

January 26, 2018

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SENT VIA EMAIL ONLY

Re: A Comment on Heavy Metals Limits for Medical Cannabis and Cannabis-Infused Products as Defined in the Emergency Rules for the MMFLA

Dear Gary,

Thanks for taking the time to read through my concerns regarding Michigan's heavy metals limits. As you know, my background as a geochemist is in trace metal isotopic analysis – so this subject is near and dear to my heart. This is an important issue – for the health and safety of patients, as well as the health and safety of the cannabis industry as a whole.

Limits for Heavy Metals are Prohibitively Low for Labs, Growers & Processors

The limits for heavy metals as currently defined by the Emergency Rules and subsequent Technical Bulletin on the subject are problematic for Safety Compliance Facilities, as well as Growers and Processors. Labs will have difficulty providing an economical test where they have to attain such low detection limits in cannabis, and growers/processors will likely have trouble delivering any product that can pass such stringent standards.

The Financial Implications of Improper Detection Limits

Having such low detection limits required by the MI emergency rules can also create problems for laboratories trying to plan future business because it can have implications for which instruments are needed to meet the demands of the test. Analytical instruments can vary drastically in price and performance. If very high performance is required by unnecessarily low limits, then it can become an undue financial burden on the labs that have to purchase very expensive equipment, as well as the clients who will bear some of the cost of those tests.

California's Rules Allow Cannabis to Have 500 Times More Arsenic Than Michigan's

For example, the limit for Arsenic in cannabis as defined by the Emergency Rules is 0.14¹ ug/kg or

¹ Nevada amended their limit for Arsenic from <0.14 to <2 ppm (<https://www.leg.state.nv.us/nac/nac-453a.html>)

0.14 parts per billion (ppb). By comparison California has set their limit for Arsenic at 0.2 ug/g, or parts per million (ppm), for inhaled cannabis products. This means that a safe cannabis flower in CA is allowed to have ~1,500 times more Arsenic than is currently allowed in MI. The current heavy metals limits are set far too low in the MI emergency rules.

Michigan's Limits are so Low That One Would Have to Consume over 100 lbs. Cannabis/Day to Reach the Maximum Recommended Arsenic Consumption of 10 ug per Day in an Herbal Supplement

Limits for heavy metals are based on total amount of a particular toxic metal consumed per day. According to the American Herbal Pharmacopeia's Cannabis Inflorescence Monograph, the safe amount of Arsenic in an herbal product would be 10 micrograms per daily dose. If a cannabis flower failed the very strict limit for Arsenic set by MI by having, for example, 0.2 ug/kg of Arsenic (i.e., >0.14 ug/kg), a patient would have to consume 50 kg (110 lbs.!) of that cannabis flower in one day to reach the limit at which it is no longer considered safe at that daily dose because of Arsenic levels. Needless to say, this is an impossible daily dose and further demonstrates that the limit currently set by the state is far too low. The same is true for the other heavy metals on the list.

LARA's 12/28/2017 Technical Bulletin – Tries to Fix Issues, Creates New Problems

While the technical bulletin released by LARA on December 28, 2017 attempts to clarify this limit by introducing an average body weight and frequency (per day), this actually introduces a new problem that makes these quantities unmeasurable by any laboratory. The limit was initially set in units of ug (microgram) of a metal per kg of substance, which is another way of saying the concentration of a particular metal in parts per billion in a cannabis product. While this limit is too low, as described above, it is something that can, theoretically, be measured by a lab.

New Variables - Body Weight, and Amount Consumed Daily

However, by multiplying the limit by a factor of body weight (in kg) per day, the resulting limits for the heavy metals are now in units of ug/day. Multiplying an average body weight/day of 70 kg/day by the current limits results in a total amount of ~10 ug Arsenic per day. While this number is in line with the recommendations of total Arsenic per day from herbal products as described in the Cannabis Inflorescence Monograph, a laboratory cannot measure a quantity in ug/day unless they know the amount of a particular product that a patient consumes per day.

Because daily consumption by patients is unknown to the labs, variable by patient and variable by product, it is impossible for a lab to measure this.

Michigan Must Set Appropriate Units of Concentration

In order to set metals limits that a laboratory can design and execute a test for, the limits will need to be set in a unit of concentration. For example, the units should be in ug of metal per gram of product. Limits set by states including CO, NV, PA and CA are far more reasonable in

terms of their feasibility and are also in an appropriate unit (ug/g or ppm) that can be measured by a laboratory in a particular batch of cannabis or cannabis infused products.

Please feel free to contact me if you have any questions.

Sincerely,



Lev Spivak-Birndorf, Ph.D.