

Publications

Client Alert: USDA To Begin Reviewing State Hemp Plans and Producer License Applications

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On October 31, 2019, the U.S. Department of Agriculture (USDA) published in the Federal Register an interim final rule which – as required by last December’s Agricultural Improvement Act of 2018 (popularly known as the “2018 Farm Bill”) – establishes both (1) guidelines for States and Tribes that choose to take on primary regulatory authority over the production of hemp within their respective borders, and (2) USDA’s own plan to monitor and regulate hemp production in those States and territories that do not.

While much of the framework for hemp regulation was outlined in the 2018 Farm Bill, the USDA rule provides additional detail with respect to certain key issues, such as the appropriate means of testing for delta-9 tetrahydrocannabinol (THC). In particular, the rule specifies that a representative sample must be submitted within 15 days of harvest to a laboratory registered with the Drug Enforcement Administration (DEA), and must be tested using “reliable” methodologies such as gas or liquid chromatography with detection. The laboratory must then calculate the test results’ “measurement of uncertainty” (MU), which is conceptually similar to a margin of error and expressed as a range of values within which the sample’s *actual* THC content is reasonably likely to fall. The sample will be found to have an “acceptable hemp THC level” if this range covers a value of 0.3% or less.[1] For example, if a testing laboratory reports a result of 0.35% with a MU of +/- 0.06 (and thus a range of 0.29% - 0.41%), the sample will be deemed to have an “acceptable hemp THC level” because the lower end of the range (0.29%) is below 0.3%.[2]

Relying on a “good cause” exception to the requirement for public notice and comment on administrative rules, USDA has indicated that the interim final rule is effective immediately; however, the agency will not begin to accept applications for producer licenses until **November 30, 2019**. This delay period is intended to allow States and Tribes time to submit their own regulatory plans for approval, as 20 (including Pennsylvania and Texas)[3] have already done. USDA will **not** issue departmental licenses to hemp producers while there is a draft plan pending approval for their State.

In Ohio, the Department of Agriculture (ODA) published proposed rules for the licensing of hemp producers on October 9, closing the relevant comment period just one day before the USDA rule was published. Ohio will now have the benefit of USDA's guidelines in preparing to submit its regulatory scheme for review, which it may do as soon as the proposed rules are finalized.

ODA also proposed rules for the licensing of hemp processors, including separate standards for laboratory testing of hemp products prior to distribution. Notably, because these rules contemplate that hemp processors may use cannabinoids in human and animal food, dietary supplements, cosmetics, and personal care products, they are substantially more permissive than applicable Federal law.[4]

The USDA and ODA rules are available in full at the links below:

- [USDA interim final rule](#);
- [ODA proposed rule for cultivating licenses](#);
- [ODA proposed rule for processing licenses](#).

If you have questions about the new rules or their potential impact on your business, please contact Elizabeth T. Smith, Dan Shuey, Mairi K. Mull or your regular Vorys attorney.

[1] Per the 2018 Farm Bill, cannabis with a THC content above 0.3% is considered to be "marijuana" and a Schedule I controlled substance.

[2] This example is found in the interim final rule at p. 58525.

[3] To view the status of submitted plans, visit: <https://www.ams.usda.gov/rules-regulations/hemp/state-and-tribal-plan-review>.

[4] The federal Food and Drug Administration has issued "generally recognized as safe" ("GRAS") notices for three food ingredients derived from hemp seeds, and has approved certain specific cannabis-based drugs; otherwise, the agency has taken the position that cannabis products may not yet be legally marketed as foods, dietary supplements, or drugs.