

MEMORANDUM

From: Martin J. Hahn
Samantha Dietle

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Re: **USDA Publishes Interim Final Rule on Hemp: Key Takeaways**

On October 31, 2019, the United States Department of Agriculture (USDA) published an interim final rule (IFR) on domestic hemp production.^{1/} This rule establishes a regulatory framework for USDA oversight of domestic hemp production in accordance with the 2018 Farm Bill.^{2/} While many questions remain about how the federal government, including the U.S. Food and Drug Administration (FDA), will regulate hemp-derived products, including cannabidiol (CBD) cosmetics, dietary supplements, and food products, we've addressed below the most important takeaways from the IFR with regard to the provisions that would apply to the farmers who are growing hemp.

Scope of Interim Final Rule

The scope of the IFR is limited to the production, sampling, testing and disposal of hemp plants. The 2018 Farm Bill and the IFR's requirements (licensing, etc.) apply to hemp producers, and the regulations define producers as, essentially, farmers that grow (or cultivate) hemp plants for market.^{3/} In other words, the USDA is not regulating the processing, manufacture, testing, or marketing of hemp-derived products (including CBD products) through the IFR. FDA retains authority over the manufacturing and marketing^{4/} of CBD, and other cannabinoid-containing pharmaceuticals, foods, dietary supplements, and cosmetics, and the federal Drug Enforcement Administration (DEA) retains jurisdiction over any plants or products that contain greater than 0.3% THC on a dry weight basis. USDA also reiterates that states may not prohibit the transportation or shipment of hemp produced in accordance with the IFR (and the 2018 Farm Bill) or the 2014 Farm Bill.

^{1/} Establishment of a Domestic Hemp Production Program, 84 Fed. Reg. 58522, October 31, 2019, *available* at <https://www.govinfo.gov/content/pkg/FR-2019-10-31/pdf/2019-23749.pdf>.

^{2/} For a summary of the 2018 Farm Bill hemp provisions, see our alert at <https://www.hoganlovells.com/en/publications/president-signs-2018-farm-bill-with-hemp-reforms>.

^{3/} See 7 CFR 990.1

^{4/} The Federal Trade Commission also retains authority over the advertising of these products.

State Plans May Now Be Submitted and Federal License Applications Will Soon Follow

Under the IFR, a state or Indian tribe may submit a plan to regulate hemp cultivation within that state or Indian tribe to USDA for approval. If a state or Indian tribe does not have an approved plan, hemp cultivation in that jurisdiction is subject to USDA's own plan to regulate hemp, as set forth in the IFR.

With the publication of the IFR, USDA will now begin its review of state plans to regulate hemp production. A number of states have submitted plans to regulate hemp to USDA for approval since the passage of the 2018 Farm Bill. USDA had indicated that it would not begin its review and approval of state plans until the agency published its IFR. Therefore, for state plans submitted in the period between the passage of the 2018 Farm Bill and the publication of USDA's interim final rule, the 60-day review period began on October 31. In addition, USDA will not be issuing licenses under USDA's plan (to apply in states and Indian tribes without approved plans) for 30 days in order to allow USDA time to begin its review of state plans. USDA will not issue a license to a hemp producer under USDA's plan unless that producer is located within a state or Indian tribe that does not opt to regulate hemp. Thus, while the rule is immediately effective, USDA has delayed approval of licenses under its own plan for 30 days, and has a 60 day period to review state plans. USDA is accepting comments on the interim final rule until December 30, 2019, and intends to publish a final rule within two years.

Testing

The IFR establishes testing standards that must be met under both the federal and state plans. The regulations impose a pre-harvest sampling requirement on hemp growers.^{5/} The samples must be collected by federal, state, local, or tribal law enforcement agency or other federal, state, local, or tribal designated person and be sent to a DEA registered laboratory for testing to ensure that the plants fall below the 0.3% THC limit and, thus, are considered industrial hemp and not marijuana. The regulations allow for a "measurement of uncertainty" to be used in testing plants against this standard.^{6/} Provided that 0.3% falls within that measurement of uncertainty, the plant would be deemed to have an "acceptable hemp THC level" and be considered hemp in compliance with the federal (or state) plan. Importantly, USDA emphasizes that the definition of "acceptable hemp THC level" and the application of the measurement of uncertainty does not alter the federal definitions of marijuana or hemp.

As discussed above, the IFR does not include provisions to regulate products containing hemp-derived ingredients. Importantly, USDA emphasizes that the definition of "acceptable hemp THC

^{5/} In conjunction with the final rule, USDA has also made available on the Agricultural Marketing Service website guidelines on sampling and testing. See Sampling guidelines for hemp growing facilities, *available at* <https://www.ams.usda.gov/sites/default/files/media/SamplingGuidelinesforHemp.pdf> and Testing guidelines for identifying delta-9 tetrahydrocannabinol (THC) concentration in hemp, *available at* <https://www.ams.usda.gov/sites/default/files/media/TestingGuidelinesforHemp.pdf>.

^{6/} Specifically, the measurement of uncertainty is used to develop a range, and if 0.3% falls within the range, the sample is considered to have an "acceptable hemp THC level." The definition of "acceptable hemp THC level" contains the following example to illustrate the concept: a hemp sample is tested and reported to have a THC concentration level of 0.35%, and the measurement of uncertainty is 0.06%. The measurement of uncertainty is used to create a range or distribution based on the reported test result – in this case, 0.29% - 0.41%. Because 0.3% falls within the range created by applying the measurement of uncertainty, the sample is considered to have an acceptable THC hemp level. On the other hand, if the measurement of uncertainty for the 0.35% reported test result was 0.02%, the range would be 0.33% - 0.37%, and the sample would not be considered to have an acceptable hemp THC level because 0.3% falls outside of the range.

level” and the application of the measurement of uncertainty does not alter the federal definitions of marijuana or hemp. Thus, there should be no assumption that a measurement of uncertainty is applicable in the testing of a product to establish that the THC level falls below the threshold for DEA control.

No Seed Certification Requirements

The IFR makes clear that USDA is not establishing any seed certification requirements; however, currently, many state hemp programs impose these requirements.

No Additional Requirements Related to Importation or Exportation of Hemp Seed

The IFR does not address the importation of hemp seed, except to note the oversight of which is already regulated by USDA’s Animal and Plant Health Inspection Service (APHIS). APHIS also has jurisdiction over the import of hemp plant material for any pest-related issues that may arise. The rule does not address the export of hemp plants, but USDA stated that it would work with industry to facilitate this process if there is interest in hemp exports.

The 2014 Farm Bill, and the “Marketing Research” Exception, are Still in Effect

One issue that does not appear to be fully resolved by the interim final rule is the scope of permissible activity under the 2014 Farm Bill. USDA states that for the 2020 planting season, states and institutions of higher education can continue operating under the authority of the 2014 Farm Bill, and that the 2018 Farm Bill extension of the 2014 Farm Bill expires 1 year from the effective date of the IFR (*i.e.*, October 31, 2020). USDA explains that the 2014 Farm Bill authorized institutions of higher education and state departments of agriculture to allow for the cultivation of hemp as part of a pilot program authorized by state law for research, including market research. In the IFR, USDA acknowledges that under the authority of the 2014 Farm Bill, as a part of “market research,” hemp was cultivated and sold as inputs into various consumer products, and that USDA expects that such cultivation would have continued and even expanded in the absence of the 2018 Farm Bill. The IFR does not provide any insight into the line between bona fide market research and general commercial activity, but permits hemp cultivation and production to continue under the authority of the 2014 Farm Bill until USDA approves a state plan or begins approving licenses under USDA’s program.

The IFR Makes Clear It Does Not Preempt More Stringent State Laws on Hemp Production

USDA’s interim final rule makes clear that the 2018 Farm Bill does not preempt or limit any state or tribal law governing hemp production that is more stringent than the 2018 Farm Bill, meaning that states and tribes are free to establish requirements beyond those provided in the 2018 Farm Bill or USDA’s plan to regulate hemp, including to ban the cultivation and production of hemp.

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We will continue to monitor developments related to the implementation of USDA’s IFR, state hemp programs, and the federal and state regulation of cannabis and cannabis derived products.