

“b. Contain detectable quantities of total THC and any other intoxicant that can be derived from hemp including other forms of THC; and”

“c. Are intended to be consumed or absorbed inside the body by any means, including inhalation, ingestion, insertion, or topical application, shall be excluded from the current definition of Hemp and considered marijuana as defined by 21 USC 802(16)” [the FDA regulation defining marijuana, including language excluding hemp as defined in 7 USC 1639o].

... Maybe Better Off In Other Bill

The absence of legislation authorizing the FDA to impose a regulatory pathway for hemp’s lawful use in supplements and food likely is prompting more states to adopt their own rules. More state rules incorporating more derivatives as the THC measured for concentration also is likely.

Food and drug regulation attorney Jonathan Havens doesn’t expect increased legislative and regulatory activity in states to compel Congress to pass legislation in the farm bill reauthorization or other bill triggering the FDA’s solution to its dilemma concerning hemp’s use in non-drug products.

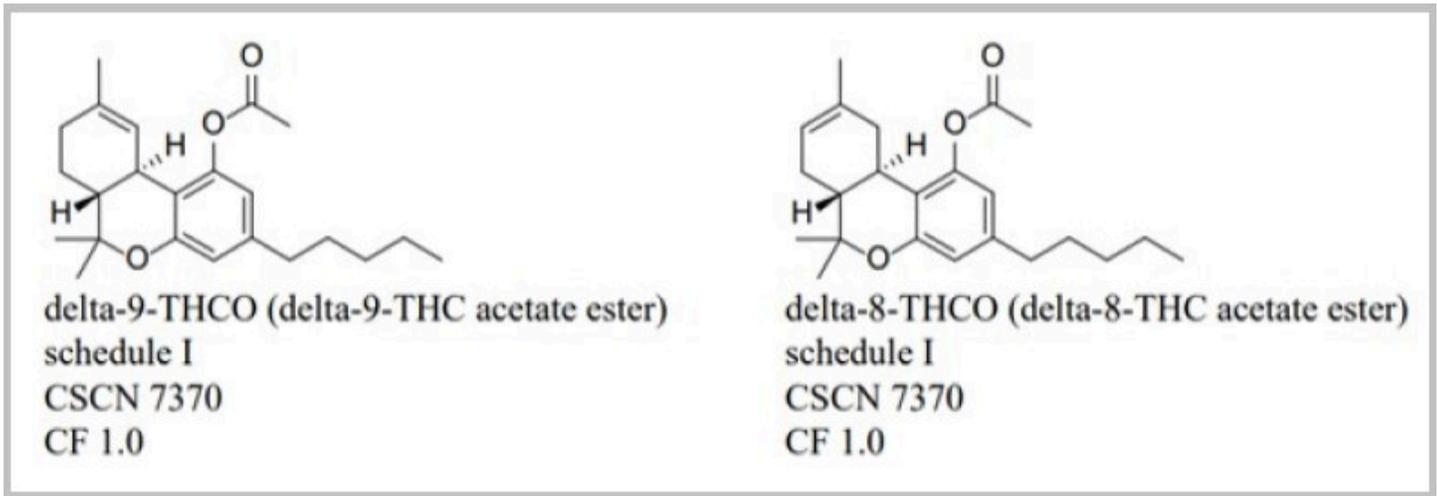
Hemp Regulation Flags Raised By States Wave Tougher Compliance Cloud Over Industry

By Malcolm Spicer

11 Apr 2024

Without FDA regulatory pathway for hemp’s lawful use in supplements and food, some states are imposing more-stringent regulations while others allow sales of intoxicating ingredients not considered controlled substances as hemp derivatives.

[Read the full article here >](#)



WHEN THE DEA IN 2023 ANNOUNCED IT CONSIDERED DELTA-8 A CONTROLLED SUBSTANCE AND NOT DE-SCHEDULED UNDER THE 2018 FARM BILL, IT INCLUDED THESE PROFILES OF ACETATE ESTERS OF DELTA-8 AND DELTA-9.

Source: Drug Enforcement Administration

That's what the agency asked lawmakers for in 2023, saying it couldn't bring the current hemp-containing supplement and food market under control and establish a regulatory pathway for lawful use under its existing authorities. (Also see "US FDA 'Punt' On Hemp Rulemaking Frustrates, Confuses Supplement Industry" - HBW Insight, 26 Jan, 2023.)

"This should prompt Congress to do it, but as a former as a former Hill staffer and as a former federal regulator at the FDA after law school. I'm uniquely qualified to understand the challenges that both Congress and agencies have," Havens said.

"We heard from the FDA last year, they're sending it back to Congress. Well, we haven't seen any legislative movement on that front. We've seen proposals and bills that have been introduced. But I don't think any of them have even made it out of committee, let alone pass both chambers. I am not holding my breath that Congress will create this smooth, uniform federal path for these products via legislation that would deal with the federal Food, Drug and Cosmetic Act."

Although the farm bill is most commonly mentioned as the most likely legislation to authorize a hemp regulatory pathway, if members of Congress make the move other legislation would work.

"Maybe the farm bill, but I kind of chuckle when I say that because that's what we all said last year. And we know what happened with that. But it's more of a likely vehicle than a standalone piece of legislation, I think now, so maybe it gets addressed," said Havens, a partner at Saul Ewing LLP in Baltimore.

However, a reauthorization of spending for Department of Agriculture and related programs might not be best for all sectors in the hemp industry.

"The flip side of that coin is the farm bill deals with inputs, agriculture and agribusiness, more than it deals with finished products, when it comes to FDA regulated products. Really, the more appropriate vehicle would be to deal with this as the underlying products themselves, like topicals, or ingestibles, which FDA regulates," Havens said.

"I'd be a bit surprised if Congress took that up in the farm bill, but I'll take surprise over lack of uniformity if that's the choice."