

Department of Licensing and Regulatory Affairs  
Bureau of Medical Marihuana Regulation  
Medical Marihuana Facility Licensing

**SENT VIA EMAIL ONLY**

**Re: Chromium Limits in Infused Products**

Dear LARA-BMMR,

Thank you for this opportunity to provide feedback on the current metals testing standards. PSI Labs believes that the current Cr action limits for infused products are too stringent at 0.6 ppm and that a higher limit of at least 2 ppm is more appropriate. There are several reasons we believe this to be the case listed below followed by additional supporting information.

1. Typical food and drug ingredients that are commercially available can have Cr concentrations above the current MI action limits for infused products.
2. Edible dose sizes can vary by several orders of magnitude. This large range is due to the variable contents of inert ingredients. This could result in large differences in the total metals consumed by a patient per day depending on what type of infused product they use (e.g., one dose of brownie can weigh 100 times more than one dose of a medicinal tablet). Levels that are appropriate for one infused product might not be relevant to a different size infused product.
3. The non-toxic form Cr (III) is more common in nature and more likely to occur in typical food ingredients. It is even considered an essential nutrient in this form with unknown daily nutritional requirements.
4. Chromium is known to primarily be an inhalation hazard and has limited uptake efficiency through ingestion. Higher limits for infused products intended for ingestion are more appropriate.

As we have previously described to BMR, we encountered two chocolate based edible products from the same client with levels of Cr that were significantly above the current action limit. Since the cannabis oil tested by the same client did not have elevated Cr levels we checked the raw chocolate for Cr. Our results showed that most of the commercially obtained high-quality raw chocolate ingredients had elevated Cr levels above the action limits. Further analyses of several chocolate bars obtained from a grocery store showed that most dark chocolate from at least two popular brands were significantly above the Cr action limit with concentrations up to 2.5 ppm in the bar with the highest cacao content.

We have also found additional ingestible products where this action limit seems restrictively low. Specifically, commercially available pharmaceutical grade compounding powders used in tablets that results in fails for Cr at levels very close to the action limits.

In this case the limits must also be considered prohibitively low because of the small size of each dose. The limits for all of these metals are listed as being based on a presumed dose of *10 grams*

*of cannabis product per day.* This is crucial because all of the recommended daily exposure limits to metals are based on *total exposure per day.*

While a lab measures the concentration of a particular metal, which would fail if above a particular action limit concentration, the large possible variance in assumed daily consumption that is possible for infused products makes it difficult to assign a single assumed daily consumption limit.

For example, while an average tablet dose weighs about 0.25 grams, an average dose of chocolate bar or brownie could be closer to 10-25 grams. The disparity in dose size means that a scenario could arise where if both samples had the same metal concentration, regardless of whether it was over the action limit, the brownie could contain 100 times more total metal per dose than the tablets. In essence, a patient would have to eat an unrealistically large number of tablet doses per day (e.g. multiple full packages of tablets) in order to get the same total metal exposure they could get from a single dose of a bulkier edible (e.g., one fourth of a brownie) with the same metal concentration.

In both of these cases, normal products from the typical supply of food and drugs are not passing Michigan's strict MMFLA Cr limit for ingestible products, which has been clearly problematic. It could result in the destruction of valuable products for levels of Cr that would otherwise be considered safe to consume.

The EPA provides a hazard summary for Cr where they describe that the majority of Cr in the environment is naturally occurring and exists in the form Cr(III), which is an essential nutrient for humans (<https://www.epa.gov/sites/production/files/2016-09/documents/chromium-compounds.pdf>). The toxic form of chromium Cr(VI) is mainly produced by industrial activities and should be of minimal concern in the cannabis supply chain as long as typical food and drug ingredients are used in production.

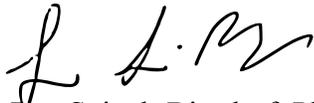
A further complication is that the required daily intake of Cr as a nutrient is not well established. The FDA has recommended 120 micrograms per day for adults (<https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf>). More recent data presented by the NIH suggests that 35 micrograms of Cr per day might be adequate intake (<https://ods.od.nih.gov/factsheets/Chromium-HealthProfessional>). However, there are currently not enough data to support a clear consensus on the total daily intake of Cr required by adults.

In either case, the amount of exposure from cannabis infused products is likely to be relatively low compared to exposure from common foods. As an example, if an infused tablet failed at 0.6 ppm total Cr and had a weight of 0.25 grams per tablet, a patient who consumed 10 tablets per day would be exposed to 1.5 total micrograms of Cr from the tablets. Even if the patient ate an entire bottle containing 30 tablets in one day their Cr exposure would be less than 5 micrograms from the tablets. As a comparison, a single half cup serving of broccoli contains 11 micrograms of Cr (<https://ods.od.nih.gov/factsheets/Chromium-HealthProfessional>).

It is also noteworthy that Cr(VI) is also primarily an inhalation hazard mostly of concern in industries where it is used and workers can be exposed to unsafe levels (<https://www.epa.gov/sites/production/files/2016-09/documents/chromium-compounds.pdf>). The harmful effects of Cr ingestion are much less clear, especially if it is the essential nutrient form Cr(III) that would typically found in normal foods.

We fully agree that measuring the different species of Cr is not feasible for safety compliance facilities and total Cr concentration must be used as a proxy. However, the limit is likely too low in infused products where “failing” levels might be induced by common ingredients that are considered safe in the currently established food and drug supply chains that exist outside of the cannabis industry.

Respectfully submitted,



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