

Cannabis Testing: The Colorado Experience

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



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** - 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

Regulatory Authority

- **Industrial Hemp** - Regulated by the CO Department of Agriculture
- **Medical Marijuana** - Regulated by the CO Department of Revenue and Department of Public Health and Environment
- **Retail Marijuana** - Regulated by the CO Department of Revenue/Marijuana Enforcement Division





Marijuana Enforcement Division Roles

Promulgate and enforce rules to control cultivation, manufacturing, distribution, sale, and testing of retail and medical marijuana.

Includes:

- Licensing of businesses and individuals.
- Maintaining seed-to-sale tracking system.
- Certification of testing facilities.



Licensed Marijuana Businesses

	Medical	Retail	Licensed Individuals	
Centers/Stores	498	529		
Cultivators	735	742	Support Occupational Licensees	26,082
Infused Product Manufacturers	254	287	Key Occupational Licensees	12,200
Operators	6	9	Associated Key (business owners)	1,660
Testing Facilities	11	12		
Transporters	8	10		



CDPHE Roles

- Medical Marijuana Registry
- Surveillance: retail MJ health effects, patterns of use, trends, impacts
- Retail Marijuana Education Program
- Laboratory Testing and Assurance
- Food Safety
- Waste disposal
- Medical Marijuana Research Grants Program
- Retail Marijuana Research Grants Program
- Routine duties for protection of public health



CDPHE Laboratory Roles

- Statutory authority to provide standards for licensing testing facilities to MED. Other roles related to testing are consultative.
- Performs audits to ensure that testing facilities meet the rules promulgated by the MED and are competent to carry out specific scientific tests.
- Provides recommendations to MED about suitability of the testing facilities for certification. ISO 17025 accreditation required January 2019.



CDPHE Laboratory Roles

- Provides consultation and recommendations to DOR pertaining to public health and safety for policy and regulation development.
- Development and maintenance of marijuana testing reference library.
- Responsibility for proficiency testing.
- Marijuana Reference Laboratory.



CDPHE Marijuana Reference Laboratory

- Promote competency and consistency in marijuana testing by acting as a technical resource for marijuana testing facilities and other state agencies by publishing methods and providing training.
- Perform testing of marijuana products to resolve questions of accuracy or to assist with licensee investigations.
- Perform testing as part of outbreak or illness investigations.



Colorado Testing Requirements

- Initial testing regulations became effective March 2014 - 3 months after retail sales began.
- Rules were based largely upon CO Board of Health Rules for forensic toxicology labs, American Herbal Pharmacopeia recommendations, and input from the “Good Laboratory Practices Advisory Group” tasked with making initial regulatory recommendations for testing to ensure product consistency and safety.
- Moved towards adopting requirements based upon USP and FDA requirements.
- Medical marijuana testing started Nov. 2016 - statutory requirement for lab proficiency testing delayed implementation.



Colorado Testing Requirements

- Required testing is performed on finished product.

Inhaled Product

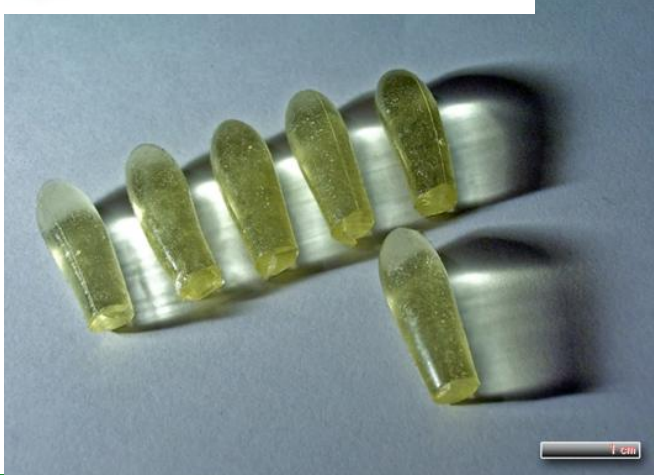
Flower or Trim (including pre-rolled joint and kief)
Solvent-Based Retail Marijuana Concentrate
Water-Based Retail Marijuana Concentrate
Heat/Pressure-Based Retail Marijuana Concentrate
Vaporizer cartridge/vaporizer pen

For Oral Consumption (edible)

Infused food or drink
Retail Marijuana Concentrate
Pills and capsules
Tinctures

Skin and Body Products

Topical
Suppository
Transdermal



Testing Requirements for Medical and Retail Marijuana

Category	Substance	Acceptable Limits Per Gram Product to be Tested	
Microbials (Bacteria, Fungus)	Shiga-toxin producing Escherichia coli (STEC)- Bacteria	< 1 CFU	Flower; Retail Marijuana Products; Water- and Food-Based Concentrates
	Salmonella species - Bacteria	< 1 CFU	
	Total Yeast and Mold	< 10 ⁴ CFU	
Mycotoxins	Aflatoxins (B1, B2, G1, G2)	< 20 PPB (total of all)	Solvent-Based Concentrates manufactured from flower or trim that failed microbial testing
	Ochratoxin A	< 20 PPB	

Category	Substance	Acceptable Limits Per Gram	Product to be Tested
Residual Solvents	Acetone	< 1000 PPM	Solvent-Based Marijuana Concentrates
	Butanes	< 1000 PPM	
	Ethanol*	< 1000 PPM	
	Heptanes	< 1000 PPM	
	Isopropyl Alcohol	< 1000 PPM	
	Propane	< 1000 PPM	
	Benzene**	< 2 PPM	
	Toluene**	< 180 PPM	
	Pentane	< 1000 PPM	
	Hexane**	< 60 PPM	
	Total Xylenes (m, p, o)**	< 430 PPM	
	Any other solvent not permitted for use.	None Detected	

Category	Substance	Acceptable Limits Per Gram	Product to be Tested
Pesticides	Abamectin (B1a & B1b)	< 0.07 PPM	Marijuana flower and trim
	Azoxystrobin	< 0.02 PPM	
	Bifenazate	< 0.02 PPM	
	Exoxazole	< 0.01 PPM	
	Imazalil	< 0.04 PPM	
	Imidacloprid	< 0.02 PPM	
	Malathion	< 0.05 PPM	
	Mycobutanil	< 0.04 PPM	
	Permethrin (isomers)	< 0.04 PPM	
	Spinosad (A & D)	< 0.06 PPM	
	Spiromesifen	< 0.03 PPM	
	Spirotetramat	< 0.02 PPM	
	Tebuconazole	< 0.01 PPM	

Category	Substance	Acceptable Limits Per Gram	Product to be Tested
Metals	Lead	Max Limit: < 1.0 ppm	Flower; Water-, Food-, and Solvent-Based Concentrates
	Arsenic	Max Limit: < 0.4 ppm	
	Cadmium	Max Limit: < 0.4 ppm	
	Mercury	Max Limit: < 0.2 ppm	
Potency	THC	Retail edible products may not exceed 100 mgs of THC	All products
	THCA		
	CBD		
	CBDA		
	CBN		
Pesticides	If testing identifies the use of a banned Pesticide or the improper application of a permitted Pesticide, then that Test Batch shall be considered to have failed contaminant testing.		
Chemicals	If Test Batch is found to contain levels of any chemical that could be toxic if consumed, then the Division may determine that the Test Batch has failed contaminant testing.		
Microbials	If Test Batch is found to contain levels of any microbial that could be toxic if consumed, then the Division may determine that the Test Batch has failed contaminant testing.		

CDPHE Marijuana Reference Laboratory Methods

- Quantitation of 15 cannabinoids by UPLC-QToF/PDA.
- Quantitation of 13 pesticide residues by UPLC-QToF - broad screening method planned.
- Quantitation of 11 residual solvents by GC-MS/FID.
- Mycotoxins by UPLC-QToF.
- Heavy metals by ICP-MS.
- *Salmonella spp.* and STEC by qPCR and plating.
- Total yeast and mold count by plating.



Challenges



Some examples:

- Proficiency testing.
- Lack of standard cannabis testing methods.
- Vast array of product types (complex matrices).
- Ensuring laboratories produce quality results in a highly competitive market.
- Determining which analytes should be tested for and the associated action limits.
- Inadequate sampling practices/sample adulteration.
- Rule changes often met with much resistance.



Current status of pesticide use on cannabis:

- Cannabis is not a specifically listed crop on any registered pesticide label.
- The label is the law!
- EPA does not consider cannabis to fit into any general crop groups, such as herbs or spices.
- No risk assessments have been conducted specifically for pesticide use on cannabis.
- Tolerance limits have not been defined for any pesticide in cannabis.
- November 2015: Executive order issued by the Governor.



- Colorado Dept. of Ag established a list allowed for use on cannabis - 324 pesticides.
- 13 pesticides defined as initial required testing.

Three multi-lab studies were performed:

- IDL (reference standard only)
- Matrix Quality Check (extracted cannabis matrix)
- MDL (homogenized cannabis - three strains including high CBD)
- Regulatory limits were defined by MDL study results.

Conclusions

Challenges:

- In the absence of the typical federal guidance, states are left to develop their own requirements, but must work with limited scientific information.
- Resistance to proper sampling and testing.
- Lack of standard cannabis testing methods.
- Complexity of product types.
- Remaining ahead of rapid industry product development.



Conclusions

Factors for success:

- Extensive coordination with other state agencies.
- Robust stakeholder engagement.
- Effective methods of communication with industry.
- Identifying the relevant expertise needed for effective regulation, execution, and enforcement.
- Formation of focus groups and advisory committees.
- Routine audits of testing facilities.
- Creativity.



Thank you!



COLORADO

**Department of Public
Health & Environment**