LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

Federal Hemp Regulation: USDA's Recent Interim Final Rule

MARCH 2020

BACKGROUND

The Agriculture Improvement Act of 2018, enacted in December 2018 and commonly referred to as the 2018 Farm Bill,[1] puts in place the most recent changes to hemp-related federal statutory law. Expanding upon the hemp-related provisions of its predecessor, the 2014 Farm Bill, the 2018 Farm Bill modifies federal hemp regulation in several ways by:

- changing the legal definition of hemp to "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;"[2]
- amending the federal controlled substance schedules by removing hemp from the definition of marijuana[3] and creating an exception for the amount of tetrahydrocannabinol (THC) in hemp[4];
- allowing private farmers (producers) to cultivate hemp;[5] and
- including hemp farmers under the Federal Crop Insurance Act[6] and adding hemp to the list of agricultural commodities.[7]

The 2018 Farm Bill grants federal regulatory oversight of hemp production to the U.S. Department of Agriculture (USDA). In order to legally grow hemp, a private producer must obtain a license from a state or tribe that establishes a hemp production program approved by the Secretary of the USDA (Secretary). Alternatively, if a producer is in a jurisdiction without a USDA-approved production program, the producer can apply for a license under the USDA's federal hemp program, assuming hemp production is not prohibited by the state or tribe where the production will occur.

USDA INTERIM FINAL RULE

On October 31, 2019, the Agricultural Marketing Service (AMS) of the USDA published an interim final rule (IFR), entitled, "Establishment of a Domestic Hemp Production Program."[8] The IFR is effective until November 1, 2021 and covers the process by which the USDA will approve state and tribal hemp production programs and details the federal hemp program available where no USDA-approved program exists. USDA accepted comments on the IFR until January 29, 2020.[9]

There are many sources available that generally review the hemp-related provisions of the 2018 Farm Bill. There are fewer resources, however, that succinctly address the contents of the USDA's IFR. This factsheet provides a summary of the IFR and how it distinguishes between the state/tribal approval process and the USDA's federal hemp program as well as some of the public comments to it.

STATE AND TRIBAL HEMP PRODUCTION PROGRAM PLANS[10]

If a state or tribe wishes to have primary regulatory authority over the production of hemp within its jurisdiction, then it is required to submit a hemp production program plan (plan) to the Secretary

explaining how it will monitor and regulate hemp production. The plan submitted must include procedures addressing the following eight program aspects: (1) collecting, maintaining, and reporting to the Secretary relevant, real-time information for each producer licensed to produce hemp under the state or tribal plan; (2) accurate and effective sampling of all hemp produced; (3) accurate testing of a sample's delta-9 THC content concentration level; (4) notifying the plan's administrator of instances where sampled plants exceed permissible delta-9 THC levels and providing the administrator with records demonstrating the appropriate disposals of non-compliant plants and materials; (5) how the state or tribe will comply with enforcement procedures; (6) conducting annual inspections of a subset of producers to verify that hemp is not produced in violation of the law; (7) submitting required information[1] to the Secretary; and (8) certifying that the state or tribe has the resources and personnel to carry out the practices and procedures.

An important part of a state or tribal plan is detailing the procedure for sampling and testing hemp. The USDA requires states and tribes to collect samples from the flower material of the *Cannabis* plants within 15 days prior to the harvest date for delta-9 THC concentration testing. The method used for sampling must ensure that the sample represents a homogeneous composition of the lot. Sampling agency personnel must be provided with complete and unrestricted access during business hours to all hemp plants and all land, buildings, and structures used for the cultivation, handling, and storage of hemp. The producer cannot harvest any of the hemp crops prior to samples being taken.

According to the IFR, all sample testing must be completed by a Drug Enforcement Administration (DEA) registered laboratory for the testing to be considered valid. In February 2020, however, USDA informally announced that it is delaying enforcement of this provision until the final rule is published, or October 31, 2021, whichever comes first.[11] According to the USDA, this decision allows the DEA time to increase its analytical lab capacity.

The testing methodology for a state or tribal hemp production program must consider the potential conversion of delta-9 tetrahydrocannabinolic acid (THC-A) into THC and measure the total available THC derived from the sum of the THC and THC-A content. Measurements of uncertainty must be estimated and reported out with the test results. In order for hemp product to be considered acceptable, the reported range of THC content concentration level on a dry weight basis must encompass 0.3 percent or less. For example, if testing shows that a sample has a THC content concentration level of 0.35 percent with an uncertainty of +/- 0.06 percent, the sample's THC content concentration ranges from 0.29 percent to 0.41 percent. Because 0.3 percent is within that range, the sample has an acceptable THC level for hemp. If a sample exceeds the acceptable THC level, it is conclusive evidence that the lot represented by the sample is not in compliance.

Hemp product lots that do not meet acceptable THC levels may not be handled or processed any further, and the producer is required to ensure that the lot is discarded. Non-conforming lots are considered marijuana because of the THC content. Accordingly, the IFR requires the disposal to be handled by an entity authorized to handle schedule I controlled substances under federal law, such as a law enforcement officer or DEA-registered reverse distributor.[12] With respect to the provision that requires testing by DEA-registered laboratories, in February 2020, the USDA informally announced

[1] States and tribes are required to submit a hemp producer report and a hemp disposal report each month to the USDA. Additionally, states and tribes must submit an annual report to the USDA by December 15 of each year describing the (1) total planted acreage; (2) total harvested acreage; (3) total acreage disposed; and (4) a laboratory test results report.

that it is delaying enforcement of the requirement that producers use a DEA-registered reverse distributor or member of law enforcement to dispose of non-compliant plants until the final rule is published, or October 31, 2021, whichever comes first.

Within 60 days after the receipt of a state or tribal plan, the Secretary will either approve or disapprove it. Once a plan is approved by the USDA, the plan remains in effect unless an amended plan is needed due to a state or tribe making substantive revisions to its hemp production program. The Secretary may conduct an audit of the compliance of a state or tribe with its approved plan. Compliance audits can be scheduled, at a minimum, once every three years. If the audit reveals noncompliance with the USDA- approved plan, the USDA will provide the state or tribe with corrective measures that must be completed. If the USDA determines that the state or tribe is still not in compliance after a second audit, then the USDA may revoke its approval of the plan for up to one year.

The IFR requires that each state or tribal plan address so-called "negligent violations" by hemp producers. These negligent violations include, but are not limited to: (1) failure to provide a legal description of the land used for farming; (2) failure to obtain a license from the state or tribe; and (3) producing *Cannabis* with a THC concentration exceeding the acceptable hemp THC level.[13] It is not a negligent violation to exceed the acceptable THC level if a producer makes a reasonable effort to grow hemp and the *Cannabis* does not have a THC concentration of more than 0.5 percent. If a producer negligently violates plan requirements three times in a five-year period, he or she will be ineligible to produce hemp for a period of five years. Additionally, plans must contain provisions related to producer violations made with a culpable mental state greater than negligence (*e.g.*, recklessness). If a producer violates plan requirements with a culpable mental state greater than negligence, the state or tribe must immediately report the producer to the U.S. Attorney General and the chief law enforcement officer in the state or tribe. Finally, each plan must provide that a potential producer with a state or federal felony conviction relating to a controlled substance is ineligible to participate in the program and cannot produce hemp for 10 years from the date of his or her conviction.

USDA HEMP PRODUCTION PLAN[14]

In states or tribal areas where hemp production is legal but no USDA-approved state or tribal plan exists, hemp producers must adhere to the federal hemp production program as detailed in the USDA's federal hemp production plan (USDA plan). As in the case of state or tribal programs, a potential producer with a state or federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction from participating. Any person who intends to produce hemp under the USDA plan must obtain a valid license prior to producing, cultivating, or storing hemp. Applicants may apply to the USDA for a new license between December 2, 2019 and November 2, 2020. In subsequent years, applicants may apply for a new license or renewal from August 1 through October 31 of each year. USDA-issued licenses will be valid for three years and will expire on December 31 of the expiration year.

The USDA will not issue a new or renewal license unless: (1) the application submitted is complete and accurate; (2) the criminal history report submitted confirms that the applicant has not been convicted of a felony relating to a controlled substance within the past 10 years; (3) all required reports have been submitted; (4) the application contains no materially false statements or misrepresentations; (5) the applicant's license is not currently suspended; (6) the applicant is not applying for a license as a stand-in for someone whose license has been suspended, revoked, or is otherwise ineligible to participate; (7) the jurisdiction where the person produces (or will produce) hemp does not have a USDA-approved plan or has not submitted a plan to the USDA for

approval; and (8) that same jurisdiction does not prohibit the production of hemp. A producer with operations in a location covered under a state or tribal plan must be licensed by the state or tribe and not by the USDA.

No earlier than 15 days prior to the anticipated harvest of the plants, a producer must have an approved law enforcement agency or person designated by the USDA collect samples from the flower material of the plants for THC concentration level testing. The sampling procedures and testing methodologies for the USDA plan are identical to those required in state and tribal plans. Any sample test result exceeding the acceptable hemp THC level is conclusive evidence that the lot represented by the sample is not in compliance with program requirements. After laboratory testing is performed, the producer must harvest the crop within 15 days

of the date of sample collection. If the producer fails to do so, a secondary pre-harvest sample of the lot must be submitted for testing. Lots that meet the acceptable hemp THC level can enter the stream of commerce. Plants exceeding the acceptable hemp THC level must be disposed of in accordance with federal controlled substance and DEA regulations.

Producers may be audited by the USDA once every three years to ensure compliance with USDA plan requirements. A hemp producer will be subject to enforcement for committing the following "negligent violations;" (1) failing to provide an accurate description of the land used for farming; (2) producing hemp without a license; and (3) producing *Cannabis* that exceeds the acceptable hemp THC level. It is not a negligent violation if the producer makes reasonable efforts to grow hemp and the *Cannabis* does not have a THC concentration of more than 0.5 percent on a dry weight basis. For each negligent violation, the USDA will require a correction action plan, which will be in place for a minimum of two years from the date of the producer's approval. A producer that commits negligent violations three times in a five-year period will have his or her license revoked and will be ineligible to produce hemp for a period of five years. If the USDA determines that a licensee has violated the terms of the license with a culpable mental state greater than negligence, the USDA will report the licensee to the U.S. Attorney General and the chief law enforcement officer in the state or tribe where the producer is located. In addition, the USDA will immediately revoke the license of a producer if the producer: (1) pleads guilty to, or is convicted of, any felony related to a controlled substance; (2) makes any materially false statement to the USDA with a culpable mental state greater than negligence; or (3) is found to be growing *Cannabis* exceeding the acceptable hemp THC level with a culpable mental state greater than negligence.

APPEALS[15]

Persons who believe they are adversely affected by the denial of a license application or a license renewal under the USDA hemp production program may appeal the decision to the AMS Administrator. Additionally, those who believe they have been adversely affected by the termination or suspension of a USDA hemp production license may also appeal the decision. States and tribes who have been denied approval of their state or tribal hemp plan may also appeal the decision to the AMS administrator.

PUBLIC COMMENTS ON THE USDA INTERIM FINAL RULE

Over 4,600 public comments were filed during the public comment period on the USDA's IFR (October 31, 2019, through January 29, 2020). Submitted comments appear to most commonly relate to the following areas of the regulation:

- **Producing crops with a THC concentration of more than 0.5 percent is a negligent violation.** Commenters believe that the 0.5 percent standard for a negligent violation does not allow enough room for unintentional error or analytical test variance. There are concerns that an automatic finding of negligence at THC levels above 0.5 percent will deter farmers from entering the hemp industry and make it difficult for farmers that do to obtain crop insurance.
- **Destroying all crops with above-acceptable THC levels.** While commenters agree that non-compliant crops should not enter the stream of commerce, there are

concerns about the waste associated with destroying non-compliant plants. Commenters suggest allowing non-compliant plants, up to a certain THC level, to be used on the producing farm as feed and bedding for animals or fuel.

- **Testing by DEA-registered laboratories only.** With few laboratories registered with the DEA, commenters worry that limiting testing only to DEA-registered laboratories could place a strain on these labs, delay testing, and create a bottleneck effect that could delay the harvest of hemp. As noted above, the USDA is delaying enforcement of this provision.
- **Harvesting crops within 15 days of sample collection under the USDA plan.** Commenters believe that the 15-day harvest window is not practical for many farms and should be extended to provide greater flexibility. Factors such as large crop size, staffing shortages, inclement weather, and equipment issues, could all prevent a farm from harvesting its crop within the 15-day window.

One cannot predict exactly how or if the USDA will revise the IFR before making it final. Given the volume of comments that mention these four parts of the regulation, however, it is possible that one or more of these aspects of the rule will be modified when the final rule is published in 2021.

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[1] Pub. L. No. 115-334.
[2] 7 U.S.C. § 1639o(1).
[3] 21 U.S.C. § 802(16)(B)(i).
[4] 21 U.S.C. § 812(c)(17).
[5] 7 U.S.C. §§ 1639o – 1639s.
[6] 7 U.S.C. § 1508.
[7] 7 U.S.C. § 1518.
[8] 84 FR 58522.
[9] 84 FR 69295.
[10] 84 FR 58522, 58556-59.
[11] https://www.ams.usda.gov/rules-regulations/hemp/enforcement.
[12] A "reverse distributor" is an entity authorized by DEA to acquire controlled substances from another DEA registrant or law enforcement for the purpose of return or destruction. See https://practicegreenhealth.org/sites/default/files/2019-03/best_practices_for_disposal_of_controlled_substances_0_0.pdf.
[13] 84 FR 58558.
[14] 84 FR 58522, 58559-58562.
[15] 84 FR 58522, 58562-63.

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