Cannabis Health & Safety Advisory Committee
Meeting Minutes
Meeting # 4 – September 4, 2019

1. Committee Member Attendance

Participant	Organization
Danica Lee (co-chair)	Denver Department of Public Health &Environment
Abby Davidson (co-chair)	Denver Department of Public Health &Environment
Andrew Alfred	Chief Scientist, LivWell Enlightened Health
Anshul Bagga	Denver City Attorney's Office
Dorothy Colagiovanni	Next Frontier Biosciences
Elyse Contreras	Manager, Marijuana Health Monitoring and Research, CDPHE
Jason Ellsworth	Willow Industries
Joe Cantalini	Organa Labs
Keith Miller	Dept. of Chemistry and Biochemistry, University of Denver
Kevin Gallagher	Executive Director, Colorado Cannabis Manuf. Assoc.
Kim Stuck	Founder, Allay Cannabis Consulting
Kristi Kelli	Executive Director, Marijuana Industry Group
Linda Klumpers	Cannify
Mark Angerhoefer	Craft Concentrates
Mike Van Dyke	Colorado School of Public Health
Scott Hansen	Agricor Laboratories
Seth Wong	TEQ Analytical Laboratories
Tobias Postma	Topo Consulting

2. Agenda

- Welcome and introductions (10 mins)
- Baseline Assessment of Contaminants in Recreational Marijuana Products update (30 mins)
- Introduction of topics for small breakout groups (20 mins)
- Small group breakout discussions (50 mins)
- Public comment (10 mins)

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3. Meeting Notes

Item	Discussion
1. Welcome and introductions	• Danica Lee, Director of the Public Health Investigations Division ("PHI") for the Denver Department of Public Health & Environment ("DDPHE" or the "Department"), opened the meeting by acknowledging the work of the Cannabis Health and Safety Advisory Committee (the "Committee" or "CHSAC"). She stated that the group has been instrumental in providing a sounding board for Departmental policy. The group is made up of several experts in various fields and the Department welcomes thoughts and input about how DDPHE can continue to improve. • Next, Danica addressed the long-term plan for the Committee. Danica explained that the CHSAC started with a two (2) year commitment. The Department is not ready to disband the group but is open to revisiting the structure and function of the CHSAC. The Department would welcome suggestions about those topics going forward. • Abby Davidson (DDPHE, Food Safety and Marijuana Program Manager) introduced the members of DDPHE's marijuana team. • The Committee members then went around the table and introduced themselves.
2. Baseline Assessment of Contaminants in Recreational Marijuana Products update	• After introductions, Kara Lavaux (DDPHE, Food and Cannabis Program Supervisor) gave an update on the Baseline

	Assessment of Contaminants in Recreational Marijuana Products (the "Assessment"). • Kara explained that the Department appreciated the feedback provided by Committee members, which was incorporated in the Assessment methodology. • As of the date of this meeting, the Department completed all of the field work needed for the Assessment. Over the course of six (6) days, three (3) teams of two (2) investigators visited all twenty-five (25) of the randomly selected stores and collected six (6) samples at each store, for a total of one-hundred and fifty (150) samples. • The sampling went well. In order to replicate the consumer experience, Department staff did not handle any of the samples. The store staff packaged the pre-selected samples as they would for a consumer. A representative from the laboratory picked up the samples from the store location. • Tammy Jeronimus (DDPHE, Public Health Investigator) explained some of the challenges that the Department faced when collecting samples. All of the challenges had to do with the state marijuana inventory tracking system ("METRC"). The Department learned that the product classification assigned to a marijuana product on-site may be different than the classification assigned to that product in METRC. For example, if a sample was listed as shake and trim in METRC when it was preselected, the same product may have been used to create a pre-roll onsite, but was not re-classified as a pre-roll in METRC.. Additionally, many stores did not reconcile sales information in their point of sale system with the information in METRC,

	meaning that the METRC inventory could list products that had already been sold. • Richard Pruckler (DDPHE, Public Health Investigator) next presented the feedback that the Department received. Overall, the feedback was very positive. Many of the stores thanked the Department for their work. One complaint was received, but upon further review it was not substantiated. All sample collection was photographed. • Next, Allison Seidel (Epidemiologist, Denver Public Health) spoke about sample randomization. Allison explained that a statistical program (SAS) code was used to select twenty-five (25) random stores from a list of all active retail marijuana store licenses in Denver. Once the stores were selected, the Marijuana Enforcement Division (MED) sent a report of the METRC inventory for those stores. Another SAS code was used to randomly select product samples from the METRC inventory reports. • Preliminary results for total yeast and mold ("TYM") showed that 34% of the pre-rolls failed for TYM; 33% of the shake/trim failed; and 36% of the flower failed. Of the failed samples, 63% had 10,000-99,999 colony forming units ("CFUs"). • Preliminary results showed that, of the failed samples, 48% passed MED testing protocols prior to being sent to the retail store; 46% had not been submitted for testing; and 7% passed a retest prior to reaching the retail store. • One member asked about the next steps for product that failed during the Assessment but passed MED testing prior to being sent to the store. The Department explained that the samples which failed contaminant testing during the Assessment are

	currently on hold at the retail facility. The Department is working on tracing those products back through the supply chain. • Another member asked about potential enforcement action based on the results of the Assessment. The Department explained that they are still investigating the failed test results and will take appropriate enforcement action on a case by case basis. • Other members suggested that the Department should try to find correlations between the test results and some of the other factors present at the facility. One member suggested that it might be interesting to compare the Assessment results with MED test results for that facility, year over year. Another member suggested that the Department look at how long the product had been stored prior to being sampled. Another member suggested that the Department should compare photographs of the contaminated product with the CFUs reported on the Assessment results. • Finally, one member suggested that the Department clarify which samples were sourced from facilities that were process validated, and what testing regiment that facility was process validated for.
3. Introduction of topics for small breakout groups	• Next, the Department presented the following topics for small group discussions: • Topic # 1: Allison Seidel introduced this topic. The State of Colorado recently put out a health alert entitled "Vaping potentially related to severe acute pulmonary disease." There has been one (1) confirmed death in Illinois, and two (2) confirmed cases in Colorado. The health alert may include

	tetrahydrocannabinol ("THC") products. This group was tasked to address the following questions: what are the top priorities for keeping consumers safe (hardware concerns, heavy metals, additives, etc.); whether current testing requirements are sufficient; whether safety messaging is needed for consumers; and any additional thoughts? • Topic # 2: Kara Lavaux introduced this topic. *Clostridium botulinum* ("C.bot") is ubiquitous and it thrives in anaerobic conditions. Because the disease can be deadly, the Department has traditionally taken a cautious approach. Currently, the Department requires refrigeration for all extracts intended for ingestion unless information has been provided to substantiate shelf-stability. In 2014, the Department began offering a mini-Hazard Analysis and Critical Control Points ("HACCP") review, which is called a shelf-stability evaluation. Since 2014, the Department has spent considerable resources conducting shelf-stability evaluations. In 2014, the Department evaluated 3 products; in 2018 the Department evaluated 105 products. This year, the Department has reviewed 78 products with 117 products projected. The number of reviews submitted for hemp products has continued to increase, and hemp product reviews can be very complex. This group should consider the following questions: should the Department continue to treat extracts and other products as potentially hazardous food that requires refrigeration; should the Department replace shelf-stability evaluations with process authorities; would a potential process authority have to review each manufacturer's unique process, or could the authority verify the safety of a generally accepted extraction process?

	• Topic # 3: Richard Pruckler introduced this topic. The Department is seeking feedback from the committee about additional guidance or education that could be provided. In the past, the Department has responded to various concerns voiced by members of the industry and consumers. For example, the Department has released guidance documents to assist licensees with addressing microbial contamination in their products, and the Department is providing a no-cost basic food safety course for industry members. The Department is also assessing whether non-disclosure agreements may be appropriate for staff members. Members of this group should consider the following questions: Are there any new needs for consumers, patients, or businesses; suggestions regarding how the Department could improve current work processes (response time, transparency, etc.); suggestions about consumer and patient needs regarding hemp products; any additional thoughts?
4. Small group breakout discussions	• Topic # 1 (Vaping related illness): In response to the first question (top priorities for keeping consumers safe), the group started by discussing the fact that many illnesses are being reported, but nobody knows what is causing illnesses. The group suggested that health authorities should start thinking about minimizing additives. However, it is difficult to decide which additives should be eliminated because there is very little safety data available about what additives do when they are heated and inhaled. The group explained that the U.S. doesn't currently have standards for e-cigarettes, but health authorities could look to Europe and see what health agencies there have

	done about e-cigarettes and additives. Health authorities should talk to clinicians, conduct more research, and gather data from market and intervention studies. • In response to the second question (current testing standards), the group started by saying that there are no testing requirements that are specific to vape products. Furthermore, there is currently no requirement that additives must be safe for inhalation. Hemp-derived CBD products sold outside of a marijuana store do not have any specific testing requirements, so that could be a factor as well. • In response to the third question (consumer advisories), the group suggested that consumers should be advised of the knowns and unknowns about using these products, whether they deliver nicotine or THC. The group suggested that many of these health problems may be caused by the fact that consumers purchase many of the products online without being advised of the potential health impacts. • Finally, the group stated that local jurisdictions should advocate for federal health agencies like the Drug Enforcement Administration ("DEA"), the Food and Drug Administration ("FDA"), and the Bureau of Alcohol, Tobacco, and Firearms ("ATF") to intervene in the "black market" and make sure that unregulated products are not sold on the internet. Current federal regulations don't address e-cigarettes, vape juice, or synthetic THC, and health authorities need to understand the physiological effects of e-cigarettes and other vape products. Health agencies should also look at the hardware used for vaping products and consider potential contaminants such as the plastics and heavy metals present in the hardware of a vape

	device. Lastly, health authorities should investigate potentially false claims made by manufacturers. • Topic # 2 (C.bot and Shelf Stability): In response to the first question (should extracts require refrigeration), the group began by explaining that it depends on whether the Department is looking for the spore or the toxin. The group explained that this is important because C.bot cannot be purchased for use as a control spore in a laboratory test. Therefore, it is difficult to study how C.bot behaves on cannabis. The Department explained that the test for C.bot can be unreliable because the spores are not spread evenly throughout the product. That is why the Department focuses on the control steps used in the processing of the product. • In response to the second question (should the Department rely on a process authority), the group felt that putting the onus on the manufacturer to be verified by a process authority could help. However, the group questioned how a process authority would be defined, whether the process authority would be trained in reviewing HACCPs, whether they would be trained in reviewing good manufacturing practices ("GMPs"), and whether current facilities would have to include a C.bot control plan in their HACCP. • In response to the final question (would the process authority have to evaluate each manufacturer), the group explained that there are many different processes used by manufacturers right now, and a reviewing authority would have to know how each step in the process plays a role in the finished product. Each process may have a different control point where a "kill step" could be executed. This could include anything from radiation to

	pasteurization. A reviewing agency would have to know how spore elimination informs the overall product and what role the unique matrix (cannabis) plays in all finished products. • Topic # 3 (Improving processes): No one joined this group, so the Department will send out a survey regarding these questions.