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Government Matters

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USDA Issues Final Rule to Establish Domestic Hemp Production Program and Approve State and Tribal Oversight Plans

Effective March 22, 2021, USDA's Final Rule Sets Forth Regime for Producing Hemp Products in the United States, Superseding Interim Rule

On January 9, 2021, the U.S. Department of Agriculture (USDA) issued a [final rule](#)¹ to govern the production of hemp in the United States. This rule is currently scheduled to go into effect in two months, although new USDA officials in the Biden Administration may ultimately postpone that date. Assuming there is no delay, the final rule will take effect on March 22, superseding the [interim](#) rule that has been in place since October 2019.²

As we discussed in a previous client alert on the interim rule,³ the Agricultural Improvement Act of 2018 (1) removed non-intoxicating "hemp" from the definition of "marijuana" such that it is no longer regulated as a controlled substance; and (2) requires USDA to promulgate regulations and guidelines to establish and administer a program for the production of hemp in the United States. As the interim rule does, the final rule also establishes two, largely parallel sets of regulations that outline requirements (1) for State or Tribal licensure and regulation of hemp production within their jurisdictions; and (2) for USDA licensure and oversight of hemp production in the jurisdictions choosing not to regulate hemp.

The interim rule drew close to 6,000 comments. The final rule does not differ in major ways from the interim rule, but it is generally more favorable to hemp producers, States, and Tribes.

OVERVIEW OF USDA'S FINAL RULE

Like the interim rule, the final rule creates a regime in which regulatory authority over hemp cultivation is split amongst states, tribes, and USDA. States or tribes may obtain primary regulatory authority over the production of hemp in their State or Territory by obtaining an approved plan from the Secretary of Agriculture. USDA regulates all hemp production that exists outside a State or Indian Territory with primary regulatory authority. At the time of issuance of the final rule, USDA had (1) approved approximately 45 states' and tribes' hemp plans and (2) granted 380 licenses to producers in states or tribal territories without approved plans.

Comparable substantive and procedural requirements in the two sets of regulations address:

1. Reporting about production locations and cultivated acreage.
2. Mandatory issuance and maintenance of licenses (e.g., notification of certain changes) to persons intending to produce, cultivate, or store hemp.
3. Access for inspection of land and structures used for the cultivation, handling, and storage of hemp and related items.
4. Sampling and analytical testing requirements to confirm "acceptable hemp THC levels."
 - The final rule maintains the interim requirement that hemp must remain below 0.3% total THC on a dry-weight basis.⁴
 - The final rule maintains the interim requirement that only laboratories with a Drug Enforcement Administration (DEA) registration be used for testing. However, USDA has a policy of not enforcing this requirement until at least December 2022.
 - The final rule modifies sampling requirements to be less burdensome.
 - USDA has now provided more details about how to sample crops, which could help reduce the number of "hot" crops that have a non-acceptable amount of THC.⁵
 - The final rule will give 30 days (rather than 15 days) to collect samples before harvest, which will ease the burden on producers and regulators alike.
 - The final rule also does away with the interim rule's requirement that states and tribes use a specific methodology in collecting samples. With USDA approval, states and tribes can implement a more "performance-based" method for collecting samples that can take into account a variety of factors such as seed certification processes; whether the producer is a researcher at an institution of higher learning or funded by a federal, State, or Tribal government; whether the producer has consistently produced compliant hemp plants over an extended period of time; whether a producer is growing any kind of hemp that does not reach the flowering stage; and other similar factors.
5. Disposal of "hot" plants that exceed the 0.3% THC limit.
 - The interim rule required these "hot" crops to be totally destroyed in accordance with DEA controlled substance regulations. The final rule relaxes these requirements substantially.
 - The final rule permits several, more economical alternative ways to dispose of these crops including through plowing under; mulching/composting the hemp; disking; shredding with a bush mower or chopper; burying; or burning.

- Producers can also remediate their plants by “removing and destroying flower material, while retaining stalk, stems, leaf material, and seeds.”
 - Producers may also shred the entire plant to create a “biomass-like material” and then retest it for compliance.
 - Producers no longer need to use a DEA-registered distributor or law enforcement to dispose of hemp that exceeds acceptable TCH levels.
6. Recordkeeping and reporting obligations.
 7. Potential violations and enforcement actions.
 - USDA’s interim and final rules describe “negligent violations” that will yield a Notice of Violation and require corrective action, as well as “culpable violations” (made with a culpable mental state greater than negligence) that will be reported to federal and state law enforcement officials.
 - Producers must dispose of plants that exceed 0.3% THC. However, if the plant tests at or below a negligence threshold, the producer will not have committed a negligent violation. The final rule raises the negligence threshold from 0.5% to 1%, which means that if hemp tests above 0.3% but below 1%, it will not be considered a negligent violation (but will still need to be destroyed).
 - The final rule makes clear that the number of violations that a producer can receive is limited to one per calendar year, which means that if multiple lots or fields test above that level, a producer will not receive multiple violations.
 - If a producer receives more than three negligent violations in five years, it will be ineligible to participate in the program for a five-year period.
 - The rules further address the effect of felony convictions (which create a 10-year ineligibility restriction on producing hemp) and material false statements (which may lead to ineligibility to participate in hemp production).

PRACTICAL IMPLICATIONS

The USDA final rule—and interim rule in effect until the final rule goes into effect on March 22—directly impacts companies that currently grow and handle hemp or intend to do so.

In addition, companies that procure hemp or hemp-derivatives—for example, cannabinoids like cannabidiol (CBD) to be used as an ingredient in consumer products—should consider the impact of the final rule on their suppliers. For example, do suppliers have all necessary licenses and standard operating procedures that are required to maintain up-to-date authorizations? Will materials be tested in accordance with applicable standards, or is it possible that materials may be deemed out of compliance—potentially raising controlled substance compliance issues? Have suppliers been inspected and been found to be in violation of applicable legal standards? What is the nature, scope, and status of corrective actions undertaken by suppliers?

It is worth repeating that hemp production is regulated by a number of oversight bodies, including the federal USDA, DEA, and also many State and Tribal regulators. Awareness of the location of activities and the applicable regulatory structure will be important from compliance and due diligence perspectives.

Nothing in USDA's final rule limits other parts of the hemp and hemp product regulatory regime in the United States. Anything other than hemp cultivation—i.e., importation of seed and whatever happens after growth—is outside the scope of the final rule. Additional agencies such as the Food and Drug Administration (FDA) regulate fundamental aspects of hemp product manufacturing, marketing, and distribution. If a product is a drug, food, dietary supplement, or cosmetic, for example, requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations are an overlay to the hemp production regulatory regime.

Companies that work with hemp and hemp-derivatives should also understand that regulation in this area evolves often. The White House issued a memorandum on January 20, asking agencies to withdraw any rules that had not yet been published in the Federal Register and consider whether any newly published rules should be reconsidered. In addition, FDA has already withdrawn its "Cannabidiol Enforcement Policy," which it had submitted to the White House Office of Management and Budget in July. USDA has not withdrawn its final rule on hemp production, but it has been reported that the Agency is reviewing it.

Congressional amendment may also change this landscape. The final rule states that hemp must remain below 0.3% total TCH on a dry-weight basis. Senator Paul, however, has introduced a bill to amend that limit to 1%.

FURTHER ANALYSIS

King & Spalding works with regulated industry and other interested actors to interpret the USDA interim and final rules and other regulatory requirements (e.g., FDA, DEA, and state obligations), prepare comments to the government, perform diligence assessments, and provide transactional support.



¹ See Agricultural Marketing Service, USDA, “Establishment of a Domestic Hemp Program,” 86 Fed. Reg. 5596 (Jan. 19, 2021) (establishing new 7 C.F.R. Part 990).

² See Agricultural Marketing Service, USDA, “Establishment of a Domestic Hemp Program,” 84 Fed. Reg. 58522 (Oct. 31, 2019) (establishing new 7 C.F.R. Part 990).

³ King & Spalding Client Alert: USDA Issues Interim Final Rule to Establish Domestic Hemp Production Program and Approve State and Tribal Oversight Plans (Oct. 31, 2019), available at: <https://www.jdsupra.com/legalnews/usda-issues-interim-final-rule-to-35659/>

⁴ Total THC is the sum of the delta-9 THC and tetrahydrocannabinolic acid (THCA). Unlike the delta-9 THC, THCA does not itself produce psychoactive effects. However, THCA can be converted to THC through decarboxylation.

⁵ The sample will include more stem and leaf material, which typically contains lower levels of TCH than do flowers. The sample must be taken approximately 5 to 8 inches from the “main stem” (including the leaves and flowers), “terminal bud” (at the end of a stem) or “central cola” (cut stem that could develop into a bud) of the flowering top of the plant.

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