

Carter Ledyard Advises on Industrial Hemp: U.S. Department of Agriculture Publishes Interim Final Rule to Implement 2018 Farm Bill Program

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Client Advisory

November 19, 2019 by Guy P. Lander, Alexander G. Malyshev and Anup Khatri

On October 31, 2019, the U.S. Department of Agriculture ("USDA") published its long anticipated interim final rule (the "USDA Rule") implementing the agricultural hemp program under the Agricultural Improvement Act of 2018 (the "2018 Farm Bill").^[1] With the enactment of the 2018 Farm Bill in December 2018, hemp was removed from the definition of "marijuana" under the Controlled Substance Act ("CSA").^[2] The passage of the bill represented a major step towards establishing a nation-wide market for the hemp industry, but its implementation relied on USDA to establish and administer a program for lawful hemp production in the U.S.

The USDA Rule, which will enable growers to cultivate hemp as an agricultural commodity in the U.S., outlines the requirements for states and American Indian tribes to develop a hemp production plan for their respective jurisdictions. The USDA Rule also establishes a federal plan for hemp producers in states and tribal territories that do not have their own USDA-approved plan (and have not otherwise opted out of it by outlawing the production of hemp within their jurisdictions).

This is a significant development for the hemp industry and should provide much-needed regulatory guidance, not only to hemp producers, but also to related business who, for nearly 11 months since hemp was legalized under federal law, have been operating in a state of uncertainty. The USDA Rule will remain open to public comments through December 30, 2019. Its two-year effective period will expire on November 1, 2021, by which time USDA expects to have replaced it with a final rule that addresses any public comments it receives.

I. Brief Overview of the USDA Rule

The USDA Rule implements a system of shared federal and state/tribal regulatory oversight of hemp production in the U.S. Under the rule, any person that produces or intends to produce hemp must first be licensed or authorized under the appropriate hemp production plan, which, based on the location of the hemp producer's growing facility, could be either of the following: (1) a USDA-approved state or tribal plan governing the licensing and regulation of hemp production within the jurisdiction (a "State/Tribal Plan") or (2) the USDA-administered federal plan administered by USDA for hemp production in states and tribal territories that do not have their own USDA-approved plan and have not otherwise outlawed hemp production (the "USDA Plan").

Although the USDA Rule separately codifies the substantive requirements under the USDA Plan, and the minimum requirements for State/Tribal Plans, there are similar requirements that all licensed hemp producers must meet irrespective of their governing plan. Those requirements relate generally to various regulatory aspects of hemp production, such as:

- a. licensing requirements;
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- b. maintaining information on the land on which hemp is produced;
- c. procedures for testing the THC concentration levels for hemp;
- d. procedures for disposing of non-compliant plants;
- e. compliance provisions; and
- f. procedures for handling violations.

II. Plan Options under the USDA Rule

A. State/Tribal Plans.

Under the USDA Rule, any state or Indian tribe wishing to maintain primary regulatory authority over hemp production in its jurisdiction can develop and submit, for approval by USDA, a hemp production plan meeting certain minimum requirements. USDA expressly notes that the USDA Rule does not preempt or limit any state or tribal law that more stringently regulates hemp, but clarifies that states and Indian tribes cannot prohibit or restrict interstate transportation of lawfully-produced hemp through their borders.

USDA must review and either approve or disapprove of a proposed State/Tribal Plan within 60 days of its submission. Upon USDA's approval, hemp producers located within the jurisdiction may apply to the state or tribal government for a license to produce hemp in accordance with the governing plan. Approved State/Tribal Plans remain in effect unless revoked by USDA pursuant to the revocation procedures outlined in the USDA Rule, or the state or Indian tribe substantively revises its plan or its laws to change plan's ability to meet the requirements of the USDA Rule.

States and Indian tribes that had already submitted or were in the process of developing a hemp production plan prior to the USDA Rule's date of publication must now update their plans, as needed, to conform with the new USDA Rule's requirements.[3]

USDA's approval of a State/Tribal Plan is conditioned upon that plan meeting certain minimum regulatory requirements, some of which include:

1. *Information on Land Use.* State/Tribal Plans must establish a process for collecting, maintaining and reporting to USDA information pertaining to the land used for hemp production in the state or tribal territory (e.g., description of the land, hemp crop acreage, etc.).
2. *Sampling and Testing.* State/Tribal Plans must incorporate procedures for sampling and testing cannabis[4] plants to ensure that their THC concentration levels remain below 0.3%. Samples must be physically collected by a federal, state or tribal representative and delivered to a DEA-registered laboratory for testing within 15 days before the anticipated harvest. If the producer fails to complete a harvest within 15 days of sampling, a secondary pre-harvesting sample must be taken and submitted for testing. As a part of the testing process for the THC concentration level of a sample, the laboratory must evaluate and account for the "measurement of uncertainty" (i.e., margin of error in test results) when determining if that sample's THC concentration level exceeds its "acceptable hemp THC level."
3. *Disposal of Non-Compliant Plants.* States/Tribal Plans must include procedures for destroying non-compliant cannabis plants that exceed their "acceptable hemp THC levels" (i.e., 0.3%, plus or minus the measurement of uncertainty), as they would be deemed to be controlled substances under the CSA. Non-compliant plants must be collected and disposed of by a DEA agent or a designated law enforcement officer in accordance with the CSA.

4. *Inspections.* States/Tribal Plans must incorporate procedures for inspecting on an annual basis, at a minimum, a random sample of licensed hemp producers. They must also incorporate procedures to identify and attempt to correct certain negligent acts, such as hemp producers failing to obtain licenses or producing plants exceeding acceptable hemp THC levels.

5. *Information Reporting.* State/Tribal Plans must include procedures for reporting specific information to USDA, including contact information for all licensed hemp producers, legal descriptions and geospatial locations of the land used for hemp production and the status of each hemp producer's license. States and Indian tribes must report this information to USDA within 30 days of receipt from the hemp producers.

B. The USDA Plan.

The USDA Rule also establishes a federal plan for hemp producers in states and tribal territories that do not have their own USDA-approved plan and have not otherwise outlawed hemp production. In the absence of a USDA-approved plan, states and Indian tribes will essentially hand over regulatory responsibility to USDA, and USDA will provide licenses directly to hemp producers within those jurisdictions.

USDA will not accept applications for licenses under the USDA Plan until November 30, 2019, under the rationale that the delay will give states and Indian tribes an opportunity to develop and submit their own plans and minimize instances where USDA must issue licenses under the USDA Plan to hemp producers in states and tribal territories where the likelihood remains that there will soon be a State/Tribal Plan in place that overtakes the administration of licenses in the jurisdiction.

The requirements under the USDA Plan, which are imposed directly on licensed hemp producers, are largely similar to those under State/Tribal Plans, as also noted above. The USDA Plan does, however, include few differentiating regulations, which are justified by USDA's ubiquitous role of maintaining a federal licensing system under the USDA Plan in relation to its more limited role of oversight under State/Tribal Plans. Some of those differentiating regulations address approval standards, recordkeeping requirements and procedures for license suspension and revocation.

III. Considerations Moving Forward

Overall, the USDA Rule serves as a major step forward for the hemp industry. It clears up a significant amount of regulatory ambiguity that has plagued hemp producers and related businesses for nearly a year. One does not need to look further than the case of *Big Sky Scientific LLC v. Idaho State Police*, Case No. 19-CV-00040 (D. Idaho), where a shipment of hemp was seized in Idaho, which does not distinguish between hemp and marijuana, and which took the position that the hemp was not cultivated in accordance with the 2018 Farm Bill because no plans have been approved (and as a result the preemption provisions did not apply). USDA previously noted its disagreement with how that case has proceeded.[5]

The USDA Rule will contribute to the further expansion of lawful hemp production in the U.S. However, the regulatory framework established under the USDA Rule appears to be rather complex, and as a result, may require a considerable amount of time for the various industry participants to understand some of its implications. In light of this, USDA has encouraged states and Indian tribes to work with USDA to obtain technical assistance in developing the specifics of their plans. USDA has also made available informational tools and resources to help guide individuals through the regulations, including a recorded webinar that USDA released one week after publication, which goes over key elements of the USDA Rule, including a timeline for implementation and information about testing requirements.[6]

USDA has acknowledged that the USDA Rule is not perfect and that uncertainties remain. In just the first two weeks since publication, USDA had already received over 500 comments on the USDA Rule, with an overwhelming amount of the criticism directed towards USDA's hemp testing requirements. Nevertheless, USDA appears confident that these issues can be adequately addressed and resolved through its continuing

analysis of the regulations and their practical implications, as well the industry's feedback on any concerns and potential solutions to those concerns.

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[1] See "USDA Establishes Domestic Hemp Production Program," USDA Press Release (October 29, 2019) *available at* <https://www.usda.gov/media/press-releases/2019/10/29/usda-establishes-domestic-hemp-production-program>.

[2] The USDA Rule reiterates the 2018 Farm Bill's definition of hemp as "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 delta-9 tetrahydrocannabinol ("THC") concentration of not more than 0.3 percent on a dry weight basis." In other words, any cannabis plant or product that contains more than 0.3 percent THC will still be considered marijuana, a Schedule I drug that is illegal under federal law.

[3] Prior to the USDA Rule's publication, 10 states and 10 Indian tribes had already submitted hemp production plans for USDA approval. Since its publication and as of November 7, 2019, only one state and one Indian tribe have submitted plans. <https://www.ams.usda.gov/rules-regulations/hemp/state-and-tribal-plan-review>.

[4] Cannabis is a plant belonging to the Cannabaceae family and containing a variety of biologically active chemical compounds. Hemp and marijuana are both varieties of cannabis, though "cannabis" is often used interchangeably with "marijuana." The distinction between hemp and marijuana is the concentration of THC, a psychoactive compound. Hemp (sometimes referred to as "industrial hemp") contains no more than 0.3% THC on a dry weight basis, while marijuana contains a greater concentration of THC.

[5] See "Legal Opinion on Certain Provisions of the Agriculture Improvement Act of 2018 Relating to Hemp," USDA Memorandum (May 28, 2019) discussing *Big Sky Scientific* in a section titled "Recent Developments." *Available at* <https://www.ams.usda.gov/sites/default/files/HempExecSumandLegalOpinion.pdf>.

[6] <https://zoom.us/recording/play/TAeflEP96bk0nvHTbp6JVKoR4JX4O2hXFACZAdXjDhowNT2F6SDhHmGDAqCCv9nB>.

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