4 Top Compliance Issues Facing Hemp Industry

By Michael Phillis

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Law360 (November 5, 2019, 5:58 PM EST) -- As the hemp industry prepares to scale up production following new guidelines for cultivation from the <u>U.S. Department of Agriculture</u>, companies still face uncertainty about how they will navigate stringent testing requirements, emerging state rules and other vexing issues.

Just over 10 months after hemp production was legalized by last year's Farm Bill, the industry's long wait for regulatory guideposts **came to a close last week** when the USDA issued an interim final rule governing hemp production. The rule includes guidelines on testing to ensure marijuana is not grown and allows states and Native American tribes to submit production plans for USDA approval. The regulation also includes steps for disposing of plants and farm licensing requirements. Companies must now quickly digest these measures before the 2020 growing season.

While these steps help hemp move forward, the industry is still grappling with unknowns about how to build operations while preparing for yet-to-be-issued state guidelines and federal rules on consumer products.

"This change in the Farm Bill, we thought our life would be easier once it passed. But it just opened up all these different rabbit holes to go down and there is just so much ambiguity and details to be thought through because it impacts so many government agencies," Erica McBride Stark, executive director of the National Hemp Association, told Law360.

With the USDA's rules handed down, here are four major compliance issues facing the industry.

Protecting Against Potency

The 2018 Farm Bill says hemp can't contain more than 0.3% THC. That limit separates it from marijuana, which contains much more of the psychoactive ingredient. The USDA's new rules established testing standards that are vital for farmers who want to ensure that their crops aren't above that ceiling, as violations can mean the destruction of plants.

The new rules require crops to be tested close to when they are harvested and includes an allowance for uncertainty in testing methods. Corey Cox of <u>Vicente Sederberg LLP</u> said while the new regulations "promote a greater degree of standardization across states," THC testing remains a critical issue for growers who are trying to understand the new requirements and ensure their crops test consistently as hemp.

A lot of factors can influence THC content in a crop, including the altitude and weather where it was grown, Cox said. So cultivators will need to monitor the genetics of the crops they decide to grow to ensure that they match the local climate.

"Some hemp could test as hemp and below the 0.3% THC in Oregon, and you could grow that same hemp in South Carolina and Texas and Maine and the potency could vary based on the different conditions and climate in those states," Cox said.

Alva C. Mather, an attorney with <u>McDermott Will & Emery LLP</u>, said the issue becomes more complicated when the manufacturing process is considered, as the USDA rules are focused on hemp production. There are concerns that manufacturing of consumer, hemp-derived goods could increase THC levels and that the chemical makeup of products could change if they sit on a shelf for a long time.

The new federal guidelines do allow for some leniency for THC content. For example, producers found to be negligent will have to comply with a corrective action plan. But the consequences for ignoring the rules can be significant. Purposeful violators could be referred to law enforcement under the new guidelines.

"This threshold is moving something from a legal product into a criminally illegal product. And that raises the exposure," Mather said.

Mather added that the unfolding rules and uncertainty means that companies have to be able to adjust to new guidelines.

"We are still in the baby stages of this industry. Don't get out over your skis on this where you are committed to either one form of product or one type of production," Mather said.

State-Based Growing Pains

States and tribes will have an opportunity to submit state hemp production plans for federal approval, allowing local authorities to propose stricter standards or even forbid cultivation. Experts had worried that states would set up a patchwork of rules that would make it more difficult for companies. Jessica Wasserman, an attorney with <u>Greenspoon Marder LLP</u>, said while some variation in local rules is likely to occur, the USDA guidelines will probably push states toward a uniform standard.

The next couple years will be a turbulent transition period, she said, as companies run into the inevitable problems that occur as new rules get tested in the real world.

"This is not going to happen overnight," Wasserman said.

She said that paradoxically, states like Colorado and Oregon that had previously set up their own pilot programs for hemp cultivation will now have to expend resources to ensure they sync up with the USDA's rules. They are likely to be different in some areas, such as the granular — but important — specifics of THC testing requirements.

"It will take them a little time to get their mind around this change in policy. They also will have to change regulations," she said.

Testing will need to occur at <u>Drug Enforcement Administration</u>-licensed labs, but there just aren't enough of them in some areas right now, according to Wasserman. It is important for labs to pop up in each state so the 15-day window between THC testing and crop harvest can occur seamlessly, she said.

The new USDA guidelines are set to run for a transition period of two years. Wasserman said they are subject to changes, which keeps things in flux as the industry gets established.

Companies and states are now pushing to be ready for the 2020 growing season. States that don't want to write their own rules can defer to the USDA, which will then issue the necessary licenses for producers. But for states that want to administer their own program, growers may be unable to get a license from either the federal government or their state until a plan is approved.

For example, Wasserman said, "If someone comes to them from Pennsylvania, even though Pennsylvania hasn't finalized its plan, USDA will say we aren't going to go forward with your entity licensing application because we know Pennsylvania is working on it."

This will mean a "very confusing state of affairs for awhile," she added.

Testing for Toxins

Companies must remember that hemp acts as a kind of sponge, absorbing pesticides and heavy metals that are in the soil, said Andrew Sacks of <u>Sacks Weston Diamond LLC</u>. While hemp can help remove harmful substances from contaminated ground, this trait can pose problems for manufacturers of CBD products that can take the form of oils, lotions and a slew of other consumer products.

"Anybody who accepts a delivery of CBD or any other type of thing that is going to be in touch with humans ... they've got to supply a test with it" that detects contaminants, said Sacks, who also serves as a co-chair of the <u>Pennsylvania Bar Association Medical Marijuana</u> and Hemp Law Committee.

Third-party labs advertise hemp testing for pesticides, heavy metals and other contaminants, and some regulators are already addressing the issue of product integrity. For example, last year Colorado mandated pesticide testing for marijuana. In Illinois, the pending CBD Safety Act would require the state Department of Agriculture to set testing standards to ensure products are safe.

But the USDA said its rulemaking wasn't meant to address this area.

The hemp industry is new — its reputation is still being formed — and Sacks said it is vital that companies don't open themselves up to lawsuits or scandals. He mentioned the deaths tied to the

use of vaping products, raising concerns about whether they could have been contaminated in some way. As a result, the vaping industry is facing the threat of significant restrictions on its operations by state and federal regulators.

The hemp industry needs to ensure that it is providing a product that's safe, according to Sacks.

"Any hemp producers that are making any product that gets involved with any human being must have this full screen testing," he said.

With CBD Claims, DBC — Don't Be Careless

CBD products are widely available now that many states have loosened their regulations, but an uncertain set of rules govern the marketplace. The <u>U.S. Food and Drug Administration</u> has issued warning letters against companies making aggressive claims that their products will have significant health benefits, such as treating cancer. Several members of Congress in September also urged the FDA to quickly provide guidance on CBD's potential use as a dietary supplement and other issues. The FDA has said it is "working quickly to further clarify" its approach to CBD.

Companies need to be careful that they can back up their advertising claims and don't make outlandish claims about health-related benefits, said Jonathan Havens of <u>Saul Ewing Arnstein &</u> <u>Lehr LLP</u>. If a company is promising that a certain amount of CBD is in a product, it needs to be true and sellers must pay careful attention to what they say on their website, Havens said.

For example, some products have advertised that users will be able to pass a drug test, but that language can open them up to scrutiny and potentially lawsuits, he said.

"That's risky," Havens said. "If you make an unqualified drug claim, that to me could suggest, and I think a plaintiffs' attorney might argue this, 'You said I won't fail a drug test, that means any drug test.' So different people have different responses. I think an unqualified drug testing claim is dangerous."

The problems are reflective of the generally unregulated space that companies have to navigate.

Stark said it is rare for businesses to push for more rules, but the hemp industry is shouting, "Regulate me, regulate me."

"The good players definitely welcome regulations so they can get out of these legal gray areas and operate accordingly. And that's not only going to be good for the industry, but it's also going to be good for consumers," Stark said.

--Additional reporting by Sam Reisman. Editing by Brian Baresch and Kelly Duncan.

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