

Welcome to  
COLORADO



# Regulation of Marijuana and Hemp Products

*IN THE MILE **HIGH** CITY*



**DENVER**  
ENVIRONMENTAL HEALTH

*Denver's Nationally Accredited Public Health Department*

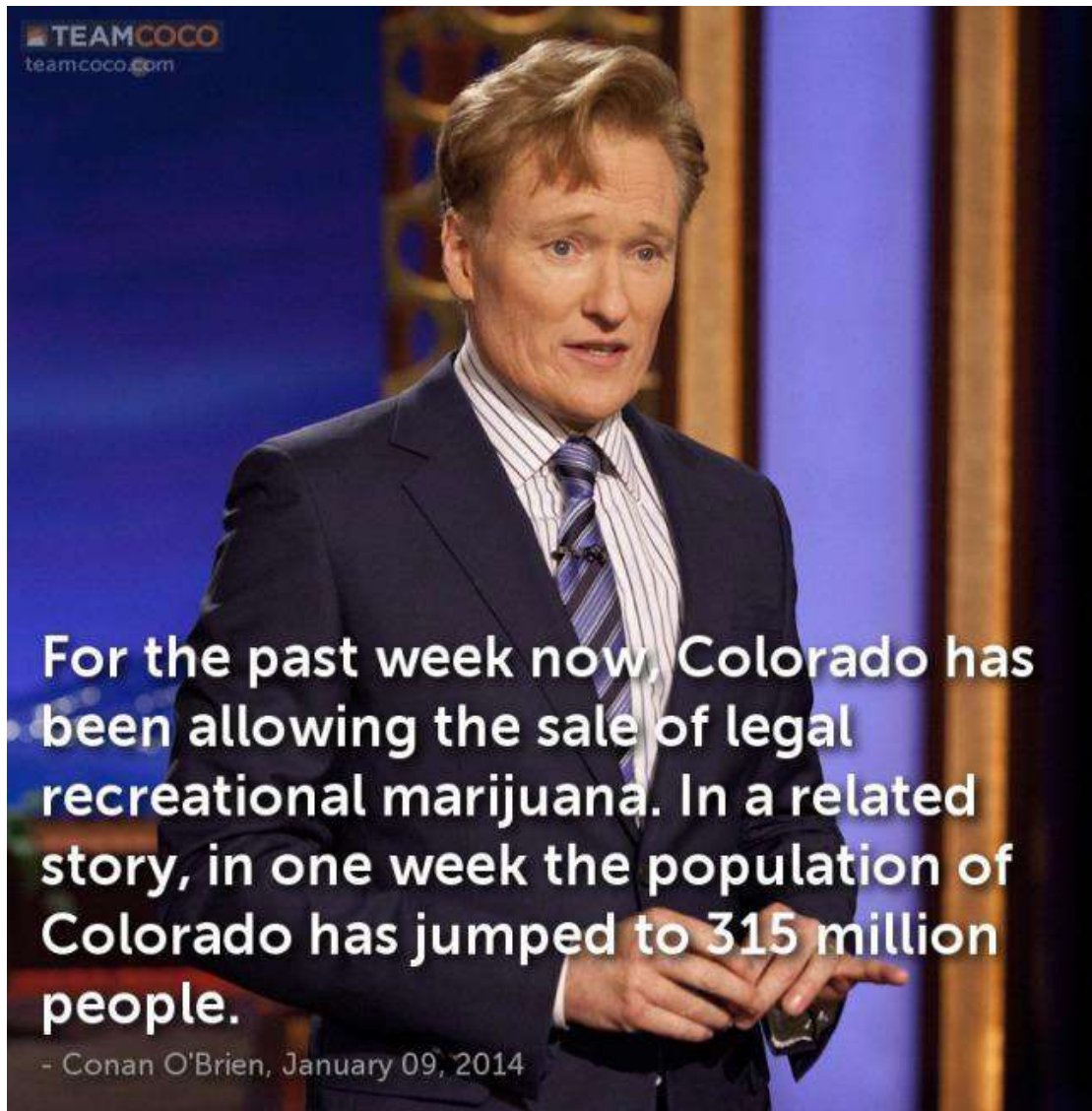


Kara Lavaux

11/29/17

Massachusetts Environmental  
Health Association Conference

Haha...



For the past week now, Colorado has been allowing the sale of legal recreational marijuana. In a related story, in one week the population of Colorado has jumped to 315 million people.

- Conan O'Brien, January 09, 2014



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# How did we get here?

- 2012: Amendment 64 petitioned onto the ballot amended the Colorado constitution legalizing the personal, private use of marijuana
- Passed in Colorado by about 55% of the vote & in Denver by 66%
- **Allows adults over 21 to:**
  - Possess up to one ounce of marijuana
  - Possess and grow up to six marijuana plants, only 3 of which can be flowering
  - Transfer up to 1oz of MJ between adults without payment
  - Private consumption of MJ
  - Assist another adult in any of these acts



# Will of the voters



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# Main Governmental Partners

## City of Denver

- Dept of Environmental Health
- Denver Fire Dept
- Denver Office of Marijuana Policy
- Dept. of Excise & Licenses
- Denver Police Dept
- Community Planning & Development
- Risk Management
- City Attorney's Office

## State of Colorado

- Dept of Revenue, Marijuana Enforcement Division
- Colorado Department of Agriculture
- Colorado Dept of Public Health & Environment
- Colorado Attorney's General

# Denver Environmental Health

*Empowering Denver's communities to live better, longer*

## 5 Divisions

- Office of the Medical Examiner
- Denver Animal Protection
- Environmental Quality
- Community Health
- Public Health Inspections

## Public Health Inspections

- 2 Division Sections
  - Food Safety & Marijuana
  - Healthy Families Healthy Homes

Partner closely with Denver Public Health

## Establishments

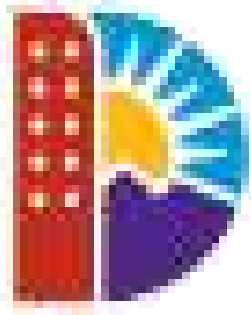
- Food Service & MJ
- Child care facilities
- Residential health
- Noise
- Lead
- Body art establishments
- Pools
- Boarding homes

# DEH Background with Legal Cannabis

- 2010: Food safety inspections of marijuana food businesses begin
- 2014: Twice annual inspections of all Denver marijuana infused product manufacturers and retailers begin; first Denver MJ recall
- 2015: Enforcement actions for pesticide contaminated MJ products begin, first Marijuana Management Symposium
- 2017: CBD product enforcement, Cannabis Sustainability Guide, Marijuana Health & Safety Hotline, Industry meeting
- 2018: Cannabis Health and Safety Advisory Committee

# Colorado Marijuana Licensing Dual Licensing System

- To operate a licensed marijuana business in Denver, you must have **BOTH** a state license AND a local license
- The Colorado Marijuana Enforcement Division (MED) licenses and regulates marijuana businesses for the state.
- The Denver Department of Excise and Licenses (EXL) licenses and regulates for the city.



# Marijuana Business Licenses

Denver has 10 distinct Marijuana Licenses

Currently, Denver has ~1,100 licenses operating out of ~500 unique locations.

## RETAIL

- Stores
- Cultivation
- Infused Products (MIP)
- Testing Facility

## MEDICAL

- Centers
- Cultivation
- Infused Products (MIP)
- Testing Facility

## BOTH

- Social Consumption
- Transport

# Denver Marijuana Landscape – Inspections

**Number of Annual Compliance Inspections Performed  
By Each City Agency per License Type**

	Environmental Quality	Excise and Licenses	Fire Department	Public Health Inspections
Retail Stores	-	1	2	2
Retail Cultivation Facilities	1	1	2	-
Retail Infused Products Manufacturers	-	1	2	2
Retail Testing Facilities	-	1	2	-
Medical Centers	-	1	2	2
Medical Cultivation Facilities	1	1	2	-
Medical Infused Products Manufacturers	-	1	2	2

# Authority

## Denver Revised Municipal Code:

- Chapter 23: Food & Food Handlers
  - Denver is a home-rule jurisdiction- only CO locality with own food safety regs
  - Regulations (Ch 23, D.R.M.C.) are applied to marijuana food businesses since 2010
  - Includes concentrates if ingested
- Chapter 24: Health & Sanitation
  - Enforcement authority for hindering an investigation
  - Authority to conduct recalls for contamination issues



# Safety

- Explosion from extraction processes
- Hydrocarbon toxicity from improper ventilation during extraction process
- Reduced oxygen, increased CO2 in grows
- Criminal activity
- Chemical exposure - Tyvek
- Denver safety video



# Inspection Process Overview

## Role of Food Safety Section with MJ Food Operations

- Conduct plan reviews
- Approve business licenses
- Inspect food businesses & apply *Denver Food Establishment Regulations*
- Investigate complaints
- Timeline:
  - 2010: Started routine inspections of MJ food operations
  - 2012 & 2013: Complaint investigations only
  - 2014 - present: Routine inspections at least twice per year & contamination investigations as needed



# MJ Products Regulated as Foods

All marijuana products that are consumed via non-smoking oral consumption:

- Infused baked goods, candies, etc.
- Infused pizza, ice cream, drinks, peanut butter
- Concentrated extractions if consumed as food
- Infusions such as tinctures, butters, honey, oils, etc.

*\*\*contaminated smoking/vaping products regulated under Ch. 24 of DRMC*



# How to get high!

## It's not just joints and pot brownies...

HIGHER LEARNING

powered by  
weedmaps®

# OSMOSIS OF MARIJUANA



### INHALATION

ONSET: 0-10 MINS

PEAK: 30 MINS

DURATION: 1-4 HRS



### ORAL

60-90 MINS

2-3 HRS

6-8 HRS

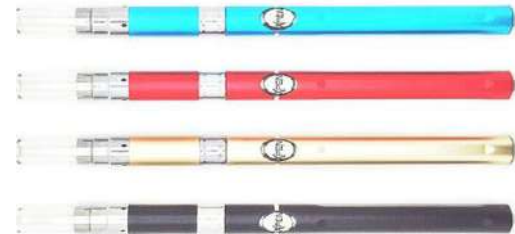


### SUBLINGUAL

5-60 MINS

1-2 HRS

1-4 HRS



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# Anatomy of Marijuana



## **Bud**

The part of the plant with the highest concentration of tetrahydrocannabinol and other cannabinoids is the bud. This is what users typically smoke. It also can be used to make edibles and tinctures after being trimmed, dried and cured.



## **Fan leaves**

The big leaves with as many as 13 leaflets are what most see as the universal image of marijuana. With the lowest concentration of THC, they are typically tossed after being trimmed from the plant.



## **Sugar leaves**

The smaller leaves with a high concentration of THC are used to make edibles after being trimmed, dried and cured.



## **Stem**

After everything is trimmed from it, the stem can be used as an additive for tinctures.



## **Trichomes**

The tiny crystals that form on the bud and leaves determine when the growing cycle is complete. They also can indicate whether a plant has a high concentration of THC.



# Concentrates 101

Low tech



High tech

Kief  
Hash  
Rosin  
Cannabutter  
Ethanol  
BHO  
CO<sub>2</sub>



# Kief



Kief is the simplest of concentrates. Kief is composed of the trichomes broken away from the dried plant material, usually via filtering screens and a little elbow grease. THC content can range from 20 percent to 60 percent.

# Water Hash

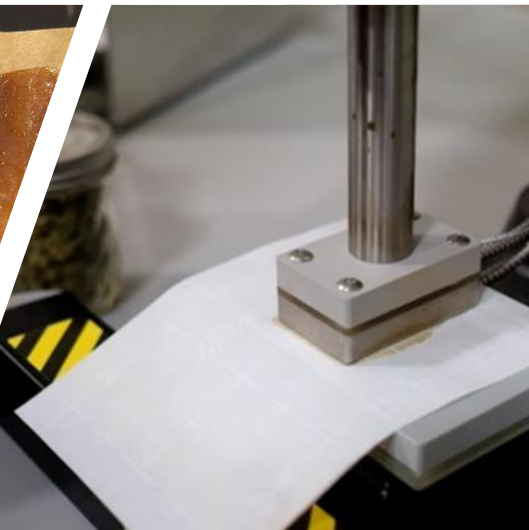
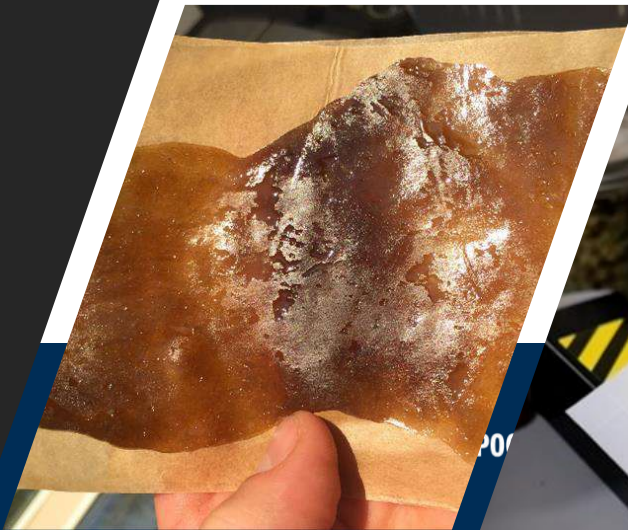


Ice water extraction is one of the most common processes used to create quality non-solvent hash. Trichome heads become brittle from the ice and break off.



# Rosin

- Rosin refers to an extraction process that utilizes a combination of heat and pressure to nearly instantaneously squeeze resinous sap from your initial starting material (bud, hash, kief)
- Dabs
- Easy, affordable



# Cannabutter

## Basic recipe:

- Bake MJ in oven to decarb
- Simmer MJ, water, butter on stove for 3 hours
- Strain mixture over bowl with cheesecloth
- Refrigerate until the butter layer separates from the cooking water
- Discard water
- Use in edibles



# Ethanol

- Soak the plant material in ethanol
- Strain out plant material
- Purge off ethanol with roto-vap
- Used in edibles



# BHO



- Butane hash oil, commonly referred to as BHO, uses butane as the solvent. Further refinement makes different textures: shatter, budder, honeycomb, and sap.
- Propane and hexane too
- Live resin
- Residual solvents
- \$20K-\$40K + cost of Fire req.





- Carbon dioxide ( $\text{CO}_2$ ) extractions use a supercritical fluid, meaning it converts from gas to liquid when pressurized.
- ~\$100K



# BHO & CO<sub>2</sub> Production Processes

## Cultivation

Hemp or marijuana plants grown, “trim” used for concentrates

## Extraction

Oils extracted from raw plant material via solvent, most commonly supercritical CO<sub>2</sub> and butane

## Refinement

Winterization, distillation, other methods to refine and purify extraction

## Decarboxylation

Decarboxylation heat step to activate THC or CBD (if not achieved during extraction or refinement)

## Final processing

Addition of terpenes, cutting agents, etc. to achieve desired flavor and viscosity



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# Hazards of Concentrate Production Processes

## Cultivation

Heavy metals,  
pesticide, mold, mites

## Extraction

Solvent impurities  
depending on grade,  
residual solvents,  
pesticides

## Refinement

Process dependent

## Decarboxylation

Higher temperature  
needed to decarb CBD  
compared to THC–  
hazards not identified

## Final processing

Addition of ingredients  
that haven't been  
evaluated for  
smoking/vaping risks

## End Product

Shelf stability concerns,  
*C. Botulinum* hazard for  
ingested products

# Challenges

## Equipment

- No standards

## Hemp derived products

- Big regulatory gaps

## Shelf stability

- *Clostridium botulinum* concerns

## Pesticides

- Numerous recalls

## Added ingredients

- Safe to smoke?

## No federal oversight

- No GMPs, guidance, research, precedents



# Production Equipment





# 2014: Denver's First Recall

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# Shelf Stability of Ingestible MJ Extracts

Plant derived oils for ingestion must be temperature controlled unless one of the following control measures are in place for c.bot spores:

- Plant material is irradiated
- Extract is suspended in alcohol and homogenous
- Thermal critical limit met
- Low pH/water activity is barrier to bacterial growth
- Product is labeled for smoking only
- Scientific research demonstrating safety of another critical limit is provided and approved



Businesses can submit HACCP-type plan for review and shelf-stability approval

# Shelf Stability of Ingestible MJ Extracts



Department of Environmental Health  
Public Health Inspections Division

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[www.denvergov.org/phi](http://www.denvergov.org/phi)

## Special Concerns Associated with Cannabis Extractions, Concentrations, Infusions, and Infused Foods

The Public Health Inspections Division (PHI) of the Denver Department of Environmental Health is responsible for enforcing regulations that preserve the health of consumers in Denver. PHI enforces the Denver Rules and Regulations Governing Food Establishments to regulate all food/products which are commercially manufactured and/or sold in Denver and that are ingested via non-smoking oral consumption (i.e. eating, drinking). Please visit [www.denvergov.org/phi](http://www.denvergov.org/phi) for more information or to view the Regulations.

Commercial manufacturing of cannabis-infused products is an emerging industry, and regulation of this industry is a new area of regulation. There is no known published research that addresses how pathogens grow in cannabis extractions and their derivatives. Until such information is available, it is the responsibility of PHI to enforce existing food regulations to protect the health of consumers and to use existing research and food science to assess the risks of foods. Requirements may change as new information becomes available regarding the safety of cannabis extractions.

### What are the public health concerns associated with cannabis extractions and infusions?

The extraction process can be dangerous if not performed properly, and the final extract can be harmful to consume if the extraction is not performed properly. All extractions must be conducted using a closed loop system with an approved solvent, and in Denver the system must be permitted by the Fire Department. Refer to the State's Marijuana Rules for further information about extraction requirements.

*Clostridium botulinum* is a bacteria whose spores are present on plant material and in soil. Spores are present in many plant material extractions and can survive cooking/pasteurization temperatures. These spores can spontaneously germinate (grow into bacteria) given the right conditions/substrate. The bacteria can produce a powerful toxin which can cause severe illness or death.

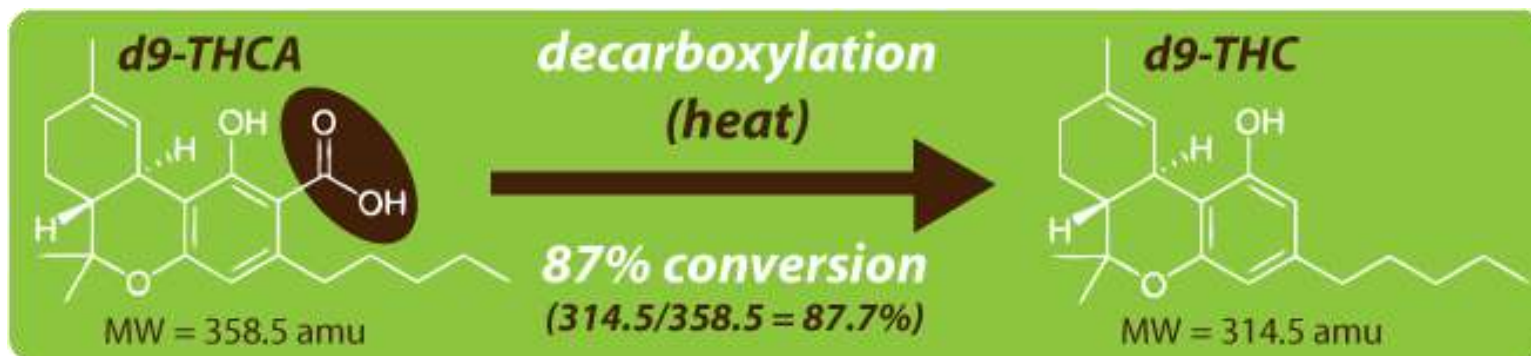
### What are the products of concern?

Affected products include:

- cannabis extractions and concentrates intended for non-smoking oral consumption (i.e. eating, drinking)
- most infusions made from these extractions, such as infused oils, butters, honey, etc.

# Decarb steps/C. bot destruction

- MJ plant material must be decarboxylated (“decarbed”) through heating to transform THCA (acid form) to THC that has psychoactive effect
- Lucky for us, this decarb step also destroys C. bot spores
- Without decarb step, ingesting plant material and derivatives has no psychoactive effect



# Pesticide Contamination

## Pot or Pesticides Color

#168858

BY MIKE KEEFE, GAGLE CARTOONS - 3/16/2015 12:00:00 AM

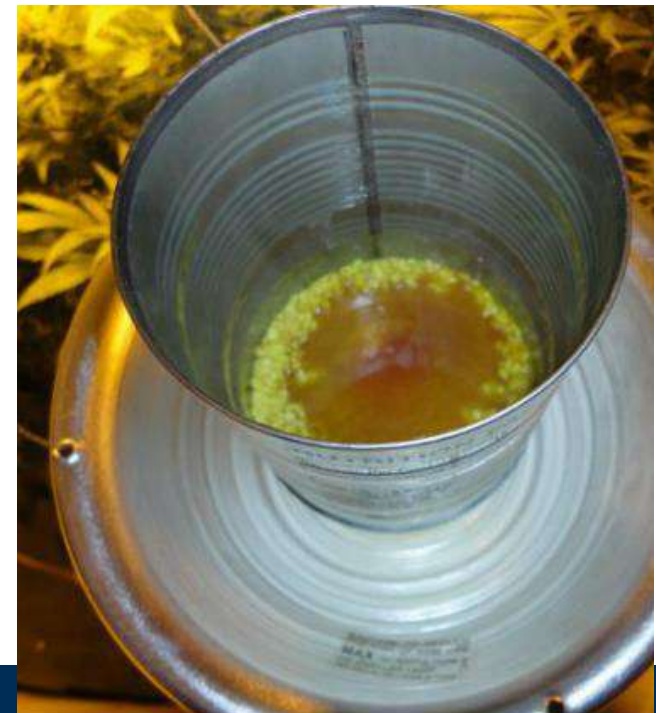




# Pesticide Contamination

# Denver's Crash Course in Pesticides

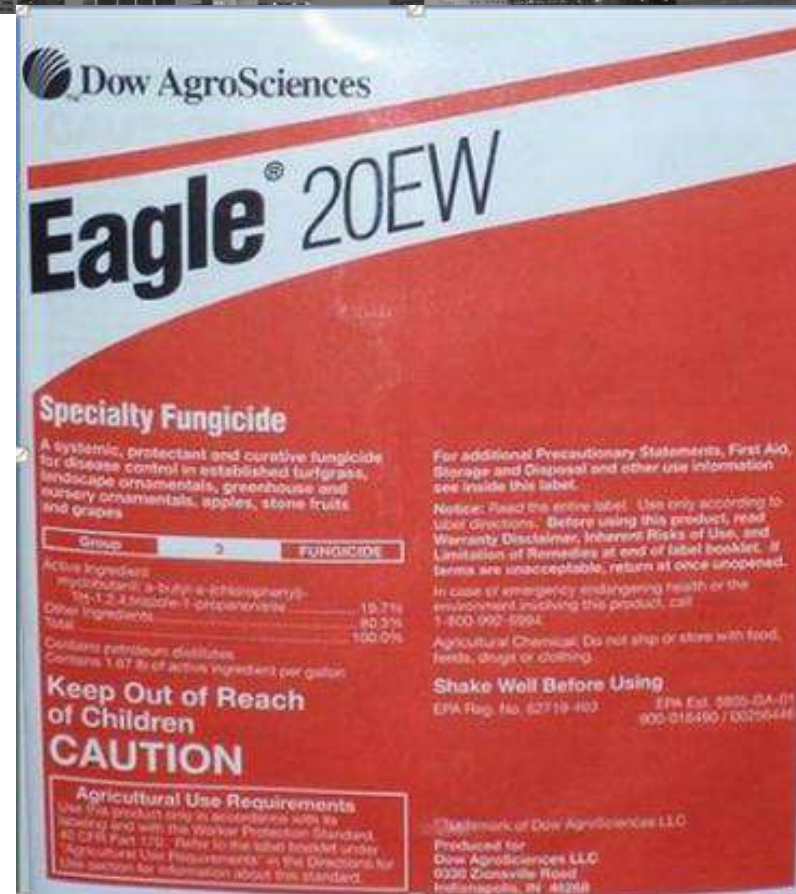
- Denver Fire started voicing concerns in late 2014 about sulfur burns for pest control
- When sulfur is burned → yields sulfuric dioxide
- Sulfur dioxide + moisture = sulfuric acid
  - Harmful to eyes, lungs, nose
- Denver fire concerned for first responders and cultivation employees



# Denver's Crash Course in Pesticides

Denver Fire started paying more attention...

*-Ornamental use only*  
*-Outdoor use only*



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# ...Which is how we made friends with the Colorado Dept of Agriculture!

- Complex jurisdictional issues
- Pesticide use and application is sole authority of Colorado Dept of Ag
- However, DEH has authority over contaminated consumer products
- Denver EH investigates off-label pesticide *contamination*, NOT off-label *use*



# Pesticide Contamination-Denver Enforcement

- Initial actions in March-May, 2015 based on complaints/referrals of off-label contamination:
  - 11 Denver “holds” on grow facilities, hundreds of millions of \$\$
  - Colorado Dept of Ag also opened off-label pesticide use investigations (no authority over products)
  - followed by a district court lawsuit alleging Denver EH pre-empted state law by addressing pesticide contamination
  - May 2015: judge ruled we were “**absolutely within our authority**” to **protect public health** by placing the holds on this potentially contaminated crop

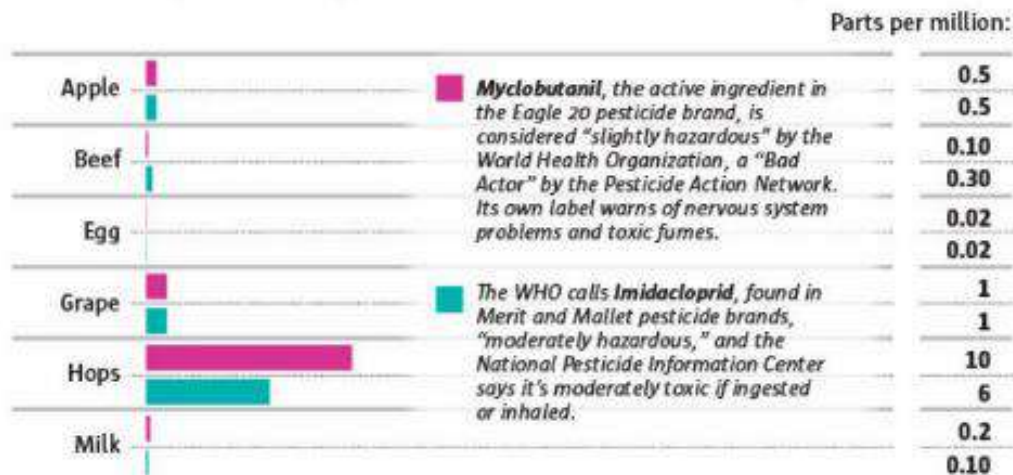
# Pesticide Contamination-Denver Enforcement

- 97 pesticide contamination investigations done since March 2015
- 36 pesticide contamination recalls since September 2015 affecting hundreds of thousands of units
- 1 recall due to unclean equipment; 2 due to shelf-stability; 1 due to mite & mold contamination
- 2 appeals of enforcement action to Denver's Board of Environmental Health

# Pesticide Contamination

## Pesticide tolerances

When Denver quarantined 100,000-plus marijuana plants this year for unapproved pesticide use, myclobutanil and imidacloprid were two of the top culprits. Below are the EPA allowable tolerance levels for those pesticides in some common foods, and the levels that The Denver Post found in independent testing of two Mahatma Concentrates cannabis products.



### Mahatma Concentrates' Black Label marijuana extracts



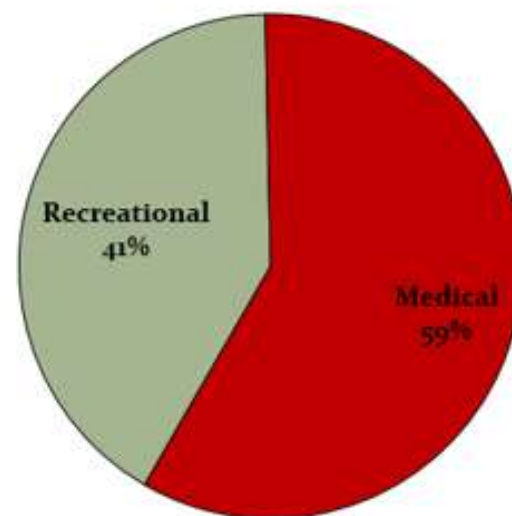
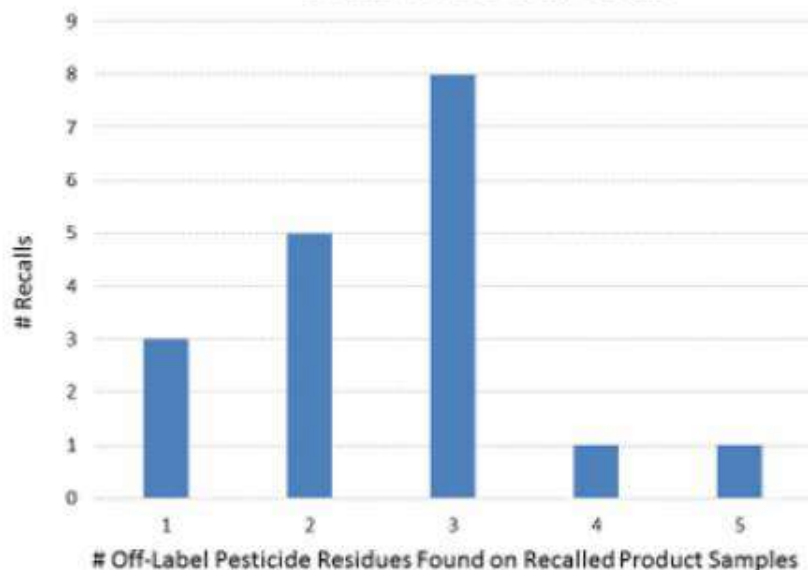
Source: Environmental Protection Agency; Gobi Analytical

Severiano Galván, The Denver Post

# Pesticide Contamination

## Medical vs Recreational Number of Products Recalled

Number of Different Pesticide Residues Found on Each Product by Recall



Median # of pesticide residues found on recalled product samples = 3

# Hemp versus Marijuana

- Both are species of cannabis

## Hemp

- Long history of industrial use
- More recent breeding for CBD/therapeutic use
- Low in THC (less than .3% by law)
- Legal to transport across state lines? Up for debate (and litigation)
- Recent breeding for high CBD strains

## Marijuana

- Long history of psychoactive use
- High in THC (5-30%)
- Not legal to transport across state lines
- All derivatives must remain within state-licensed MJ system
- Selective breeding for high THC and CBD strains, others

# CO Cannabis Legal Summary

- Both are classified as Schedule I drug under federal law

## Hemp

- 2014 Farm Bill created allowances for state hemp pilot programs
- Ingestible ingredients must be derived from seed, stalk, or stem
- 2015: Colorado Dept of Ag started industrial hemp program
- July 2017: CDPHE allows any part of hemp plant to be used in food

## Marijuana

- Medical use legalized in CO in 2000 via constitutional amendment
- Proliferation of storefronts in 2009-2010 after legal challenges to caregiver model
- Voters approved Amendment 64 legalizing rec MJ in 2014
- Licensed/regulated by MED

# Hemp Products in Early 2017

- Growing popularity of CBD products
- Increasing use of hemp as CBD source
- Concerns voiced by some in industry about snake oil phenomenon
- Hemp-derived CBD products are NOT REGULATED by anybody
- Many products coming from California; CBD concentrates sourced from Europe, China



# DEH Action in April 2017

- Administrative holds placed on consumable CBD products in Denver from unregulated sources
  - Products from 42 manufacturers held
- Based in part on info from federal agencies, DEH indicates no hemp or derivative allowed from outside CO
- Holds also affect MJ manufacturers adding hemp derived CBD to products

# DEH Action in April 2017

DEH offers remote plan and SOP review if manufacturers provide:

- Manufacturer name/address
- SOPs
- Ingredient list/sources
- Product labels
- Quality control & validation procedures
- Facility plans/layout



Department of Environmental Health  
Public Health Inspections

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April 7, 2017

## Information Regarding Cannabidiol (CBD) Products Sold or Manufactured in Denver

In recent months, Denver has seen an increase in the sale of cannabidiol (CBD) products intended for human consumption. As the local health authority, the Denver Department of Environmental Health (DEH) is responsible for addressing potential consumer safety concerns relating to products sold or served in Denver. Some of the CBD products being sold in Denver are manufactured outside the oversight of any regulatory agency. In Denver, manufacturers of ingested or inhaled CBD products are subject to Denver regulations (Chapter 23 D.R.M.C., §24-16 through 24-18, D.R.M.C.) and DEH inspection. All CBD products and additives in these products that are sold in Denver must meet safe manufacturing standards, come from an approved source, and comply with all relevant laws.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) prohibits the introduction or delivery for introduction into interstate commerce of any new drug that has not been approved by the Food and Drug Administration (FDA). To date, FDA has not approved any drug product containing CBD. In addition, FDA has concluded that CBD products are excluded from the definition of a dietary supplement in the FD&C Act. Furthermore, under the FD&C Act, it is a prohibited act to introduce or deliver for introduction into interstate commerce any food to which CBD has been added.

It has come to DEH's attention that some CBD products originate from unregulated manufacturing facilities, have been illegally shipped across state lines, contain unapproved ingredients, or have been made in unsafe manufacturing conditions. When DEH encounters these products, retailers and manufacturers may be subject to DEH enforcement and requests for additional information to demonstrate that the product was manufactured safely. Examples of information that may be required by DEH include:

- Manufacturer name and address
- Manufacturer proof of license, registration, inspection, or review of processing from a state or local Colorado authority
- SOPs for the production of the subject product(s)
- List of all ingredients and/or additives used for production and information to substantiate their safe source
- Product labeling
- Quality control procedures for verifying the product formulation and absence of contaminants such as pesticides
- Additional information as needed

Potential concerns with some CBD products that have been identified include CBD ingredients originating from other countries, improper labeling to communicate intended use of products, unsubstantiated health claims on labels of CBD products, and potentially unsafe manufacturing conditions such as no hand washing equipment or inadequate sanitation procedures. Retailers and manufacturers of CBD products are encouraged to contact DEH at [phicommments@denvergov.org](mailto:phicommments@denvergov.org) with any questions.

# State involvement

- July 2017: CDPHE accepts wholesale food facility registrations for CBD ingestible product manufacturers
- CDPHE allows hemp and derivatives from outside CO provided:
  - Hemp is grown under a regulated industrial hemp program
  - Standards for ingestion/consumption are applied
- DEH aligns with CDPHE allowance for hemp grown under an industrial hemp program with standards for consumption– even if outside CO
- Still no regulation or authority over smoking/vaping hemp-derived CBD products

# August 2017 DEH Bulletin



August 30, 2017



## Update on Requirements for Hemp-Derived CBD Products Sold in Denver

In April 2017, Denver's Department of Environmental Health (DEH) published [guidance](#) regarding cannabidiol (CBD) products manufactured or sold in Denver. At that time, DEH also restricted the sale of CBD products originating from unregulated sources due to consumer safety concerns. However, CBD manufacturers were still able to pursue approval to sell in Denver by submitting documentation demonstrating evidence of safe and standardized operations. The DEH guidance also indicated CBD products, including hemp, that originated from outside Colorado, were considered from an unapproved source due to their unregulated status and the federal restrictions on interstate transport.

In July, the Colorado Department of Public Health and Environment (CDPHE) [announced](#) they will now accept wholesale food manufacturing registration applications for edible CBD product manufacturers. Approved manufacturers will be regulated under the Colorado Wholesale Manufacturing Food Regulations. CDPHE also indicated that hemp sourced from outside of Colorado is considered from an approved source provided all utilized parts of the hemp plant originate from a cultivator operating under a regulated industrial hemp program which applies safe consumption criteria. Since CDPHE's announcement, DEH has followed the same standards set by CDPHE.

DEH is continuing to evaluate Colorado CBD product manufacturers who are located outside of Denver upon request for those businesses that have not yet been inspected and evaluated by CDPHE. These evaluations allow impacted businesses to get approval to sell products in Denver in advance of a CDPHE inspection.

Businesses interested in this DEH evaluation should refer to the information addressed in the April [DEH guidance](#). In lieu of a DEH evaluation, Colorado manufacturers outside of Denver can submit a CDPHE inspection report of their operation to DEH for review, if available. To get approval from DEH to sell in Denver, this report must demonstrate no outstanding violations that may contribute to significant consumer safety hazards.

Manufacturers of consumable CBD products outside of Colorado must show evidence of inspection or oversight by a regulatory health authority, such as a local or state health department or other regulatory authority, to proceed with sales in Denver. These products can be approved for sale in Denver provided there are no outstanding violations identified by the applicable health authority that may contribute to significant consumer safety hazards.

Questions? Contact the Public Health Inspections Division at [phicommments@denvergov.org](mailto:phicommments@denvergov.org).

As Denver's nationally-accredited local public health agency, the Department of Environmental Health (DEH) is dedicated to advancing Denver's environmental and public health goals. The divisions of DEH are: Animal Protection, Community Health, Environmental Quality, Office of the Medical Examiner, and Public Health Inspections.

For more information about DEH, visit [www.denvergov.org/EnvironmentalHealth](http://www.denvergov.org/EnvironmentalHealth) or follow us on



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# Added ingredients

- Emerging issue– hemp and MJ
- Concerns with ingredients added to smoking/vaping concentrates
- Additives commonly include GRAS flavors, propylene glycol, glycerin, essential oils
- Little research on smoking/vaping consumption
- Cannabis-derived terpenes
- FDA's regulation of Electronic Nicotine Delivery Systems (ENDS)
- Developing a Cannabis Health and Safety Advisory Committee; ingredients will be first issue tackled

# MJ Health & Safety Hotline

- Launched in May 2017 by Rocky Mountain Poison & Drug Center in partnership with DEH/City of Denver
- Intended for health surveillance, occupational safety hazard surveillance, resource for citizens and industry
- Nearly half of calls within first few months related to CBD product questions
- More than half of calls from callers outside of Denver and Colorado

## Marijuana Health & Safety Line

### Connecting you to trained medical and toxicology professionals

In partnership with the City and County of Denver, Denver Health's Rocky Mountain Poison & Drug Center offers a free and confidential 24/7 phone line — to answer all your marijuana and cannabidiol (CBD) health and safety questions.

**Medical providers and toxicology experts are here to answer marijuana health and safety questions 24/7 at 877-741-3777.**

*For immediate life-threatening emergencies, always call 911.*

**For Marijuana Consumers:** Our caring staff of registered nurses and pharmacists are here to help, whether it's explaining marijuana and CBD side effects, answering questions about edibles, or for better understanding Tetrahydrocannabinol (THC) — we're ready for your call.

**For Marijuana Industry Professionals:** Our trained staff can assist industry inspection officers with toxicology questions and consultations — in an ever-changing industry, rely on our medical safety team for questions about pesticides, toxins, contaminants, additives or other ingredients that may be used in or found in the cultivation of marijuana in Colorado.

We are here to help at **877-741-3777**.

### When to Call: For Health and Safety Advice

- If you're wondering, "can you overdose on weed?"
- If you've had any strange reactions to marijuana
- Questions about cannabidiol (CBD) products
- If you're concerned about using marijuana while taking prescription medication, or using other drugs
- If you're a health care provider with questions about marijuana
- If you're experiencing concerning medical symptoms from marijuana use
- If you have concerns about the marijuana product you've purchased (packaging, smell, taste, serving size)
- Questions about occupational safety hazards for marijuana industry workers as well as



# Will of the voters



# Questions?

Kara Lavaux, Food Safety and Marijuana Program Supervisor

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Denver Dept. of Environmental Health

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