Cannabis Health & Safe Advisory Committee
Meeting Minutes
Meeting # 3 – July 31, 2018

1. Attendance

Participant	Organization
Danica Lee (co-chair)	Denver Department of Public Health &Environment
Abby Davidson (co-chair)	Denver Department of Public Health &Environment
Anshul Bagga	Denver City Attorney's Office
Molly Duplechain	Department of Excise and Licenses
Dorothy Colagiovanni	Bona Fides Lab; Next Frontier Biosciences
Helena Yardley	Franklin Biosciences
Jill Ellsworth	Willow Industries
Joe Cantalini	Organa Brands
Judith Shlay	Denver Public Health
Laura Davis	Environmental Health and Safety Professional
Linda Klumpers	Tomori Pharmacology
Mark Angerhoefer	Craft Concentrates
Mike Van Dyke	Colorado Department of Public Health and Environment
Noel Palmer	Evolab
Scott Hansen	Agricor Laboratories
Seth Wong	TEQ Analytical Laboratories
Stacey Linn	CannAbility Foundation
Kristi Kelly	Marijuana Industry Group
Kevin Gallagher	Cannabis Business Alliance

2. Agenda

- Welcome and introductions (10 mins)
- Draft DDPHE microbial guidance documents for businesses (10 mins)
    - Documents will be emailed after meeting; please provide comments/suggested edits by 8/14/18
- DDPHE Marijuana Product Baseline Study (45-60 mins)

- Purpose and scope
- Draft study design and methodology
- Discussion

- Evaluation of added ingredients to products (30 mins)
  - Overview of issue and challenges
  - Discussion
- Public comment (10 mins)

3. Meeting Notes

Item	Discussion
1. Welcome and introductions	• Danica Lee, Director of the Public Health Inspections Division for the Denver Department of Public Health and the Environment ("DDPHE" or the "Department"), opened the meeting by going over general housekeeping items (e.g. no breaks during this session, sign-up sheet for public comment, new building for the next meeting, etc.). • Abby Davidson, Food Safety and Marijuana Program Manager for DDPHE introduced Kara Lavaux (Food Safety and Marijuana Program Supervisor) and Richard Pruckler (Public Health Investigator) who gave presentations during the meeting. • Next, the Committee members went around the table and introduced themselves.
2. Draft DDPHE microbial guidance documents for businesses	• After introductions, Sheilah Winter (Public Health Investigator) presented draft guidance documents related to the prevention of microbial growth in marijuana and marijuana products. Sheilah explained that these documents were created based on

	requests received from industry members. DDPHE responded to requests from industry to provide guidance to industry members on how to prevent microbial growth and other types of contamination in marijuana products. Sheilah presented three separate documents; one for medical marijuana centers and retail marijuana stores ("centers and stores"); one for medical marijuana infused-product manufacturers ("MMIPS") and retail marijuana product manufacturers ("RMIPS"); and one for retail marijuana cultivation facilities ("RMCs") and medical marijuana optional premises cultivation facilities ("MMOs"). • Sheilah explained that the guidance documents are not meant to be a list of requirements. The documents are intended for educational and informational purposes only. DDPHE is requesting feedback from committee members on these draft documents by August 14, 2018. • Some members provided feedback at the meeting. • One member wanted to ensure that the guidance documents include sanitation processes for cultivation equipment, such as trimming scissors. • Another member was wondering how these standards were developed. • The Department explained that the standards were developed through on-site inspections/investigations at marijuana facilities. Some guidance is consistent with standards used in the food industry. • The group member suggested that the guidance documents include a discussion about how the standards were developed. • Another group member had questions about the three-compartment sink specifically. She was wondering if the three-

	compartment sink was also required in the food industry. The Department explained that MIPs who are producing ingestible products are already required to have three-compartment sinks under existing food regulations. MIPs that do not produce ingestible products are not required to have a three-compartment sink, therefore, the guidance document recommends either the installation of a three-compartment sink, or using a different space that is equipped with dishwashing and sanitizing capability. • The Department encouraged members to flag anything that is unclear or confusing in the guidance documents and submit feedback.
3. DDPHE Marijuana Product Baseline Study	• Next, Richard Pruckler gave a presentation about the background of the Marijuana Product Baseline Study. • Mr. Pruckler is a public health investigator with the Department. The Department receives investigation referrals from government agencies and partners like the Colorado Department of Agriculture ("CDA"), the Rocky Mountain Poison and Drug Center, the Marijuana Enforcement Division ("MED"), as well industry members and private citizens. • Mr. Pruckler began his presentation with a slide that displayed results for total yeast and mold ("microbial") contamination found in samples provided by seven (7) businesses over the past eighteen (18) months. The study compared samples overseen by DDPHE from those seven (7) businesses with samples that those business provided as part of the MED required testing without regulatory oversight. Of the samples that were taken with DDPHE oversight (347 samples) 38% passed microbial testing and 62% failed. Of the samples that were provided as

	required testing without DDPHE oversight (347 samples), 71% passed microbial testing and 29% failed. • Next, Mr. Pruckler presented data related to pesticide testing. Of the samples taken by DDPHE or the CDA (578 samples), 72% passed. This includes concentrates, edibles, flower, live plants, pre-rolls, shake, and trim. At the state level, mandatory pesticide testing on flower will begin on August 1, 2018. • Mr. Pruckler then presented a slide on gaps in testing enforcement. Under the current system, no regulatory agency oversees samples submitted to the MED for testing. Mr. Pruckler explained that he has seen operators spray vinegar on samples provided for testing or segregate product intended for testing from product that is sold to customers. Similarly, he explained that testing samples have been known to look different depending on which test is being run. For example, product sent in for potency testing might look healthy and green, while product sent in for microbial testing may be brown with characteristics suggesting that heat was applied to the samples prior to testing. • Two other members wanted to clarify whether the samples taken for microbial testing were taken during contamination investigations. The Department explained that the samples taken by DDPHE were taken during contamination investigations, however the samples submitted to the MED during the same period were not taken with DDPHE oversight or based on any investigation conducted by DDPHE, but came from the same businesses during the same harvest time frame. • Abby then gave a brief overview of the purpose and scope of the baseline study. She explained that the Department has gone

	over the group's feedback related to DDPHE's proposal to begin routine sampling and testing. Some of the comments questioned who would bear the cost, and others suggested that a pilot program may be more appropriate. Based on feedback received, the Department has decided to hold off for now on any sampling and testing during routine inspections. Abby explained that the Department has secured funding to conduct a marijuana product baseline study from the (approximately $20,000). Much of the current testing focuses on samples taken "upstream" in the product cycle. After sampling, products may be exposed to several different contamination sources prior to being sold to consumers. Therefore, the purpose of the baseline study is to find out whether contaminated product is reaching store shelves and being sold consumers. She explained that the results may inform the Department's next steps. • The study will focus on approximately 100 randomly sampled marijuana products. The products will come from centers and stores and will include flower, pre-rolls, concentrates and edibles. The samples will be analyzed for microbials, pesticides, , residual solvents, and possibly heavy metals and mycotoxins. The samples will be tested by an ISO accredited laboratory and the cost of testing will be covered under the study. The Department will be collecting the samples provided for testing. Once the analytical plan is finalized, the Department will work with the Office of Marijuana Policy ("OMP") to send out an industry bulletin prior to the start of the study. The results of the study will be shared and will inform next steps. • David Tobano, an epidemiologist at Denver Public Health, explained the study design and methodology. Mr. Tobano explained that the study will focus on a stratified random

	sample of approximately twenty (20) businesses. The samples will be stratified so that they are not over-representative of one geographic area. Mr. Tobano explained that the Department is open to discussing other strata which may be considered, such as time of licensing. Approximately 100 total samples will be taken (five (5) samples per seller). He explained that the study is intended to maximize breadth. The aim of the study is to capture a quantitative view of what's going on in the industry. The manufacturers' identities will be blinded from the epidemiologists doing the analysis,. • One member wondered whether product manufacturers would be notified if their product had been selected for testing. Abby explained that the Department was still considering that point. She explained that if significant contamination is found, the Department will be tracing back the product to investigate the source of contamination. • Two industry members felt that there should be a degree of separation between enforcement action and the study. These members felt that the baseline study should not be conflated with an investigation into post-testing contamination and instead that the baseline study should focus only on information gathering. • The Department explained that it has a duty to act upon any discovery of a public health threat, and that failure to act would not be fair to consumers in Denver. • Another member questioned how the Department would be able to log and track samples taken in METRC, the program used by the MED to track marijuana and marijuana products.

	• The Department acknowledged this issue and explained that the logistics of the sampling process still have to be worked out. • Two members suggested that the scope of the study be paired down to include one product type or fewer product types and fewer contaminants being tested. For example, members suggested that the Department focus on pesticide contamination in flower, microbial contamination in concentrates, or residual solvent contamination in smoking products. A regression analysis may be difficult to run with so many products being analyzed. • Another member suggested that the water activity of samples could be analyzed to determine if there is a correlation between microbial contamination and water activity. • One member also suggested that collecting numerical data for microbial contamination may be more helpful than collecting data in binary fields like "pass" or "fail." This member also suggested that yeast or mold could be speciated if microbial contamination is found. • Another member also suggested that the Department consider "endpoints." This member explained that the total count for yeast and mold in a test result may mean different things if the person ingesting the product is immunocompromised and the microbial being ingested is aspergillus. • The Department explained that it is working on the possibility of addressing the speciation concern. • Another member suggested that the Department look at hospital visits where the primary diagnosis involves marijuana and ask doctors to collect information from those patients. One member responded by suggesting that a national level study

	(conducted by the National Institute of Health ("NIH")) may be more appropriate for that kind of data collection. • The Department explained that data about marijuana-related hospital visits is currently being collected, but the number of emergency department visits with primary illness codes tied to marijuana is very small . The Department is working with Denver Health to evaluate data colllection around patient hospital visits that involve marijuana. • Another member was concerned about the timing of the study. She explained that many MMOs and RMOs are currently "process validated and not routinely testing their products," which may cause the study to find more contamination now versus one year from now. • In terms of timeframe for the study, the Department is considering Fall of 2018, but details are still being worked out. • Other members commented on possible sources of contamination and the problem with the existing regulatory system. For example, many employees have never been trained on proper sampling techniques and training should be a larger focus. This was echoed by another member who explained that the current regulations are not clear about how samples should be taken, what products are acceptable for testing, and what methods should be used for remediation. • Another member also explained that many marijuana industry members are not involved in rulemakings held by the Colorado Department of Public Health and Environment ("CDPHE") and are unaware of CDPHE protocols for food. This member characterized these violations as "low hanging fruit" and

	wondered why no agency has taken enforcement action when they find gaps in testing. • The Department acknowledged that the results of the study may prompt several new questions and may inform future priorities such as potentially working with the MED to clarify existing rules or provide training opportunities for industry members.
4. Evaluation of added ingredients to products	• Next, Kara Lavaux (Food Safety and Marijuana Program Supervisor) gave a presentation about added ingredients in marijuana. • Kara began by explaining that the Department is finding more sublingual products and others with novel consumption routes . The marijuana industry is very innovative, and sometimes there is pressure to bring a product to market when not everything is known about the ingredients. For example, the Department recently received a complaint about a product which contained Corydalis, which is an herb used to treat depression and insomnia. The complainant said that he/she was a regular marijuana user but was experiencing some unique and odd reactions to this product. The person alleged that the product made him/her completely incapacitated. • Kara explained that the ingredients listed on the slide are items that the Department has found in edibles but are not common in traditional food products. • Evaluating these ingredients raises a number questions, such as: "How much is too much?" "Is there an entourage effect when the ingredient is added to THC?" "Can consumers make informed decisions about products marketed with ingredients

	that make vague claims like 'Chinese herbs' or when entourage effects are involved?" • Kara explained that the Department reached out to CDPHE to determine how these ingredients would be evaluated in the state's wholesale food manufacturing program. CDPHE told the Department that it would normally coordinate with the U.S. Food and Drug Administration ("FDA") and check various published lists such as the Generally Recognized as Safe ("GRAS") inventory, the Everything Added to Foods in the United States ("EAFUS") list, and the poisonous plant index, among others. • The Department reviewed various lists for the ingredients that it was finding in marijuana products. Many ingredients were not contained on any list, and some ingredients were listed on multiple lists, causing confusion. For example, none of the ingredients identified on the slide are on the Food Additives List, caffeine is the only ingredient on the GRAS inventory, and Jambu and caffeine are both listed on the EAFUS list. However, Jambu is also on the poisonous plant index. • The Department then looked at regulations in other states. For example, in California, marijuana edible products may only contain ingredients that are listed on the EAFUS list. This is a clear standard for regulators as well as industry members. • The Department clarified that it is not advocating that this standard be adopted. The California standard was presented as an example of how other jurisdictions have approached the regulation of added ingredients in marijuana. The Department wants to ensure that any adopted regulation is protective of public health while not being overly burdensome.

	• One member wanted to discuss the Dietary Supplement Health and Education Act of 1994 ("DSHEA"). He explained that DSHEA created a "subset" of foods called dietary supplements. Based on his understanding, if a dietary supplement was used in commercial food prior to the passage of DSHEA then that ingredient is "generally considered safe," which is not the same thing as GRAS. That may be why some of the ingredients mentioned during the presentation were not present on the various lists discussed. • Another member suggested that some ingredients may not fit any existing category for food regulation. For example, some operators extract terpenes during distillation, then add the terpenes back into a product. She felt as if the terpenes may be additives because they are no longer present at naturally occurring levels, but there may have to be an evolution of understanding in this area. • One member explained that currently, edible manufacturers are treated as food manufacturers. However, they are adding ingredients into food that would normally be considered dietary supplements. There are specific requirements for the manufacture and control of supplements that are different than the requirements for food manufacturing. For example, if a person is manufacturing supplements, they have to apply Good Manufacturing Practices ("GMP"). He sees this as a problem. • One member wanted to discuss allowable levels of certain ingredients like terpenes and polyethylene glycol ("PEG"). He explained that terpenes and PEG may be dangerous at certain levels. Another member chimed in and said that the FDA is looking at ingredients like that in electronic cigarettes. One

	member explained that no new electronic cigarette liquid can be introduced into commerce without FDA approval. • One member suggested that the Department conduct a survey of the ingredients in marijuana products already in circulation and the levels at which those ingredients exist. This could serve as a justifiable limit on the amount of certain ingredients. • Another member explained that added ingredients may have different effects depending on the interactions within each consumer's body and on pharmacological dynamics between multiple ingredients. • One member suggested that the Department look at "functional" food organizations like the Institute of Food Technologists ("IFT") for guidance about added ingredients in marijuana. • Another member explained that there are few regulatory controls over the product manufacturing process currently. More controls would be needed if the Department wants to regulate ingredients added to marijuana products. In other industries, the burden is on the manufacturer to prove that an added ingredient is safe, rather than on the regulators to show it is unsafe. • One member suggested that the FDA must prove that a dietary supplement is unsafe to stop the product from being marketed, like the marijuana industry. • The Department clarified that it is not looking at enforceable levels for added ingredients in marijuana at this time.

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Public Comment	
Item	**Discussion**
Public Comment	• Andrew Alfred is the chief scientist at LivWell Enlightened Health. LivWell has fourteen (14) retail and medical locations and they employ 600 people. Mr. Alfred is appreciative of the Advisory Committee and of DDPHE for bringing together a good group of scientists to help inform safe science-based policy. However, Mr. Alfred did note that cultivation facilities are minimally represented on the committee. LivWell would be happy to participate and offer its expertise if the committee is open to it. Mr. Alfred believed that the baseline study was an interesting idea. He believes that the MED has a statutory obligation to "be its own watchdog" and when using limited resources, the Department should consider using something more rigorous than the MED's pass/fail rate, because those levels are "pretty arbitrary." • Erin Diffenderfer is a co-owner of a marijuana infused-product manufacturing facility. She had a question about health and safety standards that apply to cultivation facilities. Kyle Lambert from the MED explained that the MED does inspections for general cleanliness, but the MED inspectors do not have the expertise to enforce food regulations or microbial contamination issues inside of cultivation facilities. • Lauren Withers also works at a MIP in Denver. Lauren was wondering if there was any follow up investigation on the facilities that failed certain tests with the MED. Kyle Lambert explained that MED investigators go out daily. Investigators may not go out every time a facility fails a test, and there are requirements in the MED rules about failed tests, but generally, yes, there is a follow up investigation. Lauren also wondered if marijuana concentrates have to be re-tested after they are remediated. Kyle explained that they do have to be re-tested, but there are no labeling requirements if a product has been remediated. Kyle explained that the MED is currently conducting rulemaking, and Lauren is free to submit comments regarding these issues. • Stephan Cobb wanted to comment on the design for the baseline study. Mr. Cobb explained that Intra-product and inter-product variance can make it difficult to replicate results and run a regression analysis. He encouraged the committee to think about that issue.