

**OCTOBER 31, 2019**

For more information,
contact:

Christina M. Markus
+1 202 626 2926
cmarkus@kslaw.com

Lisa M. Dwyer
+1 202 626 2393
ldwyer@kslaw.com

D. Kyle Sampson
+1 202 626 9226
ksampson@kslaw.com

Jarred L. Reiling
+1 202 626 5511
jreiling@kslaw.com

King & Spalding

Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500

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

Effective upon Publication, USDA's Interim Final Rule Sets Forth One Important Part of the Regime for Marketing Hemp Products in the United States

This week, the U.S. Department of Agriculture (USDA) issued an interim final rule to govern the production of hemp in the United States.¹ In December 2018, Congress removed non-intoxicating "hemp" (defined as 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) from the definition of "marijuana."² Hemp therefore is no longer regulated as a controlled substance. Hemp producers, however, must be licensed and operate in accordance with either (i) a USDA-approved, State or Tribal regulatory plan, or (ii) regulations directly administered by USDA's Agricultural Marketing Service.

USDA's interim final rule becomes effective today. Comments from interested stakeholders will be accepted until December 30, 2019. USDA intends ultimately to replace the interim final rule with a (potentially modified) final rule on or before November 1, 2021 (i.e., two years from now).

OVERVIEW OF USDA'S INTERIM FINAL RULE

Under the interim final rule, USDA has established two, largely parallel sets of regulations: The first set of regulations outlines requirements for State or Tribal licensure and regulation of hemp production within their jurisdictions; the second set outlines requirements for USDA licensure and oversight of hemp production in the jurisdictions choosing not to regulate hemp



production. It is not yet known how many States and Tribes will seek to administer their own agricultural programs. USDA's "[State and Tribal Plan Review](#)" table identifies 10 States and 10 Tribal governments that submitted proposed plans before the interim final rule was put into place. The National Association of State Departments of Agriculture [suggests a much larger number](#), stating this week: "Hemp is currently legal to grown in 46 states, and all of those states have indicated they will submit a plan to the USDA."

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":
 - Samples of pre-harvest flower material must be collected within 15 days prior to an anticipated harvest. Testing during this period is intended to accurately determine THC levels (which can change over time) at the point of harvest, yet also allow for variables such as rain and equipment delays.
 - The interim final rule requires that only laboratories with a Drug Enforcement Administration (DEA) registration be used for testing.
 - Testing methodologies must be validated, and must consider the potential conversion of delta-9 tetrahydrocannabinolic acid (THC-A) present in hemp into THC. Total THC levels are to be determined and reported on a dry weight basis. A "measurement of uncertainty" must be reported with test results. USDA's current views on sampling and analytical testing methods are discussed in detail [here](#), and USDA has specifically requested that stakeholders comment on these topics.
5. Disposal of material that exceeds acceptable hemp THC levels. Such material, by definition, is "marijuana" and must be handled in accordance with DEA controlled substance regulations.
6. Recordkeeping and reporting obligations.
7. Potential violations and enforcement actions:
 - USDA's interim final rule describes "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. The rule further addresses 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 interim final rule 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 interim 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, 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.

Hemp importation and exportation issues require further elucidation. USDA clarified that the interim final rule generally does not address these issues.

Finally, nothing in the USDA's interim final rule limits other parts of the hemp and hemp product regulatory regime in the United States. 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.

FURTHER ANALYSIS

King & Spalding works with regulated industry and other interested actors to interpret the USDA interim final rule and other regulatory requirements (e.g., FDA, DEA, and state obligations), prepare comments to the government, perform diligence assessments, and provide transactional support. We invite you to join our upcoming [webinar roundtable](#) on November 21, 2019, concerning "FDA Regulation of Cannabis Products: What You Should Know."

ABOUT KING & SPALDING

Celebrating more than 130 years of service, King & Spalding is an international law firm that represents a broad array of clients, including half of the Fortune Global 100, with 1,100 lawyers in 21 offices in the United States, Europe, the Middle East and Asia. The firm has handled matters in over 160 countries on six continents and is consistently recognized for the results it obtains, uncompromising commitment to quality, and dedication to understanding the business and culture of its clients.

This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice. In some jurisdictions, this may be considered "Attorney Advertising."

ABU DHABI	BRUSSELS	DUBAI	HOUSTON	MOSCOW	RIYADH	SINGAPORE
ATLANTA	CHARLOTTE	FRANKFURT	LONDON	NEW YORK	SAN FRANCISCO	TOKYO
AUSTIN	CHICAGO	GENEVA	LOS ANGELES	PARIS	SILICON VALLEY	WASHINGTON, D.C.

¹ 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).

² See generally The Agriculture Improvement Act of 2018, Public Law 115-334, § 10113 (commonly referred to as the 2018 Farm Bill).