

CLIENT ALERT

USDA Rule Implementing Hemp Production Plans

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On October 28, 2019 the U.S. Department of Agriculture (“USDA”) issued a long-awaited regulation (“USDA Rule”)¹ authorizing the legal production and interstate transport of hemp as contemplated by the 2018 Farm Bill.² As a result of the USDA Rule, hemp,³ which is a type of cannabis plant and a key source of cannabidiol (“CBD”), may be produced and sold in the U.S. consistent with Federal law, provided that: (i) the plants and extracts contain levels of delta-9 tetrahydrocannabinol (“THC”) no greater than 0.3 percent and (ii) production is carried out by a licensed producer under a USDA approved State or Indian Tribe plan or a Federal plan.⁴ The 40 States and Indian Tribes that have adopted hemp production plans may now submit them to the USDA for approval. The USDA Rule does not, however, change the status of cannabis having a THC level of greater than 0.3 percent, which remains a Schedule I Controlled Substance under the

¹ Establishment of a Domestic Hemp Production Program, Department of Agriculture, 84 Fed. Reg. 58522 (Oct. 31, 2019) (“Adopting Release”).

² Agriculture Improvement Act of 2018, Pub. L. No. 115-334 (“2018 Farm Bill”).

³ “Hemp” is defined in the USDA Rule and in the 2018 Farm Bill 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 concentration of not more than 0.3 percent on a dry weight basis.”

⁴ Because licensees would be acting consistently with Federal law by producing hemp in accordance with these plans, service providers to such hemp producers, such as commercial banks, accountants, insurance companies and attorneys, should be able to provide services to the businesses without concern that they might be aiding and abetting an illegal enterprise.

USDA Rule Implementing Hemp Production Plans

Controlled Substances Act (“CSA”), the production and distribution of which is illegal under Federal law.⁵ In addition, the USDA regulations do not address compliance by CBD products with regulations of the Food and Drug Administration.⁶

Background

The 2018 Farm Bill removed hemp having a THC level of no greater than 0.3 percent from the list of controlled substances in Schedule I of the CSA and authorized production of hemp in the U.S. for commercial purposes provided it is grown under a U.S. State or Indian Tribe plan (“State or Tribal Plan”) that has been approved by the USDA or a Federal plan adopted by the USDA (a “USDA Plan”).⁷ Hemp producers under the approved plans will be eligible to participate in Federal crop insurance programs, and hemp products produced under approved plans may be freely transported throughout the U.S., including through States and territories in which production is not authorized under a State or Tribal Plan.⁸ The USDA Rule, which became effective on October 31, 2019, sets forth a process for USDA approval of State and Tribal Plans for hemp production (which under the 2018 Farm Bill must be approved by the USDA within 60 days of submission), as well as a licensing process under the USDA Plan.

Prior to the 2018 Farm Bill, hemp was not distinguished from marijuana and was treated as a Schedule I Controlled Substance under the CSA, with the exception of specific parts of the plant, such as the mature stalks. Under the Agricultural Act of 2014 (“2014 Farm Bill”), State departments of agriculture and institutions of higher education were permitted to produce hemp as part of a pilot program for research purposes only.

The 2018 Farm Bill directed the USDA to promulgate regulations and guidelines to establish a program for production of hemp and to authorize or reject hemp production plans adopted by a State or Indian Tribe. For States and Indian Tribes that do not have approved plans, the USDA is directed to establish a departmental plan. The production plans are expected to contain similar requirements, including: (i) licensing requirements for producers, including a requirement that a licensee not have been convicted of a felony related to controlled substances under Federal or State law over the past 10 years and diligence requirements for the licensing entity; (ii) procedures for sampling and testing the THC concentration levels for the hemp produced; (iii) procedures for disposing of non-compliant plants; (iv) inspection requirements and procedures to address handling of violations; (v) a process by which specified information regarding the land used for hemp production is collected and maintained and under which hemp crop acreage is provided to the USDA;

⁵ Congress enacted the Controlled Substances Act as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801, *et seq.*

⁶ In April 2019, the Food and Drug Administration issued a press release noting that distribution of food and beverage products containing CBD and distribution of CBD as a dietary supplement were federally unlawful. See Statement of Commissioner Scott Gottlieb, Food & Drug Administration (Apr. 2, 2019), *available here*.

⁷ Adopting Release at 58523.

⁸ 2018 Farm Bill § 10114(a).

USDA Rule Implementing Hemp Production Plans

(vi) procedures for reporting contact and other information to the USDA regarding each hemp producer licensed by a State or Indian Tribe; and (vii) certification by the State or Indian Tribe that it has the resources and personnel necessary to carry out the practices and procedures described in the plan. Under the USDA Rule, the USDA must conduct an audit to confirm compliance of a State or Indian Tribe with an approved plan at least once every three years.

Neither the USDA Rule nor the 2018 Farm Bill authorizes the export of hemp outside the U.S. The USDA suggests that regulatory action would be required in order to allow hemp to be exported.⁹ The USDA also noted that the importation of hemp seeds is separately regulated by the USDA's division of Animal and Plant Health Inspection Service.¹⁰

Scope of the USDA Rule

Although the 2018 Farm Bill legalizes the production of hemp under Federal law, it preserves the authority of the States and Indian Tribes to establish more stringent production standards within their borders or to prohibit hemp production entirely. State and Tribal Plans that authorize hemp production must be approved by the USDA. The conditions for approval of a State or Tribal Plan are as follows:

- ***Licensees***: State and Tribal Plans must provide for procedures for review of each applicant's criminal history in connection with the licensing process, and persons convicted of a Federal or State law felony related to a controlled substance during the past 10 years must be prohibited from obtaining a license.¹¹
- ***Sampling and testing for THC Levels***: Plans must establish procedures for sampling and testing of hemp produced under the State or Tribal Plan to ensure that the product does not exceed 0.3 percent THC, measured on a dry weight basis.¹² Testing must be carried out in a laboratory registered with the Drug Enforcement Agency ("DEA"), applying a reliable methodology for testing THC levels,¹³ and samples must be collected by a USDA-approved sampling agent, or by a Federal, State or local law enforcement agent authorized by the USDA to collect samples, within 15 days prior to the anticipated harvest of the hemp plants.¹⁴

⁹ See Adopting Release at 58523.

¹⁰ *Id.*

¹¹ An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018 and whose conviction also occurred before that date.

¹² The 2018 Farm Bill requires that all domestically produced hemp be tested for total THC content on a dry weight basis. The dry weight methodology is described as one that takes account of the percentage of a chemical in a substance after removing the moisture. 7 C.F.R. § 990.1 "Dry weight basis."

¹³ See 7 C.F.R. § 990.1 The USDA Rule describes how State, Tribal and USDA plans must account for uncertainty in test results in their treatment of cannabis.

¹⁴ 7 C.F.R. § 990.3(a)(2)(i).

USDA Rule Implementing Hemp Production Plans

- Disposal of non-compliant plants: State and Tribal Plans must include procedures for the effective disposal of plants with levels of THC greater than 0.3 percent in accordance with DEA regulations.¹⁵ The Adopting Release notes that a plant having a THC concentration level above 0.3 percent would constitute a Schedule I Controlled Substance under the CSA.
- Collection of information regarding land used for production: State and Tribal Plans must establish a process for collection and maintenance of information related to the land used for production of hemp, including a legal description of the land and the geospatial location for each field, greenhouse, or other site where hemp will be produced.¹⁶ In addition, the plans must include a reporting procedure for States and Indian Tribes to provide information regarding each licensed producer to the USDA.
- Compliance with enforcement procedures: State and Tribal Plans must provide for annual inspections and a process for handling violations, including definitions regarding when producers have violated the plan and what constitutes a negligent act by a producer, as well as a corrective action covering violations. The USDA Rule provides that negligent violations should not be subject to criminal enforcement action but that the occurrence of three negligent violations within a 5-year period should result in suspension of the producer's license. Intentional violations would also lead to a loss of license and would be required to be reported immediately to the U.S. Attorney General, the USDA and the chief law enforcement officer of the applicable State or Tribe.
- Information sharing: State and Tribal Plans must provide for the provision of basic identifying information regarding licensees to the USDA and for retention of such records by the State or Indian Tribe for at least three years.¹⁷
- Certification of resources: All State and Tribal Plans must certify to the USDA that they have the resources and personnel necessary to carry out the practices and procedures detailed in the applicable plan.
- USDA approval and oversight: The USDA will review any submitted plan within 60 days and either approve or reject the plan by issuing an approval letter or a notification of the rejection. Rejections are subject to appeal. Amendments to a plan may not become effective until approved by the USDA.¹⁸ In the case of revocation of a

¹⁵ 7 U.S.C. §§ 1639p(a)(2)(A)(iii); 1639q(a)(2)(C).

¹⁶ See 7 C.F.R. § 990.3(a)(1)(ii).

¹⁷ See 7 C.F.R. § 990.70.

¹⁸ If a State or Indian Tribe fails to submit an amended plan to the USDA for approval within one calendar year of such plan's modification, the USDA will issue a notice to the State or Indian Tribe stating that the approval of its plan will be revoked effective as of the beginning of the next calendar year.

USDA Rule Implementing Hemp Production Plans

State or Tribal Plan, producers in the State or Tribal territory will be able to submit applications for a license under the USDA Plan.¹⁹

Department of Agriculture Plan

The USDA Rule also establishes the USDA Plan, which regulates production of hemp in State or Tribal territories in which hemp production is legal but there is no State or Tribal Plan in place and no State or Tribal plan is pending with the USDA that governs the activity.²⁰ All producers of hemp growing the plant in a State or Tribal territory that does not have an approved State or Tribal Plan must submit a license request to the USDA. The conditions for approval of a licensee under the USDA Plan are expected to be similar to those for State or Tribal Plans, and the operating conditions under the USDA Plan are also expected to be similar to those under the State and Tribal Plans. The USDA will accept applications during the initial period of one year after the effective date of the USDA Rule. After the first year, applications must be submitted between August 1 and October 31 of each year. Licenses will be valid for three years.

Effectiveness of the USDA Rule and Continued Effectiveness of the 2014 Farm Bill

The USDA adopted the USDA Rule as an interim final rule under the “good cause exception” to the Administrative Procedures Act without first circulating the proposed rule for notice and comment. In doing so, the USDA noted Congress’s directive to it to issue regulations as expeditiously as practicable and indicated that it was seeking comments on the USDA Rule and would reflect them in the final rule, which it expected to finalize within the next two years. The USDA also provided that hemp production plans adopted for research purposes under the 2014 Farm Bill will sunset on October 31, 2020.

* * * *

Adoption of the USDA Rule is a first step by the U.S. Government toward rationalizing the provisions of the CSA relating to cannabis. As noted in the Adopting Release, “this action eliminates the uncertain legal status at the Federal level of hemp production and allows the USDA to provide hemp producers with crop insurance programs, potentially reducing risk to producers and providing easier access to capital.”²¹ Although the legality of ingestible CBD as well as the conflict between State and Federal law in relation to cannabis continue to create legal uncertainty for producers, distributors and

¹⁹ Once the USDA issues a notice of revocation to the State or Indian Tribe, producers may submit production license applications to the USDA under the USDA Plan for a period of 90 days. The USDA will accept such applications whether or not that time period coincides with the annual period in which the USDA normally accepts applications.

²⁰ 7 C.F.R. § 990.20(a).

²¹ See Adopting Release at 58540.

USDA Rule Implementing Hemp Production Plans

their service providers, the USDA Rule establishes a clear safe harbor for hemp producers and their service providers and therefore provides helpful certainty to businesses to ensure that they are acting in compliance with Federal law.

If you have any questions regarding this client alert, please contact the following attorneys or the Willkie attorney with whom you regularly work.

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