Public Health Supplemental Materials - Sep

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Draft indoor air quality recommendations Cannabis Advisory Commission Public Health Subcommittee September 29, 2021

Jennifer Pearson, PhD, MPH



Recommendation #1

- For cannabis consumption lounges that offer indoor smoking, vaping, and/or dabbing:
 - Require a separate smoking room
 - Pretty common (13 jurisdictions & 3 states)
 - This will NOT <u>eliminate</u> SHS exposure risks



Recommendation #1 continued

- Businesses with an onsite consumption endorsement must be freestanding.
- A Designated Smoking Room must meet the following standards:
 - Must have a separate heating, ventilation, and air-conditioning (HVAC) system so that Smoking Room air is not recirculated into other parts of the premises.
 - Smoking Room air must be directly exhausted to the outdoors by a filtration system so that it cannot enter the non-smoking area through windows, doors, outdoor intakes, etc.
 - Filtration system must be sufficient to remove visible smoke and adequate to eliminate odor at the property line.
 - Could require smokestack or certain height requirement before released in the air.
 - Might not work if there is an inversion layer. Better to control with filtering.
 - Require odor control programs submitted to CCB. Could require odor control program for applicants for CLs.



Recommendation #1 continued

- A Designated Smoking Room must meet the following standards:
 - Must be completely separated from the remainder of the premises by solid partitions or glass without openings other than doors.
 - All doors leading to the Smoking Room must be self-closing and installed with a gasket to provide a seal where the door meets the stop.



Recommendation #2

- Mandate indoor air quality standards and protocols that minimize employees' exposure to SHS and ensure safe & healthy workplace for employees
- Excluding the Smoking Room, consumption lounge indoor air must conform to the following standards:
 - Does not exceed X ppm on average during operating hours
 - Peak PPM does not exceed X during operating hours



Recommendation #2 continued

- Employers may not require employees to enter the Smoking Room as a condition of employment.
 - Modify so that they have to provide PPE/the equipment to enter room safely.
 - Could be complicated see OSHA requirements. May not rely on it; for emergencies.
 - Have to provide an employee protection plan that is reviewed/approved by CCB.
- Consumption lounges must design Smoking Rooms and work protocols such that:
 - Need for employees to enter Smoking Room is minimized
 - Employees can monitor activities in the Smoking Room from a smoke-free room
 - Employees can fulfill regular patron requests without entering the Smoking Room (e.g., serving more products, answering questions, taking payment)
 - Must be a two-way street



Recommendation #3

- Mandate indoor air quality standards and protocols that reduce risk of cardiopulmonary or other acute health effects for workers and patrons while in the Smoking Room
- Smoking Room air quality must conform to the following standards:
 - Does not exceed X ppm on average during operating hours
 - Peak PPM does not exceed X during operating hours
 - Ways to accomplish these goals:
 - Include exhaust hoods over all seating areas
 - Limit capacity



Recommendation #4

- Outdoor Smoking Areas must meet the following standards:
 - Must employ a filtration system sufficient to remove visible smoke from the smoking area and adequate to eliminate odor at the property line.
 - Outdoor Smoking Area must not be visible from the property line
 - Must provide same protections to employees as in R#2



Other things to consider

 How to deal with lounges that will have mixed clientele (e.g., concert spaces)?



Ready to Consume Products Discussion Points

Cannabis Advisory Commission

September 29, 2021

Benjamin G.M. Chew, Ph.D.

General Considerations

- No leftovers may be taken out of the Lounge (NV)
 - Including purchase of multi-serving pre-packaged items
 - Can a patron purchase flower and roll their own or are prerolls required?
 - Vape cartridges
 - Bring their own pens and buy cartridges?
 - How many "servings" are in a single cartridge? 0.5 g of 80% oil = 400 mg THC
 - How to control left-over flower or vape?
 - Control of outside items being brought into the facility?
 - May promote overconsumption
- No Alcohol may be served (NV)
- Standard food permits required (food safety handling, etc.) if preparing fresh food
 - Options to serve non-infused items e.g., uninfused beverages, patron preferences
- Are food permits required if selling single serve prepackaged items for consumption?

General Considerations

- Metrc
 - Should track total purchase history from both Lounges and Dispensaries for overall limit
 - Perform Metrc transfer at time of ordering
 - May potentially block someone who just purchased close to the limit at a Dispensary from buying more at a Lounge (train employees on dealing with customers)
 - Need to control sharing of items (edibles, vaping, smoking, etc.)
- Testing requirements

Pre-Packaged Products

- Single serving (max 10 mg THC +/- 15%) items (rec)
- Multi-serving item (max 100 mg THC +/- 15%)
 - No leftovers can be taken home
 - Cannot be bought and shared by a group, could not track in Metro
 - Avoid this by not allowing multi-serving items
- Medical patients exempted from limits can they sell higher dosage (single serving) items?
 - How to control sharing of items or mistakenly swapping high potency item?
 - Each customer is a single transaction to avoid mixups
- Full testing will already have been performed by Labs
 - Certificate of Analysis should be available if requested (same as Dispensaries)
- Similar to alcohol, prepacked items need to be opened when sold and handed to the customer (or transferred to a non-sealable serving container)
 - How do vape cartridges work with this?

Freshly prepared products - challenges

- Testing to verify final dosing
- Cooking might alter THC (decomposes at high temperatures, reactions with other components present – acids, bases, sugars, etc.)
 - Remember all cooking (heating) procedures involve chemical reactions
 - Difficult to predict
- Homogeneity how to keep it from separating
 - e.g., salad dressing or sauces oil and water layers how to keep the THC suspended and consistent every time dispensed
 - Brewed coffee and tea be aware that THC oil will often separate and will likely coat the mug/container surface, lowering the effective dosage (discourage bulk dispensers)
 - Surfactants may help, consult a food scientist
- General food safety

Testing of final product

- Very difficult to test to verify final dosing
- Testing of recipe likely difficult, especially if trying to accurately measure 10 mg in an entire dish or drink
 - Very low level and homogeneity will play a large role
 - If using an oil in cooking process could easily decompose the THC at high temperatures
- Current edible product testing includes potency, terpenes*, microbial testing, water activity/pH
 - *Terpenes are usually removed (and regulations may change to remove this)
 - Microbial reason is for a shelf stable product that may be at a Dispensary for weeks/months

Testing Recommendation

- Initial bulk oil standard full testing (potency, metals, pesticides, solvents, etc.)
- Dilute the bulk oil down to final concentration (1% or 10 mg/g), and submit for potency, microbial contamination to verify (match edible requirements) TAC, Enterobacteria, Salmonella, Pathogenic E Coli, water activity/pH, terpenes (optional) requires about 10 grams of product
 - Dilution needed to thin out for easy dispensing
 - May be dispersed in a surfactant (for beverages)
 - Example Category Edible Oil (or similar name) for Lounges
- Create pre-dosed containers/syringes that contain 10 mg (+/- 15%) doses of oil
 - 10 mg dose = 1 g of a 1% oil
 - Higher concentrations of oil would be difficult to dispense < 1 g of sample consistently or to mix
 - Add at plating (avoid high heat) or at last step, clean mixing container between service
- Pre-dosed makes it easier to avoid accidental mis-dosing of the final product
- If standard food safety protocols are followed, then avoid testing the final infused product

Considerations of the oil

- Should there be an expiration date on the oil being used?
 - Potency can change over time, light exposure, etc.
 - 6 months? 9 months?
- Can a perishable matrix (e.g., butter or other dairy) be used?
 - Same expiration date?
 - Defer to Dept of Ag for dairy
- Storage requirements?
 - Heat can accelerate decomposition or make an oil go rancid (hot kitchens)
 - Locked up with restricted access fridge/freezer requirement? not walkin fridges/freezers
 - Metrc inventory checks
 - Defer to standard food safety protocols
 - Fridge/freezer failure unless in a perishable matrix, OK for short term

Final dish or drink

- Should be added at the end of the cooking process to avoid decomposition from high temperatures
 - While often available as an "oil", avoid high temperatures (no sauteing, etc.)
 - Needs to be thin enough to easily dispense and distribute
 - Single serve pre-weighed dosage (10 mg) to avoid accidental over/underdosing
 - No bulk infused products to avoid homogeneity issues (sauces, dressings, beverages that may separate)
 - May mix into the final dish or into a preportioned component at the end
 - Simplifies Metrc transfer 1 syringe of oil, not creating multiple items in Metrc
- How to avoid mixing up dishes (medical vs. rec)?
 - Servers handing to wrong person?
 - Tag system how to avoid customers swapping tags?

Information Disclosures

- Allergy information
- Should include the source of the oil that was used to dilute the cannabis
 - Some places use derivatives of coconut oil can be an allergen
 - This needs to be disclosed from the oil supplier
- Standard warnings about THC posted or on menu
- Explain which portion of the dish is infused

Limits on servings?

- Like alcohol, cannabis affects people differently
 - Difficult to enforce to provide a good experience for every patron
- Recreational limits are 10 mg for single dose (100 mg for multi-serving)
- Some customers will have built up a tolerance
- Some customers may have a genetic intolerance and 1-2 mg could have a major effect
- Recommend 10 mg dosage for each item, but customers may purchase additional 10 mg doses. Options to offer lower dosage for beginners (or clear instructions to ingest part of the item and wait).
- Can Medical customers access higher dosages (request more than 10 mg be added)
 - What are risk/liability issues if dishes are mixed up?
- Proper training for staff to recognize when someone has had enough.
- No sharing of dishes/drinks how to enforce?
- Metrc should be tracking how much customer purchased from Dispensaries and the Lounges for total purchase allowed in the time period what is the reasoning behind the sales limit? Is this for selling on the black market? Or is this a safety question ask CCB.
- Do not recommend limits, post recommended amounts, amount/item, health effects
- Allow customers to specify dosage, allow multi-serving prepackaged items
- Markings of items required? Mark on the menu undercooked items.
- Mark plate with dosage to avoid accidental mixing of plates
- Individual tally of how much consuming for each person

Disposal

- All uneaten items need to be disposed of per State Regulations
- Garbage needs to be locked and under control until disposal is performed
 - Other trash controlling what goes where (outside front trash, satellite trash)
- Mixed with material to make unusable.
- Can unfinished beverages be poured down a sink? Low dosage
- Grease traps likely to catch THC

Summary

- Prepackaged items are straightforward
 - Only allow single serving sizes
 - Vape cartridges may be an interesting hurdle
- Freshly made items add premeasured cannabis oil at the end
 - Avoids potential over or under dosing (sauces, dressings, premade large desserts) from inconsistent portion sizing
 - Avoids homogeneity issues
 - Keeps food safety in the standard restaurant experience area and separate from cannabis
- Policies needed to avoid mistakes/swapping items/sharing
- Novel items to be approved by CCB as needed

2. Health NoticesB. For Employees

Employee health exclusion criteria

- An employee shall not come to work while experiencing diarrhea, vomiting, sore throat with fever, jaundice, infected cuts or sores on hands, or while diagnosed with norovirus, shigella, E. coli O157:H7, salmonella, hepatitis A
- Example on next slide

Secondhand Smoke Effects

- Repeated and/or sustained exposure to secondhand smoke may result in damage to respiratory and cardiovascular health
- Visible to public
- QR Code to webpage with more info?

Air Quality Levels

- Real-time read out of current PM2.5 levels in the main entrance/service counter/smoke free area
- Color chart to interpret levels: green, yellow, red
- Visible to public
- Requirement to maintain and calibrate per manufacturer directions



Employee Health Policy



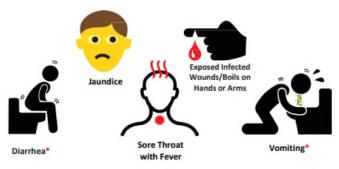
The Regulations Governing the Sanitation of Food Establishments, Chapter 2, Section 2, Employee Health, requires that a permit holder, person in charge, food handlers and conditional food handlers reduce the risk of transmission of foodborne disease transmission by:

- 1. Reporting symptoms such as:
 - Vomiting*
 - o Diarrhea*
 - Jaundice
 - Sore throat with fever
 - Infected cuts or burns on hands and wrists

*Note: Employees should not return to work until free of symptoms for at least 24 hours (without the use of medication).

- Excluding employees from handling food when diagnosed with an illness that can be transmitted through food such as:
 - Salmonella Typhi (typhoid-like fever)
 - Shigella spp. (causes shigellosis)
 - o E-coli 0157:H7
 - Hepatitis A virus
 - Norovirus

5 Symptoms of Foodborne Illness





4. Occupational Health and Training A. Certifications/Licenses



For all:

- Registered agent card
- Cannabis consumption training license (next slide)
 - Make our own, NEHA has guidance document on what to include
- Or use existing courses: Cannabis Core and others



For lounges serving food or beverage:

- Food handler card
- Not all jurisdictions offer this
- Accept ServSafe or equivalent food HANDLER training
- Allow CFPM to document training?
- Certified Food Protection Manager at all hours of operation (ServSafe or equivalent ANSI accredited course)

4. Occupational Health and Training C. Training



Employees:

Cannabis Consumption
 Training/License (see next slide)



Lounges:

- Written plan for how to handle:
 - customer incapacitated and at risk of assault, sexual or otherwise
 - customer attempts to drive? Yes

NRS 369.625 Development and contents of curriculum for program; certification and operation of program; adoption of regulations.

- 1. The Commission shall, in cooperation with state and local law enforcement agencies, develop a curriculum for an alcoholic beverage awareness program.
- 2. The curriculum described in subsection 1:
- (a) Must consist of not fewer than 2 hours of instruction; and
- (b) Must include, without limitation, instruction on the following topics:
 - (1) The clinical effects of alcohol on the human body;
 - (2) Methods of identifying intoxicated persons;
 - (3) Relevant provisions of state and local laws concerning the selling and serving of alcoholic beverages;
 - (4) Methods of preventing and halting fights, sexual assault, acts of affray and other disturbances of the peace; and
 - (5) Methods of preventing:
 - (I) The entry of minors into establishments in which minors are prohibited from loitering pursuant to NRS 202.030;
- (II) The purchase, consumption and possession of alcoholic beverages by minors as prohibited pursuant to NRS 202.020, including, without limitation, the recognition of altered or falsified forms of identification; and
 - (III) The selling and furnishing of alcoholic beverages to minors as prohibited pursuant to NRS 202.055.
 - 3. The Administrator of the Commission may certify an alcoholic beverage awareness program if the Administrator determines that:
 - (a) The program meets the curricular requirements set forth in subsection 2; and
 - (b) The persons who will serve as instructors for the program are competent and qualified to provide instruction in the curriculum of the program.
 - 4. An alcoholic beverage awareness program certified by the Commission:
 - (a) Must not cost a person more than \$40 to complete; and
- (b) May be presented through the use of audiovisual technology. As used in this paragraph, "audiovisual technology" includes, without limitation, the use of closed-circuit video, videoconferencing, videotapes, computers, television, the Internet or any other electronic means of communication, or any combination thereof.
 - 5. The Commission shall adopt such regulations:
 - (a) As the Commission determines to be necessary or advisable to carry out the provisions of this section; and
- (b) As are necessary to ensure that a person who successfully completes an alcoholic beverage awareness program certified pursuant to subsection 3 receives a card which verifies that the person has successfully completed that program. The regulations must provide additionally that a card described in this paragraph:
- (1) Is valid for a period of 4 years from the date of issuance and may be renewed for like consecutive periods upon successful completion by the holder of the card of an alcoholic beverage awareness program certified by the Commission; and
- (2) Must be honored, in any jurisdiction in which the provisions of NRS 369.630 apply, as indicia of the successful completion of an alcoholic beverage awareness program certified by the Commission.
 - 6. As used in this section, "minor" means a person who is under 21 years of age.

4. Occupational Health and Training B. Cleaning of Devices

- One use model
 - All devices provided to each party brand new, party leaves with device
 - Lowest risk option
 - Food contact surfaces are required to be smooth and easily cleanable
 - Devices are not and some have small inaccessible parts, unable to scrub
- Allow empty personal devices, employees to verify
 - Leave with empty device, employees to verify
- Disposable mouthpieces for sharable devices?
- Avoid cleaning of devices, too hard to ensure done safely
- Ozone and UV discouraged for CPAP and other air intake tubing
 - https://www.fda.gov/medical-devices/safety-communications/potential-risks-associated-use-ozone-and-ultraviolet-uv-light-products-cleaning-cpap-machines-and
- Soap and water recommended by FDA
 - EPA temporarily approved alcohol for food grade sanitizing PRN 98-10: Notifications, Non-Notifications and Minor Formulation Amendments | US EPA

Health Notices & Disclosure Recommendations

What health notices will we require for patrons?

- Statement for pregnant/breastfeeding women
- Statement for people with asthma/breathing problems
- Statement for people with cardiovascular disease
- Statement about co-use of marijuana and alcohol
- Statement about driving after cannabis use
- Statement about general health effects of smoking and/or exposure to secondhand smoke
- Statement about poly-pharmacy interactions
- Statement about over consumption
- Statement about delayed onset

NCCR 12.050 Cannabis Sales Facility: Required disclosures and warnings

- 1. A cannabis sales facility must provide with all usable cannabis sold at retail accompanying material that discloses any pesticides applied to the cannabis plants and growing medium during production and processing.
- 2. A cannabis sales facility must provide with all usable cannabis and cannabis products sold at retail a written notification which contains the following warnings:
- (a) That cannabis and cannabis products must be kept out of the reach of children;
- (b) That cannabis and cannabis products can cause severe illness in children;
- (c) That allowing children to ingest cannabis or cannabis products or storing cannabis or cannabis products in a location which is accessible to children may result in an investigation by an agency which provides child welfare services or criminal prosecution for child abuse or neglect;
- (d) "THE INTOXICATING EFFECTS OF CANNABIS MAY BE DELAYED BY 2 HOURS OR MORE AND USERS OF CANNABIS PRODUCTS SHOULD INITIALLY INGEST A SMALL AMOUNT OF THE PRODUCT CONTAINING NO MORE THAN 10 MILLIGRAMS OF THC, THEN WAIT AT LEAST 2 HOURS BEFORE INGESTING ANY ADDITIONAL AMOUNT OF THE PRODUCT;"
- (e) "This product may have intoxicating effects and may be habit forming. Smoking is hazardous to your health;"
- (f) "Ingesting cannabis or cannabis products with alcohol or other drugs, including prescription medication, may result in unpredictable levels of impairment and a person should consult with a physician before doing so;"
- (g) "There may be health risks associated with consumption of this product;"
- (h) "Pregnant women should consult with a physician before ingesting cannabis or cannabis products;"
- (i) "Cannabis or cannabis products can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of cannabis or cannabis products;" and
- (j) "Ingestion of any amount of cannabis or cannabis products before driving may result in criminal prosecution for driving under the influence."
- 3. The text used on all accompanying material and warnings must be printed in at least 12-point font and may not be in italics.

https://ccb.nv.gov/wp-content/uploads/2021/02/Searchable-Effective-NCCR-as-of-Nov-2020.pdf

NCCR 12.050 Cannabis Sales Facility: Required disclosures and warnings

What recommendations should we make to the CCB?

Extend the existing regulations for required warnings and disclosures to apply to consumption lounges to maintain consistent industry wide disclosure language.

- Maintains industry consistency with disclosure language
 - Consistent information is beneficial to public education
- Existing standards for dispensaries, cultivation facilities, and production facilities should apply to consumption lounges.

These disclosures and warnings do need some improvement though.

NCCR 12.050 (2)(h) requires the following disclosure on cannabis products sold at a cannabis sales facility.

"Pregnant women should consult with a physician before ingesting cannabis or cannabis products;"

Issues:

- This statement is opened ended.
- Doesn't convey possible health effects of cannabis use during pregnancy or while breastfeeding.

NCCR 7.030 (8) A cannabis sales facility shall not recommend products to women that are pregnant or breastfeeding.

The CDC, FDA, and US Surgeon General all advise against pregnant or breastfeeding women from consuming cannabis.

CDC

 "Marijuana use during pregnancy can be harmful to your baby's health. The chemicals in marijuana (in particular, tetrahydrocannabinol or THC) pass through your system to your baby and can harm your baby's development."

CDC Website: https://www.cdc.gov/marijuana/factsheets/pregnancy.htm

FDA

• "[The] FDA strongly advises against the use of cannabidiol (CBD), tetrahydrocannabinol (THC), and marijuana in any form during pregnancy or while breastfeeding."

FDA Website: https://www.fda.gov/consumers/consumer-updates/what-you-should-know-about-using-cannabis-including-cbd-when-pregnant-or-breastfeeding

US Surgeon General

• "Studies have shown that marijuana use in pregnancy is associated with adverse outcomes, including lower birth weight"

US Surgeon General Website: https://www.hhs.gov/surgeongeneral/reports-and-publications/addiction-and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html

In 2020, the State of Colorado implemented a new disclosure regarding cannabis consumption while pregnant or breastfeeding.

WARNING: USING MARIJUANA, IN ANY FORM, WHILE YOU ARE PREGNANT OR BREASTFEEDING PASSES THC TO YOUR BABY AND MAY BE HARMFUL TO YOUR BABY. THERE IS NO KNOWN SAFE AMOUNT OF MARIJUANA USE DURING PREGNANCY OR BREASTFEEDING.

https://hightimes.com/news/colorado-cannabis-stores-will-begin-posting-warning-signs-about-thc-risks-during-pregnancy/

What recommendations should we make to the CCB?

Recommend to change to the existing language of NCCR 12.050 (2)(h)

"WARNING: Pregnant or breastfeeding people should not use cannabis or cannabis products. Using cannabis during pregnancy or while breastfeeding may be harmful to your baby's development."

- Add image regarding cannabis & pregnancy

Require this warning to be posted in restrooms similar to how alcohol warning signage must be posted in bars and food establishments per NRS 446.842

https://www.leg.state.nv.us/NRS/NRS-446.html#NRS446Sec842

Statements for pregnant or breastfeeding women

HEALTH WARNING

PREGNANT OR BREASTFEEDING PEOPLE SHOULD NOT USE CANNABIS OR CANNABIS PRODUCTS. USING CANNABIS DURING PREGNANCY OR WHILE BREASTFEEDING MAY BE HARMFUL TO YOUR BABY'S DEVELOPMENT.

Statements for people with respiratory and/or cardiovascular conditions

The current NCCRs require the following health disclosures:

NCCR 12.050 (2)

- (g) "There may be health risks associated with consumption of this product;"
- No current disclosures direct address respiratory or cardiovascular conditions.
- The issue is that we reasonably cannot address all health risks associated with cannabis consumption to people with respiratory conditions and/or cardiovascular conditions. People's health conditions vary widely and we need to be able to keep disclosures concise. For example, are we addressing someone who has bronchitis or emphysema?
- There are a wide variety of health concerns outside of heart or lung conditions that should also be wary of cannabis consumption such as mental health conditions or other bodily conditions not specified herein.

Statements for people with respiratory and/or cardiovascular conditions

What recommendations should we make to the CCB?

Recommend to add on to the existing language of NCCR 12.050 (2)(g)

"There may be physical and mental health risks associated with consumption of this product cannabis or cannabis products. People with health concerns should consult with a physician before ingesting cannabis."

Statements about co-use of marijuana, alcohol, and poly-pharmacy interactions

NCCR 12.050 (2)(f) requires the following disclosure with cannabis products sold at a cannabis sales facility:

(f) "Ingesting cannabis or cannabis products with alcohol or other drugs, including prescription medication, may result in unpredictable levels of impairment* and a person should consult with a physician before doing so;"

*simplify this statement / CDC plain language resource

Statement about driving after cannabis use

NCCR 12.050 (2)(i)(j) requires the following disclosure on cannabis products sold at a cannabis sales facility:

- (i) "Cannabis or cannabis products can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of cannabis or cannabis products;" and
- (j) "Ingestion of any amount of cannabis or cannabis products before driving may result in criminal prosecution for driving under the influence."

Statement about general health effects of smoking and/or exposure to secondhand smoke

NCCR 12.050 (2)(e) requires the following disclosure on cannabis products sold at a cannabis sales facility:

(e) "This product Cannabis or cannabis products may have intoxicating effects and may be habit forming. Smoking is hazardous to your health;"

Nothing in the current NCCRs address secondhand smoke.

Statement about general health effects of smoking and/or exposure to secondhand smoke

Arkansas Clean Indoor Air Act required disclosures at smoking venues:

HEALTH WARNING

THIS IS A SMOKING AREA.

OCCUPANTS WILL BE EXPOSED
TO SECONDHAND SMOKE.

IT IS UNLAWFUL FOR ANYONE
UNDER 21 YEARS OF AGE TO ENTER
OR WORK IN ANY PART OF THIS
ESTABLISHMENT AT ANY TIME.

SmartSign.com • 800-952-1457 • S-942

https://www.healthy.arkansas.gov/images/uploads/rules/CleanIndoorAirActRule.pdf

Statement about general health effects of smoking and/or exposure to secondhand smoke

What recommendations should we make to the CCB?

Recommend to add a disclosure specific to consumption lounges regarding secondhand smoke:

"WARNING: This is a smoking lounge. Occupants will be exposed to secondhand smoke. Secondhand smoke is hazardous to your health. It is unlawful for anyone under 21 years of age to enter or work in any part of this establishment at any time."

- Add line re: cannabis?

This warning statement should also be posted on any external doors or points of entry to a smoking consumption lounge.

Statement about delayed onset

NCCR 12.050 (2)(f) currently requires the following disclosure for products sold at a cannabis sales facility:

(d) "THE INTOXICATING EFFECTS OF CANNABIS MAY BE DELAYED BY 2 HOURS OR MORE AND USERS OF CANNABIS PRODUCTS SHOULD INITIALLY INGEST A SMALL AMOUNT OF THE PRODUCT CONTAINING NO MORE THAN 10 MILLIGRAMS OF THC, THEN WAIT AT LEAST 2 HOURS BEFORE INGESTING ANY ADDITIONAL AMOUNT OF THE PRODUCT CANNABIS;"

Statement about overconsumption

Currently, the NCCRs do not contain recommendations or warnings regarding the overconsumption of cannabis.

What recommendations should we make to the CCB?

Recommend to add a warning regarding overconsumption:

"Overconsumption of cannabis or cannabis products may cause negative health effects such as nausea, vomiting, anxiety, agitation, paranoia, and psychosis. Individuals with symptoms of overconsumption should seek immediate medical attention."

https://www.hhs.gov/surgeongeneral/reports-and-publications/addiction-and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html

Part 1: Recommendations to the CCB

Cannabis consumption lounge: Required disclosures and warnings.

- 1. A cannabis consumption lounge must provide with all usable cannabis and cannabis products served a written notification which contains the following warnings:
- (a) "THE INTOXICATING EFFECTS OF CANNABIS MAY BE DELAYED BY 2 HOURS OR MORE AND USERS OF CANNABIS PRODUCTS SHOULD INITIALLY INGEST A SMALL AMOUNT OF THE PRODUCT CONTAINING NO MORE THAN 10 MILLIGRAMS OF THC, THEN WAIT AT LEAST 2 HOURS BEFORE INGESTING ANY ADDITIONAL AMOUNT OF CANNABIS;"
- (b) "Cannabis or cannabis products may have intoxicating effects and may be habit forming. Smoking is hazardous to your health;"

Part 2: Recommendations to the CCB

- (c) "Ingesting cannabis or cannabis products with alcohol or other drugs, including prescription medication, may result in unpredictable levels of impairment and a person should consult with a physician before doing so;"
- (d) "There may be mental or physical health risks associated with consumption of cannabis products. People with health concerns should consult with a physician before ingesting cannabis."
- (e) "WARNING: Pregnant or breastfeeding people should not use cannabis or cannabis products. Using cannabis during pregnancy or while breastfeeding may be harmful to your baby's development."
- Statement (e) must be conspicuously posted in a minimum of 40-point font in every restroom of a cannabis consumption lounge.

Part 3: Recommendations to the CCB

- (f) "Cannabis or cannabis products can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of cannabis or cannabis products;"
- (g) "Ingestion of any amount of cannabis or cannabis products before driving may result in criminal prosecution for driving under the influence." and
- (h) "WARNING: This is a smoking lounge. Occupants will be exposed to secondhand smoke. Secondhand smoke is hazardous to your health. It is unlawful for anyone under 21 years of age to enter or work in any part of this establishment at any time."

⁻ Statement (h) must be conspicuously posted in a minimum of 72-point font on every point of entry point to a smoking consumption lounge.

Part 4: Recommendations to the CCB

- (i) "Overconsumption of cannabis or cannabis products may cause negative health effects such as nausea, vomiting, anxiety, agitation, paranoia, and psychosis. Individuals with symptoms of overconsumption should seek immediate medical attention."
- 2. The text used on all accompanying material and warnings must be printed in at least 12-point font and may not be in italics.

Resources

- Nevada Cannabis Compliance Regulations
 - https://ccb.nv.gov/wp-content/uploads/2020/07/Final-NCCR-002.pdf
- Centers for Disease Control & Prevention
 - https://www.cdc.gov/marijuana/factsheets/pregnancy.htm
- US Food & Drug Administration
 - https://www.fda.gov/consumers/consumer-updates/what-you-should-know-about-using-cannabis-including-cbd-when-pregnant-or-breastfeeding
- Nevada Signage Requirements for Alcohol & Birth Defects
 - https://www.leg.state.nv.us/NRS/NRS-446.html#NRS446Sec842
- Colorado Cannabis & Pregnancy Warning
 - https://hightimes.com/news/colorado-cannabis-stores-will-begin-posting-warning-signs-about-thc-risks-during-pregnancy/
- Arkansas Clean Indoor Air Act
 - https://www.healthy.arkansas.gov/images/uploads/rules/CleanIndoorAirActRule.pdf
- Office of the US Surgeon General
 - https://www.hhs.gov/surgeongeneral/reports-and-publications/addiction-and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html

Cannabis consumption lounge: Required disclosures and warnings.

- 1. A cannabis consumption lounge must provide with all usable cannabis and cannabis products served a written notification which contains the following warnings:
- (a) "THE INTOXICATING EFFECTS OF CANNABIS MAY BE DELAYED BY 2 HOURS OR MORE AND USERS OF CANNABIS PRODUCTS SHOULD INITIALLY INGEST A SMALL AMOUNT OF THE PRODUCT CONTAINING NO MORE THAN 10 MILLIGRAMS OF THC, THEN WAIT AT LEAST 2 HOURS BEFORE INGESTING ANY ADDITIONAL AMOUNT OF CANNABIS;"
- (b) "Cannabis or cannabis products may have intoxicating effects and may be habit forming. Smoking is hazardous to your health;"
- (c) "Ingesting cannabis or cannabis products with alcohol or other drugs, including prescription medication, may result in unpredictable levels of impairment and a person should consult with a physician before doing so;"
- (d) "There may be mental or physical health risks associated with consumption of cannabis products. People with health concerns should consult with a physician before ingesting cannabis."
- (e) "WARNING: Pregnant or breastfeeding people should not use cannabis or cannabis products. Using cannabis during pregnancy or while breastfeeding may be harmful to your baby's development."
- Statement (e) must be conspicuously posted in a minimum of 40-point font in every restroom of a cannabis consumption lounge.
- (f) "Cannabis or cannabis products can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of cannabis or cannabis products;"
- (g) "Ingestion of any amount of cannabis or cannabis products before driving may result in criminal prosecution for driving under the influence." and
- (h) **"WARNING:** This is a smoking lounge. Occupants will be exposed to secondhand smoke. Secondhand smoke is hazardous to your health. It is unlawful for anyone under 21 years of age to enter or work in any part of this establishment at any time."
- Statement (h) must be conspicuously posted in a minimum of 72-point font on every point of entry point to a smoking consumption lounge.
- (i) "Overconsumption of cannabis or cannabis products may cause negative health effects such as nausea, vomiting, anxiety, agitation, paranoia, and psychosis. Individuals with symptoms of overconsumption should seek immediate medical attention."
- 2. The text used on all accompanying material and warnings must be printed in at least 12-point font and may not be in italics.

National Environmental Health Association

Food Safety Guidance for

Cannabis-Infused Products

Contents

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Visit: NEHA's Online Cannabis Resources



I. Purpose

The purpose of this document is to provide a comprehensive compilation of research on food safety provisions that have been approved, implemented, or are in trial phases throughout various states that have legalized cannabis as of March 2018. This document seeks to provide a list of considerations for states implementing a food safety program for cannabis edibles and provide examples of states that have strong written legislation to support their regulations and ensure its success. This document will focus solely on the food safety of cannabis-infused products (CIPs) from "seed-to-sale." Regulations and/or information regarding the safety of cannabis consumption, political perspectives on the cannabis industry and its legalization, and/or any topic not directly related to food safety lies outside the scope of this document and will not be discussed. This information is provided as a guidance document and is not intended to constitute legal advice and should not be relied upon in lieu of consultation with appropriate legal advisers in your jurisdiction.

Finally, for purposes of this document, food will be defined as "any raw, cooked, or processed edible substance, gum, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption, including cannabis-infused products" (City and County of Denver, 2014). This definition includes all edible candies, gummies, baked goods, canned goods, chocolates, beverages, homemade goods, oils, capsules, extracts, concentrates, and tinctures. This definition does not include flowers or buds used for vaping or smoking, resins, topical creams, sprays, waxes, or shatter. Please note that the terms "cannabis-infused products" and "edibles" will be used interchangeably throughout the document. Additionally, cannabis and marijuana will be used interchangeably through the document. Finally, regulations are constantly changing. For this reason, this document is recent as of March 2018 and will be updated on an annual basis.



II. Introduction

Among the states and the District of Columbia that have legalized either medical and/or adult use cannabis, few measures have been implemented directly involving food safety. Many states have yet to decide how to regulate the various stages of cannabis edible production from seed-to-sale. With lack of federal oversight and standardization, it is imperative that states look to best practices to implement food safety standards for CIPs. This document seeks to compile food safety practices that states have implemented as a result of legalization. This document will discuss food health and safety in detail and serve as a guidance document for states seeking to implement a food safety program. Specifically, this document will examine how states have addressed regulating the following: growing, cultivation and testing practices, extraction, infusion, storage, distribution and tracking, packaging, transportation, food handling education, and labeling.

These types of food safety regulations are important for the following reasons: 1) immunocompromised individuals are the consumers of medical cannabis edibles; 2) cannabis edibles have a delayed effect, leading individuals to consume more than necessary in order to get a high, which calls for a better understand of dosing and need to ensure proper labeling of tetrahydrocannabinol (THC) and other cannabinoids, and 3) as states continue to legalize medical and/or recreational cannabis, it is important that they can readily seek recommendations and information for food safety regulations provided by states that have already implemented such regulations. This document includes research from academic peer-reviewed articles, information from public health officials, webinars, written position statements, and data collected from a focus groups at the Canna East Compliance Summit in Orlando, Florida, in January 2018. This document has been drafted for state public health officials, growers, distributors, producers, retailers, enforcement officers, and/or other regulating bodies of the medical and recreational cannabis food safety industry.

Acknowledgements: The completion of this document would not have been possible without the National Environmental Health Association's (NEHA) Guidance Document Advisory Board and interns. Special thanks to Kelsi Sullivan for compiling the document. Further special thanks to the Advisory Board members—Melissa Bartsche, Camille Gourdet, Tim Gunther, Elizabeth Landeen, Kara Lavaux, Joe Lillis, Peggy Moore, Marc Nascarella, and Cindy Rice—for providing their expertise and guidance. The document would not have been completed without their revisions, edits, and support.



III. Background: Food Safety and Cannabis

Barrus and coauthors (2016) state that cannabis is the most widely used illicit drug in the U.S. As of January 2018, 29 states and the District of Columbia have legalized either medicinal and/or recreational use of cannabis, while several other states have legalized cannabidiol (CBD)-only or low-THC products (National Conference of State Legislatures, 2018). Please Figure 1 for a current map of cannabis legalization.



Figure 1: States That Have Legalized Medical and/or Recreational Cannabis

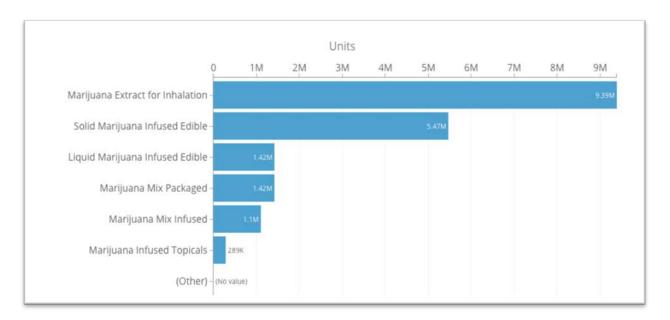
Source: ILoveCompliance.biz, 2018 (https://tgunthergroup.com/2017-cannabis-map/).

In 2015, 9.5% of adults and 23.7% of youth self-reported using cannabis at least once in the past year (Hasin et al., 2015). With the increased legalization of medicinal and recreational cannabis, the rates of adult and youth use across states are expected to increase (Hasin et al., 2015). Additionally, while public perception and cultural trends continue to evolve, the range of cannabis-infused products, in the form of edibles, has seen tremendous growth. In 2014, Colorado sold over 1.96 million units of medicinal edibles and 2.85 million units of recreational edibles, representing 45% of their total sales (Brohl, Kammerzell, & Koski, 2015).

Washington has also been very successful with cannabis edibles. Washington's <u>open source data</u> demonstrates that total production of solid cannabis-infused edibles since market open in 2015 is 5.47 million units (Figure 2).



Figure 2: Production of Cannabis-Infused Products in Washington, 2015



Finally, in general, cannabis sales in Colorado have risen every year since 2014 and the upward trend is expected to continue for 2018 (Figure 3) (Colorado Department of Revenue, 2018).

Figure 3: Cannabis Sales in Colorado, 2014–2018

Calendar Year	Total Marijuana Sales	Total to Date
2014	\$683,523,739	\$683,523,739
2015	\$995,591,255	\$1,679,114,994
2016	\$1,307,203,473	\$2,986,318,467
2017	\$1,507,702,219	\$4,494,020,686
2018 (Jan)	\$117,993,222	\$4,612,013,908

The expansion of CIPs has presented a unique challenge for policy makers and regulators due to the diverse range of products, coupled with little to no research evaluating its efficacy and safety to consumers (Barrus et al., 2016). The U.S. has federal agencies (e.g., Food and Drug Administration, U.S.



Department of Agriculture, etc.) and regulations to help ensure that consumers across the country are being provided food choices that are safe, as well as minimize risk of foodborne illness. As a Schedule I controlled substance under the U.S. Drug Enforcement Administration, there is no overarching regulatory body that can recommend, oversee, and verify the health and safety of CIPs. For this reason, CIPs present a serious food safety concern and states must take initiative and implement food safety standards to protect consumers of CIPs. Most importantly, states must be attentive to contamination due to improper growing conditions, handling and storage, chemical residues on plants and edibles, pathogenic contamination from pests and improper food handling practices, and concentration levels of cannabinoids (Burton, 2018).

Improper growing conditions, handling, and storage can result in dangerous health problems for consumers. One example are aflatoxins that are produced by mold growth and can lead to liver problems (Burton, 2018). For this reason, it is important to monitor and record water activity and temperature during storage and transportation (Burton, 2018). When products arrive at a facility, they should be tested and all contaminated products should be rejected, segregated, and disposed of safely (Burton, 2018). Additionally, it is important to ensure adherence to good agricultural practices.

The U.S. Environmental Protection Agency (U.S. EPA) has generated a list of pesticide residue tolerance levels on food based on their toxicity to humans. A current tolerance level search engine can be found at the National Pesticide Information Center's Food and Drinking Water Limits for Pesticides website. While there are U.S. EPA guidelines for these pesticides, they do not include residue levels for cannabis. A few states have taken the initiative to provide guidance to growers, processors, and distributors, and/or ban certain pesticides. Oregon has also been a leader in this arena and has provided a list of commercially available products and ingredients that are not prohibited for use. Their guide list can be found on their Cannabis and Pesticides website. The guide list is regularly updated. Oregon also provides information on potentially harmful products and includes information on protection for agricultural workers. States must actively set pesticide residue limits and designate a regulating body to oversee its adherence to the policies.

Additionally, states must be concerned with contamination of etiologic agents associated with disease such as molds, mildew, and bacteria including *Clostridium botulinum*, *Salmonella*, and *E. coli* (Gourdet, Giombi, Kosa, Wiley, & Cates, 2017). Contamination can be minimized or eliminated with testing and basic food safety education and training. Testing a product before and after production is the best way to reduce the amount of contamination of etiologic agents in edibles to protect consumers. Moreover, proper food handling is an effective way of reducing contamination. It is important for growers, processors, and distributors to receive adequate training on proper hand washing techniques, sanitation standards, and food handling and storage.

Finally, THC and cannabidiol limits are another crucial part of food safety. Cannabis edibles have a delayed onset of an effect for users because it needs to be processed and digested by the liver. Inhalation and other methods of consumption act much faster and allow the consumer to feel an effect. For this reason, many consumers unknowingly consume more than one serving of an edible. Studies have found that individuals take a serving, feel no effect, and then take another serving. This process



leads to an incredibly strong and unexpected high for consumers and for some, it leads to an overdose. For this reason, many states have implemented mg/serving concentrations and set maximum serving sizes for each food item.

In consequence to such rapid legalization, many states retrospectively implemented food safety regulations for their CIPs leaving inconsistencies across state borders and many states lack governing jurisdictions that oversee these safety precautions. These inconsistencies have led to recalls due to pesticide contamination, an uptake in poison control visits by children due to unintentional consumption, an uptake in hospital visits for cannabis overdoses due to delayed effects, and high levels of heavy metals and other toxic contaminants found in lab testing results (Baca, 2018; Baca & Migoya, 2015; Hancock-Allen, Barker, VanDyke, & Holmes, 2015). These outcomes pose serious risks to all consumers and should encourage states to designate adequate agencies that can implement and oversee such regulations. This document seeks to compile the works of various states and provide food safety recommendations to states looking to legalize medical and/or recreational cannabis in the near future.



IV. Food Safety Considerations and State Examples

This section will focus on food safety policies and laws that have been implemented across different states. Due to the lack of any federal laws governing the cultivation, manufacturing, or sale of cannabis products, there is a great deal of variation in state laws that regulate CIPs. Therefore, this section is broken down into a list of topic areas that pertain to food safety. Under each topic area is a list of things to be considered when implementing regulations. These considerations are derived from specialists in food safety and from thorough analysis of legislation that has already been implemented by states that have legalized cannabis. Finally, under considerations, examples of comprehensive and strong state laws have been provided. No state has passed a perfect law that takes every food safety issue into consideration. It is our belief, however, that some state laws can serve as examples for other states. Please note that these laws are constantly changing. For this reason, these policies are current as of March 2018 and will be updated on an annual basis.

Food Safety Topic Areas

- 1. Storage and Sanitation
- 2. Collection and Testing
- 3. Laboratory Accreditation
- 4. Tracking, Transport, and Distribution
- 5. Serving Size and Homogeneity
- 6. Labeling and Packaging
- 7. Education and Training
- 8. Food Safety Plans
- 9. Waste Disposal
- 10. Regulatory Considerations

1. Storage

Storage refers to keeping products safely stored at any point of production, which can include storage at a cannabis kitchen facility, dispensary, during transportation, or during testing and sampling.

Considerations for Regulation

- Lighting, ventilation, temperature, humidity, space, and equipment
- Sanitation, clean and orderly space for storage, pest and rodent free space
- Space/storage area for all cannabis products that is damaged, contaminated, or has been tampered with
- Security precautions for all storage areas and access for individuals who have been trained in food safety and are 21 years or older



- Require storage legislation for all stages of production including cultivation, production, distribution, testing, and sale
- Labeling requirements for varying stages of production and sale
- Contamination and storage during transport
- Storage separation for multiple deliveries
- Consider specific legislation for storage during production (i.e., sampling and testing), dispensary storage, and transport

Examples of Strong State Regulations

Massachusetts

<u>Massachusetts drafted cannabis regulations</u> in December 2017 to ensure safe access to cannabis. These laws put into place various requirements pertaining to the safe and proper storage of cannabis products.

- "A marijuana establishment shall provide adequate lighting, ventilation, temperature, humidity, space, and equipment" (935 Mass. Code Regs. 500.105)
- "A registered marijuana dispensary (RMD) shall have separate areas for storage of marijuana that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging have been opened or breached, until such products are destroyed" (2018 Mass. Reg. Text 11143, Proposed Rule)
- "RMD storage areas shall be maintained in a clean and orderly condition" (2018 Mass. Reg. Text 11143, Proposed Rule)
- "RMD storage areas shall be free from infestation by insects, rodents, birds, and pests of any kind" (2018 Mass. Reg. Text 11143, Proposed Rule)
- "RMD storage areas shall be maintained in accordance with the security requirements" (935 Mass. Code Regs. 500.105)

Other regulations that mention and pertain to storage include:

- "Mixed use business licensees must maintain a separate, locked storage area on its premises
 for marijuana products. Such separate, locked storage area shall be limited in access to only
 those employees who are 21 years of age or older and have completed a responsible vendor
 program training" (2018 Mass. Reg. Text 11143, Proposed Rule)
- "Management and operations...shall submit...a detailed summary of operating policies and procedures for the marijuana establishment, which shall include, but not be limited to, provisions for storage" (2018 Mass. Reg. Text 11143, Proposed Rule)
- "There shall be sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations" (2018 Mass. Reg. Text 11143, Proposed Rule)
- "There shall be adequate safety lighting in all processing and storage areas, as well as areas



where equipment or utensils are cleaned" (935 Mass. Code Regs. 500.105; 105 Mass Code Regs. 725.105)

• "Storage and transportation of finished products shall be under conditions that will protect them against physical, chemical, and microbial contamination as well as against deterioration of them or their container" (105 Mass Code Regs. 725.105)

Storage requirements for vehicles:

- Vehicles must be "equipped with functioning heating and air conditioning systems appropriate for maintaining correct temperatures for storage of marijuana and marijuana products" (2018 Mass. Reg. Text 11143, Proposed Rule)
- "Marijuana and marijuana products must be transported in a secure, locked storage compartment that is a part of the vehicle transporting the marijuana or marijuana products" (2018 Mass. Reg. Text 11143, Proposed Rule)
- "The storage compartment must be sufficiently secure that it cannot be easily removed" (935 Mass. Code Regs. 500.105)
- "If a marijuana establishment, pursuant to a marijuana transporter license, or a marijuana transporter is transporting marijuana or marijuana products for more than one marijuana establishment at a time, the marijuana or marijuana products for each marijuana establishment shall be kept in a separate locked storage compartment during transportation and separate manifests shall be maintained for each marijuana establishment" (2018 Mass. Reg. Text 11143, Proposed Rule)

Oregon

In <u>Oregon</u>, the handling and testing of cannabis is overseen by three separate state agencies: the Oregon Liquor Control Commission, Oregon Health Authority, and Oregon Department of Agriculture. In regard to storage while sampling and testing cannabis, Oregon requires the following:

- "A producer must, within 45 days of harvesting a harvest lot, physically segregate the harvest lot from other harvest lots, place the harvest lot in a receptacle or multiple receptacles and assign a UID tag to each receptacle that is linked to each plant that was harvested" (OR Admin. R. 845-025-2080)
- "Following samples being taken from a harvest or process lot batch a grower or processing site must:
 - (a) Label the batch with the following information:
 - (A) The registrants registration number;
 - (B) The harvest or process lot unique identification number;
 - (C) The name and accreditation number of the laboratory that took samples and the name and accreditation number of the laboratory responsible for the testing, if different;
 - (D) The test batch or sample unique identification numbers supplied by the laboratory personnel;



- (E) The date the samples were taken; and
- (F) In bold, capital letters, no smaller than 12 point font, "PRODUCT NOT TESTED." (OR Admin. R. 333-007-0380)
- The grower or processing site must "[s]tore and secure the batch in a manner that prevents the product from being tampered with or transferred prior to test results being reported." (OR Admin. R. 333-007-0380)
- The bath must "[b]e able to easily locate a batch stored and secured under section (1)(b) of this rule and provide that location to the authority or a laboratory upon request" (OR Admin. R. 333-007-0380)

Additionally,

- "Transfer Records: At the time a marijuana item is transferred to a dispensary the dispensary registrant must:
 - (a) Document, on a form prescribed by the Authority, as applicable:
 - (A) The weight in metric units of all usable marijuana received by the registered dispensary;
 - (B) The number of seeds and immature plants received by the registered dispensary;
 - (C) The amount of a medical cannabinoid product, concentrate, or extract received by the registered dispensary, including, as applicable, the weight in metric units, or the number of units;
 - (D) The name of the marijuana item;
 - (E) The date the marijuana item was received;
 - (F) The harvest or process lot numbers, and batch numbers; and
 - (G) The amount paid by the registered dispensary." (OR Admin. R. 333-008-1230)

2. Collection and **Testing**

Collection and testing methods are essential to the food safety of CIPs. To ensure consumer safety, it is imperative that product is being collected to ensure a representative sample, testing methods are similar, and laboratories are testing for similar pesticides, solvents, and microbials.

Considerations for Regulation

- Uniform sampling and collection methods
- Ensuring sanitation in laboratories
- Determine if sampling is conducted by dispensary, state, or laboratory
- In-process testing: testing at various stages (i.e., flower, concentrate, end product)
- Testing completed by a third-party independent laboratory



- Establish protocol for product that fails
- Ensure laboratories are using similar methods for testing product, which will allow for final product comparison
- Consider sampling standards beyond state recommendations
- Consider validation requirements and establish uniform methods to determine accuracy of testing
- Reporting results, which can be done through a certificate of analysis (COA)
- Test for the following:
 - Potency: Ensure methodologies are consistent to ensure accuracy across dispensary products. It will be important to allow for third-party proficiency testing as part of the process and set up random off the shelf testing. In the random testing it will be important to state that the random samples will be selected by a third-party tester not by the licensee.
 - O **Homogeneity:** An area that should be considered in CIPs. Homogeneity is meant to ensure that THC is distributed uniformly throughout a batch of a CIPs to provide users with the assurance of a consistently prepared edible.
 - Example: "For testing whether the THC content is homogenous, the marijuana testing facility shall report the THC content of each single serving in a multi-unit package; the reported content must be within 20 percent of the manufacturer's target; for example, in a 25 milligrams total THC package with five servings, each serving must contain between four and six milligrams of THC" (3 Alaska Admin. Code § 306.645)
 - Residual Pesticides: Consider organic growing standards. Studies indicate that the extraction process yield higher rates of pesticides (Voelker & Holmes, 2015). Long-term use or chronic exposure could result in serious human and environmental health issues. Alternatively, states can provide guidance for use and tolerance levels. A few states that have been active in this arena area are Oregon, Colorado, and California.
 - Cannabinoids: THC, tetrahydrocannabinolic acid, CBD, cannabidiolic acid, and cannabinol.
 - **Terpenoids**: Alpha-bisabolol, alpha-humulene, alpha-pinene, alpha-terpinolene, beta-caryophyllene, beta-myrcene, beta-pinene; caryophyllene oxide, limonene, and linalool.
 - O Others: Heavy metals, microbial impurities, mycotoxins, residual solvents and processing chemicals, moisture content and water activity, and homogeneity.



Examples of Strong State Regulations

California

<u>California</u> includes distributors into their sampling and testing model. All product is sent to a distributor. The laboratory goes to the distributor and chooses a sample. If any of the sample fails testing, all product is disposed. Recently, California developed a <u>chart for required laboratory testing</u>.

Colorado

In <u>Colorado (pp. 125–127)</u>, a representative sample is required for collection and testing. Essentially, growers are asked to take a sample from their grow and send it to the laboratory. For more information, please see Colorado's <u>Marijuana Inspection: Validation Guidelines</u>.

Massachusetts

In <u>Massachusetts</u>, as in Colorado, the grower chooses a sample to send to the laboratory. Massachusetts laboratories may send a representative sample to the grower and pick up the sample.

Nevada

<u>Nevada</u> laboratories go to the grower/processor to collect the sample. The laboratory chooses which sample to take.

Figure 4 (next page) is an example of a COA that a laboratory would produce for dry flower. Figure 5 is an example of a COA for concentrates. Some states require these to be provided to the retailers from the manufacturer or cultivation center.



Figure 4: Example of a Certificate of Analysis for a Dry Flower Cannabis Product

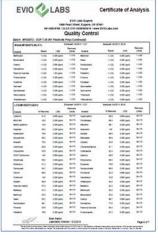












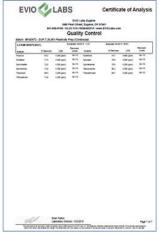
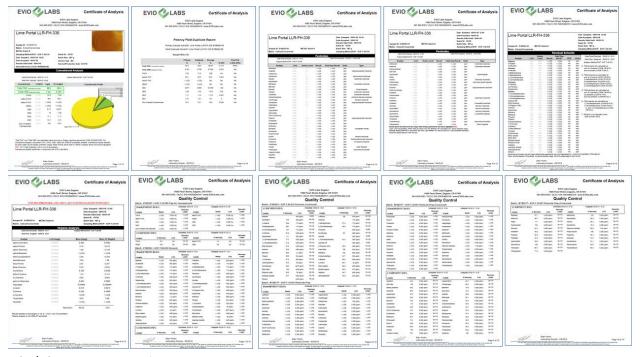


Figure 5: Example of a Certificate of Analysis for a Concentrate Cannabis Product



Disclaimer: These COA's are to be used solely as examples for this guidance document. Other examples of COA's have been made public and can be found on <u>EVIO's website</u>. NEHA has no affiliation to EVIO Labs or any other marijuana testing laboratory.

3. Laboratory Accreditation

Currently, laboratory accreditation is the only way to ensure testing standardization across different laboratories. Many states have relied on International Organization for Standardization (ISO)-17025 laboratory accreditation. ISO-17025 ensures that methods are being done properly, but it does not determine whether results are accurate. Additionally, ISO accreditation is required for each sector of testing and many laboratories get accredited for only one, but test for various sectors. For instance, a laboratory can be ISO accredited for pesticide testing but not for microbial testing. Often times laboratories will still conduct microbial testing despite not having the proper ISO accreditation for that specific test. This topic is still heavily debated in the cannabis industry and we are unsure how this situation will change and evolve as the industry grows. There are groups like ASTM International that have put together committees to develop national cannabis standards. The D37 Cannabis Committee is focused on developing laboratory standards specific to cannabis.

Considerations for Regulation

- Define testing facility
- Require all laboratories that test cannabis to be accredited by ISO- 17025 (give the licensee up to 12 months to obtain certification)
- Require all laboratories that test cannabis to have the same accreditation
- Require accrediting body to validate results
- Require accreditation via a third-party accrediting body with no financial tie to dispensary or cannabis industry
- Define educational requirements for laboratory director
- Future considerations: Require laboratories to publish all the testing information through a COA, which will allow academics and consumers to validate their work

Examples of Strong State Regulations

Colorado

- "Medical marijuana testing facility" means a public or private laboratory licensed and certified, or approved by the Division, to conduct testing and research on medical marijuana, medical marijuana concentrate, and medical marijuana-infused product" (1 CO Code Regs. § 212-1)
- "The laboratory director is responsible for the overall analytical operation and quality of the results reported by the medical marijuana testing facility, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurately, and proficiently and for assuring compliance with the standards set forth in this Rule....The laboratory director must be a) a medical doctor (MD) licensed to practice medicine in Colorado and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; b) the laboratory director must hold a doctoral degree in one of the natural sciences and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or c) the laboratory director must hold a master's degree in one of the natural sciences and have at least five years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body" (1 CO Code Regs. § 212-1)



Massachusetts

- "All testing must be conducted by an independent laboratory that is:
 - 1. Accredited to ISO-17025 by a third party accrediting body that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement; or
 - 2. Certified, registered, or accredited by an organization approved by the Department" (105 MA Code Regs. 725.105)

4. Tracking, Transport, and Distribution

Tracking and transport are important food safety issues and are therefore required in many states to <u>trace and track cannabis from seed-to-sale</u>, which often requires manufacturers to identify each plant, track it through the extraction and infusion process into finished products, and track it during transportation and distribution.

Considerations for Regulation

- Implement trace and track system before allowing a cannabis facility to operate
- Require training for personnel to operate and oversee trace and track system
- Include all phases and movement of cannabis in trace and track system, which may include packaging, sale, transport, receipt, return, laboratory results, etc.
- Provide definition of transport
- Consider vehicle alarms, security, refrigeration/temperature controls, and licensed personnel

Examples of Strong State Regulations

California

California requires a track-and-trace system that is a state approved system used to track commercial cannabis activity and movement. Every retailer must be registered for state mandated training for the track-and-trace system. The system was created to ensure that cannabis waste is identified, weighed, and tracked while on the licensed premises and disposed of in accordance to California law. It is essential for any movement of cannabis to be documented in the track-and-trace system.

Below are some examples of regulation; the full regulation can be found on page 34 of the <u>Emergency</u> <u>Regulations</u> proposed by California in January 2017.

• "A licensee shall create and maintain an active and functional account within the track and trace system prior to engaging in any commercial cannabis activity, including the purchase,



sale, test, packaging, transfer, transport, return, destruction, or disposal, of any cannabis goods" (CA Code Regs. Tit. 16, § 5048)

- "A licensee shall monitor all compliance notifications from the track and trace system, and timely resolve the issues detailed in the compliance notification" (CA Code Regs. Tit. 16, § 5048)
- "A licensee shall record in the track and trace system all commercial cannabis activity, including:
 - Packaging of cannabis goods
 - Sale of cannabis goods
 - Transportation of cannabis goods to a licensee
 - Receipt of cannabis goods
 - Return of cannabis goods
 - Destruction and disposal of cannabis goods
 - Laboratory testing and results
 - Any other activity as required pursuant to this division, or by any other licensing authority" (CA Code Regs. Tit. 16, § 5049)
- "The following information shall be recorded for each activity entered in the track and trace system:
 - O Name and type of the cannabis goods
 - Unique identifier of the cannabis goods
 - Amount of the cannabis goods, by weight or count
 - Date and time of the activity or transaction
 - Name and license number of other licensees involved in the activity or transaction
 - o If the cannabis goods are being transported" (CA Code Regs. Tit. 16, § 5048)

Colorado

In the <u>Code of Colorado Regulations</u>, there is a list of tracking requirements for all cannabis retail stores. Colorado requires the use of an inventory tracking system to ensure that all cannabis inventories are identified and tracked from cultivation to sale, a testing facility, or disposal.

Some examples of the regulation are listed below.

- "The retail marijuana store must have the ability to reconcile its inventory records with the inventory tracking system and the associated transaction history and sale receipts" (1 CO Code Regs. § 212-2)
- "A retail marijuana store is prohibited from accepting any retail marijuana or retail marijuana product from a retail marijuana cultivation facility or retail marijuana products manufacturing facility without receiving a valid transport manifest generated from the inventory tracking system" (1 CO Code Regs. § 212-2)
- "A retail marijuana store must immediately input all retail marijuana and retail marijuana product delivered to the licensed premises, accounting for all RFID tags, into the inventory



tracking system at the time of delivery to the retail store" (1 CO Code Regs. § 212-2)

- "All delivered retail marijuana must be weighed and the scale used shall be tested and approved in accordance with measurement standards established" (1 CO Code Regs. § 212-2)
- "A retail marijuana store must reconcile transactions from their point of sale processes and on-hand inventory to the inventory tracking system at the close of business each day" (1 CO Code Regs. § 212-2)

5. Serving Size and Homogeneity

Edible products typically have a delayed onset of effect. To avoid over consumption and to protect recreational consumers, some states now require producers to label serving sizes, individually mark serving size, and limit THC mg/serving size and package. Additionally, producers have found that ensuring homogeneity throughout an edible product is difficult. Moreover, states have set different homogeneity requirements. Some states now require a uniform distribution of THC throughout the edible product to ensure that not all the THC is concentrated in one area of the edible and to ensure that consumers are consuming only the amount of THC that is labeled on the serving size.

Considerations for Regulation

- Individually marked or delineated servings
- Limit THC per serving (generally 10 mg [MA] or to 5 mg [OR])
- Limit THC per package (generally 100 mg, which can differ for medicinal users)
- Require labeling for serving size and suggestions for use (also under Section 6: Labeling and Packaging)
- Consider testing for homogeneity
- Consider variance requirement for potency of products (i.e., +/- 10–20%)

Examples of Strong State Regulations

California

California's <u>emergency draft regulations</u>, developed by the Bureau of Cannabis Control, includes comprehensive regulations on serving size and homogeneity.

Serving Size

- "Beginning January 1, 2018, licensees shall not transport or sell any edible cannabis product that exceeds 10 mg of tetrahydrocannabinol (THC) per serving" (CA Code Regs. 16, § 5029)
- "An M-licensee may transport or sell medicinal edible cannabis products that are 10 mg of



THC or less per serving regardless of the THC amount in the package" (CA Code Regs. 16, § 5029)

Homogeneity: § 5716. Homogeneity Testing of Edible Cannabis Products

- "A sample of edible cannabis product shall be deemed to have passed homogeneity testing if the relative standard deviation of THC concentration between the samples collected does not exceed plus or minus 10%" (CA Code Regs. 16, § 5716)
- "If a sample fails homogeneity testing, or the laboratory fails to perform homogeneity testing...the batch from which the sample was collected fails homogeneity testing and may not be released for retail sale" (CA. Code Regs. 16, § 5716)

Colorado

Colorado has new permanent rules for <u>retail marijuana</u> and <u>medical marijuana</u> that went into effect in February 2018. The regulations have clear guidelines for serving size and homogeneity. Here, only retail marijuana is shown as an example.

Serving Size for Retail Marijuana

- "Multiple-serving edible retail marijuana product" means a unit for sale to consumers containing more than 10 mg of active THC and no more than 100 mg of active THC" (1 CO Code Regs. 212-2)
- "Single-serving edible retail marijuana product" means an edible retail marijuana product unit for sale to consumers containing no more than 10 mg of active THC". (1 CO Code Regs. 212-2)
- THC content container restriction: "Each individually packaged edible retail marijuana product, even if comprised of multiple servings, may include no more than a total of 100 mg of active THC" (1 CO Code Regs. 212-2)
- Multiple-serving edible retail marijuana product:
 - o "A retail marijuana products manufacturing facility must ensure that each single standardized serving of marijuana of a multiple-serving edible retail marijuana product is **physically demarked** in a way that enables a reasonable person to intuitively determine how much of the product constitutes a single serving of active THC
 - Each demarked standardized serving of marijuana must be easily separable in order to allow an average person 21 years and older to physically separate, with minimal effort, individual servings of the product
 - o Each single standardized serving of marijuana contained in a multiple-serving edible retail marijuana product shall be marked, stamped, or otherwise imprinted with the universal symbol_directly on the product in a manner to cause the universal symbol to be distinguishable and easily recognizable" (1 CO Code Regs. 212-2)

Homogeneity for Retail Marijuana:



- "If the THC content of a retail marijuana product is determined through testing not to be homogenous, then it shall be considered to have failed potency testing" (1 CO Code Regs. 212-2)
- "A potency variance of no more than plus or minus 15% is allowed" (1 CO Code Regs. 212-2)
- "A retail marijuana product shall be considered to not be homogenous if 10% of the infused portion of the retail marijuana product contains more than 20% of the total THC contained within entire retail marijuana product" (1 CO Code Regs. 212-2)
- "Homogeneity of edible retail marijuana product: A retail marijuana products manufacturing
 facility must ensure that its manufacturing processes are designed so that the cannabinoid
 content of any edible retail marijuana product is homogenous" (1 CO Code Regs. 212-2)
- Retail marijuana product ongoing potency and homogeneity testing: After successfully obtaining process validation, once per quarter a retail marijuana products manufacturing facility shall subject at least one production batch of each type of retail marijuana product that it produces to potency and homogeneity testing required by paragraph (D) of this rule. If during any quarter a retail marijuana products manufacturing facility does not possess a production batch that is ready for testing, the retail marijuana products manufacturing facility must subject its first production batch that is ready for testing to the required potency and homogeneity testing prior to transfer or processing of the retail marijuana" (1 CO Code Regs. 212-2)

Washington

Washington has made all of their cannabis legislation available for public use online at its State
Legislature website. These regulations are set in place for recreational cannabis use. Medicinal serving sizes differ.

Serving Size

- "A single serving of a marijuana-infused product must not exceed 10 mg active THC, or Delta
 9" (WA Admin. Code § 314-55-095)
- "The maximum number of servings in any one single unit of marijuana-infused product meant to be eaten or swallowed is ten servings or 100 mg of active THC, or Delta 9. A single unit of marijuana concentrate cannot exceed 1 g" (WA Admin. Code § 314-55-095)

Homogeneity (no specific potency limit is specified in the regulations)

- "Products must be homogenized to ensure uniform disbursement of cannabinoids throughout the product" (WA Admin. Code § 314-55-077)
- "Liquid edibles must be homogenized to ensure uniform disbursement of cannabinoids throughout the product" (WA Admin. Code § 314-55-077)



6. Labeling and Packaging

Labeling and packaging are key facets of any food product in terms of compliance, safety, and quality management. Labeling refers to ensuring that important food safety information is properly labeled and available to consumers. Packaging refers to ensuring that packages are properly secured.

Considerations for Regulation

- Disclosure of product, name of strain, universal symbol for THC, serving size, amount of THC per serving/per package
- Ingredient list, pesticide use, allergen list, nutrition facts
- Restricting the use of the word "organic" or suggesting any "cures or natural remedies"
- Statement product was tested, name of laboratory in which it was tested, when it was tested
- Date of cultivation, manufacture date, date of expiration
- Warning labels: intoxicating/delayed effects, keep away from children/animals, do not consume
 if pregnant, health risks
- If medical, patient name
- Net weight, concentration
- Instructions for use, dosing information (i.e., serving size)
- Specifications for font size
- Child/tamper proof, water resistant
- Resealable packaging if contains more than one serving
- Individually demarcate servings (See Section 5: Serving Size and Homogeneity)
- Individually label servings with universal symbol (See Section 5: Serving Size and Homogeneity)

Examples of Strong State Regulations

California

California built a robust labeling program that is available on the <u>California Department of Public Health (CPDH) website</u>. There are two categories for labeling: primary panel requirements and informational panel requirements.

The primary panel should be the one that will be displayed to the consumer and should include:

- Identity of a product
- Amount of THC/CBD in the package
- Universal symbol a state has required



- Net weight or volume
- Amount of THC/CBD per serving. (2017 CA S.B. 94)

The informational panel can be located somewhere else on the package and should include:

- Manufacturer name and contact information (website or phone number)
- Date the product was manufactured
- Government warning statement (if applicable)
- Ingredient list
- Instructions for use
- Unique ID/batch number
- Allergen information, a list of artificial food colorings, and basic nutritional information (amount of sodium, sugar, carbohydrates, and fat per serving). Medicinal products must be labeled "For Medicinal Use Only"

CDPH published the Proposed Medical Cannabis Manufacturing Regulations that

- Prohibits packaging from resembling traditionally available food packages
- Requires packaging to be resealable if it includes more than one serving
- Requires edible products to be packaged in opaque packages. CDPH is also proposing to require all manufactured products to be packaged in their final form prior to release to a distributor.

Nevada

Nevada has extensive written requirements for the labeling and packaging of cannabis edibles, which can be found at <u>Production Forms</u>, <u>Packaging</u>, <u>and Labeling of Marijuana and Marijuana Products</u>. Some examples of Nevada legislation are:

- "Each retail marijuana store and marijuana product manufacturing facility shall, in consultation with the department, cooperate to ensure that all marijuana products offered for sale:
 - a. Are labeled clearly and unambiguously:
 - 1. As marijuana with the words "THIS IS A MARIJUANA PRODUCT" in bold type" (2017 NV Rev. 539)
- "Not packaged and labeled in a manner which is modeled after a brand of products primarily consumed by or marketed to children" (2017 NV Rev. 539)
- "A cultivation facility or facility for the production of edible marijuana products or marijuanainfused products shall not label usable marijuana, edible marijuana products or marijuanainfused products as "organic" unless the marijuana plants used are produced, processed, and
 certified in a manner that is consistent with the national organic standards established by the
 U.S. Department of Agriculture in accordance with the Organic Foods Production Act of 1990"
 (NV Admin. Code § 453A.504)
- Marijuana-infused products must be "labeled in a manner which indicates the amount of THC
 in the product, measured in milligrams, and includes a statement that the product contains



marijuana and its potency was tested with an allowable variance of the amount determined by the division by regulation" (NV Rev. Stat. Ann. § 453A.360)

Nevada provides visual examples for labeling.

Figure 6: Nevada Visual Example for Labeling

SG'S NURSERY Certificate Number: 123 456 789 001 0001 THIS IS A MARIJUANA PRODUCT Batch Number: 1234 Lot Number: 1234 Final Harvested date: 01/01/2017 Testing Date: 01/15/2017 Packaged on: 01/17/2017 Best if used by: 3/17/2017 16.7% THC 1.5% CBD 0.3% CBN Myrcene 5.6 mg/g Limonene 5.1 mg/g Valencene 3.5 mg/g Net Weight: 2 lbs.

Figure 7: Oregon Generic Example





Figure 8: Product Label in Store

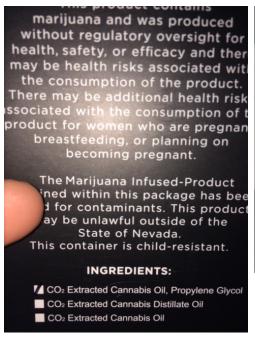




Figure 9: State Examples of Universal Symbols

California	Colorado	lo Michigan Oregon		Washington	
CA	THC THC M	CONTAINS THE	[*	NOT FOR KIDS EMERGENCY [800] 222 1222	
http://bit.ly/CA-Regs	http://bit.ly/CO-Regs	http://bit.ly/MI-Regs	http://bit.ly/OR-Regs	http://bit.ly/WA-Regs	

7. Education and Training

Food safety education and training is essential for growers, distributors, processors, laboratory workers, and dispensary personnel. Some states have gone to great lengths to ensure that these individuals receive training or require someone on staff to have food safety training or a certification.

Considerations for Regulation

- Require food handling certification or some other form of education/training
- Require training for an array of industry workers (e.g., owners, licensees, distributors, and processors)
- Include emergency procedures in training such as sewer, flood, and fire emergencies

Examples of Strong State Regulations

Colorado

Colorado's regulations devote an entire section of its <u>Health and Safety Regulations</u> to the training and education of all marijuana industry workers.

Training

- "Prior to engaging in the manufacture of any edible retail marijuana product each owner or occupational licensee must:
 - o a. Have a currently valid ServSafe Food Handler Certificate obtained through the successful completion of an online assessment or print exam; or
 - o b. Take a food safety course that includes basic food handling training
 - O Any course taken pursuant to this rule must last at least two hours and cover the following subjects:
 - i. Causes of foodborne illness, highly susceptible populations, and worker illness;
 - ii. Personal hygiene and food handling practices
 - iii. Approved sources of food;
 - iv. Potentially hazardous foods and food temperatures;
 - v. Sanitization and chemical use; and
 - vi. Emergency procedures (fire, flood, sewer backup)" (1 CO Code Regs. § 212-2)



Oregon

Oregon has passed a law requiring training for cannabis industry workers when applying for and renewing permits and licenses. Specifically, <u>Chapter 475B</u> outlines these requirements under "Issuing and Renewing Permits and Licenses."

- "The commission may require an individual applying for a permit under this section to successfully complete a course, made available by or through the commission, through which the individual receives training on:
 - Handling marijuana items;
 - If applicable, producing and propagating marijuana;
 - o If applicable, processing marijuana;
 - Any matter deemed necessary by the commission to protect the public health and safety" (OR Rev. Stat. § 475B.218)

8. Food Safety Plans

For the production and sale of cannabis edibles, it is important to include food safety plans into legislation. For many states, this includes a hazard analysis critical control point (HACCP) plan, general standard operating procedures (SOPs), inspections requirements, and recall plans.

Considerations for Regulation

- Requiring facilities to have a HACCP plan
- Requirements for SOPs
- Requirements for inspections
- Recall plans by state versus recall plans by dispensary or manufacturer
- General sanitary requirements
- Restricting the use of additives or providing guidance to restrict use of additives
- Health and sanitary audits
- How to rectify violations
- Guidance on how to determine when to suspend operations for food safety violations



Examples of Strong State Regulations

Arizona

In January 2017, a voluntary recall of medical cannabis edibles (medibles) took place in Arizona. During a routine food inspection, the Coconino County Public Health Services District found a medical dispensary was selling shelf stable products that had been processed and bottled incorrectly, making them potentially dangerous to consumers (Gaither et al., 2018). The dispensary kitchen included four new food items ('marynara' sauce, ketchup, hot sauce, and honey mustard) to their menu without informing the health district.

No guidelines had been developed for embargoing/recalling medibles. Therefore, the city sought out guidance from the <u>Food and Drug Administration</u>, which could not aid in the recall but could provide guidelines to implement a voluntary recall with the assistance and support of the dispensary owner. The health district recalled over 400 bottles of four different products and there were no foodborne-related illnesses reported or attributed to the consumption of any of the products.

Product Recalls

In general, the Coconino Public Health Department took the following steps:

- 1. Coordinate with special licensing
 - a. Draft consumer service announcement.
 - b. Instruct purchasers (medical consumers should be in database with contact information) what to do with the implicated food products and instructed purchasers not to consume those products.*
- 2. Coordinate with dispensary owner
 - a. The dispensary owner voluntarily requested to recall all implicated food products.
 - b. The health district assisted the dispensary in creating a list of all implicated items, what stores received those items, and provided all the stores with a consumer announcement to alert them of the recall.
- 3. Create product destruction list
 - a. Once the products were recalled, the dispensary provided a list of all products that were collected and from where they were collected.
 - b. The dispensary provided detailed information and pictures on how the product was destroyed and cross referenced it with the original list to ensure that all products were accounted for (Gaither et al., 2018).



^{*}This step will have to be approached differently with recreational consumers.

Colorado

In its <u>Code of Colorado Regulations</u>, Colorado has detailed guidance for food safety procedures. Colorado has broken food safety regulations into various sections including general standards, SOPs, sanitary guidelines, etc.

Below are examples of some of Colorado's regulations.

General Standards

- a. "A retail marijuana products manufacturing facility may be subject to inspection by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present" (1 CO Code Regs. § 212-2)
- b. "A retail marijuana products manufacturing facility that manufacturers edible retail marijuana product shall comply with all kitchen-related health and safety standards of the relevant local jurisdiction and...safety regulations applicable to retail food establishments" (1 CO Code Regs. § 212-2)

Standard Operating Procedures

- a. "A retail marijuana products manufacturing facility must have written standard operating procedures for each category of retail marijuana concentrate and type of retail marijuana product that it produces" (1 CO Code Regs. § 212-2)
- b. "If a manufacturing facility makes a material change to its standard...production process, it must document the change and revise its standard operating procedures accordingly" (1 CO Code Regs. § 212-2)

General Sanitary Requirements

- a. The licensee shall take all reasonable measures and precautions to ensure the following:
 - i. "Any person who...is shown to have, or appears to have, an illness; open lesion including boils, sores, or infected wounds; or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for retail marijuana or retail marijuana product shall be excluded from any operations"
 - ii. "Hand washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature"
 - iii. "All persons working in direct contact with preparation of retail marijuana or retail marijuana product shall conform to hygienic practices while on duty, including but not limited to:
 - 1. Maintaining adequate personal cleanliness
 - 2. Washing hands thoroughly in an adequate hand washing area(s) before starting work, prior to engaging in the production of a retail marijuana concentrate or manufacture of a retail marijuana product and at any other time when the hands may have become soiled or contaminated"



- iv. "Litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination"
- v. "Floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair"
- vi. "There is adequate safety-type lighting in all areas where retail marijuana or retail marijuana product are processed or stored and where equipment or utensils are cleaned"
- vii. "The licensed premise provides adequate screening or other protection against the entry of pests"
- viii. "Any buildings, fixtures, and other facilities are maintained in a sanitary condition"
- ix. "All contact surfaces, including utensils and equipment used for the preparation of retail marijuana, retail marijuana concentrate, or retail marijuana product, shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained"
- x. "Only sanitizers and disinfectants registered with the U.S. Environmental Protection Agency shall be used in a retail marijuana products manufacturing facility and used in accordance with labeled instructions" (1 CO Code Regs. § 212-2)

9. Waste Disposal

Proper waste disposal is important for two reasons: 1) bad batches must be destroyed and not make it into the food system and 2) cannabis that is disposed of must be unrecognizable to ensure that passerby do not collect waste and try to consume it.

Considerations for Regulation

- Safe disposal of waste materials and storage of waste
- Properly destroying bad batches
- Waste disposal operating systems maintenance
- Waste disposal record keeping
- Liquid versus solid waste



Examples of Strong State Regulations

Massachusetts

Massachusetts has drafted very comprehensive legislation for waste disposal of cannabis products. For complete legislation, please see page 56, section (L) Waste Disposal in the <u>Massachusetts Draft</u> Regulations.

Waste Disposal

- "All recyclables and waste, including organic waste composed of or containing finished marijuana and marijuana products, shall be stored, secured, and managed in accordance with applicable state and local statutes, ordinances, and regulations
- Liquid waste containing marijuana or byproducts of marijuana processing shall be disposed of in compliance with all applicable state and federal requirements, including but not limited to, for discharge of pollutants into surface water or groundwater (MA Clean Waters Act, M.G.L. c. 21 §§ 26 through 53; 314 CMR 3.00: Surface Water Discharge Permit Program; 314 CMR 5.00: Groundwater Discharge Program; 314 CMR 12.00: Operation Maintenance and Pretreatment Standards for Wastewater Treatment Works and Indirect Dischargers; Federal Clean Water Act, 33 U.S.C. 1251 et seq.; National Pollutant Discharge Elimination System Permit Regulations at 40 CFR Part 122; 314 CMR 7.00: Sewer System Extension and Connection Permit Program); or stored pending disposal in an industrial wastewater holding tank in accordance with 314 CMR 18.00: Industrial Wastewater Holding Tanks and Containers" (935 MA Code Regs. 500.105)

10. Regulatory Oversight

As states continue to legalize cannabis, they have had to find regulatory bodies to oversee the cannabis industry. The regulatory agency includes people who oversee dispensary inspections, operations, taxation, etc. States have implemented different approaches and it is important to remember that cities, counties, and municipalities might have their own regulations that can be more restrictive than ones imposed by states. See Table 1 for examples of different state regulatory bodies.



Considerations for Regulation

- Who will oversee the legalization and implementation of regulations of cannabis?
 - Regulatory agency versus various regulatory agencies
- How will the regulatory department be funded?
 - Consideration should be to use part of the annual licensing fee toward the regulating department
- How will you develop the qualification and rating selection process of potential licensees?
- How frequently will dispensaries and manufacturers be inspected?
- Who is responsible for seizures and closures?
- Will regulatory oversight be left to the state, a local regulatory body, or a cannabis commission?

Table 1: Different State Regulatory Bodies for Legalized Cannabis

Table 1: Different State Regulatory Bodies for Legalized Califiabls					
State	Regulator Body	Website			
California	Bureau of Cannabis Control: Responsible for licensing retailers, distributors, testing laboratories, and microbusinesses	http://www.bcc.ca.gov/			
	CalCannabis California Department of Food and Agriculture: Responsible for commercial cannabis cultivators	http://calcannabis.cdfa.ca. gov/			
	California Department of Public Health, Manufactured Cannabis Safety Branch: Responsible for regulation of all commercial cannabis manufacturing	https://www.cdph.ca.gov/ Programs/CEH/DFDCS/MC SB/Pages/MCSB.aspx			
Colorado	Colorado Department of Revenue, Marijuana Enforcement Division: Responsible for all licensees in the state	https://www.colorado.gov /pacific/enforcement/mari juanaenforcement			
Massachusetts	Massachusetts Cannabis Control Commission: Responsible for all licensees in the state	https://mass-cannabis- control.com/			
Nevada	Nevada Department of Taxation: Responsible for all licensees in the state	http://marijuana.nv.gov/			



Oregon	Oregon Liquor Control Commission: Responsible for licensing, tracking, etc.	http://www.oregon.gov/ol cc/Pages/index.aspx		
	Oregon Health Authority: Responsible for testing and labeling	http://www.oregon.gov/o ha/PH/PREVENTIONWELL NESS/MARIJUANA/Pages/I aws.aspx		
	Oregon Department of Revenue: Responsible for taxation	http://www.oregon.gov/D OR/programs/businesses/ Pages/marijuana.aspx		
Washington	Washington Liquor and Cannabis Control Board: Responsible for all licensees in the state	https://lcb.wa.gov/		

V. Special Considerations

Below is a list of special items to consider when thinking about the legalization of recreational cannabis in your state. While some of these considerations are primarily focused on food safety, others are general considerations for overall consumer health and safety.

1. Banking and the Sessions and Finance Crimes Enforcement Network Memorandums

Due to lack of federal legalization of medical and recreational cannabis, federal banks are unable to house cannabis industry profits. On January 4, 2018, Attorney General Jeff Sessions issued a memo that rescinds the Cole Memorandum and directs U.S. attorneys to enforce and prioritize previously established laws on federal cannabis enforcement policy. The U.S. Department of Justice states that its mission is to "enforce the laws of the United States, and the previous issuance of guidance undermines the rule of law and the ability of our local, state, tribal, and federal law enforcement partners to carry out this mission" (U.S. Department of Justice, 2018).

The U.S. Department of Treasury Financial Crimes Enforcement Network (FINCEN) released a memo in February 2014, <u>BSA Expectations Regarding Marijuana-Related Businesses</u>, that is still active. This memo allows financial institutions to service marijuana related businesses (MRBs) by requiring a very stringent compliance program that verifies state legalization, business licenses, etc. FINCEN has issued a quarterly report (last published September 2017), <u>Marijuana Banking Update</u>, that demonstrates business being received by banks and credit unions from MRBs.

While it is still uncertain how these memorandums will play out under the current administration, banks that are federally backed should be more hesitant to accept funds from the cannabis industry. During early legalization, lack of banking was a massive security issue. Without a banking system, cannabis industry stakeholders are required to rely on cash transactions or trading. Due to such high cash flows, multiple instances of theft have been recorded. Colorado and California are looking into banking systems such as state cannabis credit unions that will house the cannabis industry's high-volume cash flow, and hopefully, will protect industry stakeholders. As cannabis continues to become legal at the state level, it will be important for stakeholders to determine a safe way to bank.

2. Data Collection and Software

Data collection is imperative for two reasons: 1) seed-to-sale tracking ensures consistency and safety of cannabis products and 2) it ensures that states are being transparent with the data they collect. Washington provides <u>open data</u> on its programs. Figure 10 provides more information on seed-to-sale tracking software.

Figure 10: State Seed-to-sale Tracking Vendors



NEHA Food Safety Guidance for

Cannabis-Infused Products

Seed to Sale Tracking	California	Colorado	Massachusetts	Michigan	Oregon	Washington
The same of the sa	CALFORNA REPORK	C	***************************************	E	STATE OF ORLGON	®
Seed to Sale Tracking Vendors	METRC	METRC	BioTrackTHC	METRC	METRC	LEAF Data Systems

3. Health Impact Assessment

In light of legalization, Vermont conducted a <u>health impact assessment</u> (HIA). The assessment compiled data to analyze the potential health and societal effects of legalizing cannabis in Vermont. The HIA found that the legalization of cannabis in Vermont has increased the odds of motor vehicle accidents, poor academic performance among youth, a slight increase in emergency room visits, and a slight increase in mental health issues such as anxiety. While the analysis is thorough, it is not the entire picture. It simply provides the state with foreseen issues that result from legalization.

States can use this information to foresee negative consequences of legalization, implement prevention programs, and provide recommendations to other states. Vermont's HIA recommends the following:

- "Do not allow infused products on the regulated market. Do not include retail sales of products infused with marijuana for nonmedical purposes."
- "Never allow infused products that could appeal to children. Mandate that should future legislation ever allow for infused/edible products, they are never allowed in a format that could be attractive to youth (e.g., gummy bears, cookies, brownies, etc.). Before any future regulation regarding edibles is implemented, ensure that full testing and regulatory bodies are in place. This includes development, implementation, and full funding for comprehensive food inspection."

4. Home Delivery

Home delivery has been outlawed in many states in order to protect consumers and ensure that medical product is being consumed by its intended recipient. As recreational cannabis becomes more easily accessible to consumers, however, some states have implemented regulations that allow delivery with certain restrictions. Nevada is an excellent example. In Nevada's Revised Proposed Regulation of the Department of Taxation issued on December 13, 2017, a cannabis delivery may be made to a consumer. The delivery may not be made by a third party, must be delivered to the intended recipient, may not include any products other than the one contracted by the distributor, must be delivered during the distributor's operational hours, and must be within state lines. A full description of the law can be found in the Revised Regulation under Section 150.

5. Home-Grow

Nearly every state has different regulation in regard to cannabis home-grow. Food safety precautions should be provided for home growers. Most states focus solely on the growth of the plant. Below is an example of <u>regulation from Massachusetts</u>:

• Allowed to cultivate or process up to six marijuana plants for requirements and restrictions.



- Personal use so long as not more than 12 plants are cultivated on the premises at once.
- Allowed to possess any marijuana produced by marijuana plants cultivated on the premises.
- Marijuana cannot be visible from a public place without the use of binoculars, aircraft, or other
 optical aids, and must be in an area equipped with a lock or other security device. A violation is a
 civil penalty of up to \$300.

6. Liability

While cannabis continues to become legal at the state level, it is imperative that industry stakeholders are cautious with recordkeeping requirements they set for licensees. Just as licensed traditional food processing companies are susceptible to regulations (local, state, and federal) and lawsuits, so are cannabis licensees. From a liability standpoint, recordkeeping by the cannabis industry helps document good practices and can help if a legal issue should arise. Regulators should have industry licensees involved in infused product manufacturing to incorporate basic food safety training for their employees. Additionally, recordkeeping must be included in any HACCP/food safety plan to ensure safe food handling practices from seed-to-sale.

7. Special Events

Marketing or selling cannabis or CIPs at special events is a concern for food safety and consumer safety in general. States differ in the events that they allow marijuana to be sold or marketed. A special event may include, but is not limited to, a parade, pop-up markets, festivals, concerts, etc. Massachusetts requires "licenses that authorize the consumption of marijuana at special events in limited areas and for a limited time" (Chapter 334, Section 4b.[1]). This type of legislation varies by state but should be discussed when thinking about consumer safety in public spaces.

8. Topicals

While topicals are not ingested, and therefore not digested by the liver, there is significantly less regulation concerning topical ointments of CIPs. As all infused items begin from the same source and the extracts are converted into various products, it is imperative to maintain the highest safety standards when possible. This process might include requiring laboratory testing on the product for metal residues, residual solvents, metals, etc. In Section 222 of the Nevada Revised Proposed Regulation, a topical product must be tested for potency analysis and terpene analysis. Additionally, Nevada requires that a cannabis product sold as a topical must not contain a concentration of more than 6% THC, or more than 800 mg of THC per package.



VI. Definitions¹

Cannabidiol (CBD): The second most commonly used cannabinoid found in the cannabis plant. CBD is an antagonist to THC and is nonpsychoactive as it blocks the formation of 11-OH-THC and mitigates the psychoactive effects of THC. CBD has become popular for its therapeutic effects in autism, epilepsy, and nerve problems.

Cannabinoid: Chemicals that influence cell receptors in the brain and body and can change how those cells behave.

Cannabinoid profile: The amount of all cannabinoids in the cannabis plant, expressed as dry-weight percentages.

Cannabinol: Comes from the *Cannabis sativa* plant and contains only a minimal amount of THC.

Cannabis: Genus of flowered plants indigenous to Central Asia and the Indian subcontinent. Also known as marijuana, ganja, pot, bud, and Mary Jane.

Concentrate (or extract): Refers to any material created by refining cannabis flowers, such as hash, dry sieve, and hash oils. Concentrates or extracts have much higher potency.

Cultivator: An entity licensed to cultivate, process, and package cannabis, to deliver cannabis to cannabis establishments, and to transfer cannabis to other cannabis establishments, but not to consumers.

Edible: Cannabis products that are orally consumed. These products can contain THC, CBD, or a combination of both. Common edible products include cookies, brownies, candies, gummies, chocolates, beverages, or homemade goods.

Homogeneity: Refers to how evenly distributed the cannabis extract is through a product. For example, if 10% of the infused portion of the cannabis product contains less than 20% of the total THC contained in the product, it is homogeneous. Homogeneity allows users assurance that they are consuming a consistently prepared edible.

ISO 17025: General requirements specified by the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) for the competence of testing and calibration laboratories.

¹Taken from Cannabis 101: Glossary of Related Terms, National Environmental Health Association, 2018.



Medical use of cannabis: The acquisition, cultivation, possession, processing (including development of related products such as food, tinctures, aerosols, oils, or ointments), transfer, transportation, sale, distribution, dispensing, or administration of cannabis for the benefit of qualifying patients in the treatment of debilitating medical conditions or the symptoms thereof.

Mycotoxin: A secondary metabolite of a microfungus that is capable of causing death or illness in humans and other animals. They include aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2, and ochratoxin A.

Packaging: Any container or wrapper that might be used for enclosing or containing any cannabis goods for final retail sale. "Package" and "packaging" do not include a shipping container or outer wrapping used solely for the transport of cannabis goods in bulk quantity to a licensee.

Pesticide: Chemical or organic substances that might be used on cannabis plants to protect against insects and/or fungus. Due to the Schedule I status of cannabis, as well as the lack of research and understanding, there are no federal regulations on the application of pesticides on cannabis. Some pesticides commonly used on cannabis can be highly toxic. There have been numerous recalls of cannabis products due to pesticides. The most commonly found pesticides during these recalls in Colorado in 2015 (Baca, 2015) include:

- Myclobutanil: A fungicide known to be slightly hazardous by the World Health Organization.
- Imidacloprid: An insecticide known to be moderately hazardous if ingested or inhaled.
- Abamectin: A harmful insecticides if inhaled.
- Etoxazole: Primarily used in landscaping.
- Spiromesifen: An insecticide.

Processing: To harvest, dry, cure, trim and separate parts of the marijuana plant by manual or mechanical means

Retailer: An entity licensed to purchase and deliver cannabis and cannabis products from cannabis establishments and to deliver, sell, or otherwise transfer cannabis and cannabis products to cannabis establishments and consumers.

Seed-to-sale: Everything that happens to an individual cannabis plant from seed and cultivation, through growth, harvest, and preparation of cannabis-infused products, if any, to final sale of finished products. In many states, there are laws that require tracking and documentation of every movement along the seed-to-sale lifespan.

Tetrahydrocannabinol (or delta-9-tetrahydrocannabinol) (THC): The most common cannabinoid found within the cannabis plant. THC accounts for most of the psychoactive effects as the 11-OH-THC metabolite, formed after first pass metabolism, is 4 times more psychoactive than THC.



VII. References

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