March 7, 2024

To Cannabis Regulatory Bodies across the US,

I am a microbiologist who has directly worked in cannabis manufacturing operations in New York state, and I have consulted on cannabis quality issues in the US, Canada, and Australia. I currently work as a consultant with my company, Rogue Micro LLC, and I am a Senior Research Scientist in the Bioaerosol and Disinfection Lab at the University of Colorado Boulder. I would like to bring attention to the rampant abuse of remediation technologies that "cover up" microbial contamination in the cannabis industry.

Without important crop- and consumer-protection mechanisms, cannabis flower can be cultivated and processed in environments with elevated levels of biological hazards, including but not limited to viable plant and human pathogens (*Fusarium* species and *Aspergillus fumigatus)*, allergenic proteins (mold allergens), and toxigenic agents (bacterial endotoxins and fungal mycotoxins). Many states across the country do not require that cannabis manufacturers preventively control and minimize the risks of these biological hazards through a "Quality by Design" approach, as is required in parallel culinary herbs (Ajeska et al., 2013). Therefore, a "Quality by Testing" approach has been adopted in many states to test cannabis flower for select microbial contaminants via third-party testing labs as a consumer protection mechanism.

Cannabis flower typically undergoes testing for select microbial contaminants before it is sold to consumers. However, many states allow contaminated cannabis flower that has failed microbial testing (or likely to fail testing due to signs of plant infection or post-harvest spoilage) to be "remediated" to kill microorganisms on the flower, despite the United States Pharmacopeia specifically speaking against this practice in their cannabis quality guidelines (Sarma et al., 2020). While remediation methods may reduce the viability of bacterial and fungal microorganisms on contaminated plant matter, there is no evidence this process can remove harmful primary and secondary microbial metabolites like endotoxins, mycotoxins, or mold allergens in cannabis flower. Moreover, many of these biological agents are not tested across the US, despite their abundance and negative health impacts in parallel agricultural products (Gwinn et al., 2023).

The abuse of these remediation technologies to "get flower passing" is likely allowing for the accumulation of these harmful biological agents on cannabis flower, as there is no impetus for cultivators to address their microbial contamination at the root cause if they can simply remediate failing, poor-quality flower at the end of their process and sell to consumers without disclosure.

As >90% of cannabis users report smoking flower products as a common means of consumption (Schauer et al., 2020), it should be a top priority for regulators to ensure cannabis flower comes from healthy plants and that this flower is processed in clean and controlled environments. This is especially important for vulnerable populations within the medical patient population as biological hazards are well established to carry over from tobacco plant matter into tobacco smoke, and these bioaerosols include viable microorganisms and bacterial endotoxins (Hasday et al., 1999; Larsson et al., 2008, 2012; Malayil et al., 2022). Indeed, it is thought that these biological hazards in tobacco smoke contribute to lung infection and chronic lung inflammation associated with tobacco use (Pauly et al., 2010; Pauly & Paszkiewicz, 2011), suggesting there is a large gap in our understanding of the biological inhalation risks to cannabis smokers.

It is possible for remediation technologies to be used in-line with good practices only on compliant, high-quality product—not to recover contaminated product or proactively treat "likely-to-fail" product. In the case where decontamination methods are used on compliant, high-quality flower, the decontamination method(s) must be listed on the label (ozone, x-ray irradiation, radio frequency, etc.), as is consistent with FDA food guidelines and medicinal herbal product guidelines by the European Medicines Agency and the World Health Organization (European Medicines Agency, 2015; FDA, 2016; World Health Organization, 2003).

It is my hope that this practice of recovering microbially contaminated, adulterated cannabis flower will end, and the abuse of remediation technologies will not be tolerated by governing bodies.

Thank you for your time,
Tess Eidem, Ph.D.

References:

Ajeska, S., Foods, N. F., Atwill, R., Bauer, A., Becker, R., Crawford, W. M., Cueto, C. J., Produce, P., Cuevas, M., Eisenberg, B., Gregory, A., Harris, L., Hepner, J., Jay-Russell, M., Kawata, J., Farms, T., Klein, B., Produce, F., Kline, W., … Leaman, S. (2013). *Western Growers Association: Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Processing of Fresh Culinary Herbs*.

European Medicines Agency. (2015). *Committee on Herbal Medicinal Products (HMPC) Reflection paper on microbiological aspects of herbal medicinal products and traditional herbal medicinal products Final*. www.ema.europa.eu/contact

FDA. (2016). *Food Facts From the U.S. Food and Drug Administration*. http://www.fda.gov/educationresourcelibrary

Gwinn, K. D., Leung, M. C. K., Stephens, A. B., & Punja, Z. K. (2023). Fungal and mycotoxin contaminants in cannabis and hemp flowers: implications for consumer health and directions for further research. In *Frontiers in Microbiology* (Vol. 14). Frontiers Media SA. https://doi.org/10.3389/fmicb.2023.1278189

Hasday, J. D., Bascom, R., Costa, J. J., Fitzgerald, T., & Dubin, W. (1999). Bacterial Endotoxin Is an Active Component of Cigarette Smoke. *Chest*, *115*(3).

Larsson, L., Pehrson, C., Dechen, T., & Crane-Godreau, M. (2012). Microbiological components in mainstream and sidestream cigarette smoke. *Tobacco Induced Diseases*, *10*(1). https://doi.org/10.1186/1617-9625-10-13

Larsson, L., Szponar, B., Ridha, B., Pehrson, C., Dutkiewicz, J., Krysinska-Traczyk, E., & Sitkowska, J. (2008). Identification of bacterial and fungal components in tobacco and tobacco smoke. *Tobacco Induced Diseases*, *4*(1), 4. https://doi.org/10.1186/1617-9625-4-4

Malayil, L., Chattopadhyay, S., Bui, A., Panse, M., Cagle, R., Mongodin, E. F., & Sapkota, A. R. (2022). Viable bacteria abundant in cigarettes are aerosolized in mainstream smoke. *Environmental Research*, *212*. https://doi.org/10.1016/j.envres.2022.113462

Pauly, J. L., & Paszkiewicz, G. (2011). Cigarette smoke, bacteria, mold, microbial toxins, and chronic lung inflammation. In *Journal of Oncology*. https://doi.org/10.1155/2011/819129

Pauly, J. L., Smith, L. A., Rickert, M. H., Hutson, A., & Paszkiewicz, G. M. (2010). Review: Is lung inflammation associated with microbes and microbial toxins in cigarette tobacco smoke? In *Immunologic Research* (Vol. 46, Issues 1–3, pp. 127–136). https://doi.org/10.1007/s12026-009-8117-6

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. https://doi.org/10.1021/acs.jnatprod.9b01200

Schauer, G. L., Njai, R., & Grant-Lenzy, A. M. (2020). Modes of marijuana use – smoking, vaping, eating, and dabbing: Results from the 2016 BRFSS in 12 States. *Drug and Alcohol Dependence*, *209*. https://doi.org/10.1016/j.drugalcdep.2020.107900

World Health Organization. (2003). *WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants*.