



A watershed moment for hemp and hemp-based CBD

Food and Beverage Alert

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By:

With the passage of the Agricultural Act of 2018 (or the 2018 Farm Bill) by both houses of Congress, industrial hemp and its derivatives, including hemp-based CBD, are positioned to move from an era fraught with legal uncertainty to full commercial legalization across the entire nation.

Four years ago, Congress began the process of hemp legalization with the 2014 Farm Bill. Specifically, Section 7606 provided for the development of industrial hemp defined as "the plant *Cannabis sativa L.* and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol (or THC) concentration of not more than 0.3 percent on a dry weight basis" by either an institution of higher education or a state department of Agriculture for research purposes under the auspices of an "agricultural pilot program."

While the 2014 Farm Bill legalized industrial hemp for these purposes, many lingering questions remained regarding (1) the relationship between the Farm Bill and the Controlled Substances Act (the CSA), specifically with regard to the definition of "marijuana"; (2) whether industrial hemp could be produced and sold commercially; (3) whether industrial hemp could be sold in interstate commerce; and (4) who was responsible for the regulation and enforcement of industrial hemp.

The 2018 Farm Bill attempts to address each of these uncertainties by **creating a clear regulatory structure for**

the commercial development of industrial hemp as well as stronger legal protection for hemp and hemp-based derivatives such as cannabidiol (or CBD). For example, the 2018 Farm Bill amended the definition of "hemp" to specifically include "all derivatives, extracts, cannabinoids" which is significant in the face of existing DEA guidance which specified that cannabinoids like CBD were included in the definition of marijuana under the CSA. Further, the Farm Bill sets out a clear structure for development of state, tribal or federal regulatory and licensing schemes for the lawful production of industrial hemp to insure its protection and oversight.

The bill also sets forth protections for farmers and other industry participants by shielding them from federal prosecution for negligent behaviors, including failing to obtain the necessary licensure or for producing cannabis with a THC level of greater than 0.3 percent, so long as they take corrective action and do not engage in such behavior more than three times in a five-year period.

To protect the interstate commercial sale of industrial hemp, the bill specifically provides that interstate sales are allowed, and bars states or Indian tribes from prohibiting the transportation or shipment of hemp or hemp products through their territory – which would include both physical transportation as well as issues regarding Internet-based sales.

Finally, and potentially of greatest significance, the 2018 Farm Bill specifically amends the CSA to provide that the legal term "marihuana" explicitly "does not include hemp" as defined by the Farm Bill.

Once signed into law by President Trump, the 2018 Farm Bill **will pave the way for the fuller realization of an industry that has already demonstrated tremendous growth**, particularly with regard to the sale of hemp-based CBD.

With this growth, however, key restrictions remain, in particular regarding the inclusion of CBD in food and/or beverages. While the 2018 Farm Bill amended the definition of marijuana under the CSA, it explicitly specified that nothing in the bill shall affect or modify the Federal Food, Drug, and Cosmetic Act (the FDCA) or the authority of the Commissioner of Food and Drugs (*ie*, the FDA) to enforce the FDCA. This is significant because the FDA has determined that section 301(ii) of the FDCA prohibits the introduction into interstate commerce of any food (including beverages) to which CBD has been added, given that CBD was studied in "substantial clinical investigations" prior to CBD being "marketed in food."

While this position currently prohibits the interstate sale of food products infused with CBD, the FDA has recognized the substantial clinical investigations regarding CBD with regard to the approved drug Epidiolex, which may set the tone, together with the passage of the Farm Bill, for further clinical research regarding CBD.

Finally, with regard to the development of CBD-infused food products which do not travel in interstate commerce, there remains some uncertainty and continued risk given the FDA's position. For this reason, the California Department of Public Health, for example, recently issued guidance noting that, because California incorporates federal law regarding food additives, it would adopt the FDA's position that CBD (or THC) could not be lawfully added to food products in California, despite the legality of both CBD and THC under state law.

In sum, then, questions regarding the implementation and resulting impact of the 2018 Farm Bill remain and will for some time.

Learn more about this development and its implications by contacting the author.