

March 1, 2019

Q. **With the passage of the [Agricultural Improvement Act of 2018](#)¹ (known as the “2018 Farm Bill”), may university researchers legally grow the variety of cannabis known as industrial hemp and use hemp and hemp derivatives in their research without obtaining a Schedule I controlled substances registration from the federal Drug Enforcement Administration (DEA)?**

A. **Yes, but note that:**

- 1. Federal law continues to regulate which entities and individuals may legally grow hemp (i.e., not all growers/providers of hemp and hemp seed are currently authorized to do so under federal law), as discussed below;**
- 2. California state law also regulates hemp cultivation.** Although “established agricultural research institutions” are exempt from most provisions, some state hemp cultivation requirements do apply to the University (including a signage requirement and a requirement to provide advance notice and GPS coordinates of cultivation sites to the relevant county agriculture commissioner);²
- 3. Federal law prohibits a person from participating in hemp production if they have a state or federal felony Controlled Substances (CS) conviction, for 10 years following the date of their conviction;**³ and
- 4. The federal Food & Drug Administration (FDA) continues to regulate products containing cannabis or cannabis-derived compounds (including compounds derived from hemp).** FDA has stated that it continues to be illegal to introduce such compounds into food and dietary supplements without FDA approval, and has announced that FDA will hold hearings in April regarding regulation of cannabidiol (CBD), in particular, which may result in clarification or modification of the rules regarding CBD.⁴

¹ Enacted December 20, 2018, pursuant to H.R. 2.

² See CA Food and Ag. Code Sections 81011 (requiring established agricultural research institutions to provide GPS coordinates of planned hemp cultivation sites to the Ag commissioner in the county where the site is located) and 81006(b) (requiring all hemp cultivate plots to have signage indicating that they are industrial hemp), as amended by [Senate Bill 1409](#), enacted September 30, 2018.

³ The restriction on hemp production by individuals convicted of a felony controlled substances conviction does not apply to any person growing hemp lawfully with a license, registration or authorization under a pilot program authorized by Section 7606 of the 2014 Farm Bill before the enactment of the 2018 Farm Bill. Sec.297B (e) of the Ag. Marketing Act of 1945, added by the 2018 Farm Bill.

⁴ See Statement from FDA Commissioner Scott Gottlieb, issued December 20, 2018 (<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm?source=techstories.org>); and

University of California researchers who wish to work with hemp must comply with all applicable laws, regulations, and University/campus policies.

Hemp (and hemp seeds and derivatives) for use in University research should be obtained from legal sources. Procedures/practices should be adopted to assure that individuals at UC participating in cultivation do not have prohibited felony CS convictions, that hemp obtained/cultivated for research does not exceed the levels of the psychoactive compound delta-9-tetrahydrocannabinol (THC) permissible for hemp, and that there is appropriate signage and notification of the County Ag. Commissioner prior to cultivation.

BACKGROUND

In December, 2018, the [Agricultural Improvement Act of 2018](#) (known as the “2018 Farm Bill”) was signed into law, removing hemp (sometimes known as “industrial hemp”) from the federal Controlled Substances Act definition of marijuana. As defined in the 2018 Farm Bill, hemp is any part of the plant *Cannabis sativa* L. (including seeds, derivatives and extracts) with very low concentrations (less than 0.3 percent on a dry weight basis) of the psychoactive compound delta-9-tetrahydrocannabinol (THC).⁵ The 2018 Farm Bill expanded (but continues to regulate) the legal cultivation of hemp.

Hemp and substances derived or extracted from hemp -- including cannabidiol (CBD) extracted from hemp, *but not including CBD extracted from marijuana* – are no longer Schedule I controlled substances under the federal Controlled Substances Act.⁶ Thus, University researchers may now legally cultivate hemp for research and may use hemp and hemp derivatives in their research without obtaining a Schedule I registration.

Hemp cultivation continues to be regulated under both federal and state law (not all entities are currently legally authorized to grow hemp), and the Federal Food & Drug Administration (FDA) continues to regulate products containing cannabis or cannabis-derived compounds (including CBD derived from hemp), as described below. As noted above, researchers who wish to work with hemp must comply with all applicable laws, regulations, and University/campus policies.

press reports from February 27, 2019 regarding FDA’s announcement regarding forthcoming hearings (<https://www.cnbc.com/2019/02/27/fda-plans-first-public-hearings-on-legalizing-cbd-foods-in-april.html>).

⁵ The [2018 Farm Bill](#) defines hemp 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 concentration of not more than 0.3 percent on a dry weight basis.” Pub. L. No. 115-334, H.R. 2 (signed into law December 20, 2018), Section 10113, adding Sec. 297A to the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.).

⁶ 21 U.S.C. 801 et seq.

LEGAL STATUS OF HEMP PRIOR TO THE 2018 FARM BILL:

Hemp is a low-THC variety of the Cannabis sativa plant (the same plant used for producing marijuana). Prior to the passage of the 2018 Farm Bill, hemp was included in the definition of marijuana under the federal Controlled Substances Act (“CSA”).

The CSA classifies marijuana as a Schedule I controlled substance and prohibits most cultivation, distribution and use of marijuana, with limited exceptions for research conducted under a Schedule I research registration from the federal Drug Enforcement Agency (DEA). Thus, prior to December 20, 2018, hemp (and hemp derivatives) were regulated as Schedule I controlled substances.

Notwithstanding that classification, universities and state departments of agriculture with established research “Pilot Programs” were legally authorized to cultivate hemp for research purposes under Section 7606 of the 2014 Farm Bill.⁷ But there were significant limitations and uncertainties. For example, there was no clear federal authorization to cultivate for research absent a Schedule I DEA registration. There also were uncertainties about how research institutions could legally obtain viable hemp seed and cultivars for research.⁸ In addition, because the CSA definition of marijuana included marijuana extracts and derivatives, and because the DEA separately lists marijuana extracts as Schedule I controlled substances, prior to December 20, 2018, it was necessary to obtain a Schedule I DEA registration in order to conduct research with hemp extracts like CBD (unless those extracts came from a part of the cannabis plant – like the mature stalks – that fell outside of the CSA definition of marijuana).

The 2018 Farm Bill has removed or greatly reduced most of these hurdles, easing the way for researchers to work with hemp and hemp-derived extracts.

KEY HEMP-RELATED PROVISIONS OF THE 2018 FARM BILL

The 2018 Farm Bill:

Removes Hemp From the Federal CSA Definition of Marijuana:

The most significant change made by the 2018 Farm Bill, in terms of its effect on easing research, was to remove hemp from the definition of marijuana under the Federal Controlled Substances Act.⁹ That change means that there is no longer a need to obtain a Schedule I DEA registration in order to work with hemp.

Defines Hemp to Include Hemp Derivatives and Extracts:

Also of great significance to researchers is the fact that the 2018 Farm Bill for the first time defined hemp to include not only any part of the plant Cannabis sativa L. with a THC concentration of not

⁷ Section 7606 of the Agricultural Act of 2014 ([7 U.S.C. 5940](#)).

⁸ This stemmed from the fact that prior to passage of the 2018 Farm Bill, hemp continued to be regulated under the CSA as a Schedule I controlled substance. Prior to December 20, 2018, one clearly permissible avenue for obtaining viable hemp seed for research was to import the seeds from abroad, but that required a DEA import license.

⁹ Sec. 12619 of the 2018 Farm Bill amended Section 102(16) of the Controlled Substances Act (21 U.S.C. 802(16)) to specify that the term “marihuana” does not include hemp, as defined in section 297A of the Agricultural Marketing Act of 1946

more than 0.3 percent on a dry weight basis, but also all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers of the plant with a THC concentration of not more than 0.3 percent.¹⁰ That change means that it is no longer necessary for researchers to obtain a Schedule I DEA registration in order to conduct research with hemp-derived extracts like CBD.

Authorizes Hemp Production By Growers Who Meet One of the Following Criteria:

- a) the grower is operating in compliance with a state regulatory plan that has been approved by the U.S. Department of Agriculture (USDA); (note that as of the date of this Advisory, there are no such growers, because USDA has not yet approved any state hemp regulatory plans); or
- b) the grower has obtained and is operating in compliance with a USDA license to produce hemp (note that as of the date of this Advisory, there are no such growers, because USDA has not yet issued hemp cultivation licenses); or
- c) the grower is part of a state Department of Agriculture Pilot Program, or a university, and the hemp is being grown exclusively for research, pursuant to the 2014 Farm Bill. This avenue will expire when Section 7606 of the 2014 Farm Bill is repealed 1 year after USDA issues hemp production regulations as required under the 2018 Farm Bill.¹¹

Because USDA has not yet adopted regulations to implement the 2018 Farm Bill,¹² currently, the only legal domestic sources of hemp are entities that are part of a state's Department of Agriculture research Pilot Program (California does not currently have such a program) or universities.

Sets out Criteria for State Hemp Production Regulatory Plans:

In order for a state's regulatory plan to receive approval from the USDA¹³ it must include provisions for:

- Maintaining for 3 years relevant information regarding the land on which hemp is produced;
- Testing THC levels of hemp using post-decarboxylation or other similarly reliable methods;
- Effective disposal of plants (and products from those plants) that don't meet the regulatory standards;
- Complying with enforcement procedures set out in the 2018 Farm Bill;

¹⁰ Ibid.

¹¹ Section 7605 of the 2018 Farm Bill specifies that Section 7606 of the 2014 Farm bill (7 U.S.C. 5940) will be repealed one year after the date on which the Secretary of USDA establishes a plan under Section 297C of the Ag. Marketing Act to regulate hemp production in cases where there is no USDA-approved regulatory plan. Section 10113 of the 2018 Farm Bill adds Section 297C to the Ag. Marketing Act, which includes a requirement for USDA to promulgate regulations and guidelines to implement regulations and guidelines to implement the Farm Bill's provisions

¹² See USDA announcement released February 27, 2019 (<https://www.ams.usda.gov/content/hemp-production-program>), which stated that USDA intends to issue regulations in the Fall of 2019 to accommodate the 2020 planting season and which noted that until then, States, Tribes, and institutions of higher education can continue operating under the authorities of the 2014 Farm Bill (which allowed cultivation only by those entities and only for research purposes).

¹³ See Section 297B of the Agricultural Marketing Act, added by the 2018 Farm Bill.

- Submitting certain information to USDA, as required by the Farm Bill;
- Certifying to USDA that the State has the resources and personnel to carry out the required elements noted above.

Once a state's hemp regulatory plan has received USDA approval, individuals and entities in that state (including commercial growers) will be able to cultivate hemp legally, as long as they comply with the state regulatory plan. If a hemp producer negligently violates the state plan, they will have an opportunity to correct the violation, and shall not as a result of that violation be subject to any Federal, State or local enforcement action.¹⁴

Under the 2018 Farm Bill, it is unlawful to produce hemp in a state that does not have a USDA-approved hemp regulatory plan, unless the producer has a license issued by USDA (or unless the producer is a university or part of a state Department of Agriculture Pilot Program cultivating for research).

Prohibits Cultivation By Persons With Felony Controlled Substances Convictions.

The 2018 Farm Bill prohibits a person from participating in hemp production if they have been convicted of a felony relating to a controlled substance under State or Federal law, for 10 years following the date of their conviction.¹⁵ Because of this prohibition, any cultivation of hemp at UC should include a mechanism for determining in advance that no individual participating in the hemp production has a disqualifying felony controlled substances conviction.

Preserves FDA and HHS Regulatory Authority.

The law specifies that USDA has sole authority to promulgate Federal regulations and guidelines that relate to the production of hemp under the 2018 Farm Bill, but also specifies that the Commissioner of the Food and Drug Administration (FDA) and the Secretary of Health and Human Services (HHS) retain authority to promulgate regulations and guidelines under the Federal Food, Drug, and Cosmetic Act¹⁶ and Section 351 of the Public Health Service Act,¹⁷ respectively. Researchers still must comply with all applicable FDA and HHS rules (e.g., FDA rules still apply to use of cannabis and cannabis extracts in a clinical trial, regardless of whether those extracts are derived from hemp).

Prohibits State Restrictions on Interstate Commerce of Hemp.

The law specifies that nothing in Title X of the 2018 Farm Bill prohibits interstate commerce of hemp (including hemp derivatives) or hemp products. It also bans states from prohibiting

¹⁴ Note that this forbearance from criminal prosecution applies only to “negligent” violations (and presumably any violation with less than negligent intent); on its face, it would not protect a grower who violated the rules intentionally or recklessly.

¹⁵ The restriction on hemp production by individuals convicted of a felony controlled substances conviction does not apply to any person growing hemp lawfully with a license, registration or authorization under a pilot program authorized by Section 7606 of the 2014 Farm Bill **before the enactment of the 2018 Farm Bill**. Sec. 297B(e) of the Ag. Marketing Act of 1945, added by the 2018 Farm Bill.

¹⁶ [21 U.S.C. 301](#) et seq.

¹⁷ [42 U.S.C. 262](#) et seq.

transportation or shipment through the state of hemp or hemp products produced in accordance with the Farm Bill.¹⁸

FOLLOWUP:

The Office of General Counsel will continue to monitor developments in this area, and work with relevant Office of the President and campus offices (including the Research Policy Analysis & Coordination unit of the systemwide office of Research and Graduate Studies, which has been providing policy guidance to campuses regarding the rules governing cannabis research and acceptance of funding from cannabis industry entities, and with campus Controlled Substances Program Administrators and research offices to provide advice and assistance as needed.

CONTACT:

Questions about this Advisory can be directed to Principal Counsel Ellen Auriti (ellen.auriti@ucop.edu; 510-987-9429).

¹⁸ See Section 10114 of the 2018 Farm Bill. Note that Title X of the Farm Bill includes Section 10113, related to Hemp Production, which is the section of the bill that adds provisions to the Agricultural Marketing Act of 1946 defining hemp and allowing hemp production under a USDA-approved state regulatory plan or pursuant to a USDA license.