



DENVER
THE MILE HIGH CITY

Consumer Protection & Legal Marijuana in Denver

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Denver Department of Environmental Health

- 5 Divisions with 200 employees:
 - Office of the Medical Examiner
 - Denver Animal Protection
 - Environmental Quality
 - Community Health
 - Public Health Inspections
 - 2 Sections:
 - Food Safety & Marijuana
 - Healthy Families/Healthy Homes



Food Safety Inspections of MJ

- Local food safety regs have been applied to Denver marijuana food businesses since 2010
- Includes concentrates if ingested
- All MJ manufacturers & retailers receive EH plan review and min. 2 inspections annually
- All complaints investigated
- MJ businesses outside of Denver receive no food safety inspections; MJ products not regulated as “food” by State Health Dept



Shelf-Stability Concerns with Hash Oils for Ingestion

- Plant-derived oils may have *C. botulinum* spores
- Concerns about micro-environment supporting *C. botulinum* growth and toxin formation
- DEH requires one of the following for hash oils:
 - labeled for smoking/vaping only
 - Stored at 41F or less
 - Product evaluation/approval by Denver EH for shelf-stable storage
- Handout for industry:
<https://www.denvergov.org/content/dam/denvergov/Portals/771/documents/PHI/Food/Special%20Concerns%20with%20MJ%20extractions.pdf>



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Special Concerns Associated with Marijuana 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 Food Establishment Rules and Regulations 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 for more information or to view the Regulations.

Commercial manufacturing of marijuana-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 marijuana 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 marijuana extractions.

What are the public health concerns associated with marijuana 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:

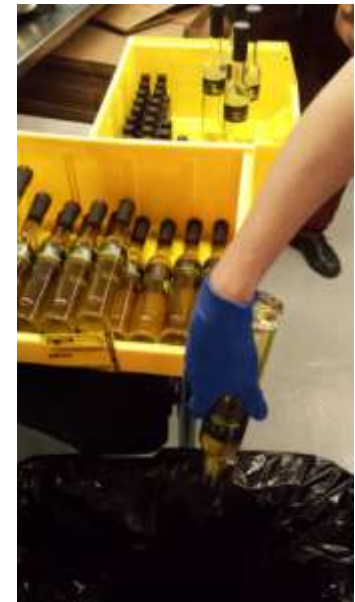
- marijuana extractions and concentrates intended for non-smoking oral consumption (i.e. eating, drinking)
- most infusions made from these extractions, such as infused oils, butters, honey, etc.
- many foods that have such infusions/extractions as an ingredient

What are the known controls for preventing *C. botulinum* toxin formation?

- Irradiating plant material destroys the spores and bacteria, preventing toxin formation.
- Refrigerating the plant material extractions/concentrates and derivatives at 41 °F or less prevents the growth of existing *C. botulinum* spores. (Please note that if a marijuana extraction, concentrate, or infusion has been continuously refrigerated and is then added as an ingredient into baked goods that have a low water activity, such as most cookies and brownies, these baked products are considered shelf-stable.)

- Continued food safety inspections
- Started to receive more referrals from other agencies and consumer complaints
- Started to see big increase in types of products and distribution
- We started to develop increased understanding of products, processes, and associated risks

- Authorities in Chapters 23 & 24, DRMC
- DEH staff are badged and can issue criminal summons
- Administrative citations assessed for repeat violations
- Food disposals, facility closures where imminent health hazards exist
- First ever recalls of marijuana food product conducted in 2014



First MJ Product Recall, July 2014

- -Issue identified at routine inspection of MJ-baking mix business
- -Marijuana ingredient extracted in old domestic laundry machine



- Constant industry innovations
- Unapproved equipment
- Industry lacks consumer safety expertise, GMPs
- Establishing standardized policies
- Safety
- Complex supply & distribution
- Staffing
- Communications



- Explosions from concentrate production
- Hydrocarbon toxicity from improper ventilation during concentrate production
- Reduced oxygen, increased CO₂ in grows
- Criminal activity
- Cross contamination between grows- Tyvek
- Denver safety video

- Cultivation practices influenced by plant value
- Solvent grade; impure solvents are much cheaper
- Heavy metal absorption
- Nutrients
- Off-label pesticide residues
- Hash oil shelf-stability, *C. bot* concern with ingestion
- Unsafe equipment for food/smoking production

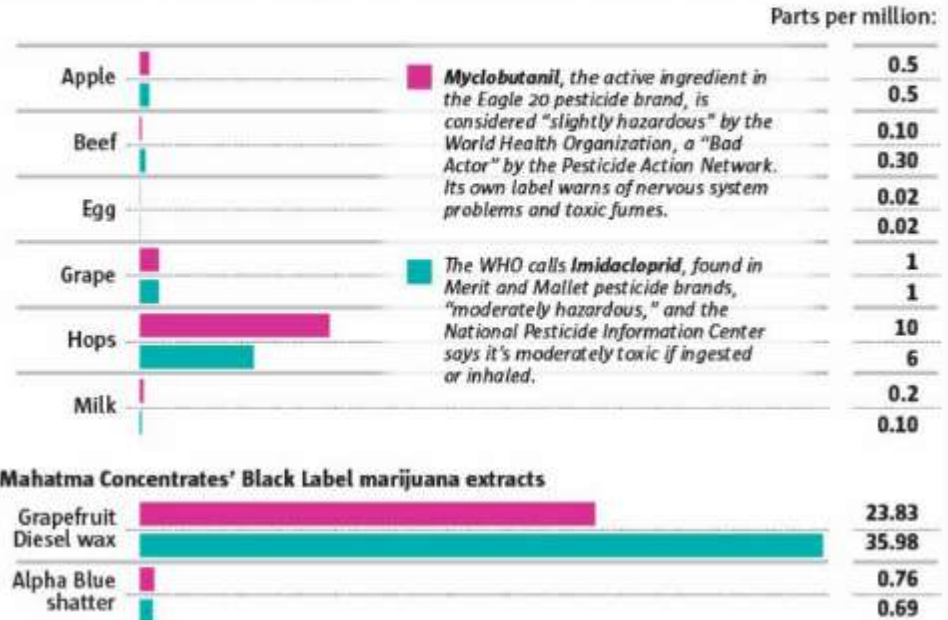
Pesticide Contamination: Denver Enforcement

August 2015: Denver Post commissions tests and finds high level contamination in concentrates

One lab director indicated that between April and September 2015, approximately 10% of samples were free of off-label residues.

Pesticide tolerances

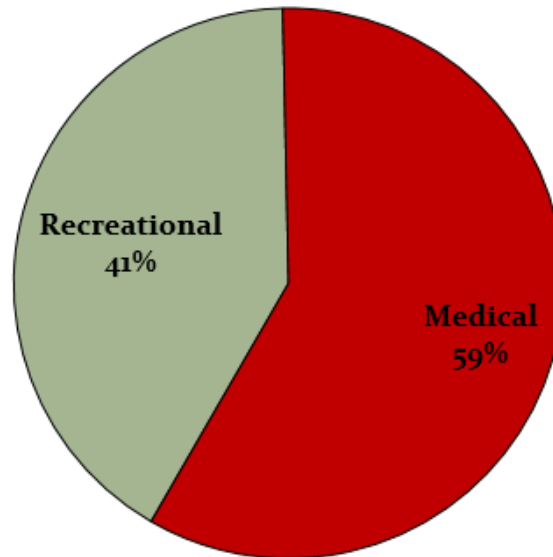
When Denver quarantined 100,000-plus marijuana plants this year for unapproved pesticide use, myclobutanil and imidacloprid were two of the top culprits. Below are the EPA allowable tolerance levels for those pesticides in some common foods, and the levels that The Denver Post found in independent testing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



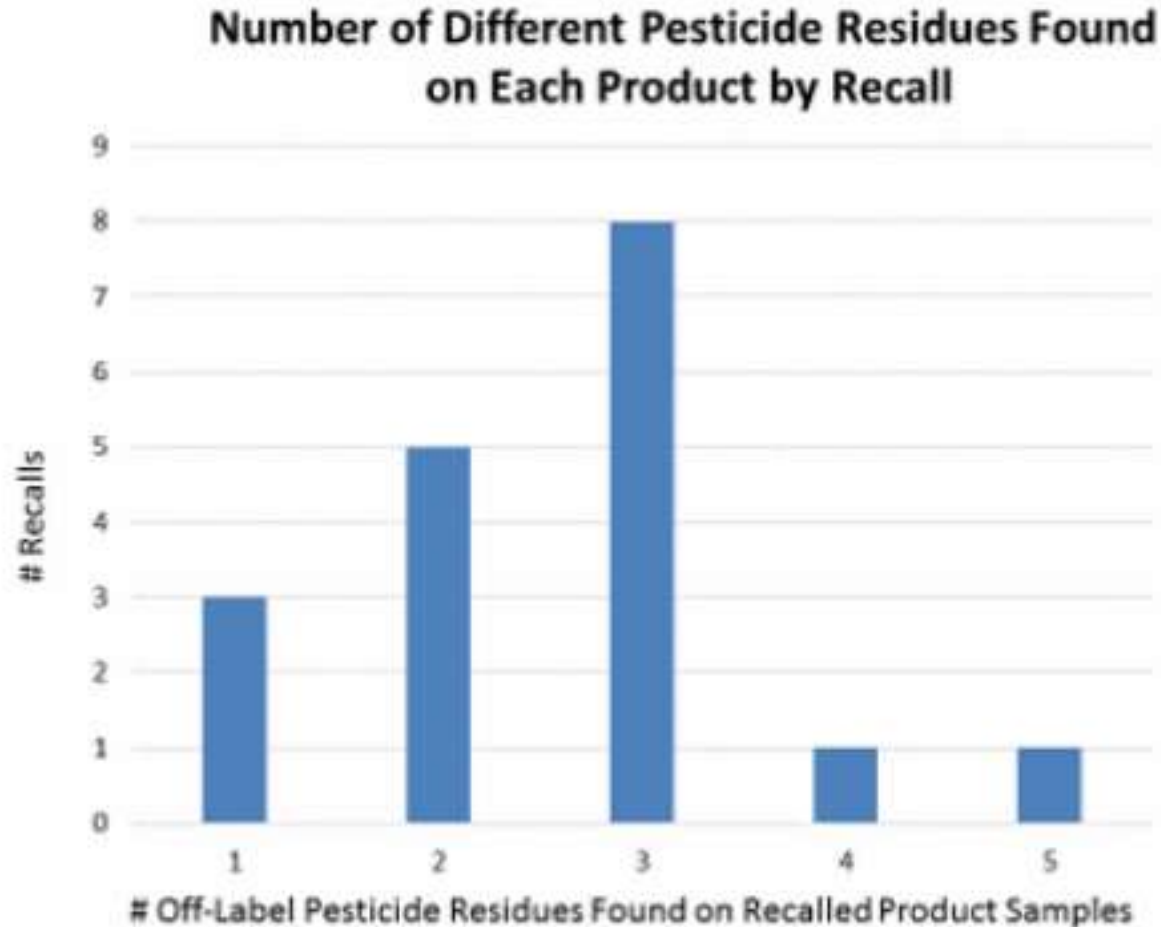
Pesticide Contamination: Denver Enforcement

- Prompted Denver involvement addressing contaminated MJ-derived products
- 24 pesticide contamination recalls since September 2015 affecting ~300K units
- 1 recall due to unclean equipment; 2 due to shelf-stability
- 2 appeals of enforcement action to Denver's Board of Environmental Health

Medical vs Recreational Number of Products Recalled



Product	Number of Product
Recreational	174
Medical	247



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

Why do we care?

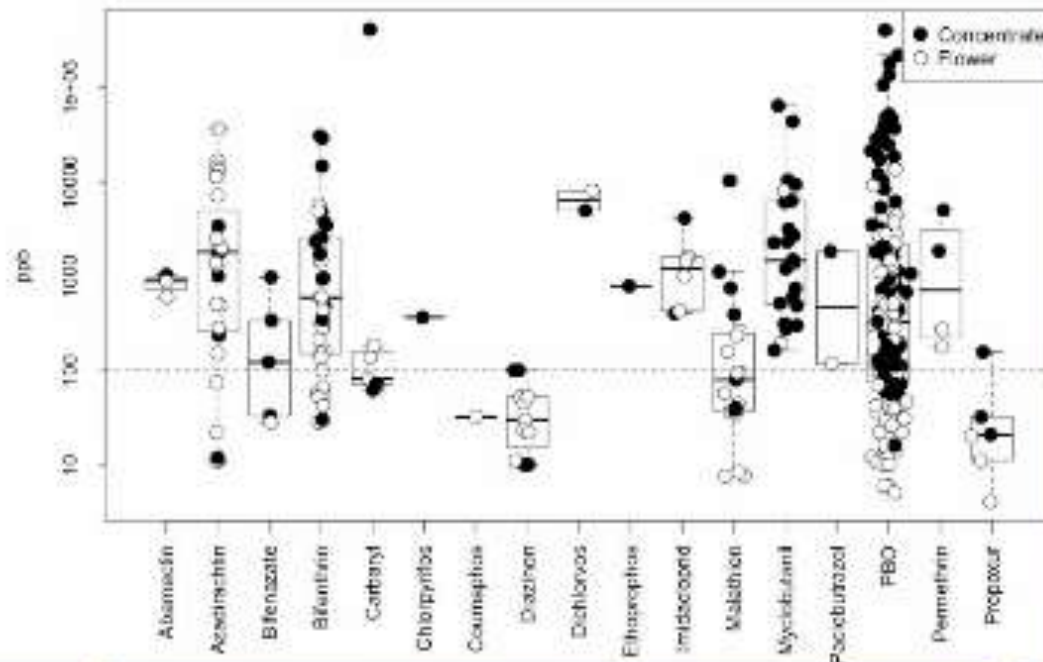
- NO studies on health impact of mixing pesticides, concentrating, burning, inhaling
- Potential to be pervasive confounding factor when studying health and therapeutic impacts
- Used as medicine for children and severely immunocompromised



Public Health Significance: Concentrates vs Flower

Pesticide Use on Cannabis,
Cannabis Safety Institute White Paper, 2015

4d. Levels of pesticides detected.



Note: the y axis is log scaled so each increment represent a **10x level** than the previous increment

- Detectable residues can persist in products many months
- Residues persist in mature plants clipped from “mothers” that were sprayed
- Low residues still a concern, especially for concentrates
- Cleaning of ventilation systems, grow rooms, plant containers needed
- Still seeing spiked residues indicating recent use in some investigations

- October 2016:
 - Two unrelated investigations where “hot” plant material was tested by manufacturer and then returned to medicinal cultivator
 - Cultivators proceeded to resell hot plant material
 - One of the facility’s plant material had 4 off label residues
 - Recall press release sent out 10/24/16.