

# USDA Issues Hemp Production Interim Final Rule

October 31, 2019

Food, Beverage, and Dietary Supplements

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Today, the U.S. Department of Agriculture (USDA) issued the long-awaited [interim final rule](#) (“the rule”) [establishing regulations for a domestic hemp production program](#). The rule provides clarity for hemp growers and related businesses and is a critical next step after the passage of the 2018 Farm Bill last December. Among other things, the rule outlines provisions for USDA to approve plans submitted by states and Indian Tribes for the domestic production of hemp, establishes a federal plan for hemp producers in states or territories of Indian Tribes that do not have their own USDA-approved plan, and includes provisions for maintaining information on the land where hemp is grown and testing levels of delta-9 tetrahydrocannabinol (THC).

This rule is relevant not only for hemp growers but also for entities that may be interested in purchasing cannabidiol (CBD) and want to ensure the CBD is derived from hemp that is produced in accordance with the USDA’s requirements. We note, however, that the rule has no bearing on the Food and Drug Administration’s (FDA’s) current position that CBD cannot be used in food or dietary supplements due to the prior investigation, and subsequent approval, of CBD as a new drug.

## Legal Framework for the Rule

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Hemp has been regulated in the United States since the Marihuana Tax Act of 1937, which required all producers of *Cannabis sativa* to register with and apply for a license from the federal government. In 1970, the Controlled Substances Act (CSA) granted the Attorney General the authority to regulate hemp production. Until recently, CBD was considered a Schedule I controlled substance under the CSA because it fell within the CSA definition of “marihuana.”

The 2014 Farm Bill defined “hemp” as the plant *Cannabis sativa* L. and any part of that plant with concentrations of THC no greater than 0.3% on a dry weight basis. This represented the first distinction in federal law between hemp and cannabis. The 2014 Farm Bill authorized institutions of higher education and state departments of agriculture to allow hemp cultivation as part of a pilot program for research purposes, including market research; however, it did not modify the scope of the CSA “marihuana” definition, so CBD remained a Schedule I controlled substance.

The 2018 Farm Bill went much further in creating a national market for the hemp industry, amending the Agriculture Marketing Act (AMA) to add several hemp-related provisions, including adding a definition of “hemp” and modifying the CSA definition of “marihuana” to

exclude “hemp.”<sup>1</sup> In doing so, the 2018 Farm Bill effectively descheduled certain cannabis products, such as CBD, derived from *Cannabis sativa* containing no more than 0.3% THC. The 2018 Farm Bill also allows for interstate transportation and shipment of hemp in the United States, prohibiting interference of interstate transport of hemp by states, including those states that do not allow hemp production and sales.

In addition, the 2018 Farm Bill required USDA to (1) evaluate and approve or disapprove State or Tribal plans regulating hemp production; (2) establish a federal plan for producers in states and territories of Indian Tribes not covered by state/Tribal plans; and (3) issue regulations and guidelines relating to hemp production.

Notwithstanding the requirements of the 2018 Farm Bill itself, the absence of a regulatory framework from USDA since the law’s passage had placed the U.S. hemp industry in a legal limbo, leaving the industry open to seizure of interstate hemp shipments and in some cases unable to obtain access to banking and insurance. The issuance of today’s rule should help eliminate some of this uncertainty by providing necessary clarity for the hemp industry and related entities, as well as state and Tribal governments that regulate these businesses.

## Key Elements of the Rule

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As directed by the 2018 Farm Bill, USDA issued the rule to establish the domestic hemp production program, facilitate the production of hemp, and expand production and sales of domestic hemp. The rule creates a set of minimum standards to ensure that hemp produced under the program meets all statutory requirements. The rule will also allow USDA to begin to implement the hemp program, including review of state and Tribal plans and issuing licenses under the USDA hemp plan.

USDA defines “hemp” in the rule with the 2018 Farm Bill definition: the plant species *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 THC concentration of not more than 0.3% on a dry weight basis. Cannabis with a THC level over 0.3% is considered marijuana, which remains a Schedule I controlled substance regulated primarily under the CSA.

### State and Tribal Plans

The rule outlines the procedures under which a state or Indian Tribe may exercise primary regulatory authority over hemp production in that state or territory. Per the rule, the state or Indian Tribe must submit, for USDA approval, a plan concerning the monitoring and regulation of such hemp production, and such plans must be approved by USDA before they are implemented. States or Tribes may adopt provisions that are stricter than those of the 2018 Farm Bill.

The rule outlines the requirements that state or Tribal plans to regulate hemp production must include, such as:

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<sup>1</sup> For more detail on the 2018 Farm Bill, see Covington’s [December 13, 2018 client alert](#).

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- A process by which relevant information regarding the land used for hemp production in their jurisdiction is collected and maintained;
- Procedures for sampling and testing hemp to ensure cannabis grown and harvested does not exceed the acceptable hemp THC level;
- Procedures for ensuring effective disposal of plants produced in violation of the rule, e.g., cannabis exceeding the acceptable hemp THC level;
- Compliance procedures to ensure hemp is being produced in accordance with the requirements of the rule, including requirements to conduct annual inspections of hemp producers, a procedure for handling violations, and procedures to identify and attempt to correct certain negligent acts;
- Procedures for reporting specific information to USDA, including contact information for each hemp producer covered under the plan; and
- Certification stating the state or Tribe has the resources and personnel needed to carry out the practices and procedures described in the plan.

USDA has provided a summary PDF of state and Tribal government plan requirements on its [website](#), along with necessary [forms](#).

Notably, the rule allows for certain ranges of uncertainty for the amount of THC that results from testing of the crops. Thus, an allowance for limited variation of THC concentration among individual crops is built into the rule, but some hemp producers have expressed concern that this allowance is not sufficient.

In the preamble to the rule, USDA encourages states and Tribes to work with USDA to obtain technical assistance in developing the specifics of their plans. USDA will have 60 days to review a submitted plan. Approved plans remain in effect unless revoked by USDA pursuant to the revocation procedure outlined in the rule, or the state or Tribe substantively revises the plan or its laws that alter the way the plan meets the requirements of the rule. The rule also describes the procedure for rejection of state or Tribal plans, for submitting requests for reconsideration, and for amending plans.

### **USDA Plan**

The rule establishes a USDA plan to regulate hemp production by producers in areas where hemp production is legal but is not covered by an approved state or Tribal plan. All hemp produced outside of states or Tribes with approved plans must meet the USDA plan's requirements, which are similar to those under state or Tribal plans.

The USDA plan requirements include hemp producer licensing requirements, sampling and testing for THC level requirements, requirements for disposing of non-compliant product, and certain compliance requirements for USDA licensees, including audits of USDA licensees.

USDA is delaying acceptance of applications for USDA hemp producer licenses until 30 days after the effective date of the rule to allow states and Tribal governments to submit their plans first. Likewise, USDA will not issue USDA hemp production licenses to producers located in states or Tribal nations where a draft hemp production plan is pending USDA approval.

**Interference with interstate commerce, including transport, of lawfully grown hemp by states or Tribes is explicitly prohibited**

The rule is explicit that nothing within it prohibits the interstate commerce of hemp, and that no State or Indian Tribe may prohibit the transportation or shipment of hemp produced in accordance with the rule and with section 7606 of the 2014 Farm Bill. In other words, the rule clarifies that states and Indian Tribes may not prevent the movement of legally produced hemp through their states or territories even if they prohibit its production or sale. According to USDA, this will ensure that hemp producers have access to nationwide markets.

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The rule is effective immediately, with a 60-day comment period ending on December 30, 2019. USDA will draft and publish a final rule within two years of publication of the rule. Additional information, including guidance and forms, is available on the Agricultural Marketing Service [website](#).

Covington continues to monitor USDA and FDA developments regarding hemp and CBD, and will keep our clients and contacts updated. If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Beverage, and Dietary Supplements practice:

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