Cannabis-Infused Products

Contents

I. Purpose	
II. Introduction	
III. Background: Food Safety and Cannabis	
IV. Food Safety Considerations and State Examples	
V. Special Considerations	
VI. Definitions	
VII. References	

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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 January 2019. 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.

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Cannabis-Infused Products

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, 2019

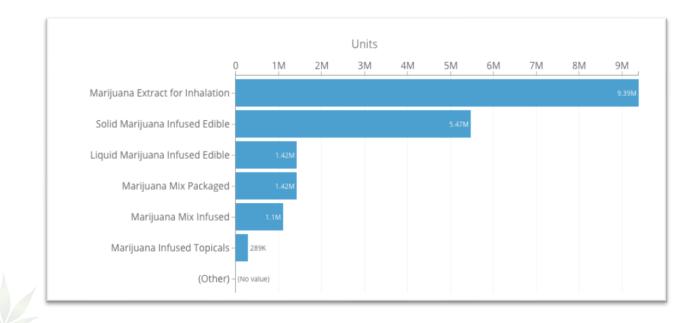
In 2015, 9.5% of adults and 23.7% of youth self-reported using cannabis at least once in the past year (Hasin et al., 2015). With the increased legalization of medicinal and recreational cannabis, the rates of adult and youth use across states are expected to increase (Hasin et al., 2015). Additionally, 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).



Cannabis-Infused Products

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 <u>Cannabis and Pesticides website</u>. 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. Microbial Testing in Food
- 4. Pesticides
- 5. Terpenes
- 6. Laboratory Accreditation and Testing Standards
- 7. Tracking, Transport, and Distribution
- 8. Serving Size and Homogeneity
- 9. Labeling and Packaging
- **10. Education and Training**
- 11. Food Safety Plans
- 12. Waste Disposal
- 13. Regulatory Considerations
- Additional Topic Areas:
 - 14. Hemp

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



Cannabis-Infused Products

- 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 registrant's registration number;
- (B) The harvest or process lot unique identification number;





Cannabis-Infused Products

(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



Cannabis-Infused Products

- 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.
 - **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 <u>Oregon</u>, <u>Colorado</u>, and <u>California</u>.
 - **Cannabinoids:** THC, tetrahydrocannabinolic acid, CBD, cannabidiolic acid, and cannabinol.
 - **Terpenoids**: Alpha-bisabolol, alpha-humulene, alpha-pinene, alpha-terpinolene, betacaryophyllene, beta-myrcene, beta-pinene; caryophyllene oxide, limonene, and linalool.
 - **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

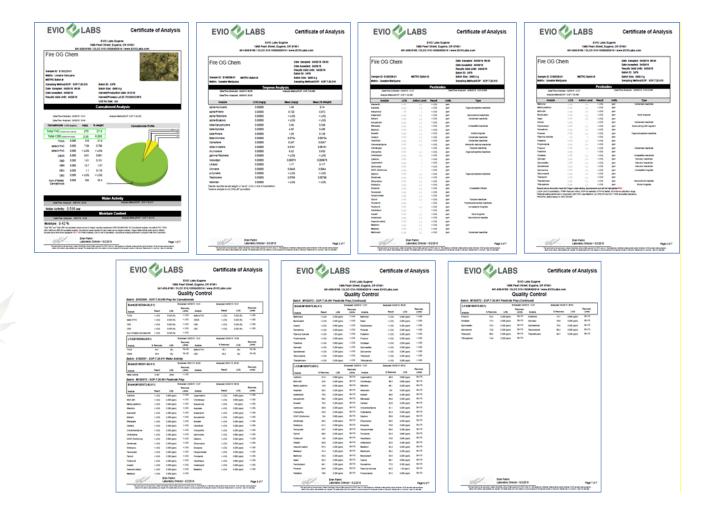
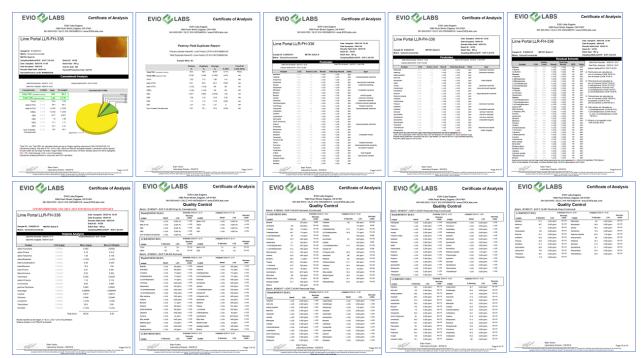




Figure 5: Example of a Certificate of Analysis for a Concentrate Cannabis Product



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. Microbial Testing in Food

With the industry constantly evolving, cannabis testing regulations are also evolving as cannabis grows and gains acceptance. Currently, microbial testing regulations vary on a state-by-state basis. A few of the current challenges with microbial testing include varying sample sizes, short testing deadlines, and incongruities in testing requirements (Ward, 2018). Due to these challenges, this section of the guidance doc is intended to provide information to aid laboratories and regulators in the resolution of these difficulties.

There are rapid regulatory changes to the industry and a lack of consensus on methods. States usually require an array of tests, including total aerobic, enteric, and yeast and mold plate count, *Salmonella*, pathogenic *E.coli*, as well as other specific bacterial contaminants. However, state regulations do not usually match one another. For example, New York requires testing for *Clostridium spp., Streptococcus spp., Penicillium spp., Aspergillus spp*, and *Mucor spp.*, while Nevada does not test for *Clostridium spp., Streptococcus spp., Penicillium spp., or Mucor spp.* (Ward, 2018). These inconsistencies have led to skepticism regarding microbial testing as a legitimate need in the cannabis industry. However, microbial testing is necessary depending on the product type and the end consumer for which the product is for. Contamination of certain products by *E. coli* or *Salmonella* may be unlikely, but rules should be drafted and implemented based on a worst-case scenario only. For example, direct inhalation of 10^2 CFU/g yeast and mold might not be a problem for an immunocompetent person, but



Cannabis-Infused Products

for someone with a debilitating disease, proper testing could be the difference between life and death (Ward, 2018). It is always better to err on the side of caution, and if the product could be destined for immunocompromised individuals, then strict testing requirements are necessary. To address the issue of determining appropriate target contaminants in cannabis products these basic questions should be considered (Ward, 2018):

- Who is the product destined for?
- What is the likelihood of contamination in the product?
- What impact would there be if the product was contaminated?
- Are there process controls or steps in manufacturing during which contamination is likely controlled?

To aid regulators, the Association of Public Health Laboratories released a guide outlining potential contaminants in various cannabis products (see Figure 6).

Figure 6: APHL Regulatory Guidelines

Preparation	Definition	USP Microbial Limits		
Other raw materials and ingredients		Total aerobic microbial count < 10 ³ Total combined yeast and mold count < 10 ² Absence of <i>E. coli</i> in 10 g		
Nutritional products with other highly refined ingredients	Edibles	Total aerobic microbial count < 10 ³ Total combined yeast and mold count < 10 ² Absence of <i>E. coli</i> in 10 g		
Rectal use products	Rectal suppositories For nonsterile products for pharmaceutical prep- arations and substances for pharmaceutical use	Total aerobic microbial count < 10 ³ Total combined yeast and mold count < 10 ²		
Vaginal use	Ointments, creams, inserts, and so forth For nonsterile products for pharmaceutical prep- arations and substances for pharmaceutical use	Total aerobic microbial count < 10 ² Total combined yeast and mold count < 10 Absence of Pseudomonas aeruginosa, Staphylo- coccus aureus, and Candida albicans in 1 g or 1 mL		
Transdermal patches	For nonsterile products for pharmaceutical prep- arations and substances for pharmaceutical use	Total aerobic microbial count < 10 ² Total combined yeast and mold count < 10 Absence of <i>Pseudomonas aeruginosa,</i> <i>Staphylococcus aureus</i>		
Oral mucosal, gingival, cutaneous, nasal, or auricular use	For nonsterile products for pharmaceutical prep- arations and substances for pharmaceutical use	Total aerobic microbial count < 10 ² Total combined yeast and mold count < 10 Absence of <i>Pseudomonas aeruginosa,</i> <i>Staphylococcus aureus</i>		
Ophthalmic use		Must meet the requirements of USP 771 for Ophthalmic Preparations		

Source: Cannabis Science and Technology, 2018.

(http://www.cannabissciencetech.com/article/microbial-testing-cannabis-regulatory-and-analytical-challenges)

*Disclaimer: The limits in the graph are based on various methods. This graph is only to be used as an example. *

Additionally, methodologies adopted by each state for various microbial testing vary tremendously. It is important for laboratories to recognize the limitations of microbial testing and follow well established conventions. Turnaround times are one of the main issues for laboratories. Yeast and mold testing generally tends to be the bottleneck, and the most common yeast and mold method used for this test is the rapid yeast and mold plates, such as those produced by 3M, and can read at a minimum of 48 hours. Methods such as molecular DNA-based methods offer even faster turnaround times, but the conversion between genomic copies and colony forming units must be further established



and shown as statistically comparable (Ward, 2018). Molecular methods also have an added challenge of pulling DNA from both live and dead tissue and spores that normally would not show up on agar methods. Laboratories can find guidance by adopting microbial conventions as published by the U.S. Department of Agriculture (USDA), FDA, AOAC, American Herbal Products Association (AHPA), and other sources.

4. Pesticides

Like any plant, cannabis plants are prone to pests and disease. Examples include tiny leafsucking spider mites, which can produce a new generation in less than a week, or powdery mildew, which is a fungus that forms talcum-like coating on leaves and spreads rapidly through greenhouses (Borel, 2015). The Environmental Protection Agency (EPA) is responsible for registering the labels that guide the use of products across the country. These labels minimize health risks and states cannot allow the use of pesticides that aren't approved at the federal level. However, due to cannabis being a Schedule I drug, no label for marijuana exists. Without oversight, some states are creating their own lists of approved marijuana pesticides. For example, Massachusetts disapproves the use of any pesticide on medical cannabis, while other states are less stringent (Schoonmaker, 2018). Figure 7 shows the pesticides and action limits tested by Nevada, Oregon, California, and Colorado.



Figure 7: Pesticides Tested Per State

	Nevada	ADI	ARfD			
	flower	% max	% max	Oregon	California	
Pesticide/ PGR	(ppm)	chronic	acute	Action level	Inhalable limits	
Abamectin	0.05	1.33	0.67	0.5	0.1	
Acequinocyl	4	0.72	0.2	2	0.1	
Bifenazate	15	16.7	1.67	0.2	0.	
Bifenthrin	0.05	1.11	0.56	0.2	3	
Cyfluthrin and beta-cyfluthrii	4	22.2	3.33	1	2	
Cypermethrin	0.05	0.67	0.17	1	1	
Daminozide	0.05	0.04		1		
Dimethomorph	60	1.33	0.11		2	
Etoxazole	7	0.08		0.2	0.1	
Fenhexamid	30	0.02			0.1	
Flonicamid	7	0.13	0.13	1	0.1	
Fludioxonil	0.02	0.01		0.4	0.1	
Imidacloprid	0.05	0.06	0.04	0.4	5	
Myclobutanil	4	0.13	0.01	0.2	2 0.1	
Paclobutrazol	0.05	0.15	0.03	0.4		
PCNB	0.2	0.02			0.1	
Piperonyl Butoxide	10	0.08		2	3	
Pyrethrin	1	0.42	0.08	1	0.5	
Spinetoram	1.7	0.13	0.03		0.1	
Spinosad	10	0.14		0.2	0.1	
Spirotetramat	10	0.07		0.2	0.1	
Thiamethoxam	0.02	0.01	0.13	0.2	5	
Trifloxystrobin	11	0.03	0.01	0.2	0.1	
Pesticides To Be Added						
Chlorpyrifos^		100	20			
Cyprodinil						
*Based on LOQ data from a survey of independent labs. ^Chlorpyrifos has been found in 87% of all newborn cord blood Most difficult to quantitate			Acute Refe	e Daily Intake (AD erence Dose (ARfi eporting Limit (MR		
Not permitted for use					,,	

Source: Nevada Department of Taxation Independent Laboratory Advisory Committee Meeting (August 05, 2019).

*Disclaimer: This list is not exhausted, and other states might have different requirements. The purpose of this graph is to be used as an example. *

5. Terpenes

Terpenes are a large and diverse class of organic compounds produced by a variety of plants, including cannabis, that offers a unique scent in every strain (Rahn, 2018). Terpenes are secreted by the same glands that produce cannabinoids such as THC and CBD. Different combination of terpenes can result in a distinctive scent, such as citrus, berry, mint, and pine. Certain factors influence a plant's



development of terpenes, including climate, weather, age and maturation, fertilizers, soil, type, and even the time of day (Rahn, 2018). Over 100 different terpenes have been identified in the cannabis plant. Many cannabis testing labs now test for terpene content, so you may have a better idea of what effects a strain might produce. Terpenes are believed to exhibit medicinal properties in addition to the cannabinoids.

Terpenes can be derived from many different plants, so companies are turning to alternative terpene sources outside of cannabis. Similar terpene profiles and aromatic properties in cannabis can be found in different plants, herbs, and fruits (Smith, 2017). Economically, it is a benefit to use plant-based terpenes after the product goes through a high-heat distillation process and companies can buy natural terpenes in bulk versus a smaller yield from a cannabis plant (Smith, 2017). However, terpenes that are extracted from a cannabis plant will provide a more natural entourage effect and the consumer will get the most therapeutic and medicinal value of the individual terpene (Smith, 2017). Most popular terpenes include:

Limonene

Odor: Citrus



Source: Tim Gunther, NEHA. Terpenes 101 Presentation. Presented by IloveCompliance.biz

Gastric reflux



Alpha-Pinene



Formula: C10H16 Molecular Mass: 136.1252 g/mol Boiling Point: 155 °C (311 °F) Vapor Pressure: Not Available Aroma: Pine-like

- α-Pinene is one of the principle monoterpenes, and is important physiologically in both plants and animals, and to our environment.
- α-Pinene tends to react with other chemicals, forming a variety of other terpenes (like D-Limonene) and other compounds.
- α-Pinene has been used for centuries as a bronchodilator in the treatment of asthma; ever notice how your lungs seem to open up when hiking through a pine forest in the warm summer?
- α-Pinene is also anti-inflammatory. It's found in conifer trees, orange peels among others, and known for it's sharp sweet odor. α-Pinene is a major constituent in turpentine.

Purported Therapeutic Effect

- Anti-inflammatory
- Broncho dilating
- Memory boosting

Source: Tim Gunther, NEHA. Terpenes 101 Presentation. Presented by IloveCompliance.biz

Beta-Myrcene



Formula: C10H16 Molecular Mass: 136.1252 g/mol Boiling Point: 168 °C (334 °F) Vapor Pressure: 7.00 mmHg (20 °C) Aroma: Earthy, fruity, and clove-like

β -Myrcene is a monoterpene, and for a wide variety of reasons, one of the most important terpenes.

- It is a precursor in the formation of other terpenes, as well. β-Myrcene is found fresh mango fruit, hops, bay leaves, eucalyptus, lemongrass and many other plants.
 β-Myrcene is known to be anti-tumor, antiinflammatory, and used in the treatment of spasms. It is also used to treat insomnia, and pain.
- It also has some very special properties, including lowering the resistance across the blood to brain barrier, allowing itself and many other chemicals to cross the barrier easier and more quickly.
- In the case of cannabinoids, like THC, it allows it to take effect more quickly. More uniquely still, β-Myrcene has been shown to increase the maximum saturation level of the CB1 receptor, allowing for a greater maximum psychoactive effect.
- For most people, the consumption of a fresh mango, 45 minutes before inhaling cannabis, will result in a faster onset of psycho activity and greater intensity. β-Myrcene can be used in this same manner to improve uptake with a wide variety of chemical compounds.
 - Purported Therapeutic Effec
 - Sedating
 - Pain relieving
 - Muscle relaxant
 - Antitumor
 - Anti-inflammatory
 - Liver protective



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Source: Tim Gunther, NEHA. Terpenes 101 Presentation. Presented by IloveCompliance.biz

Linalool



Source: Tim Gunther, NEHA. Terpenes 101 Presentation. Presented by IloveCompliance.biz

6. Laboratory Accreditation and Testing Standards

Currently, there are no reference methods for cannabis testing. Laboratory accreditation is one 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 <u>heavily debated</u> in the cannabis industry and we are unsure how this situation will change and evolve as the industry grows.

Because there are no official standards, some cannabis testing laboratories base their testing methods off AOAC standards because they develop analytical methods for a variety of safety interests including: food and beverages, dietary supplements, fertilizers, pharmaceuticals, soil and water, etc. AOAC International is a "globally recognized, 501(c)(3), independent, third party, not-for-profit association and voluntary consensus standards developing organization founded in 1884. When analytical needs arise within a community or industry, AOAC INTERNATIONAL is the forum for finding appropriate science-based solutions through the development of microbiological and chemical



Cannabis-Infused Products

standards. AOAC standards are used globally to promote trade and to facilitate public health and safety (AOAC, 2015)." AOAC International has an *Official Methods of Analysis* (OMA) program that evaluates chemistry, microbiology, and molecular biology methods. Methods approved in this program have undergone meticulous scientific and systematic scrutiny such that methods in the OMA of AOAC International are highly credible and defensible. As shown in the figure below, major vendors, such as Bio-Rad Laboratories, validate their kits with AOAC OMA.

Figure 8: Bio-Rad i-Q Check Real-Time PCR Solution

Validations									
iQ-Check Method	NF Validation by AFNOR Certification		NordVal	Health Canada	iQ-Check Method	NF Validation by AFNOR Certification		NordVal	Health Canada
Campylobacter spp.		•			Listeria spp.	•	•		•
Cronobacter spp.	•				Salmonella spp.	•	OMA***) •	٠
E. coli O157:H7	•	٠			STEC virulence genes**		•	20 A.	
Listeria monocytogenes	•	•	•	•	STEC 7 major O-groups**		•		

* EP1911852B1, AU2007306019B1, CA2666388B1, JP5330250B1

** USDA No Objection Letter *** Official Method of Analysis First Action, 2017.06

Source: Bio-Rad Laboratories, 2018. (https://www.biorad.com/webroot/web/pdf/fsd/literature/Bulletin_16439.pdf)

Additionally, in 2019 the AOAC developed the Cannabis Analytical Science Program (CASP) to develop reference methods for hemp and cannabis testing. Major contributors to the program include Bio-Rad, Association of Food and Drug Officials (AFDO), PathogenDx, Medicinal Genomics, and many more. The CASP program plans on focusing on food products infused with cannabis products first. Areas for the Standard Method Performance Requirements (SMPRs) include accuracy in label claim potency; and/or public safety issues such as detection of pathogens and/or residual solvents (AOAC, 2019). For more information, please visit the AOAC website:

https://www.aoac.org/AOAC_Prod_Imis/AOAC_Member/SDCF/CASP/CASP_Main.aspx?CASPCC O=1&WebsiteKey=2e25ab5a-1f6d-4d78-a498-19b9763d11b4&hkey=a86e6520-635f-431c-98aa-84bd61eaecf8#CASPCCO

There are also groups like ASTM International that have put together committees to develop national cannabis standards. The <u>D37 Cannabis Committee</u> is focused on developing laboratory standards specific to cannabis.



Cannabis-Infused Products

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; b) 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 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)



Cannabis-Infused Products

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)

7. 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.



- 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,



Cannabis-Infused Products

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
 - o 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:
 - 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
 - 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 onhand inventory to the inventory tracking system at the close of business each day" (1 CO Code Regs. § 212-2)

8. 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)



Cannabis-Infused Products

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:
 - "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
 - 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 <u>State</u> <u>Legislature website</u>. 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)



Cannabis-Infused Products

9. 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</u> (<u>CPDH</u>) website. 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)



Cannabis-Infused Products

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, Packaging, 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.



Cannabis-Infused Products

Figure 9: 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 10: Oregon Generic Example



Figure 11: Product Label in Store



Cannabis-Infused Products

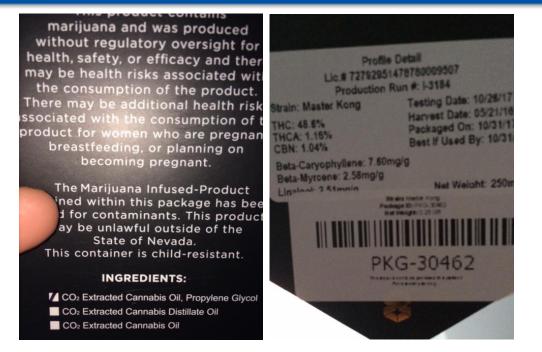


Figure 12: State Examples of Universal Symbols

California	Colorado	Michigan	Oregon	Washington
		CONTAINS THE	.*	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



10. 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:
 - a. Have a currently valid ServSafe Food Handler Certificate obtained through the successful completion of an online assessment or print exam; or
 - b. Take a food safety course that includes basic food handling training
 - 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)





Cannabis-Infused Products

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;
 - If applicable, processing marijuana;
 - Any matter deemed necessary by the commission to protect the public health and safety" (OR Rev. Stat. § 475B.218)

11. 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.



Cannabis-Infused Products

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"
х.	"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 ascerdance with labeled instructions" (1 CO Code Page § 212-2)
	accordance with labeled instructions" (1 CO Code Regs. § 212-2)

12. 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> <u>Regulations</u>.

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)

13. 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.



Cannabis-Infused Products

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

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	<u>http://calcannabis.cdfa.ca.</u> 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/



Cannabis-Infused Products

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/		

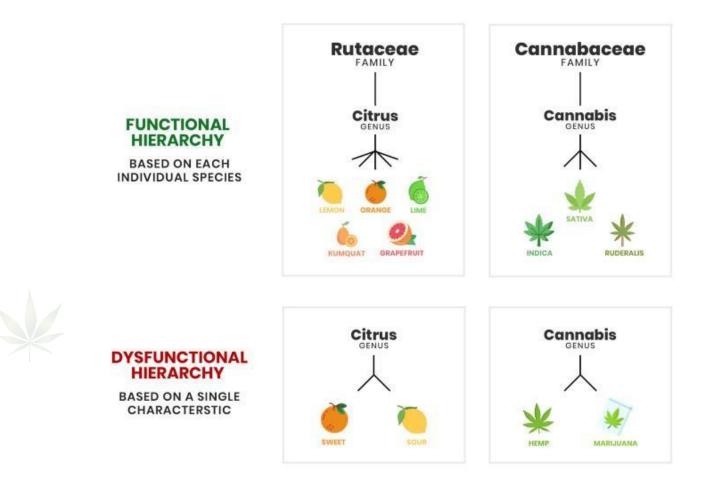
14. Hemp

The <u>Cannabaceae</u> family consists of three primary species: *Cannabis sativa, Cannabis indica,* and *Cannabis ruderalis.* Hemp and marijuana are broad classifications of Cannabis and it is important to clarify the difference for the purposes of this document. Hemp is a term used to classify varieties of Cannabis that contain 0.3% or less THC content (dry weight) (Cadena, 2018). Generally, the term hemp refers to the non-psychoactive varieties of *Cannabis sativa L.* (Hempsters, 2015). On the other hand, marijuana is a term used to classify varieties of Cannabis that contain more than 0.3% THC (dry weight) and can induce psychotropic or euphoric effects (Cadena, 2018). Hemp and marijuana can often appear indistinguishable from one another, and the main characteristic between the two is the chemical composition contained within each plant. High amounts of CBD can be produced from both hemp and marijuana, but THC is produced at various levels.

Categorizing Cannabis based on a single characteristic prevents users from fully understanding the plants diversity. For a better comparison, consider this taxonomic hierarchy:



Cannabis-Infused Products



Source: Leafly, 2015 (https://www.leafly.com/news/cannabis-101/hemp-101-what-is-hemp-whats-it-used-for-and-why-is-it-illegal).

As portrayed in the chart above, hemp and marijuana can often appear very similar, but they have starkly different properties.

Hemp can be grown as a renewable source for raw materials and can be incorporated into thousands of products (Hempsters, 2015). Hemp can be used in various health foods, organic body care, and other nutraceuticals. When hemp is grown as a fiber, it is planted as a high density to maximize stalk production. The fibers and stalks of the plant are used in hemp clothing, paper, biofuels, and much more (Figure 13).

Figure 13: Hemp Stalk Structure





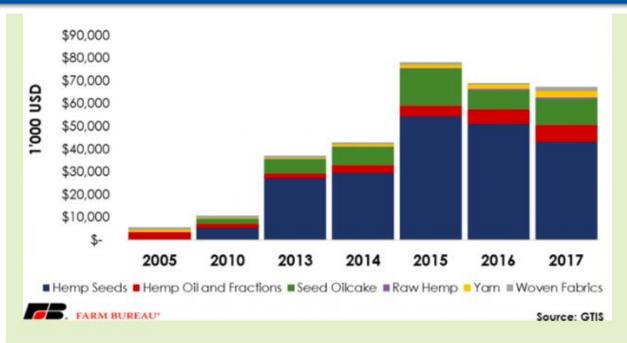
Source: Leafly, 2015 (https://www.leafly.com/news/cannabis-101/hemp-101-what-is-hemp-whats-it-used-for-and-why-is-it-illegal).

Hemp is an attractive rotation for farmers. As hemp grows, it breathes CO2, detoxifies the soil, and prevents soil erosion (Hempsters, 2015). It also requires much less water to grow and no pesticides. The hemp industry in the U.S. received a huge boost with the passage of the 2018 farm bill. The bill legalized the production of hemp as an agricultural commodity while removing it from the list of controlled substances (American Farm Bureau, 2019). The 2014 farm bill allowed for the production of hemp under specific conditions, while the current bill expands the potential for hemp production. According to Figure 14, hemp imports have been growing over the past few decades, reaching a high of \$80 million worth in 2015, then declining to just under \$70 million in 2017 (American Farm Bureau, 2019).

Figure 14: U.S. Hemp Product Imports



Cannabis-Infused Products



Source: American Farm Bureau, 2019 (https://www.fb.org/market-intel/2018-farm-bill-provides-a-path-forward-for-industrial-hemp).

Until the 2018 bill is implemented, there are still nine states that have not legalized the cultivation of hemp under the previous farm bill law: Connecticut, Georgia, Iowa, Idaho, Louisiana, Mississippi, Ohio, Texas, and South Dakota (American Farm Bureau, 2019). Additionally, because hemp was classified as a Schedule I substance when the 2019 Whole Farm Revenue Protection Plan (WFRP) was published in 2018, hemp as a commodity is not insurable in 2019. This means that a producer is allowed to grow hemp in 2019 and will not be ineligible to insure other commodities, but the hemp will not be insured under WFRP. It is believed that in 2020 hemp will be a covered commodity for crop insurance.



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 <u>memo</u> 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. <u>Colorado</u> and <u>California</u> 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



Seed to Sale Tracking	California	Colorado	Massachusetts	Michigan	Oregon	Washington
	CLEFORM REPORT	C	١		STATE OF OPEGON	(3)
Seed to Sale Tracking Vendors	METRC	METRC	<u>BioTrackTHC</u>	METRC	METRC	LEAF Data Systems

3. Health Impact Assessment

In light of legalization, Vermont conducted a <u>health impact assessment (HIA)</u>. 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 <u>Revised Proposed Regulation of the Department of Taxation</u> 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 homogenous. 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.



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