

November 6, 2019

One Step Toward Clarity: USDA Issues Interim Final Rule Establishing Hemp Production Program

On October 31, 2019, the U.S. Department of Agriculture (“USDA”) published an [interim final rule](#) (“IFR”) establishing a domestic hemp production program consistent with provisions of the Agriculture Improvement Act of 2018 (“2018 Farm Bill”) related to hemp production. The IFR (i) outlines the provisions a state or Indian tribe, if they wish to have primary authority over the production of hemp in that state or tribal territory, must include in hemp production plans submitted to the USDA for approval (hereinafter “State/Tribal Plans”), and (ii) establishes a federally administered plan for hemp producers in states or tribal territories that do not have their own USDA-approved plan (hereinafter “USDA Plan”).

The IFR is a significant regulatory development not just for hemp producers, but also for other stakeholders in the hemp-derived products industry, including manufacturers and marketers of cannabidiol (CBD) and other hemp-derived products. Although the USDA’s IFR does not affect the regulatory authority of the U.S. Food and Drug Administration (“FDA”) or resolve the ongoing FDA regulatory uncertainty relating to CBD-containing products (see prior Ropes & Gray [Podcast](#) and [Alert](#)), the IFR nonetheless provides important clarity regarding the pathway for legally produced hemp products. Entities that grow or process hemp or that manufacture or market products with hemp-derived ingredients should review the provisions of the IFR carefully and ensure compliance with the IFR requirements, especially those relating to product testing.

The 2018 Farm Bill

As explained in a prior Ropes & Gray [Alert](#), the 2018 Farm Bill exempted hemp (including hemp derivatives) with a THC concentration of 0.3% or less from the definition of marijuana, which is a Schedule I controlled substance under the Controlled Substances Act (“CSA”). This shifted primary regulation of hemp from the federal Drug Enforcement Administration (“DEA”) to the USDA. The 2018 Farm Bill legalized the possession, processing, distribution, purchase, and sale of hemp. However, the *production* of hemp remained unlawful until the USDA established a regulatory framework to license and oversee its production—although there was a limited exception for states that had been licensing hemp production under the 2014 Farm Bill’s pilot program. The 2018 Farm Bill tasked USDA with setting minimum standards for the approval of State and Tribal hemp production Plans and with establishing regulations for federal licensure of hemp producers in states without approved production plans.

Justification for an Immediately Effective “Interim” Final Rule

Under the usual rulemaking procedures of the Administrative Procedure Act, a proposed rule must be subject to notice and comment before it may be finalized and take effect. However, the APA provides that notice and comment are not required prior to the issuance of a final rule if an agency, for good cause, finds that it would be “impracticable, unnecessary, or contrary to the public interest” to do so. The USDA determined that requiring notice and comment prior to publication of a final rule in this case met the exception based on Congress’ repeated and clear interest in the expeditious implementation of a regulatory program for domestic hemp production and the need to provide guidance prior to the 2020 growing season to other regulatory entities, the banking industry, law enforcement, and individuals and companies engaged in the production, harvesting, transportation, storage, and processing of hemp. Therefore, the agency published the rule as an IFR, effective immediately upon publication. The USDA has solicited public comments on the IFR through December 30, 2019. The IFR will technically expire on November 1, 2021, by which time the USDA intends to replace it with a final rule that addresses any public comments it receives.

Key Provisions of the IFR

State/Tribal Plans. If a state or Indian tribe wishes to have primary regulatory authority over the production of hemp within its borders, the state or tribe may submit for approval by the USDA a plan concerning monitoring and regulation of such hemp production that meets the IFR’s minimum requirements. Once a State/Tribal Plan is received, the USDA has 60 days to review and either approve of the plan or disapprove the plan and provide written notification of the basis for the disapproval.

USDA Plan. In states or tribal territories without a USDA-approved State/Tribal Plan, hemp producers may apply for a license directly from the USDA and be subject to the requirements of the USDA Plan. However, if a State/Tribal Plan is pending approval, the USDA will place any applications to produce hemp in that territory on hold until the agency makes a determination on the State/Tribal Plan.

Common Requirements of Both State/Tribal Plans and the USDA Plan. The substantive requirements of both the USDA Plan and the minimum requirements of State/Tribal Plans address the same core areas, including:

- Reporting of land information, including a legal description of the land, geospatial location, crop acreage, and licensing information associated with the site where hemp is produced.
- Sampling of hemp plants at least 15 days prior to the anticipated harvest by law enforcement or other designated persons.
- Testing of samples by a DEA-registered laboratory using post-decarboxylation or a similarly reliable analytical method to determine whether the samples contain THC content at a level that exceeds the acceptable 0.3% THC level on a dry weight basis (accounting for the measurement of uncertainty). Samples with test results above 0.3% THC may still be considered hemp, so long as 0.3% THC falls somewhere within the laboratory-determined measurement of uncertainty.
- Disposal of hemp plants that exceed the acceptable THC level in a manner consistent with the Controlled Substances Act and DEA regulations (e.g., collection and destruction by a DEA-registered reverse distributor or an authorized law enforcement official).
- Compliance and enforcement procedures to ensure hemp is being produced in accordance with the IFR, including periodic audits or inspections of hemp producers, procedures to identify and attempt to correct certain negligent violations, and reporting of violations with a culpable mental state greater than negligence to the U.S. Attorney General (among others).
- Submission of criminal history reports for all “key participants” of the hemp-producing entity, where “key participants” means “[a] sole proprietor, a partner in partnership, or a person with executive managerial control in a corporation” and “a person with executive managerial control includes persons such as a chief executive officer, chief operating officer and chief financial officer.”

Effect on Interstate Transportation. The 2018 Farm Bill and the IFR explicitly preserve the right of states and Indian tribes to regulate (or even outright ban) the production of hemp more stringently than the federal standards. However, the 2018 Farm Bill prevents a state or Indian tribe from prohibiting the interstate transportation of lawfully produced hemp or hemp products. Prior to publication of the IFR, the [USDA interpreted](#) this provision to only protect the interstate transportation of hemp produced pursuant to pilot programs under the 2014 Farm Bill. And in at least one highly publicized incident, state law enforcement officials in Idaho (where hemp production is not permitted) seized a hemp shipment passing through the state from a Colorado producer. Now that the IFR is effective, so long as hemp or hemp

products are produced according to either a state, Indian tribe, or USDA plan, no State or Indian Tribe can prohibit interstate transportation of hemp lawfully produced consistent with the requirements of the IFR. The IFR's implementation of a pathway for legally produced hemp under the 2018 Farm Bill should provide needed clarity on this issue.

Key Takeaways

Hemp producers, entities that manufacture or market hemp-containing products (and are therefore dependent on a supply of legally produced hemp), and investors in either of the foregoing should pay close attention to the implementation of the IFR in the coming months. Prior to the publication of the IFR, 10 State Plans and 10 [Tribal Plans](#) had already been submitted to the USDA for consideration. The USDA has stated that it intends to begin reviewing these State/Tribal Plan applications in November 2019 and that it will not accept any individual producer applications under the USDA Plan until December 2019. For those hemp producers located in states or tribal territories that have not yet submitted plans to USDA for approval, they may contact their State department of agriculture or tribal government to see if the state or Indian tribe intends to submit a plan. Additionally, as the USDA approves State/Tribal Plans, interested stakeholders should evaluate the extent to which these plans are more stringent than the USDA Plan.

The USDA will be accepting comments on the IFR through December 30, 2019. Ropes & Gray will continue to monitor this area for further developments. If you have any questions regarding this Alert, please contact your usual Ropes & Gray advisor.