May 1, 2024

Dear Marijuana Enforcement Division and Colorado Department of Public Health & Environment,

I am writing to express my concerns about the reduced testing allowances for cannabis products and the implementation of ASTM Standard D8250-19 as the mandated Hazard Analysis and Critical Control Points (HACCP) system for cannabis manufactures, as well as the use of remediation technologies to be used to recover microbially adulterated flower products. While I support the need to bring consumer safety frameworks into the cannabis cultivation and manufacturing processes, I believe the current approach may compromise public health and safety.

My concerns with reduced testing allowances, implementing ASTM HACCP standards, and allowing "decontamination" technologies to be used on failed flower products center on the following issues:

Outdated and Incomplete Information
The ASTM D8250-19 is not updated with the Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) guidance, which provides a more comprehensive HACCP/Food Safety Plan. Updated FDA FSMA guidelines also include additional allergen, sanitation, and supply chain controls, which are directly relevant to cannabis edible production and not outlined in the ASTM standard. Moreover, there are few details available about prerequisite program requirements for reduced testing allowances. For example, will cultivators and manufacturers be required have good agricultural practices (GAP) and/or good manufacturing practices (GMP) certification? If so, by which certifying bodies and to which standards? More readily available information on these important details is needed.

No Requirement for Expertise and Training
The ASTM standard does not require involvement of food safety-trained experts like a Preventive Controls Qualified Individual (PCQI), which is required by FDA FSMA. This raises concerns about the adequacy of expertise within companies developing HACCP plans under ASTM Standard D8250-19.

Incomplete Risk Assessments based on Ingestion Hazards
The ASTM standard appears to focus primarily on ingestion hazards and does not address the unique risks associated with inhalable cannabis products, which may significantly differ in this route of administration. For example, vitamin E acetate is not hazardous to ingest but is linked to E-cigarette or Vaping Use-Associated Lung Injury (EVALI) when inhaled.

Similarly, biological contaminants like molds and bacteria pose unique biological inhalation hazards that are not typically evaluated in traditional food safety frameworks. Pathogenic organisms and harmful microbial metabolites may accumulate on cannabis flower products due to plant disease, post-harvest spoilage, improper handling, and/or poor storage conditions. If the "Intended Use" section describes an inhaled product, biological inhalation risks must be evaluated in the hazard analysis to include both viable pulmonary pathogens as well as microbial metabolites with known inhalation risks like endotoxins, mycotoxins, and mold allergens. Many of these harmful biological agents are not evaluated by current compliance testing, therefore the inhalation risks to consumers remain largely unknown.

Remediation "Decontamination" of Failed Flower Violates all Hazard Prevention Frameworks
The ASTM Standard D8250-19 and similar FDA HACCP/Food Safety Plans all require a manufacturer to proactively identify and address hazards, including biological hazards like microbial contamination. Thus, the practice of cannabis flower remediation, which is the use of decontamination technologies to recover microbially contaminated products that have failed third-party testing, is not in-line with hazard prevention frameworks, and these technologies should be prohibited when used in this way. Indeed, remediation "decontamination" cannot be a Processes Preventive Control or Critical Control Point (CCP) if the product is already contaminated at levels above the allowed limits. Moreover, this remediation/decontamination

approach is a violation of the United States Pharmacopeia (USP) guidelines for cannabis inflorescence (Sarma et al., 2020).

Additionally, there are few resources on the decontamination efficiencies of these technologies or studies investigating the safety of these technologies, especially those technologies that may generate hazards to consumers. For example, ozone reacts with terpenes to create formaldehyde, yet ozone remediation is used to recover failed cannabis flower without an understanding of formaldehyde generation on the product. Therefore, extensive validation and safety studies must be performed before these technologies may be used as a CCP/Process Preventive Control in a HACCP/Food Safety Plan.

In the ASTM Standard D8250-19 and in FDA guidelines, critical limits must be defined in the hazard analysis and CCP/Process Preventive Control monitoring plan. Critical limits are defined as “the maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard.” The critical limits of many remediation technologies are not established or disclosed to cannabis manufacturers by the remediation technology manufacturer, and these important decontamination parameters are often considered “proprietary” by remediation companies. For example, the ozone dose as measured by parts per million (ppm) is not disclosed to cannabis manufacturers using this technology to treat flower products. Thus, without established critical limits for these decontamination technologies, there is no ability to build a monitoring plan, verify that decontamination treatments reached critical limits, establish corrective actions, or keep accurate records documenting the effective using these technologies.

I strongly recommend the following to protect cannabis consumers and medical patients:

- **Prioritize FDA FSMA Guidelines:** I urge you to consider adopting the latest FDA guidelines, incorporating FSMA as the primary framework to ensure cannabis product safety, specifically for edible cannabis products.
- **Require Qualified Expertise:** Mandate the involvement of PCQI-trained personnel in developing and implementing HACCP/Food Safety plans for cannabis manufacturers.
- **Address Inhalation Risks:** Develop comprehensive guidelines that address the specific safety concerns associated with inhalable cannabis products, specifically those biological hazards known to associate with cannabis plant matter, including viable pathogenic organisms and microbial metabolites like mycotoxins, endotoxins, and allergens.
- **Prohibit Remediation Practices:** Prohibit the use of remediation technologies as a means to recover contaminated cannabis products that do not meet state-mandated compliance testing specifications, as outlined by USP cannabis inflorescence guidelines (Sarma et al., 2020). Decontamination methods may only be used on compliant cannabis flower products only after their antimicrobial efficacy has been validated, critical limits have been established, and safety data is available through rigorous scientific research. Only then can these technologies be used safely and effectively within the parameters of these risk-prevention frameworks.

I believe that the Colorado cannabis industry can create a regulatory system that fosters a thriving cannabis industry while prioritizing the health and safety of consumers and medical patients.

Sincerely,

Tess Eidem, Ph.D., PCQI

Reference:
Sarma, N. D., Waye, A., Elsohly, M. A., Brown, P. N., Elzinga, S., Johnson, H. E., Marles, R. J., Melanson, J. E., Russo, E., Deyton, L., Hudalla, C., Vrdoljak, G. A., Wurzer, J. H., Khan, I. A., Kim, N. C., & Giancaspro, G. I. (2020). Cannabis Inflorescence for Medical Purposes: USP Considerations for Quality Attributes. In Journal of Natural Products (Vol. 83, Issue 4, pp. 1334–1351). American Chemical Society.