

U.S. Congress Passes the Farm Bill and Removes Restrictions on Hemp

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Food, Drugs, and Devices

On December 12, 2018, the House passed H.R. 2, the Agricultural Improvement Act of 2018 (“the Farm Bill”). The vote follows the Senate’s passage of the bill on December 11, 2018. If President Trump signs the bill, it would change the regulatory status of hemp and hemp products.

Summary of the Hemp Provisions of the Farm Bill

Subtitle G of the Farm Bill amends the Agricultural Marketing Act (“the Act”) by adding several hemp-related provisions. Under new section 297A of the Act, “hemp” would be defined to mean “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 [THC] concentration of not more than 0.3 percent on a dry weight basis.” A later section in the bill modifies the definition of “marihuana” within the Controlled Substances Act (“CSA”) to exclude “hemp, as defined in section 297A of the Agricultural Marketing Act of 1946.” The same section would exclude “tetrahydrocannabinols in hemp” from control as a schedule I substance.

Further, the Farm Bill expands state authority over the production of hemp, allowing states and tribal territories to develop and submit a plan to the U.S. Department of Agriculture (“USDA”) for the growing and production of hemp, consistent with the limits outlined in the bill. Such states would have primary jurisdiction over hemp production upon receiving USDA approval for their plans. States and tribal territories may propose plans to regulate the production of hemp that are more stringent than the requirements set out in the Farm Bill. For states and tribal territories that do not develop and submit a hemp production plan, the USDA will develop a hemp production plan for implementation in such states.

Of note, the Farm Bill explicitly specifies that the bill does not affect or modify FDA’s authorities for hemp-derived products. The bill also explicitly addresses interstate commerce concerns for hemp products. While states and tribal territories may limit the production and sale of hemp and hemp products within their borders, they cannot limit the transportation or shipment of hemp or hemp products through the state or territory.

Implications of the Farm Bill for CBD

The Farm Bill, if signed by the President, would effectively deschedule certain cannabis products, such as cannabidiol (“CBD”), derived from *Cannabis sativa* containing no more than

0.3% THC. Unlike the 2014 Farm Bill, which did not amend the CSA, the Farm Bill modifies the definition of marijuana, a schedule I substance under the CSA, as described above. CBD is currently a controlled substance under the CSA because it is derived from marijuana, so removing “hemp” from the definition of marijuana would remove CBD from control when it is derived from such hemp.

While the 2014 Farm Bill authorized limited pilot programs to grow industrial hemp, the Farm Bill envisions a national system for the growing, production, and sale of hemp. Manufacturers of CBD products derived from hemp would be able to ship their products across state lines, even in states where hemp production and sale are restricted.

The Farm Bill leaves intact other provisions of the law that are relevant for manufacturers and sellers of hemp products, such as CBD. Unless interpreted differently by DEA, the Farm Bill would not deschedule all cannabinoids, such as CBD, but only those derived from *Cannabis sativa* plants with no more than 0.3% THC. DEA would likely continue to regulate CBD derived from *Cannabis sativa* with more than 0.3% THC as a schedule I controlled substance.

The Farm Bill would not change FDA’s restrictions on sales of certain products containing CBD. Currently, FDA takes the position that CBD may not be sold as or in a food or dietary supplement for humans and animals in the United States because FDA believes that CBD was not used in dietary supplements or foods before the start of substantial drug clinical investigations on CBD, and thus, is excluded from use in dietary supplements and foods under particular provisions of the Federal Food, Drug, and Cosmetic Act. Additionally, FDA has long taken the position that it will regulate any CBD-containing products as drugs if the products make disease claims. FDA has not taken the position that CBD is restricted from use in cosmetics. The Farm Bill would not alter FDA’s authorities.

While the Farm Bill would remove certain types of CBD from the CSA, it remains to be seen how states will regulate CBD products. Each state has controlled substance laws, which are not preempted by the CSA. Further, as the Farm Bill emphasizes, states can develop hemp production plans with more stringent requirements than those envisioned under the Farm Bill. To date, most states have not systematically enforced against CBD products. States will need to decide how to regulate CBD products as they harmonize their existing regulatory schemes with the Farm Bill’s hemp provisions.

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