A Proposal to **Amend the Microbiological Screening Requirements** for the **Washington State Cannabis Industry**

Introduction

The Washington State Liquor and Cannabis Board (WSLCB, or "the Board") in cooperation with the Quality Assurance Work Group (the Work Group), have engaged in a discussion toward a proposal for revising the microbial action levels set for production of Cannabis products in Washington State.

Background

The WSLCB is the state agency governing the legal marijuana (Cannabis) marketplace Washington State (WA). Other states, as they consider legalization and draft their own laws concerning marijuana production and sale, are increasingly looking to WA and the Board for guidance. The Board regulates, among other things, the Quality Assurance (QA) testing requirements for the Cannabis industry in WA. Of particular concern to this paper are the rules related to microbiological bioburden screening, especially the action levels, or "limits" (expressed in colony forming units per gram, or "CFU/g"), which determine pass or fail designation.

In the original drafting of the rules, the Board references the American Herbal Pharmacopoeia's *Cannabis Inflorescence and Leaf Monograph* (the Monograph) as the determiner of legal action levels for microbiological contaminants. Specifically, Washington Administrative Code 314-55-102(9) states that action levels are based on the "table of required quality assurance tests defined in the most current version of *the Cannabis Inflorescence and Leaf monograph* published by the American Herbal Pharmacopoeia."

Table 9 on page 49 of the most recent version of the Monograph reads as follows:

Table 9 Microbial and fungal limits recommended for orally consumed botanical products in the US (CFU/g)

	Total viable aerobic bacteriat	Total yeast and mold	Total coliforms	Bile-tolerant gram-negative bacteria	*E. coli* (pathogenic strains) and *Salmonella* spp.
Unprocessed materials*	10^5	10^4	10^3	10^3	Not detected in 1 g
Processed materials*	10^5	10^4	10^3	10^3	Not detected in 1 g
CO_2 and solvent-based extracts	10^4	10^3	10^2	10^2	Not detected in 1 g

* Unprocessed materials include minimally processed crude cannabis preparations such as inflorescences, accumulated resin glands (kief), and compressed resin glands (hashish). Processed materials include various solid or liquid infused edible preparations, oils topical preparations, and water-processed resin glands ("bubble hash"). Significant microbial contamination can occur during post-harvesting handling.

The Monograph explains that "microbiological and fungal values do not typically represent pass or fail criteria. Rather they are recommended levels when plants are produced under normal circumstances and growing conditions." Despite this language, the Board has implemented the values as pass or fail

criteria, creating a scenario whereby cannabis products do necessarily "fail" if microbial presence is detected above these limits, leading to significant losses to farmers.

The Monograph goes on to explain that "individual herbs such as mints (*Mentha* spp.), which have a high concentration of trichomes, are prone to higher levels of molds than crops with fewer trichomes. As cannabis also possesses high concentrations of trichomes, this may be a factor and recommended limits may require adjustment over time." Indeed, given what has been found during the brief history of cannabis testing, cannabis does appear to be especially prone to higher levels of molds than other crops with fewer trichomes. Furthermore, the sticky nature and spindly structure of the cannabis trichomes appear to make them especially susceptible to capturing yeast and bacteria through wind-born exposure.

Two years have passed since the beginning of the regulated legal marijuana industry in WA. It is now time for these limits to be revised. As the Monograph points out: "the presence of microbes is typical for all natural products", and while "reports in which a causal association between microbial exposure through cannabis use and infections has been established, [such] instances appear to be rare considering the prevalence of exposure." When considering that not a single case of such causal association has been documented in Washington state in the last two years despite an estimated 30 metric tons of legal marijuana sold in that same time, the rarity of those instances may have been understated.

The Board has communicated that they interpret their own rules such that what is listed in the Monograph is "pass or fail criteria." As a result, an undue burden is placed on marijuana manufacturers despite no evidence to support such strict pass/fail criteria protect the public health in a measurable or meaningful way. The Board has also stated that the most effective mitigation strategy would be to see a revision to the Monograph, and without a change to the Monograph a change in rule would be necessary to amend the limits. To that end, the Board has organized the Work Group to propose an alternative.

Proposal

Propose revision of Table 9, Page 49, of the most current version of the American Herbal Pharmacopoeia's *Cannabis Inflorescence and Leaf Monograph* (revision 2014, or newer as appropriate) to read as follows:

	Total viable aerobic bacteria	Total yeast and mold	Enterobacteria (bile-tolerant gram-negative bacteria)	*E. coli* (pathogenic strains) and *Salmonella spp.*
Dried, Unprocessed Green Plant Material*	10^7***	10^6***	10^4**	Not Detected in 10 g**
Extracted or Powdered Botanical Product	10^5***	10^4***	10^3**	Not Detected in 10 g**

*Green Plant Material includes marijuana inflorescence, trim, or leaf that has been dried and trimmed. Green Plant Material does not include marijuana inflorescence, trim, or leaf that has been infused or otherwise further processed.

***E coli* and *Salmonella spp.* screening should be performed on a routine basis using sample sizes common in the industry. If Enterobacteria are detected at more than 5 times the recommended limit, further in-depth examination for pathogenic organisms is recommended: using a new representative sample of the material, extract from 10 grams and examine for *E coli* and *Salmonella spp.* using an appropriately validated testing methodology (e.g., enrichment broth or genetic assay). Detection of pathogenic organisms shall constitute a failure.

***If total viable aerobic or total yeast and mold are measured at more than 5 times the recommended limit, organoleptic analysis and water activity tests are recommended to examine shelf stability. It should be up to the manufacturer's discretion to interpret these findings as pass or fail.

Propose additional clarification that solid or liquid infused products such as edibles, oils, and topicals should be held to standards of food sanitation, safety, and hygiene appropriate for the product type. In these cases, the cannabis is simply an ingredient in a product that is otherwise familiar to modern standards of food and cosmetic manufacturing.

Rationale

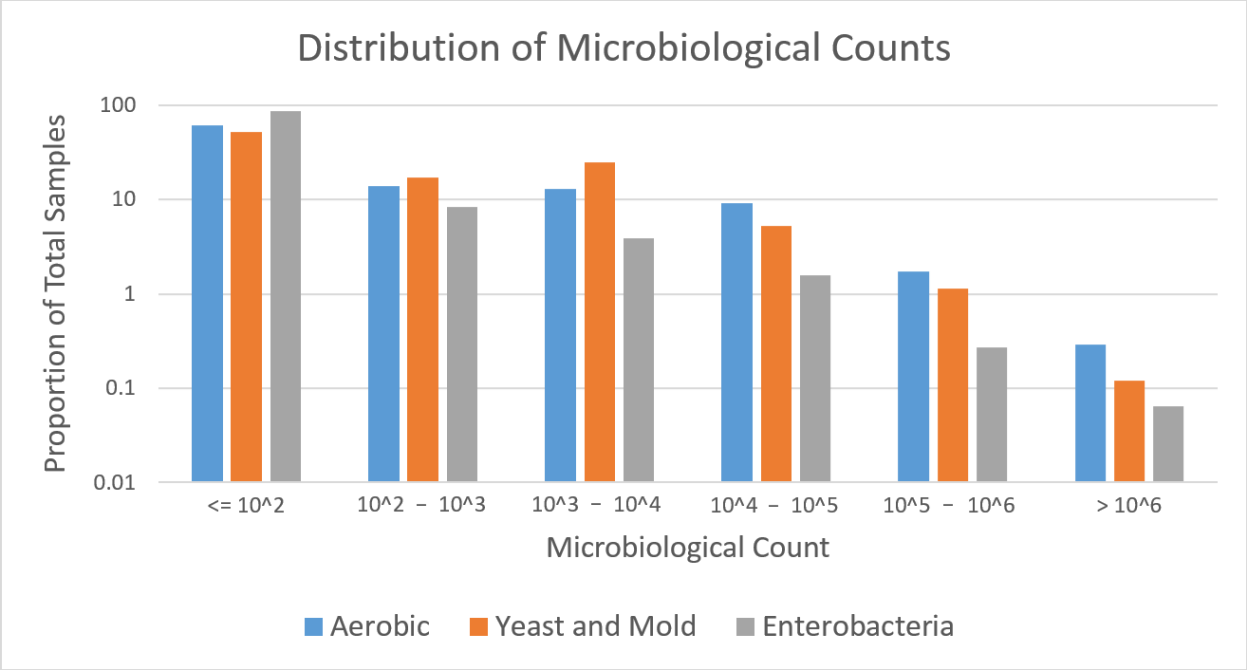
With the exception of pathogenic organisms such as *E. coli* and *Salmonella spp.*, higher than normal counts of microbiological contaminates are ***not*** generally considered a public health hazard. Rather, these measurements are used as indicators of crop quality. For example, agricultural manufacturers use microbiological screening to monitor process performance. When the manufacturer receives microbiological results significantly above what is typical for their operation, they may – at their option – seek additional investigation of cause and additional verification (through organoleptic analysis and/or chemical assay) that the product does not present an obvious health hazard or a quality issue that would

tarnish their brand or reputation. Rarely do governments force destruction of agricultural product based solely on total aerobic bacterial or total yeast and mold counts.

Despite lack of evidence supporting health concerns associated with high counts of innocuous microbial presence on dried herbs, it should still be appreciated that colony counting is widely recognized as a meaningful indicator of crop quality. From a QA perspective, these ***are*** meaningful tests; they are a strong indicator of processing cleanliness and hygiene, they are likely to be factors in shelf stability, and they can provide clues about environmental stressors affecting plant performance. The past two years bears witness that many marijuana production and processing operations can consistently demonstrate very low levels of microbiological contaminant due largely to their facility's cleanliness. Post-harvest processing, in particular, is a very common source of contamination. Cleanliness of facility and adherence to sanitation and hygiene procedures has proven successful at reducing microbiological counts at many marijuana processing operations.

While screening for pathogenic organisms is highly desirable, and should be considered the ultimate pass/fail criteria for microbiological screening, it is not feasible to screen for these organisms with high sensitivity given the marijuana industry's standards for sample size. Not only that, but pathogenic contamination is very unlikely for this crop. Fewer than 1 in 1,000 samples tested so far have detected any pathogenic strains of bacteria, and 3 out of 4 of those samples also failed for Enterobacteria. A sensible approach would be to continue screening using the current sample size (4-gram minimum, not all of which is dedicated to microbiologics) and require additional screening (with a 10-gram sample dedicated to microbiologics) when Enterobacteria are 5 times over the recommended limit.

The following graph visualizes the distribution of microbiological counts for 28,266 cannabis samples tested in WA through 2015. The data include all samples of inflorescence (flower) tested in WA where microbiological screening was required by the Board. Excluded from the data are samples tested by 3 laboratories out of 15 who either (a) do not report microbiological counts in numerical format (binary: pass/fail), or (b) have had their certification suspended.



Under the current action limit schedule, 2,683 of these samples failed on at least one count. That's an industry-wide failure rate of 9.5%, mostly coming from the yeast and mold category. In comparison, the proposed action limit schedule would have passed 80% of these for an industry-wide failure rate of 2%, mostly coming from the Enterobacteria category. A rough cost estimation of the current microbiological limit schedule to the marijuana industry in Washington State is 36.5 million dollars per year when assuming the average sample represents a 3 lb lot and average retail value is $10/g, which are conservative assumptions. The proposed limit schedule would save the industry an estimated 28.9 million dollars per year, with no evidence that it would create increased public health risks.

The proposal above does not deviate significantly from recommended microbial limits for other dried herbs. The following table lists recommended limits from around the world for products comparable to marijuana:

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

Recommended Microbial Limits for 'Finished' Botanical Products (in colony-forming units (cfu)/g)
© AHPA 2014

[Current as of July 2012]

Organization	AHPA	EP	EP	NSF/ANSI	USP	WHO	AHPA	NSF/ANSI
Product	Herbal supplements in solid form consisting of dried, unprocessed herbs	Antimicrobial pre-treatment and/or microbial reduction in production process	If pretreatment or process fail to achieve compliance	Containing botanical ingredients, non-extract	Containing botanical ingredients	Plant materials for internal use	Herbal supplements in solid form consisting of powdered extracts or soft extracts	Containing botanical extract
Total aerobic microbial count	10^7	10^{4**}	10^{5**}	10^7	10^4	10^5	10^4	10^4
Total combined yeast & mold count	10^5	10^{2**}	10^{4**}	10^5	10^3	10^3	10^3	10^3
Enterobacteria count (bile-tolerant Gram-negative bacteria)	10^4 (total coliforms)	10^2	10^3 (inc. certain others)***	10^4	NA	10^3	10^2 (coliforms)	10^2
Escherichia coli	Not detected in 10 g*	Absent in 1 g	Absent in 1 g	10^{2****}	Absence in 10 g	10	Not detected in 10 g*	Not detected in 10 g
Salmonella spp.	Not detected in 25 g*	Absent in 25 g	Absent in 10 g	Not detected in 10 g	absence in 10 g	none	Not detected in 25 g*	Not detected in 10 g
Staphylococcus aureus	NA	NA	NA	Not detected in 10 g	NA	NA	NA	Not detected in 10 g

AHPA – American Herbal Products Association, Guidance, 8630 Fenton St. #918, Silver Spring, MD 20910; 301-588-1171.
EHIA – European Herbal Infusions Association
EP – European Pharmacopoeia Edition 6.8, Chapter 5.8.1 – Category B and C
NSF/ANSI – NSF International Standard/American National Standard for Dietary Supplements 173 – 2006
USP – United States Pharmacopeial Convention, USP-NF 35-30, 2012
WHO – World Health Organization, *Quality control methods for medicinal plant materials*, Geneva, 1998
NA – Not Assigned
*Sample size may vary depending on the method used.
** Acceptance criterion. Maximum acceptable count is five times this value.
***Other types of organisms (e.g. *Aeromonas*, *Pseudomonas*) may be recovered.
****If the presence of *Escherichia coli* is confirmed, then testing shall be performed based on the USFDA *Bacteriological Analytical Manual* in Chapter 4A to determine whether the colonies are pathogenic enterovirulent *Escherichia coli* (EEC), not limited to 0157:H7. There is a zero tolerance for the presence of EEC.

Source: http://www.nutraceuticalsworld.com/issues/2016-04/view_columns/understanding-mitigating-microbial-contaminants-in-herbal-dietary-supplements

Notable from the source above, is the fact that the European Pharmacopoeia has recently adopted a tiered approach to microbiological examination, which is becoming a preferred method worldwide. Under this paradigm, the recommended limits are "goals" below which is considered "good." Above the recommended limits can still be considered "acceptable" so long as it is not more than 5 times the

recommended level. A tiered approach is sensible for the marijuana industry where sample sizes limit our sensitivity to pathogenic organisms on a routine basis, and we would like to reexamine product that has high counts in other categories, especially Enterobacteria.

Finally, it should be noted that this proposal eliminates from Table 9 the recommendations for Coliform limits. All Coliform bacteria are bile-tolerant and gram-negative, but not all bile-tolerant gram-negative bacteria are Coliforms. If Coliform bacteria are listed in Table 9, the Board will require testing for that group of organisms, requiring a superfluous test. We strongly recommend removing Coliforms from Table 9 and describing “Enterobacteria” as the colloquial term for bile-tolerant gram-negative bacteria.