

USDA PUBLISHES FINAL RULE AND GUIDANCE FOR DOMESTIC HEMP PRODUCTION

Hodgson Russ Hemp & Medical Cannabis and Agriculture Alert February 10, 2021

The U.S. Domestic Hemp Production Program—the USDA's Final Rule regulating the domestic production of hemp—is scheduled to take effect on March 22, 2021. The Final Rule, which supersedes the interim rule published on October 31, 2019, incorporates public comments to the interim rule, and "lessons learned" during the 2020 growing season.

In our January 22 alert, we mentioned that the Final Rule was subject to the Biden Administration's "Regulatory Freeze Pending Review." However, there is no indication that the USDA will review the Final Rule or open any comment period prior to it becoming effective on March 22, 2021. This alert will be updated if additional details become available.

Under the Final Rule, in order to produce hemp, a producer must be licensed or authorized under a state hemp program, a tribal hemp program, or the USDA hemp program. The USDA recommends that producers first reach out to their local state department of agriculture or tribal government to determine if a production plan has been submitted or approved by the USDA. If the applicable state or tribe has an approved plan, or is in the process of developing a plan, a producer must apply and be licensed with the state or tribe. If the state or tribe does not have a pending or USDA approved hemp production plan, a producer may apply for a USDA hemp production license.

Here is a rundown of the key provisions in the USDA hemp production plan:

USDA Licensing Requirements. Any person producing or intending to produce hemp under the USDA plan must apply for, receive, and maintain a valid license from the USDA. The USDA accepts applications on a rolling basis. An applicant cannot receive a hemp production license from a state, tribe, or USDA, if he or she has been convicted of a felony related to a controlled substance in the last 10 years. Additionally, a person cannot produce under the USDA plan if hemp production is prohibited by the state where production will occur, or the production will be conducted in a state with a USDA-approved state plan (even if the state plan is awaiting USDA approval). Producers that produce hemp for research must also obtain a USDA hemp production license. Such producers, however, are not subject to the same sampling requirements as non-research producers.

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Unless revoked or suspended, USDA-issued licenses will be valid until December 31 of the year three years after the issuance year. Licenses are non-transferable, and may be renewed by submitting an application for renewal prior to expiration. If an application is denied, the applicant can appeal the denial.

Recordkeeping requirements. USDA licensees are required to report hemp crop acreage to the Farm Service Agency (FSA) within 30 days of hemp being planted. Licensees must also provide a street address and geospatial location (where practicable) of each lot, greenhouse, building, or site where hemp will be produced, as well as the acreage or indoor square footage dedicated to the production of hemp.

Sampling Procedures. No more than 30 days prior to the anticipated harvest, USDA licensees must have samples collected by a USDA-approved sampling agent—producers cannot collect their own samples. The samples must be collected from the flowering tops of the plants by cutting the top five to eight inches from the main stem, terminal bud, or central cola of the flowering top of the plant. Hemp producers may not harvest hemp prior to the hemp being sampled. An authorized representative of the licensee must be present during a scheduled sample collection, if possible. In addition, the sampling agent must have complete and unrestricted access to the entire premises and all hemp and other cannabis plants during business hours. Producers must harvest the crop no later than 30 days from sample collection. Otherwise, a second preharvest sample must be submitted for testing. Detailed information on sampling protocols and guidelines is found in USDA's published Sampling Guidelines.

Testing Procedures. Prior to harvest, all samples from hemp lots produced under the USDA, state or tribal hemp production plans must be tested for THC concentration levels. Testing laboratories must meet certain USDA requirements. Among them, laboratories must ensure and demonstrate the validity and reliability of both its test results and of the analytical method selected. In addition, the laboratory must be able to successfully perform the method. The laboratory must also have an effective disposal procedure for non-compliant samples. The USDA's published Laboratory Guidelines provide additional details on sampling and testing requirements. The Final Rule provides that after December 31, 2022, licensees must use testing laboratories that are registered with the DEA.

Lots that meet the acceptable hemp THC level may enter the stream of commerce. Lots that do not meet the accepted THC level are considered non-compliant cannabis plants. A producer may request additional pre-harvest testing if they believe the original delta-9 THC concentration test results were in error—and may use the same or a different laboratory.

Disposing of Noncompliant Cannabis. If results of a test sample show that any cannabis plant exceeds the acceptable 0.3 percent hemp THC level, the plant constitutes marijuana. In that event, producers must: (1) use a DEA-registered reverse distributor or law enforcement to dispose of noncompliant plants; (2) ensure the disposal of the noncompliant plants on site at the production facility; or (3) perform remediation activities to render noncompliant cannabis, compliant. If the producer elects to remediate the crop, the post-remediated crop must be sampled and tested again to determine the THC concentration levels. Producers must notify USDA of their intent to dispose of or remediate noncompliant plants, and must verify the disposal or remediation after it is completed. FDA has issued Remediation and Disposal Guidelines for Hemp Growing Facilities.



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Compliance. The USDA may verify a licensee's compliance by conducting an audit once every three years, unless otherwise determined by the USDA. Audits can entail records reviews and visits to farms, storage facilities, or any other location affiliated with a producer's hemp operation. If an audit determines that a producer is not in compliance with the hemp program, the USDA will issue a corrective action plan to the producer. If additional instances of noncompliance occur, the USDA may revoke the producer's license for one year or until the producer becomes compliant, whichever occurs later.

Violations. Producers will be subject to a negligent violation (which is not subject to criminal enforcement) if they fail to provide an accurate legal description of land where hemp is produced, produce hemp without a license, or produce cannabis exceeding the acceptable hemp THC level. A negligent violation is not committed, however, if producers make "reasonable efforts to grow hemp and the cannabis does not have a total THC concentration of more than 1.0 percent on a dry weight basis." For each negligent violation, USDA will require a corrective action plan from the producer, which will be in effect for a minimum of two years from the date of the violation. Any subsequent negligent violation will result in a new corrective action plan with a heightened level of quality control, staff training, and quantifiable action measures. A producer that negligently violates their license 3 times in a 5-year period will have their license revoked and be ineligible to produce hemp for 5 years from the date of the third violation.

Appeals. A person may appeal the denial of a license application. Additionally, a licensee may appeal the denial of a license renewal or license suspension or revocation.

Production of Hemp for Research. The Final Rule includes a provision governing the production of hemp for research purposes. In particular, any hemp that is produced for research that does not enter the stream of commerce is not subject to certain sampling requirements under the Final Rule. Alternatively, a producer for research must adopt and carry out a USDA approved alternative sampling method "that has the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis Sativa* L. that will be subject to this alternative method will not test above the acceptable hemp THC level."

Note that the Final Rule does not affect industrial hemp that was or is being cultivated under the 2014 Farm Bill programs—such industrial hemp remains subject to the 2014 Farm Bill's requirements.

This alert will be updated as soon as more details emerge. For more information, please contact Melissa Subjeck (716.848.1719), Sarah Miller (716.848.1509), or any member of Hodgson Russ's Agriculture Practice or Hemp & Medical Cannabis Practice.

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