

Cannabis: Regulation, Testing, and Standardization

Heather Krug, MS

State Marijuana Laboratory Sciences Program Manager
Colorado Department of Public Health and Environment
Laboratory Services Division

303-691-4028

heather.krug@state.co.us



COLORADO
Department of Public
Health & Environment

Legal Cannabis

Colorado has legalized three types of cannabis:

- **Industrial Hemp** - authorized by US FARM Bill and CO legislation enacted in 2013 [C.R.S. 35-61-101]
- **Medical Marijuana** - (requires physician recommendation) - voter initiative approved in 2000; State Constitution - Amendment 20
- **Retail Marijuana** - (adult use over age 21) - voter initiative approved in 2013; State Constitution - Amendment 64



COLORADO
Department of Public
Health & Environment

Regulatory Authority

Industrial Hemp



Medical Marijuana

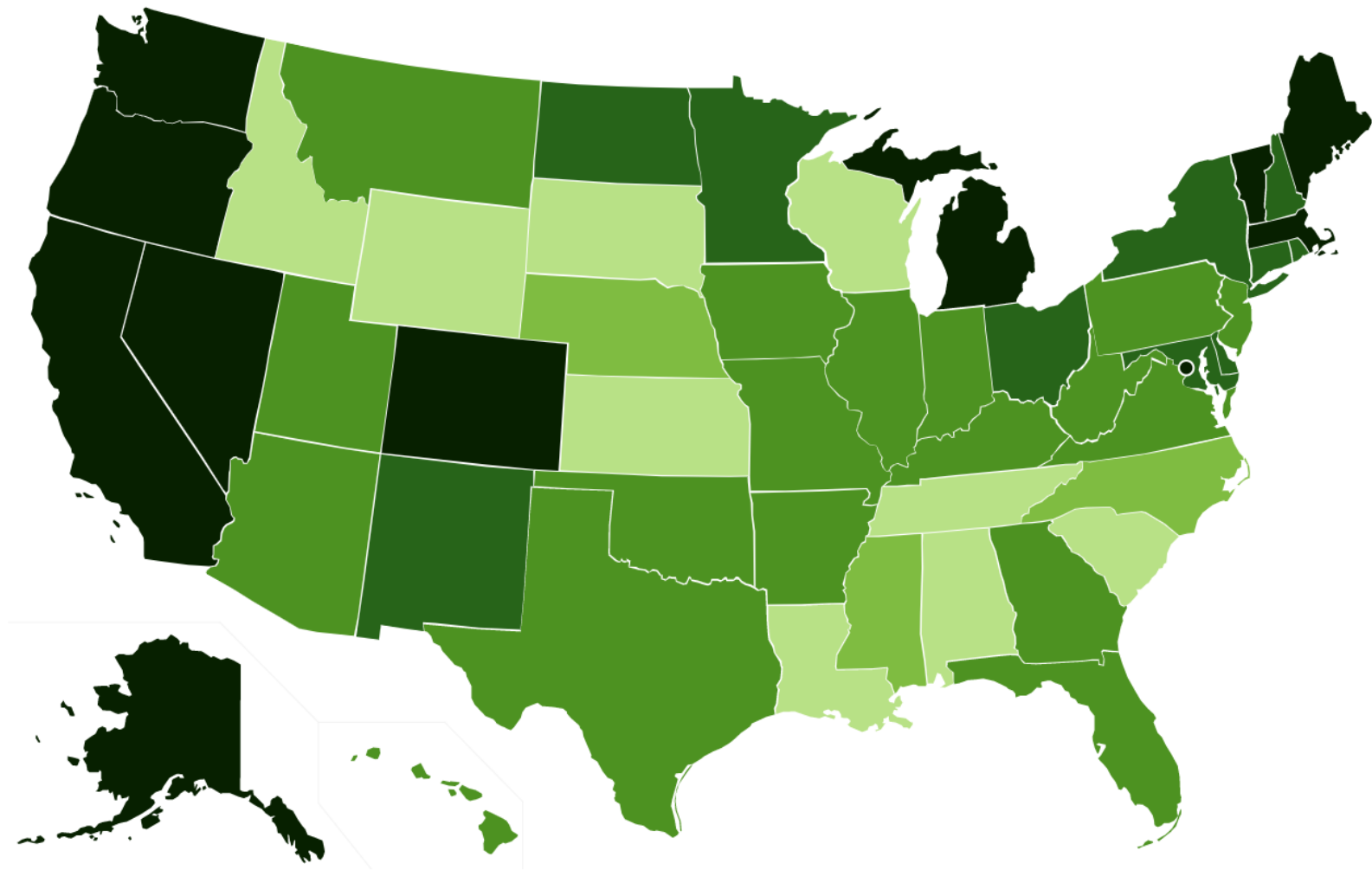


Retail Marijuana



National Status

Legalized Medical and decriminalized Medical Decriminalized Fully illegal



COLORADO
Department of Public
Health & Environment



Need for Standards

Why is standardization needed in the cannabis industry?

- Most importantly - public health and safety.
 - Variability in:
 - Product types (including additives and ingredients).
 - Quality/manufacturing practices.
 - Testing.
 - Labeling.
- Reducing consumer and industry confusion.

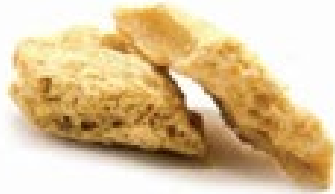


Orally Consumed Products



COLORADO
Department of Public
Health & Environment

Concentrates



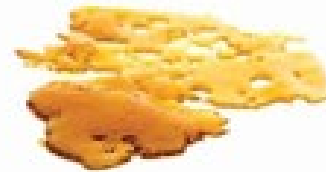
CRUMBLE

Dried oil with a honey-comb like consistency



BADDER/BUDDER

Concentrates whipped under heat to create a cake-batter like texture



SHATTER

A translucent, brittle, & often golden to amber colored concentrate made with a solvent



DISTILLATE

Refined cannabinoid oil that is typically free of taste, smell & flavor. It is the base of most edibles and vape cartridges



CRYSTALLINE

Isolated cannabinoids in their pure crystal structure



DRY SIFT

Ground cannabis filtered with screens leaving behind complete trichome glands. The end-product is also referred to as kief



ROSIN

End product of cannabis flower being squeezed under heat and pressure



BUBBLE HASH

Uses water, ice, and mesh screens to pull out whole trichomes into a paste-like consistency



COLORADO
Department of Public
Health & Environment

Topicals



COLORADO
Department of Public
Health & Environment

Other Products

Many unexpected products appeared on the market.



COLORADO
Department of Public
Health & Environment



Manufacturing Practices

Many states do not require conformity to specific standards such as cGMP or ISO. Regulations typically contain only some components.

- Implications:
 - Lacking detailed records.
 - Inadequate training of staff.
 - Misapplication of pesticides.
 - Sample adulteration.
 - Ingredients/additives and supplies not verified.
 - Lack of complete safety profile of product.





Testing and Labeling

- Required laboratory testing is intended to ensure final products are free of harmful contaminants and ensure label accuracy, protecting patients and consumers.
- However, end-point testing alone cannot ensure product safety.
- Further, testing and labeling requirements vary significantly from state to state for marijuana products.
- Hemp products are currently largely unregulated.



Testing Variability

Compliance Testing Requirements (Flower)

	Potency	Micro	Mycotoxin	Heavy Metals	Residual Solvents	Pesticides	Water Activity	Moisture Content
Colorado	X	X		X		X		
Maryland	X	X	X	X		X	X	X
Oregon	X	Random				X	X	X

Compliance Testing Requirements (Processed Products)

	Potency	Micro	Mycotoxin	Heavy Metals	Residual Solvents	Pesticides	Water Activity	Moisture Content
Colorado	X	X		X		X		
Maryland	X	X	X		X	X		
Oregon	X	Random			X	X		

Laboratory Methods

- Standard cannabis testing methods largely don't exist.
- Labs develop their own in-house methods.
- Staff experience, product type, and required testing result in different methodologies and processes in labs.





Conformity Assessment

Why is conformity assessment needed?

- Consistency in production/manufacturing.
 - Application of quality assurance in supply chain and manufacturing practices.
- Confidence in lab results.
 - Independent assessment of lab competence.
 - Data defensibility.
- Consumer clarity and confidence.
- Mitigates risks to public health and safety.



COLORADO
Department of Public
Health & Environment

Colorado's Progress

- ISO 17025 accreditation requirement added Jan 2019.
- Testing varies depending on intended use of the product.
- Manufacturers of higher risk products such as nasal sprays have additional requirements such as 3rd party audits, master formulation and batch manufacturing records, and equipment verification.
- Marijuana Science and Policy Work Group
 - Regulation change: required recall plans and corrective/preventative action

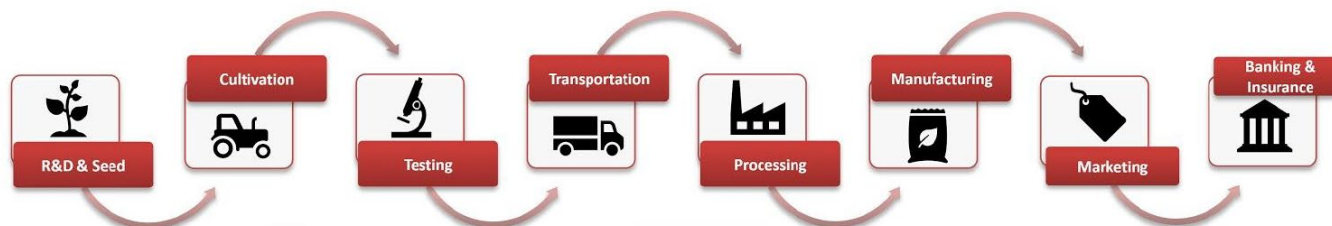


Colorado's Progress

Nasal sprays, MDIs, suppositories, and vaporizer delivery systems:

- Ingredient/additive restrictions - FDA inactive ingredient database for the route of administration
- Required ingredient verification through testing and/or COAs.
- Additional labeling requirements to include additives and the statement “Not approved by the FDA.”

Colorado Hemp Advancement and Management Plan (CHAMP)



International Standardization

- AOAC Cannabis Analytical Sciences Program (CASP)
 - Developing standard analytical methods for cannabis testing.
- ASTM - Committee D37 on Cannabis
 - Developing standards to include horticulture, QMS, processing, security and transportation, personnel, cannabis devices, and testing.





Conclusions

- The cannabis industry is innovative and growing rapidly. Regulation is continuously evolving to keep up.
- State cannabis regulatory testing and manufacturing requirements struggle to encompass all the possible risks due to the variety of cannabis product types, modes of use, and ingredients/additives.
- Federal guidance is limited and in early stages.



Conclusions

- Standardization in production, processing, manufacturing, and testing is necessary to ensure consistent, safe products for patient and consumer use.
- Conformity assessment to these standards is critical to ensuring adherence to these standards.
- Provides benefits and protections to both the industry and to public health and safety.





Thank You!



COLORADO
Department of Public
Health & Environment