Colorado Lessons: The Intersection of Regulation, Production, and Markets of Industrial Hemp
2018 Lessons: Legislation, Regulation, Production, and Market of Industrial Hemp

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1. GENERAL OVERVIEW
2. PRODUCTION
3. MARKETS
The 2014 Federal Farm Bill defined Industrial Hemp and separated it from marijuana:

“The term ‘industrial hemp’ means the plant *Cannabis sativa* L. and any part of such plant, whether growing or not, with a THC concentration of not more than 0.3 percent on a dry weight basis.”
An institution of higher education or a State department of agriculture may grow or cultivate industrial hemp if:
(1) it is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and
(2) it is allowed under the laws of the State in which such institution of higher education or State department of agriculture is located and such research occurs.

Agricultural pilot program means a pilot program to study the growth, cultivation, or marketing of industrial hemp

The conflict: The Farm Bill didn’t change the Controlled Substances Act (CSA)
State Landscape – 37 states have passed legislation, most have regs
U.S. Domestic Production Industry

• Domestic production continues to increase as more states provide regulatory structures and more processors begin to enter the market.

• 2014 – 220 acres
• 2015 – 2,500 acres
  • 2016 – 8,900 acres
• 2017 – 16,000 acres

Numbers are based on State surveys where hemp has been legalized. Colorado has represented more than 50% of the U.S. production every year since the passage of the 2014 Farm Bill.
Lack of uniform interpretation of the Farm Bill: Federal Agencies

• Bureau of Reclamation doesn’t allow the use of ‘appropriated’ water.
• The USDA seed lab won’t enforce the Federal Seed Act resulting in the U.S. becoming a dumping ground for low quality ‘certified’ seed from other countries.
• USDA will authorize phytosanitary certificates for export but the DEA says you can’t export.
• DEA, FDA, & USDA’s Statement of Principles.
Varied State Interpretations on regulation

- What does delta-9 THC concentration mean?
- How do you sample and what material is included?
- What testing method should be used?
- Can non-institutions of higher education grow hemp?
- What does marketing research allow?
- Who regulates products and at what THC level?
- Is CBD regulated by the state?
Solution? 2018 Federal Industrial Hemp Farming Act

• S.2667 (McConnell) Skipped Committee and on Senate Legislative Calendar

• HR 3530 (Comer)

Please SUPPORT!
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General Overview Questions: Fed/state interaction?
Regulation of

1. Production Methods
   a) Permitting
   b) Reporting
   c) Testing
   d) Pesticides
Cornerstones of the Hemp Production Regulatory System

- CDA Registration/Permitting
- CDA Testing/Inspection
- AOSCA and CDA - Certifying seed
- Local Law enforcement engagement/information sharing
Marijuana (high THC cannabis) and industrial hemp (low THC cannabis) are the same genus and species of plant –
• May look the same and may be grown the same way.
• Only difference: CONTROL OVER THC: level of delta-9 THC concentration (only determined through laboratory analysis)
After initially providing a path forward to use FIFRA 24(c) to register pesticides, the EPA later stated that it “does not believe that Congress intended the process under section 24(c) of FIFRA to be used for the purpose of facilitating activities that are generally in violation of federal law.”

Production: Seed Based
FIFRA 24(c). A red herring.

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Registration and Reporting

Applicants:
  Name, GPS location and size of field or square feet of greenhouse, map, variety name if known, intended use, fees

Registrants’ Reports:
  Planting - within 10 days
  Harvest – 30 day window
TESTING: THC/THC(A)

Understanding THC concentration:

The plant produces primarily the *acid form* of THC: THCa - not psychoactive, UNTIL it is heated – it then converts to psychoactive THC.

For regulation and public health, THC concentration limits should include *both* present THC, and the level of converted THCA.

Methods to measure: gas (GC) or liquid (HPLC) chromatography
TESTING: THC/THC(A)

Cannabinoid analysis results from dried flower

THC: 0.28%. below 0.3%, = industrial hemp.

THCA: 25.07%. once heated, (minor loss)= 22.27% THC

This is actually high grade marijuana.
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Questions: Program administration, testing?
What is Certified Seed?

- Validates the variety’s genetic purity, weed absence, uniformity
- Administered in N America by AOSCA, in EU by OECD
- US recognizes both Cert agencies, any cert seed is allowed importation to US
Certified Hemp Seed Regs in Canada/EU

• Only certified varieties may be grown, must be registered
• Breeders apply to these agencies for new varieties to be accepted
• In US, some states began to mandate that only certified seed be imported and grown. Challenges with that?
US bred AOSCA Certified Seed

Four Part Process:
Variety submitted to variety Review Board
If accepted, then:

THC trials conducted by CDA

AOSCA standards validated
Certified Hemp Seed Label

TWO labels:

CDA Label:

This seed package contains CDA Approved Certified Seed of Industrial Hemp.

Variety: Elite  
Class: Foundation  
CSGA Field Number: 17-1505A  
Seed Lot #: F17-16-1505  
Weight: 50 Pounds  

Distributed under CDA Distribution #: 17-68912F-00002

Note: Colorado Industrial Hemp Seed Certification is only valid if seed package has both CDA Distribution number and a current Colorado Seed Certification Seed Tag.

AOSCA standards label

NEW WEST GENETICS
FORT COLLINS, CO
Hemp, Industrial
03/18
35.75% Pure Seed
0.00% Weed Seed
0.00% Other Crop
0.25% Inert

Lot No. C17-181-1505
36,560 SEEDS/LB

ONLY VALID WHEN ACCOMPANIED WITH CDA THC APPROVAL TAG

GROWER: NEW WEST GENETICS  
LOCATIONS: FORT COLLINS, CO  
 inspection:

MEMBER OF THE ASSOCIATION OF OFFICIAL SEED CERTIFYING AGENCIES

This certification is made by the CSU Seed Certification Service, authorized by the Board of Governors of the Colorado State University System (the Board), pursuant to C.R.S. § 35-27-101(1)(e) as amended. Notice to Buyer: Disclaimers of Warranties and Limitation of Damages (May not be altered or amended in any manner) The sender is hereby notified of any and all seed health claims as per the Colorado Hemp Act, as enacted. The sender hereby certifies that the seed is free of disease, insect pests, and nematodes, and that the seed is free from damage that may be caused by mites, soilborne pathogens, or other pests. The sender also certifies that the seed is free from damage that may be caused by mites, soilborne pathogens, or other pests. The sender also certifies that the seed is free from damage that may be caused by mites, soilborne pathogens, or other pests.
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Questions: Certified Seed?
Pesticides Challenge
Pest Pressure

**Insects:** hops aphid, hemp russet mite, hemp borer, Lygus bugs, grasshoppers, thrips, two spotted spider mite

**Diseases:** Powdery mildew, Xanthomonas campestris pv. cannabis, Fusarium wilt, Hemp canker

**Nematodes:** Columbia root knot nematode, stem and bulb nematode

**Viruses:** Alfalfa mosaic, Cucumber mosaic, Hemp mosaic, Hemp streak

**Weeds**
After initially providing a path forward to use FIFRA 24(c) to register pesticides, the EPA later stated that it “does not believe that Congress intended the process under section 24(c) of FIFRA to be used for the purpose of facilitating activities that are generally in violation of federal law.”

Outdoor production: Weed, some pest pressure
Unlike any other crop, states are on their own to determine which pesticides can be used on cannabis. The state is also solely responsible for enforcing pesticide standards.

Indoor production: Pest, disease pressure

Marijuana production
The Colorado Solution

Standards for Pesticide Use:
- Broad label language
- For use on tobacco products
- For use on food products
- Tolerance exempt.

Education
- Department of Agriculture provides compliance assistance

Enforcement:
- Short-term: Department of Agriculture perform random and complaint based tests, Department of Revenue destroys (note: this requires a lot of legal guidance).
- Long-term: Department of Agriculture conducts inspections and continues random and complaint based tests.; required testing by industry; Department of Revenue destroys.
Proposed bills and rule-making issues in CO

1. Use of failed material
1. Raising of THC maximum
1. Contentions over analytics methods/testing protocol
1. Regulating of boundaries between female production and dioecious production, certified seed production
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General Production questions?
MARKETS
1. Overview
2. Legislative/Regulatory Involvement

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Colorado Hemp in a global market

- In 2014 the first year of the Industrial Hemp Program in Colorado, just 200 acres were produced.

- Colorado cultivated 9,800 acres in 2017 and is estimated to grow 14-18,000 acres this year.

- 50% of all US Hemp was grown in Colorado in 2017.

- 80% of Colorado industrial hemp production is Flower.

- Established markets across the world produce only 20% flower and the rest in fiber and flower.

- The primary driver expanding the global consumer market is food including seed, and seed oils.
Market Potential

- The potential market expansion could represent jobs in the farming, manufacturing, tourism and retail industries.
- Some speculate Hemp will surpass marijuana sales in Colorado in the next 4 years
- The Brightfield Group estimated the U.S. market for CBD was $291 million in 2017 and they project growth of more than 500% in four years to $1.65 billion by 2021!
Uses by Plant Parts

Fig. 1. Flowchart of multi-purpose hemp utilization.
Strengths in Colorado Hemp

• Colorado currently leads the country in Hemp Production
• State and federal legislators are invested in promoting the industry.
• Colorado has a unique economy of agriculture and green tech - ideal for the industry
• The CBD marketplace holds best opportunities – highest value plant part, plus processing solutions in place, i.e.: mobile extraction units
• Recognized seat of innovation with a highly educated work force and businesses driven by entrepreneurship
• Labor force that is experienced in agriculture and are eager to benefit from hemp production and the creation of processing centers
US Market Challenges

- the current legal climate provides a challenge to importing seeds for cultivation from other countries with proven levels of THC concentration below .3% - while US hemp industry is in process of breeding own varieties that are better adapted and can enable farmers to compete with international production - lag there.
- legal implications for transporting Hemp as a raw commodity
- supply chain has gaps in processing centers that can take the raw commodity: seed, stem and flower and process it into market ready materials for insertion into products and manufacturing
- still a lot of confusion between regulatory agencies at the federal, state and even the municipal levels
- Lack of education for law enforcement and agency professionals
Colorado Hemp Industry Opportunities

• new emerging technologies are relocating to Colorado including Hemp Adobe Houses
• seed genetics companies have unique opportunities to drive adaptation to the US and markets, as well gain Intellectual Property
• new patent and IP opportunities in Green tech including: plastics, building materials and industrial applications
• Environmental benefits of growing hemp can create new applications/products for removing carbon and heavy metals
• The head start that Colorado has in commercial Hemp Production gives opportunity to also export products and intellectual property
• other well established international companies are interested in having US operations
Challenges to US Hemp Industry

- International hemp producers have jump start on grain and fiber markets – pricing competition as we catch up. Is less expensive to import stalk for fiber than to buy it from a producer who may be miles away.

- Overregulation at federal and state levels, and under-regulation on foreign products as well as inconsistent regulation from state to state and agency to agency.

- The US market needs to resemble more closely the global market if it is to survive – this means increasing and improving the processing of seed and stalk as well as flower (CBD). –These gaps are slowing the growth of the Industry.

- When farmers overproduce a commodity with no point of entrance into the market it depresses the price of that commodity and lowers the farmer’s income.
Pathways to products

Largest Hemp grain producer in North America is Manitoba Harvest in Canada. These products can be found in most grocery stores today.

Colorado companies:

- **PureVision Technologies** is pulping hemp stalks into paper and fuel.
- **Adobe Hemp Houses** is selling orders for pre-fabricated hemp homes
- **New West Genetics** - Industry leader in seed genetics
- **Functional Remedies** and **Charlotte’s Web** - industry leaders in CBD production
**Policy Issues: Grain products**

<table>
<thead>
<tr>
<th>Human</th>
<th>Animal</th>
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<tbody>
<tr>
<td><strong>Status:</strong> Legal. Use of sterilized grain and hemp seed oil legalized for importation in 2004 court decision</td>
<td><strong>Status:</strong> Not yet legal for use in Animal Feed: industry application to the FDA required</td>
</tr>
<tr>
<td><strong>Policy issues:</strong> none yet</td>
<td><strong>Policy issues</strong> – safety and research on levels of residual THC Content left from processing, particularly for consumption animals</td>
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<td><strong>State by State regs – no bueno! Need full federal approval for any sale of such product.</strong></td>
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Colorado policy that supported industrial hemp:

CO 17-109: Study of Hemp in Animal Feed

• **Summary:** Created a stakeholder group under the Commissioner of Ag to study the feasibility of including hemp products in animal feed. The group included representatives from multiple state depts of Ag, the FDA- CVM, AAFCO representatives, hemp industry advocates, legal experts, researchers from universities, and cattle and companion animal industry associations.

• **Status:** Passed 2017, recommendations submitted to legislators December of 2017.

• **Result:** Ongoing task force led by hemp industry took over to work with many of those stakeholders to submit and FAP to the FDA. That effort is branded the HEMP FEED COALITION.
• **Summary:** The bill gives the state licensing authority rule-making authority to address conditions under which a medical or retail marijuana licensee is authorized to transfer marijuana fibrous waste to a person for the purpose of producing only industrial fiber products.

• **Status:** Passed final reading in Senate on April 10; signed into law on April 26.
CO SB 235: Colorado Industrial Hemp Research and Development Authority

• **Summary:** The bill creates the Colorado industrial hemp research and development task force to study whether to develop an industrial hemp research and development authority to develop, fund, and promote educational, research, and development programs and collaborative efforts concerning industrial hemp. The task force consists of 8 members with expertise in the industrial hemp industry or higher education. On or before December 31, 2018, the task force is required to prepare a report on its findings and recommendations and to submit the report to the Colorado office of economic development and the agricultural committees in the house of representatives and the senate.

• **Status:** Passed third House reading on May 3; awaiting signature of the President of the Senate and the Speaker of the House.
Policy Issues: Flower products

What about CBD and other constituents from the flower in Foods?

Industry stance:
CBD is not psychoactive, should be regulated like any food product. Best industry practices/self reporting will solve need for customers to be assured of no THC content.
CO HB 1295: Hemp Products Deemed Not Adulterated or Misbranded

• **Summary:** The bill establishes that food and cosmetics are not adulterated or misbranded by virtue of containing industrial hemp. The bill also sets forth the department of public health and environment's powers with regard to applicants and registrants engaged in, or attempting to engage in, the wholesale food selling, manufacturing, processing, or storage of an industrial hemp product, as that term is defined in the bill.

• **Status:** Passed final House reading on May 4; awaiting signature of the President of the Senate and the Speaker of the House.
CO HB 1187: Food and Drug Administration Cannabidiol Drug Use

• **Summary:** The bill amends the definition of 'marijuana' to exclude prescription drug products approved by the federal food and drug administration and dispensed by a pharmacy or prescription drug outlet registered by the state of Colorado. The bill also specifies that the change does not restrict or otherwise affect regulation of or access to:

  • Marijuana that is authorized by the Colorado constitution and statutes; or

  • Industrial hemp and derivatives therefrom, as authorized by the Colorado Constitution and statutes.

• **Status:** Passed third Senate reading on April 24; signed by the President of the Senate and the Speaker of the House on May 1; awaiting governor's signature.
A winding pathway to a stable hemp market

• The Colorado Department of Public Health and Environment (CDPHE) regulates anyone processing industrial hemp for food in the same way that all other food processors or manufacturers are regulated.

• *However* the Denver Department of Public Health and Environment requires additional applications and information for any CBD products manufactured or sold in Denver.

• Most law enforcement in Colorado is supportive of industrial hemp, other states vary.

• *However* interstate distribution or shipments are still problematic.

• The pharmaceutical industry is moving forward with drug patents on CBD extracted from Marijuana – Epidiolex.
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Questions: Markets, Products
Federal Legal Landscape: CBD

- April 30 2018: 9th Circuit Court of Appeals stated that the DEA’s Rule on CBD extracts does not apply to hemp or hemp-derived products developed under programs authorized by 2014 Farm Bill. The Court concisely states that the Farm Bill “contemplates potential conflict between the Controlled Substances Act [CSA] and preempts it.” The DEA admitted this rule was not intended for anything but what is defined as marijuana.

- Affirms Hemp Industry’s stance: All parts of hemp plant made legal by Farm Bill, thus CDB sourced from hemp is legal. Passage of Hemp Farming Bill will remove hemp from CSA.