

## Background

Industrial hemp is a variety of the *Cannabis sativa* L. plant that contains no more than 0.3% concentration (on a dry weight basis) of the psychoactive compound delta-9-tetrahydrocannabinol (THC). Traditionally, industrial hemp has been used for manufacturing purposes rather than any psychoactive or therapeutic effects.

In December 2018, Congress passed the Agricultural Improvement Act of 2018, commonly known as the 2018 Farm Bill, which legalized hemp production pursuant to federal USDA regulations. Prior to the 2018 Farm Bill, industrial hemp was included within the federal Controlled Substances Act definition of marijuana as a Schedule I drug and under the purview of the Drug Enforcement Administration (DEA). The 2018 Farm Bill amended the federal Controlled Substances Act to exclude hemp and hemp derivatives from the definition of marijuana. Thus, industrial hemp is no longer a Schedule I Controlled Substance. Nevertheless, hemp research must be conducted in compliance with both Federal and California law and regulations.

Applicable Federal law currently includes the 2014 Farm Bill (which, under Section 7606<sup>1</sup>, allows research cultivation of hemp by a state Department of Agriculture that has established a research Pilot Program or a University), the 2018 Farm Bill (which allows for hemp cultivation pursuant to USDA regulations), FDA regulations (applicable to products intended for human or animal consumption and to interstate commerce of such products) and USDA regulations.

Specific to USDA regulations, hemp may only be cultivated by entities operating in a state that has received USDA approval for its state plan, or, in the absence of such a state plan, by a grower that has applied for and obtained a license directly from the federal USDA. As of the publishing of this Guidance memo, the USDA has not yet promulgated regulations for industrial hemp production nor approved state regulatory plans or licenses. This means that there are several remaining implementation issues, which will require further Federal and State rulemaking or guidance. In addition to USDA, the 2018 Farm Bill explicitly preserved the FDA's authority to regulate products containing cannabis or cannabis-derived compounds as a drug subject to FDA oversight.

Applicable State law can be found in [Division 24 of the state Food and Agricultural Code](#), which, though it exempts Established Agricultural Research Institutions (like UC) from many of the requirements that apply to commercial hemp growers, does set out requirements that apply to research institutions, as discussed below. California is still developing regulations and policies that apply to hemp cultivation in the state, and is providing updates through [CDFA's webpage](#).

The following information provided in question and answer style is meant to assist campus researchers and administrators in understanding the requirements for conducting research with hemp and hemp derivatives, and for cultivating industrial hemp for research purposes.

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<sup>1</sup> Note that Section 7606 of the 2014 Farm Bill will be repealed one year after the date on which USDA establishes a plan to monitor and regulate hemp production under Section 297C of the Agricultural Marketing Act of 1946. Once Section 7606 is repealed, university production of hemp will be governed by the 2018 Farm Bill.

## **Questions about Industrial Hemp Research**

### **1. Who should researchers consult prior to conducting research with industrial hemp?**

Campuses may wish to designate an office or officer(s) as a point of contact for hemp-related research questions, such as the research compliance office or other office. In addition, researchers may wish to seek practical advice from their campus Office of Environmental Health and Safety or Controlled Substance Program Administrator.

### **2. Can UC collaborate with or accept funding or materials from entities that grow industrial hemp?**

Generally, yes, however each campus will need to make a determination about whether it will collaborate with or accept funding or materials from entities that grow industrial hemp but that are not entities authorized to do so under the 2018 Farm Bill. Under the 2018 Farm Bill, hemp (other than that grown exclusively for research purposes by a state Department of Agriculture Pilot Program or University, in compliance with Section 7606 of the Farm Bill of 2014) may only be cultivated pursuant to a USDA-approved state plan that includes certain regulatory elements or, in the absence of such a state plan, by a grower that has applied for and obtained a license directly from the federal USDA. These restrictions mean that not all entities are legally permitted to cultivate hemp, thus some commercial hemp entities may not be operating in accordance with applicable rules, including those of the 2018 Farm Bill.

### **3. Do researchers need a Schedule I registration to conduct research with industrial hemp?**

NO. The 2018 Farm Bill makes it clear that hemp and hemp derivatives are no longer categorized as a Schedule I Controlled Substance, so conducting research with hemp and hemp derivatives does not require a DEA Schedule I registration.

### **4. What are the requirements for conducting clinical trials with hemp or hemp-derived compounds such as hemp-derived cannabidiol (CBD)?**

Research with industrial hemp or hemp derivatives involving human or animal subjects remain subject to FDA requirements. Specifically, the 2018 Farm Bill preserved FDA's authority to regulate products containing cannabis and cannabis-derived products, including CBD that is derived from hemp. This means that the FDA continues to regulate cannabis, including hemp-derived CBD, as a drug that requires FDA authorization. In addition, it is still illegal to introduce food containing added CBD or THC into interstate commerce or to market such products as or in dietary supplements. Therefore, researchers conducting clinical trials involving the use of hemp products for human use, including products containing hemp-derived CBD, must submit an investigational new drug application (IND) to the FDA prior to conducting the clinical study. This is in addition to meeting the usual requisite approvals for research, including IRB approval for human subject research.

## **Questions about Hemp Cultivation Research**

### **1. How can researchers obtain hemp seeds or cultivars in order to cultivate industrial hemp for research purposes?**

Researchers should obtain hemp seeds and cultivars from providers who can provide an assurance that:

1. The seed or cultivars contain no more than 0.3% THC on a dry weight basis (e.g., by providing a report from a certified analytical lab); and
2. The seed or cultivars originated from a source that is in compliance with both federal and state requirements.

With respect to the second requirement above, the 2018 Farm Bill provides that hemp may be grown legally in the United States in one of the following ways:

1. The hemp grower is operating in a state that has received USDA approval for its state regulatory plan, and is operating in compliance with those state regulations; or
2. In states without a USDA-approved plan, the hemp grower has received a license from USDA to grow hemp and is operating in compliance with the terms of that license; or
3. The hemp grower is a state Department of Agriculture that has established a research Pilot Program or a University, authorized to grow hemp by Section 7606 of the 2014 Farm. This applies only to hemp grown for the purpose of research.

The [USDA has announced](#) that it will not begin approving state plans or issuing licenses until it has promulgated regulations implementing the 2018 Farm Bill. Also, as of the date of this Guidance memo, the California Department of Food and Agriculture (CDFA) has not established a research Pilot Program pursuant to the Section 7606 of the 2014 Farm Bill. Therefore, if researchers want to conduct hemp related-research prior to California obtaining USDA approval for its state regulatory plan or before the USDA has issued licenses to individual hemp growers, researchers should obtain hemp seeds or cultivars only from growers that fall into category #3 listed above (or from abroad). There are a number of universities and state departments of agriculture that have established hemp cultivation research pilot programs pursuant to the 2014 Farm Bill, including in Colorado, Oregon, North Dakota, and Kentucky, among others. On a case-by-case basis, campuses may decide to obtain hemp seeds or cultivars that have been produced by growers other than those authorized under the 2018 Farm Bill.

Outside of the Farm Bill framework, hemp seeds can be imported from abroad, consistent with applicable USDA regulations, and used for research purposes. Information on USDA hemp seed importation requirements can be found here: <https://www.ams.usda.gov/content/importation-hemp-seeds>. Note that a DEA import license is no longer needed, since hemp is not regulated under the Controlled Substances Act.

### **2. Are there any shipping requirements for mailing hemp and hemp-derived CBD products?**

YES. The United States Postal Service (USPS) recently issued an updated policy for mailing hemp and hemp-derived CBD products. The USPS says that to be in compliance, products made from industrial hemp may be mailed if they are grown in accordance with the requirements of the 2014 Farm Bill, including that the THC concentration is not higher than 0.3%. The USPS notes that once the 2018 Farm Bill is fully implemented, they expect to further modify the conditions under which hemp and hemp-based products may be transported. [Additional information about this USPS update can be found in Postal Bulletin 22521.](#)

**3. The 2018 Farm Bill prohibits participation in hemp cultivation by anyone with a felony conviction related to controlled substances within the last 10 years. What does this mean for UC researchers?**

The 2018 Farm Bill prohibits any person convicted of a felony related to a controlled substance under State or Federal law to participate in a hemp cultivation program for 10 years following the date of conviction. Campuses need to establish mechanisms to ensure that individuals who will participate in the cultivation aspect of a University research protocol, on or off campus, do not have such felony convictions.

**4. What plans should be in place prior to industrial hemp cultivation?**

USDA has not yet issued regulations and will not begin approving state plans or issuing licenses until it has promulgated regulations implementing the 2018 Farm Bill. Until then, campuses that support industrial hemp cultivation should ensure that plans for doing so incorporate the key elements of the 2018 Farm Bill criteria, including:

- Maintaining relevant information regarding the land on which hemp is to be grown for three years;
- Obtaining certified hemp seeds or cultivars, such by requesting that hemp suppliers provide a testing report certifying that seeds contain no more than 0.3% THC;
- A procedure for on-going testing of THC concentration levels of the hemp produced; and
- A procedure for effective disposal of plants, growing or not, and their derivatives, that exceed 0.3% concentration of THC.

For organizations registered with CDFA to cultivate hemp, the CDFA is developing regulations for sampling procedures for testing industrial hemp for THC content (updates are available on [CDFA's webpage](#)). While as an Established Agricultural Research Institution UC is exempt from these regulations, they contain practical applications UC can consider. This may include, for example, seeking a state approved laboratory to test industrial hemp for THC content.

**5. Are there additional state requirements pertaining to industrial hemp cultivation that researchers must comply with?**

YES. In accordance with Division 24 of the California Food and Agricultural Code, an Established Agricultural Research Institution, like UC, must notify and provide certain information to the county agricultural commissioner prior to cultivation of hemp, and all plots, including greenhouses, must have adequate signage indicating that they are industrial hemp. As such, prior to commencing any hemp cultivation project, **it is strongly recommended that researchers meet with their local agricultural commissioner regarding their research plans.**

CDFA [issued guidance](#) on what information should be provided to the commissioner, including:

1. Name of institution that is cultivating, including the name and contact information for the primary point of contact;
2. GPS coordinates, in decimal degrees up to six decimals, of all sites used for cultivating industrial hemp;
3. Names of all individuals involved with cultivation activities as members of, or on behalf of, the institution, and the nature of their relationships with the institutions; and

4. At the commissioner's discretion, additional documentation to confirm that a planting of industrial hemp is being cultivated by the institution, and that the institution is authorized to cultivate industrial hemp at the site, including, but not limited to, contracts, lease agreements, memoranda of understanding, and verification of employment.

Based on this CDFA guidance, researchers should be prepared to post signage on all cultivation sites indicating that the University of California is cultivating industrial hemp. In addition, researchers must provide GPS coordinates of all research cultivation sites to the local agricultural commissioner.

#### **6. Can UC researchers grow industrial hemp and then sell or donate hemp byproducts?**

Once USDA promulgates regulations allowing commercial cultivation, commercial cultivation and sales will be permissible if done in accordance with a USDA-approved state regulatory plan, and UC will be able to dispose of excess hemp as it does other agricultural byproducts. Under the current regulatory scheme, hemp cultivation by UC can only be conducted for research purposes. As such, before USDA promulgates regulations, hemp and hemp-derived materials should not be sold or donated after the completion of the research project. There may be some cases, however, in which the research itself involves studying of marketing or distribution; in those cases, researchers are advised to ensure that their protocol is consistent with University policies and practices.

#### **7. Can UC researchers and/or Cooperative Extension Advisors and Specialists provide agricultural advice and/or assistance to non-university hemp growers?**

UC researchers and Cooperative Extension Advisors or Specialists can advise or provide agricultural assistance to non-university hemp growers that are in compliance with federal and state law. As explained above, not all entities are legally permitted to cultivate hemp. In those cases, campuses may want to evaluate risks on a case-by-case basis.

#### **8. Can UC enter into agreements with local hemp entities to allow them to grow industrial hemp as part of a UC research program, which in turn may arguably create exemptions from state regulations for the hemp entity and/or permit them to grow under Section 7606 of the 2014 Farm Bill?**

Division 24 of the Food and Agricultural Code creates exemptions from certain state requirements for growing industrial hemp when done by an Established Agricultural Research Institution. These requirements – from which UC as an Established Agricultural Research Institution is exempt – include using only approved seed cultivars, registering with the county agricultural commission, and paying registration fees, among others. In addition, Section 7606 of the 2014 Farm Bill allows universities and state departments of agriculture to grow hemp for research purposes (without the requirement to do so only pursuant to a USDA-approved state plan, as is required by the 2018 Farm Bill). Several hemp companies have approached UC to enter into agreements with UC campuses, and appear to be under the impression that doing so will allow them to qualify for the authorizations/exemptions granted to the University under state and federal law. We are not aware of state or federal guidance as to whether commercial entities or individuals who enter into contracts with a university qualify for such authorizations/exemptions, and it is up to those entities and individuals, in consultation with their own legal counsel, to determine their own compliance obligations.

Individual UC researchers are not authorized to enter into agreements on behalf of the University, and must work with their appropriate authorized campus office if they are contemplating agreements with hemp companies. Campuses wishing to contract with such entities are advised to evaluate risks on a case-by-case basis and to coordinate with campus counsel as appropriate.

## **Contact**

Contact UC Research Policy Analysis & Coordination (RPAC) if you have questions about the guidance provided above or about cannabis-related research policies at UC. Contact the Office of General Counsel for legal advice. Points of contact in each of those offices are listed below.

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