Regulation of Cannabis - CBD and Edibles

State Perspective
Cannabis, hemp and marijuana, contain psychoactive and non-psychoactive cannabinoid compounds.

Tetrahydrocannabinol (THC) used for psychoactive properties.

Marijuana  >  0.3 % THC
Hemp  <  0.3 % THC

Cannabidiol (CBD) non-psychoactive, promoted as having medicinal properties.
State Regulation of Cannabis and Edibles

Baked goods, candies, beverages, salad dressings, and a broad spectrum of other food products are manufactured with hemp or marijuana plant or plant extract ingredients.

• Marijuana edibles contain THC, CBD and other cannabinoids promoted for psychoactive and medicinal properties.

• Hemp edibles contain CBD promoted for health supplement and medicinal properties.
Legality of Marijuana by State

Establishes standards for licensing analytical laboratories to collect, sample, and analyze cultivated and/or manufactured medical marijuana products.

To ensure the qualifications and competence of personnel and to ensure the adequacy of equipment, facilities, procedures, and quality systems required to characterize cannabinoid identity and content profiles, and test samples.
Marijuana Market – by State *

1. CA $3.1 billion
2. CO $1.6 billion ($1.3 billion recreational, $0.3 billion)
3. WA $1.1 billion
4. FL $1 billion (all medical)
5. MI $1 billion projected (new 12/2019)
6. NV $770 million ($700 million recreational, $70 million)
7. OR $752 million ($707 million recreational, $45 million)
8. AZ $705 million (all medical)
9. MA $484 million ($250 M recreational, $234 M medical)
10. PA $298 million (all medical marijuana)
11. IL $1 billion projected (new 01/2020)

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USDA 's 2018 farm bill PL 115-334 removed hemp from the Controlled Substances Act.

Specifies that legal industrial hemp is any cannabis containing equal to or below 0.3 percent delta-9 tetrahydrocannabinol (THC) level per dry weight.

Hemp had been classified as an illegal substance under the act along with its cousin, marijuana.
Interim Final Rule

Allows the interstate commerce of hemp. No State or Indian Tribe may prohibit the transportation or shipment of hemp produced in accordance with this part.
At harvest hemp must be tested by an approved laboratory to certify it contains < 0.3 % THC (dry wt.)

If THC > 0.3 % entire crop must be destroyed
USDA Hemp Laboratory Approval
• Laboratories must be DEA registered

USDA is considering
• Establish Hemp Laboratory Approval Program like the USDA Aflatoxin and Meat Export Testing Laboratory Approval Program

• ISO 17025 accreditation requirement for THC testing.
States may amend existing marijuana laboratory regulations to include hemp testing by requiring laboratories to meet federal requirements for hemp testing.

Reciprocity between state laboratory approval programs is needed to recognize hemp certification (< 0.3 % THC) prior to interstate shipments.
Laboratory Testing in States with Legalized Marijuana

State Concerns:

Will DEA register laboratories for hemp if they test marijuana?

Will a USDA Laboratory Approval Program accept applications from marijuana testing laboratories?

Will hemp farmers trust their hemp harvest tested in laboratories where marijuana is also tested?
CBD from HEMP

Hemp can be grown for seed, fiber, or flower (oil extracts). The majority of production is growing hemp for flower, primarily the cannabidiol (CBD) market.

FDA has not approved CBD from hemp as a “dietary supplement.” It may only be sold as an industrial application, unofficial botanical or research compound.
CBD’s legality is affected by how it was made and its intended use.

CBD from hemp legal in majority of states except Idaho, Nebraska, South Dakota (unclear).

CBD from marijuana is legal in 38 states that have legalized it as medical or recreational marijuana.
Many states do not enforce FDA prohibition of CBD in food and dietary supplements.

FDA has approved Epidiolex, a treatment for epilepsy that contains CBD.
Hemp producers claim it’s legal to sell CBD products through interstate commerce.

DEA hasn’t made CBD purity a priority to enforce.
States CBD and Edibles

CBD products claim to be certified 100% pure however accredited laboratory testing is lacking for CBD and contaminants including THC in hemp and hemp infused products.

Increase consumer confidence through education and product testing for quality and safety.
Many states have regulations for testing marijuana edibles requiring standardized methods adapted from food testing methodology for the analysis of cannabinoids and contaminants including microbials, pesticides, metals, and solvents.
State Marijuana Edibles

Sampling principles and protocols should include best practices for sampling food products for laboratory testing.

Adopt standardized food laboratory testing methods for preparing, extracting and testing plant material, oils and edibles.
State Marijuana Edibles

Sample preparation, extraction, digestion – blender, homogenizer, cryo-mill, QuEChERS, microwave, freeze-drier, etc.

Cannabinoid – solvent extraction / GC or HPLC
Microbial pathogens – culture / PCR
Pesticides – solvent extraction / LC/MS/MS or GC/MS
Metals – acid digestion / ICP or ICP/MS
Solvents – Headspace analysis
Recommendations for Regulation of Hemp Sourced CBD and CBD Products

• Ensure interstate supplies of hemp derived CBD products are certified not to contain psychoactive components or contaminants before they are used as ingredients in edible and other products.

• Establish reciprocity between state CBD laboratory approval programs.

• Adapt current marijuana sampling and testing laboratory regulations for hemp derived CBD products.