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Production of Industrial Hemp in the U.S.: Overview, Status, & Legal Issues

UofA

**DIVISION OF AGRICULTURE
RESEARCH & EXTENSION**

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38 minutes ago

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Federal Register Announcement – 6/24/19



Washington, DC 20250, *Phone: 202 720-7311, Email:*
erin.taylor@ams.usda.gov.

RIN: 0581-AD87

DEPARTMENT OF AGRICULTURE (USDA)

Agricultural Marketing Service (AMS)

FINAL RULE STAGE

3. • Establishment of a Domestic Hemp Production Program

E.O. 13771 Designation: Deregulatory.

Legal Authority: [7 U.S.C. 1621](#)

Abstract: This action will initiate a new part 990 establishing rules and regulations for the domestic production of hemp. This action is required to implement provisions of the Agriculture Improvement Act of 2018 (Farm Bill).

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/00/19	

Regulatory Flexibility Analysis Required: Yes.





Discussion Points:

- Discussion
 - Agricultural Act of 2014
 - Agriculture Improvement Act of 2018
 - States Activity
 - Recent Federal Activity
- Comments/Q&A



2014 FARM BILL

Agricultural Act of 2014



- Pub. L. 113-79, Title VII, § 7606, Feb. 7, 2014, 128 Stat. 912) (codified at 7 U.S.C. § 5940)
- Title: “Legitimacy of industrial hemp research”

2014 Farm Bill Language



(a) In general

“Notwithstanding the Controlled Substances Act, . . . or any other Federal law, an institution of higher education (**as defined in section 1001 of Title 20**), or a State Department of Agriculture may grow or cultivate industrial hemp”:

2014 Farm Bill Language



(b) Definitions

“Agricultural pilot program” is “a **pilot program to study** the growth, cultivation, or marketing” of IH:

(A) in States that permit the growth or cultivation of IH under laws of the state;

and

(B) in a manner that:

2014 Farm Bill Language



(i) ensures that **only** institutions of higher education and State departments of agriculture are used to grow or cultivate IH;

(ii) requires that sites used for growing or cultivating IH in a State be certified by, and registered with, the State department of agriculture; and

(iii) authorizes State departments of agriculture to promulgate regulations to carry out the pilot program in the States



2018 FARM BILL

2014 Farm Bill

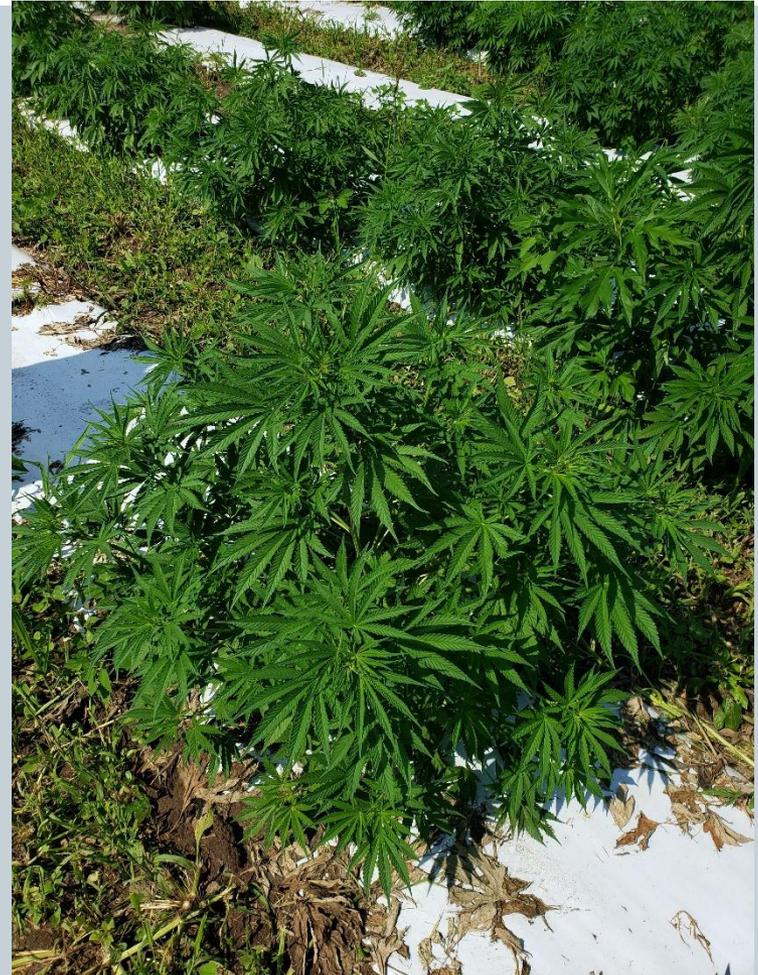


- This is currently what we are operating under at the moment for the 2019 growing season.
 - One big difference is that the 2018 Farm Bill did remove industrial hemp from the Schedule 1 status under the Controlled Substances Act.
 - ✦ This change does not make medical or recreational marijuana legal though...

2018 Farm Bill



- **Felony Conviction Requirement**
 - No one with a felony conviction related to a controlled substance offense shall be eligible for a license for industrial hemp for 10 years following the date of their conviction



Industrial Hemp Plan Requirements



- A practice to maintain relevant information regarding land on which hemp is produced in the State or territory of the Indian tribe, including a legal description of the land, for a period of not less than 3 calendar years;
- A procedure for testing, using postdecarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp produced in the State or territory of the Indian tribe;
- A procedure for the effective disposal of: plants, whether growing or not, that are produced in violation of this subtitle; and products derived from those plants;
- A procedure to comply with the enforcement procedures under subsection (e) of the Farm Bill;
- A procedure for conducting annual inspections of, at a minimum, a random sample of hemp producers to verify that hemp is not produced in violation of this subtitle;
- A procedure for submitting the information described in section 297C(d)(2) of the Farm Bill to the Secretary not more than 30 days after the date on which the information is received; and
- A certification that the state or Indian tribe has the resources and personnel to carry out the practices and procedures described in clauses (i) through (vi) of the Farm Bill.

The Devil is in the Details...



- We know the basics for the plans, but we are waiting on USDA-AMS to promulgate the regulations
 - Those were expected in late summer and could be released as soon as October of 2019
- State laws may need to be amended to comply with the 2018 Farm Bill
- Logistical difficulties abound...
 - What kind of THC test is sufficient? Sampling protocols?
 - How will the federal program be funded?
 - What about other issues such as crop insurance...



STATE STATUTES ON HEMP

State Activity: General Picture



- 46 states have enacted legislation to allow commercial and/or research cultivation of IH
 - January of 2015 = approximately 20 states
 - Some far more comprehensive than others (Kentucky has been the leader in this industry)
- The National Ag Law Center has them posted at:
<https://nationalaglawcenter.org/state-compilations/hempprovisions/>

Common Provisions



- Some of the enacted state laws do not meet all of the requirements from the 2018 Farm bill...
 - In some states the regulations may take care of the Farm Bill requirements
 - The prohibition against people with a controlled substances conviction within the last 10 years will likely need to be added
 - There will likely be lots of legislative activity after the federal regulations are released later this fall.
 - ✦ Could be tricky with states that have biannual legislative sessions.

Industrial Hemp -- Definitions



- “any and all parts of the plant, whether growing or not, with a delta-9- tetrahydrocannabinol concentration that does not exceed 0.3 per cent on a dry weight basis...” (Massachusetts - 128 §116)
- “Marijuana does not include the mature stalk of such plant, . . . or industrial hemp, as defined in 7 USC 5940, as amended from time to time.” (Connecticut - §21a-240(29))

Fees



- Many authorize ag department to develop
 - The department shall issue a hemp license to the applicant if he, she, or it meets the requirements of this chapter, upon the applicant paying a licensure fee of two thousand five hundred dollars (\$2,500). Said license shall be renewed every two (2) years upon payment of a two thousand five hundred dollar (\$2,500) renewal fee. (Rhode Island)
 - License application fee “not less than \$50 and more than \$100”; license fee “no less than \$100 and no more than \$500”; “fees for monitoring, sampling, and testing . . . no less than \$1 per acre and no more than \$100 per acre” (Maine)
- These fees may end up being important depending on the number of applicants in your state and the testing protocols that you adopt.

Fees



- Currently the hope is that each state or tribe will run their own hemp program (and pay for it), but there is also a provision that requires USDA to come up for a federal program for states that do not have their own.
- The state approach is typically to assess fees to cover costs, but that's generally not a viable option with federal agencies



RECENT FEDERAL ISSUES

Interstate Transportation



- **Big Sky Scientific LLC v. Jan M. Bennetts**
 - Currently before the 9th Cir.
 - Idaho police seized 3 1/2 tons of hemp traveling through the state (currently ID is one of the states where hemp is not legal)
 - ✦ This is going on in several other states as well
- **OGC Legal Opinion by Stephen Vayden (summary)**
 - 2018 FB removes industrial hemp from the CSA
 - After USDA publishes regulations under the 2018 FB and the states (or tribes) submit a plan that is approved then other states cannot prohibit interstate transport
 - States or Tribes cannot prohibit interstate transport of hemp grown under the 2014 FB
 - ✦ Available at:
<https://www.ams.usda.gov/sites/default/files/HempExecSumandLegalOpinion.pdf>

Interstate Transportation



- This may be a none issue when the regulations are implemented and the state plans are approved by USDA-AMS
 - But this is an issue for growers trying to transport crops to CO or other states that have a larger number of processors this year

CBD Oil and the FDA



- One major issue at the moment deals with use of CBD oil in food and dietary supplements.
 - The majority of the market share for industrial hemp is in CBD
- In the past FDA (and now the FTC) has not cracked down on its usage unless the health claims are egregious and promoters are claiming all kinds of health benefits:
 - Erectile dysfunction
 - Cure for cancer
 - Alzheimer's treatment
 - Depression
 - And the list goes on...

Along came Epidiolex...



- FDA approved a highly refined CBD product as a drug for the treatment of several forms of childhood epilepsy.
- The Food, Drug, and Cosmetics Act contains a prohibition against adding drugs to dietary supplements. 21 U.S.C. 321(ff)
 - There is an exception for labeled products that were already selling before the new drug was approved
 - ✦ Does it matter if the usage was legal before the drug was introduced?

What about the Farm Bill



- Didn't the 2018 Farm Bill make industrial hemp legal? And since CBD is the most valuable component wouldn't it be covered?

Section 297D

- *(c) EFFECT ON OTHER LAW.—Nothing in this subtitle shall affect or modify—*
- *“(1) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);*

Future of CBD



There is a lot of confusion at the moment...

- FDA says that it is bound by the law, but they aren't doing much to enforce it except in extreme cases
- States are taking wildly different approaches on hemp:
 - Some states are allowing it for certain things
 - Some states are going to approve it anyways (CA had a bill to do so pending, but that has been tabled)
- Initial statements from FDA said this could take years to resolve unless Congress gets involved...

Future of CBD – 9-17-2019



- Congress may get involved sooner rather than later with Sen. McConnell pushing to expedite action from FDA through the appropriations bill
 - In 90 days FDA would report back to Congress with data on a policy of enforcement discretion (similar to a guidance doc.)
 - Within 120 days FDA shall issue a policy of enforcement discretion for certain CBD products
 - This enforcement discretion would remain in place until FDA establishes a more formal process
 - FDA should continue pursuing new drugs that use CBD

THC Testing



- This may be **the** most important issue in the regs...
- 7 U.S.C.A. § 1639p(a)(2)(A)(ii) - a procedure for testing, using post-decarboxylation **or** other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp produced in the State or territory of the Indian tribe (emphasis added)
 - One of the most critical issues is how do you measure it and what do you measure?

THC Testing



- What will be the official test(s)? Will they look at total THC?
 - Post-decarboxylation – measures not only the delta-9 THC currently present, but also the THCa that will convert to delta-9 when exposed to a high heat source
 - $\text{Delta-9 THC} + (\text{THCa} \times 87.7\%) = \text{Total THC}$
- Are there other options that USDA might allow?

THC Testing



General Sampling Protocol Requirements:

- Testing timeframe (i.e. no more than 30 days before harvest)
- Who will take the sample (typically a state employee)
 - Is it a random sample or is everyone sampled? If you have different plots then are all of them sampled?
- Number of plants to be sampled
- Location where the samples are harvested from the plant
- Testing method (“establish a testing program” or similar language)
 - What will the USDA regulations require?

THC Testing - Examples



- California – Cal. Agric. Code § 81006
 - Testing no more than 30 days before harvest
 - ✦ For a difference look at KY which has a 15 day harvest window
 - If the sample fails the test (more than 0.3%) and the % content of THC exceeds 1% then the crop shall be destroyed
 - If the sample fails the test but the THC % is less than 1% then the registrant shall submit more samples for retesting.

THC Testing Issues



- The goal is to have a simple, inexpensive, and reliable test to measure THC level
 - Anecdotal evidence...
- Law Enforcement Issues
 - Is it accurate enough for a court of law?
- Interstate Commerce (whose results do you use?)

Crop Insurance



- Starting in 2020 hemp will be insurable under the Whole-Farm Revenue Protection Plan (WFRP)
 - You can choose to cover between 50 and 85% of farm revenue
- This plan is typically used by diversified farming operations or where certain crops may not have a specific insurance product made for it (i.e. soybeans)
 - Organic crops are commonly insured under this type of policy
 - You generally need 5 years of history from your farm tax records



Crop Insurance



- Distinctions for industrial hemp:
 - No replant coverage for hemp
 - You must be operating under an approved plan (Federal, state, or tribal depending on your location)
 - You must have a production contract with a processor
 - THC levels above 0.3% are an uninsurable loss
 - ✦ THC Testing?
 - ✦ Stress and Industrial Hemp
 - What about drought losses with say apples?

Smokable Hemp



- Not just smokable hemp, but the sale of the raw hemp material direct to consumers
- There is interest in bypassing the processors for a variety of reasons
- Questionable legality in many states and not always easy to determine.
 - Is your state silent on this matter?
 - Does your state require a license to possess or transport raw hemp
 - We are currently working on a chart to explore this issue

Comments and Q&A



- Sourcing seed (expense & quality)
- Contracts with processors
 - Not a lot of good forms available
 - Confidentiality clauses are often present
- Pesticide Usage and Approval for Hemp
 - 10 – biological and microbial pesticides are currently under review
 - This is traditionally not a fast process...
- Politico reported last week that 116 groups hired federal lobbyists for the second quarter of 2019 alone...
- Politics...



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