Tess Eidem Statement at the MED Permanent Rulemaking Hearing | October 1, 2024

Good morning everyone, and thank you for allowing me to speak at the Final Rulemaking Hearing. My name is Dr. Tess Eidem, and I'm a Senior Research Scientist at the University of Colorado Boulder in the Environmental Engineering Department. I am a microbiologist, and my research investigates airborne molds, microbial toxins, and aeroallergens in the Aerobiology and Disinfection Laboratory. Before my time at CU Boulder, I worked in the cannabis space for nearly four years, first as an employee directly working in cannabis production and then as a consultant helping cannabis growers overcome microbial contamination in their facilities. I've spent thousands of hours in over 20 cannabis cultivation and manufacturing facilities and have seen similar reoccurring health and safety issues in these spaces. Bottom line, the cannabis industry has major issues with poor sanitation practices and poor indoor air quality.

There are increasing anecdotal stories and peer-reviewed literature demonstrating that the environmental conditions in cannabis operations are linked to contaminated flower products that have high levels of total yeast and mold (Punja et al., 2023). These workplace conditions are also linked to respiratory issues in cannabis workers, who cite mold exposure in these environments as contributing to their development of occupational asthma or exacerbation of existing asthma symptoms (Reeb-Whitaker et al., 2022). Two peer-reviewed publications out of Colorado found that airborne mold spore levels were high in cannabis operations, comparable to water-damaged homes and flood remediation sites, and respiratory protection was recommended by the authors (Martyny et al., 2013; Root et al., 2020). Our group at CU Boulder in collaboration with Colorado State University recently published on worker exposure risks to bioaerosols in the cannabis industry and highlighted major research gaps that must be addressed to protect workers (Eidem et al., 2024).

Today, I want to specifically address cannabis remediation. Its unregulated and unlabeled use is enabling these unsanitary cannabis cultivation and manufacturing environments to continue to operate without addressing the root causes of their microbial contamination. I strongly urge the State of Colorado to re-write rules within SB24-076 Streamline Marijuana Regulation that allow cannabis flower remediation and prohibit the state from labeling these products as remediated. These practices are putting cannabis workers, patients, and consumers at risk. Therefore, I will focus on four major areas of concern and reform:

1) Remediation is prohibited by the United States Pharmacopoeia, and Colorado should also prohibit remediation.
2) Labeling of treated product must be required, however it should only be used responsibly on compliant, high-quality product as an extra measure of safety for at-risk populations.
3) Current regulatory loopholes must be closed before an accurate assessment of remediation can be performed, as these loopholes allow cannabis cultivators to sidestep transparent documentation of remediation treatments.
4) Remediation methods must be approved by the state only after undergoing safety and efficacy validation assessments. This ensures these technologies are applied uniformly, and confirms decontamination treatment does not adulterate or leave residual harmful reaction byproducts on flower products.

**1) Remediation is Prohibited by USP**

The process of remediation is not the same as a cook step for food or a wash step for produce. Food must be produced under sanitary conditions, stored properly, and it cannot be adulterated or spoiled. In contrast, cannabis flower remediation is frequently used when flower products are spoiled, infected, handled improperly, and/or stored inappropriately. While food products would be disposed of under these conditions, Colorado allows microbially contaminated cannabis flower to be treated with decontamination methods, such as ionizing radiation or ozone, to recover cannabis flower that has failed microbial testing.

This practice of abusing decontamination treatments to recover microbially contaminated cannabis flower is called remediation, and there is no parallel process in food. Remediation is specifically prohibited in the USP recommendations for cannabis flower, which state, **"Treatment methods such as irradiation should not be used as a means to remediate cannabis contaminated above the allowed limits…"** (Sarma et al., 2020).

*Remediation should not be allowed to treat failed cannabis flower; instead, the root cause(s) of microbial contamination should be addressed, and prevention-based QA/QC programs must be implemented, as in parallel consumed goods.*

**2) Decontaminated Cannabis Flower Must Be Labeled**

There may be instances where decontamination methods can be used responsibly on compliant, high-quality cannabis flower products—for example, as an extra measure to protect immunocompromised patients. However, in food and medicinal herbal products, decontamination method(s) must be listed on the product label according to the World Health Organization and the Food and Drug Administration:

- WHO's Guidelines for Medicinal Plants states that, "**Antimicrobial treatments of medicinal plant materials (raw or processed) by various methods, including irradiation, must be declared and the materials must be labelled as required**." (World Health Organization, 2003).
- The FDA states that, "**irradiated food be adequately labeled and under the general labeling requirements, it is necessary that the food processor inform the consumer that food has been irradiated**." More information can be found here.

*If decontamination methods are used properly on compliant, high-quality flower—not to recover failed product or product likely to fail before third-party testing—it must be labeled.*

**3) Remediation Loopholes and Violations in Colorado Regulations Continue to be Exploited**

Current Colorado regulations contain loopholes that are exploited to violate testing and remediation documentation. According to 1 CCR 212-3-3-320, "The Microbial Decontamination method must be accurately documented in the Inventory Tracking System for packages that have been Decontaminated." Remediation disclosure within the inventory tracking system (METRC) is required, but **it is possible to avoid reporting the failed microbial test and to avoid reporting the remediation treatment altogether in METRC.**

There are several ways cultivators can exploit these loopholes, one is by calling remediation a “microbial control step,” which remediates likely-to-fail cannabis flower before it is sent out for testing. Using this approach, the failed test results and the remediation treatment are never entered into METRC. Another exploitation is for cultivators to submit an “R&D” sample from the final product lot, which will not be associated with the final product in METRC. If the R&D sample fails for microbial contamination, the manufacturer can remediate that product with no METRC documentation of its microbial failure or decontamination method used.

Other loopholes allow cannabis manufacturers can hire cannabis remediation companies to come to their facility and remediate their flower as a “service,” which will have no record of the remediation treatment in METRC, unless the product previously failed third-party testing. They may also transfer cannabis flower to another facility to remediate it offsite before sending for third-party testing if they know their flower will fail microbial testing. This is a violation of 1 CCR 212-3-3-320, which states, “A Regulated Marijuana Business shall not accept or Transfer to any Person any Regulated Marijuana that has failed required testing.” But as I mentioned before, microbially failed cannabis flower may not be properly documented in METRC, therefore contaminated cannabis flower products that would fail testing are being transferred for remediation, treated off site, and transferred back to the manufacturer, violating this rule, and avoiding any remediation documentation in METRC.

*Colorado cannabis rules are being violated and loopholes are preventing an accurate understanding of what products are failing and/or being remediated. To ensure proper labeling of decontaminated flower, these loopholes must be closed.*

**4) Remediation methods have not undergone safety and efficacy validation**

Unlike decontamination methods used in food, **cannabis remediation methods have not been validated for efficacy or safety.** Important parameters like exposure time, concentration of chemical treatment, and dose of irradiation have not been established or published. Indeed, some remediation device manufacturers specifically withhold this important information from their users. For example, some ozone remediation device manufacturers do not disclose the ozone concentration used in their machines, calling this information “proprietary.” These important treatment parameters are required in parallel food manufacturing. For example, when cooking chicken, the internal temperature should reach 165°F to be fully cooked. Suffice to say, the FDA would not accept cooking chicken to a “proprietary temperature,” and we shouldn’t accept that either in the cannabis space.

Importantly, **some remediation treatments are known to create reaction products that could alter and/or adulterate the product and may be harmful to consumers,** thus violating Section 1 CCR 212-3-3-330, which states, “A Regulated Marijuana Cultivation Facility may not treat or otherwise adulterate Regulated Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight, or smell.” As previously mentioned, ozone is approved in Colorado to remediate terpene-rich cannabis flower; however,

**ozone reacts with terpenes to form formaldehyde, a carcinogen**. Researchers at NIST recently published an article showing that low levels of environmental ozone reacted with terpenes from evergreen trees to produce formaldehyde (Poppendieck et al., 2024). The ozone levels used by NIST were several thousand times less than what is listed within patents for ozone remediation devices. This suggests formaldehyde generation could be significant and harmful within ozone devices, posing risks to workers in those environments and risks to consumers if harmful reaction products remain on the remediated flower.

*Robust safety and validation assessments must be performed on cannabis remediation/decontamination treatments before they can be used effectively without adulterating cannabis flower.*

These issues I mention here were echoed by the National Academies of Sciences recent report titled, "Cannabis Policy Impacts Public Health and Health Equity." This report highlights areas where state and federal leadership has failed to establish and enforce quality standards to safeguard public health. I urge Colorado legislators, the MED, and CDPHE officials to re-write SB24-076 or introduce new legislation that prohibits the abuse of remediation to recover failed product, close the loopholes that allow undocumented cannabis remediation, and require labeling for decontamination treatments applied to cannabis flower. Failure to act will perpetuate a cycle of environmental contamination, worker exposure, and the potential for contaminated products to reach consumers and patients. It is time for Colorado to stand up as a leader in the cannabis industry and prioritize these reforms to ensure a safe and sustainable cannabis market.

Thank you for your time.
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