

U.S. Hemp Roundtable

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VIA EMAIL

December 13, 2021

Ms. Madeline Kane
Rules Coordinator
Oregon Liquor Control Commission
9079 SE McLoughlin Avenue
Milwaukie, OR 97222

Re: Proposed Rules – Adult Use Cannabis Items and Hemp Item Concentration and Serving Limits

Dear Ms. Kane:

The U.S. Hemp Roundtable appreciates the opportunity to comment on the Notice of Proposed Rulemaking (“Proposed Rules”) filed by the Oregon Liquor and Cannabis Commission’s (“OLCC”) on November 11, 2021. The Roundtable is the industry’s leading national advocacy organization that represents nearly 100 firms and organizations from across the country – at each link of the hemp supply and sales chain – and includes the ex officio membership of the industry’s major grassroots associations. Our membership includes seven firms and organizations based in Oregon.

We have been advised that, due to OLCC’s deliberation timetable, we should submit these preliminary overview comments today, more than a week in advance of your December 22 deadline. We plan to submit supplementary comments closer to the deadline that will provide real world data on the challenges the Proposed Rules pose for the Oregon and national hemp industry. We would be very pleased to have clarifying conversations at your convenience.

In sum, we strongly support the legislative intent behind House Bill 3000¹, which authorized the OLCC to adopt rules to establish maximum concentrations of total THC and other cannabinoids per serving of an industrial hemp product: Intoxicating cannabis products should not be sold at retail, nor to minors, but rather only through adult-use cannabis channels. We share the state’s concerns about the marketing of delta-8 tetrahydrocannabinol (“delta-8 THC”) and other potentially intoxicating products as hemp products and have issued numerous public statements to this effect.² The legislative intent of House Bill 3000 was to direct OLCC to develop standards that treat these types of products as “adult use cannabis items” and prohibit their sale in the general market.

¹ Oregon House Bill 3000, <https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/HB3000/Enrolled>.

² See, e.g., U.S. Hemp Roundtable, Statement of Marketing Hemp Products (Mar. 8, 2021), <https://hempsupporter.com/news/for-immediate-release-statement-on-marketing-hemp-products>.

Unfortunately, OLCC's Proposed Rules extend beyond these intoxicating products. In developing the Temporary Rules concerning adult use cannabis items that were adopted in July 2021,³ and then in promulgating the Proposed Rules, OLCC has taken actions that go beyond the legislative intent by extending restrictions and retail prohibitions to a wide range of non-intoxicating hemp products. The Proposed Rules not only set arbitrary intoxication thresholds, but they also invent a burdensome extra-statutory regime for low THC products that unnecessarily creates two categories of hemp products that can be sold in the general market: one for adults age 21+ only, and another for products sold to consumers of any age.

From our discussions with OLCC staff, the cannabinoid limits and restrictions in the Temporary and Proposed Rules were developed without scientific basis or survey of existing products in the hemp marketplace. As explained below, if finalized, the Proposed Rules will have a deeply negative impact on the hemp industry, impairing Oregon farmers and businesses and limiting consumers' access to many popular, non-intoxicating hemp products. Worse, as the first state effort to impose such restrictions on non-intoxicating hemp products, the Proposed Rules could set a troublesome precedent for the rest of the country.

We ask OLCC to place a pause on finalizing its Proposed Rules, and launch a more deliberative process engaging scientists, the industry and other state regulators. If OLCC deems finalizing rules as necessary, we strongly urge the agency to adopt our recommended revisions outlined below.

I. The OLCC's 0.5 Total THC Limit Inappropriately Classifies Many Non-Intoxicating Hemp Products as "Adult Use Cannabis Items"

In its Temporary Rules, OLCC invented a new intermediate category: Products that are not intoxicating, but have trace levels of total THC (defined as 0.5 mg or more of total THC per product, including delta-9 THC, delta-8 THC, and all other forms of THC) and can still be sold in the general market, but are subject to restrictions that mirror products like alcohol, by restricting sales to adults over the age of 21. This means CBD isolate and broad-spectrum hemp extract products could be sold without restriction, but full-spectrum hemp extract products must be segregated in the store and sold only to adults with proof of age.

According to OLCC staff, in their opinion, minors should not have access to products with any THCs in them, and the 0.5 mg limit was chosen because it was "close to zero." This arbitrary determination is not supported by statute or based in science, and it burdens retailers and consumers while ultimately impairing farmers and manufacturers.

Moreover, House Bill 3000 does not suggest anywhere that people under 21 should not have access to products with any amount of THCs, or full spectrum hemp extract products. The law's references to maximum concentration for adult use cannabis, and not a ban, indicates that a zero-level was not the preferred approach. In addition, we are not aware of any scientific evidence indicating that 0.5 mg of total THCs causes or is likely to cause intoxication in minors, or adults. It is also unclear whether and what scientific evidence or studies OLCC relied upon in establishing the limit, and whether the potential for abuse was taken into consideration. Further, there is no science that supports OLCC staff's view that minors are unable to tolerate any level of THC.

As drafted, Proposed Rule 845-026-0300 will require retailers to differentiate full-spectrum hemp extract products from other hemp products in their inventory. As full spectrum definitions and labeling practices differ across the industry,

³ OAR 845-026-0100, 845-845-026-0300, 845-026-4100 (effective July 16, 2021 - December 31, 2021), <https://www.oregon.gov/olcc/Docs/rules/Division-26-Temp.pdf>.

retailers will be required to interpret certificates of analysis for finished products to determine which products may exceed the 0.5 mg total THCs limit, which requires technical expertise and creates an undue burden. Rather than undertake this complicated technical exercise, retailers may choose to segregate full spectrum products, or all hemp products, e, which would hinder commerce, chill the economy, and send an inaccurate message that hemp products are a public health or safety risk. Coupled with the burden of checking photo identification prior to selling these products, retailers may choose to not carry these products altogether – hurting farmers and business owners of every size in Oregon and the rest of country who are engaged in this industry, as well as consumers in the state who are clearly demanding access to these products. Age restrictions such as this also send an inaccurate and inappropriate message to consumers: that these safe health and wellness products are dangerous or should be associated with a vice of some sort.

The 2018 Farm Bill created new, legal markets for farmers and businesses, and mischaracterizing or otherwise demonizing these markets not only stifles these opportunities, but also deprives consumers seeking to improve their quality of life. The product restrictions and prohibitions ultimately fall heaviest on Oregon hemp farmers. Due to ongoing regulatory uncertainty at the federal and state level, exacerbated by the COVID-19 pandemic, U.S. hemp farmers have been struggling due to sharp declines in hemp biomass prices. Age restrictions and product bans serve to further limit markets for hemp products, dealing yet another blow to Oregon agriculture.

Among the 50 states that have legalized hemp, and the dozens that have explicitly sanctioned the retail sale of hemp-derived cannabinoid products, only Louisiana and Rhode Island employ age restrictions. The Rhode Island Department of Business Regulation has shared with our counsel that they are not enforcing the age restrictions, and the Louisiana Office of Alcohol and Tobacco reports that they are challenged by them given their many responsibilities involving substances that actually impose health risks and/or involve criminal activity. Indeed, any such enforcement activities create moral hazards by diverting attention from real health issues and are fiscally irresponsible. Further, there are plenty of examples of products with trace amounts of potentially intoxicating substances that are currently available for retail purchase by persons of any age: kombucha, catnip, kava kava, valerian root, melatonin, various cactuses.

In addition, Proposed Rule 845-026-0300 will pose significant challenges for companies attempting to demonstrate compliance with subsection (1)(c), which provides that a hemp product is an “adult use cannabis item” if “testing...was performed using a method with a LOQ that is not sufficient to demonstrate that the total delta-9-THC does not exceed 0.5 milligrams.” Based on discussions with industry members and qualified laboratory representatives, to substantiate that, for example, a one fluid ounce tincture hemp product contains less than 0.5 mg delta-9 THC, the product must be tested with a Limit of Quantitation (“LOQ”) of less than 0.0015%, which is impractical, unreasonable, and not reflective of current industry practices or standards. Larger volume products would present even greater challenges with regards to accuracy based on current testing methodologies. Specifically, it is not achievable to require an LOQ this low because, according to NIST, this cannot be done with accuracy.⁴ Simply put, producing a finished product certificate of analysis to prove compliance with (1)(c) is presently mathematically, and by current practical ability, impossible, and would result in many hemp products being inappropriately classified as “adult use cannabis items.” We would welcome the opportunity to discuss this issue in more detail with OLCC, along with laboratory directors who have expertise in reliably quantifying cannabinoid levels.

Rather than establish a separate category of “adult cannabis items” that forces retailers to segregate hemp products based on extremely low, arbitrary THC limits, we request Proposed Rule 845-026-0300 be revised as follows to reference the

⁴ Abdur-Rahman, M. , Phillips, M. and Wilson, W. (2021), Cannabis Quality Assurance Program: Exercise 1 Final Report, NIST Interagency/Internal Report (NISTIR), National Institute of Standards and Technology, Gaithersburg, <https://doi.org/10.6028/NIST.IR.8385>, https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=932765.

limits established under Proposed Rule 845-026-0400, so that products that exceed these limits would be classified as “adult use cannabis items” that could not be sold to minors. Our requested changes will also address the challenge described above regarding substantiating compliance with the 0.5 mg delta-9 THC limit. We also fully support OLCC enforcement efforts that take action against any retailer selling adult use cannabis items to minors.

Requested Revision:

(1) An industrial hemp commodity or product is an adult use cannabis item if it/is a hemp item/as defined in OAR 603-048-2310 and **exceeds the limits established under OAR 845-026-0400.** ~~./ ¶~~

~~(a) Contains 0.5 milligrams or more of any combination of:./ ¶~~

~~(A) Tetrahydrocannabinols or/tetrahydrocannabinolic/acids, including delta-9-tetrahydrocannabinol or delta-8-tetrahydrocannabinol; or/ ¶~~

~~(B) Any other cannabinoids advertised by the manufacturer or seller as having an intoxicating effect;./ ¶~~

~~(b) Contains any quantity of artificially derived cannabinoids; or/ ¶~~

~~(c) The testing done in accordance with ORS 571.330 or 571.339 was performed/using a method with a LOQ/that is not/sufficient to demonstrate that the/total delta-9-THC does not exceed/0.5 milligrams./ ¶~~

(2) An adult use cannabis item cannot be sold or delivered to a person under 21 years of age, except by a/marijuana retailer that holds a license issued under ORS 475B.105 and that is registered under ORS 475B.146 to sell or deliver marijuana items to a registry identification cardholder who is 18 years of age or older or as allowed under ORS 475B.785 to 475B.949. ¶

(3) Civil Penalties. The Commission may impose a civil penalty of no more than \$10,000 for each violation of section (2) of this rule.

II. The Rule’s Prohibition on “Artificially Derived Cannabinoids” Should Be Limited to Intoxicating Products.

House Bill 3000 directs the OLCC to set concentration limits for artificially derived cannabinoids, and to regulate as adult use cannabis artificially derived cannabinoids that are “reasonably determined to have an intoxicating effect.” We fully support efforts to regulate and limit access to intoxicating products like delta-8 THC, which should only be sold through adult-use channels. Unfortunately, OLCC’s Temporary and Proposed Rule prohibit the retail sale of all artificially derived cannabinoids, including those that are non-intoxicating, which goes beyond the legislative intent of HB 3000. Based on our discussion with OLCC staff, in their judgment, popular products such as certain forms of CBN are unsafe, even if they are non-intoxicating. OLCC’s extra-statutory determination is not based in science, nor is it consistent with the experience in the current marketplace.

HB 3000 provides OLCC with authority to set a maximum concentration on artificially derived cannabinoids that are intoxicating. A blanket prohibition that sweeps in non-intoxicating cannabinoids based on how they are manufactured goes well beyond the intent of the legislation and has no legal support in the legislative language. OLCC staff claims its prohibition on products like “artificially derived” CBN stems in part from the fact that these ingredients are not effectively regulated or approved by the FDA. However, the Federal Food, Drug, and Cosmetic Act provides a framework for regulating products – whether food, supplements, or other products – based on a variety of factors, with the manufacturing method being only one aspect among several it may consider. The OLCC’s approach would, in contrast, prohibit ingredients solely based on their method of manufacture.

Reasonable regulations for products like CBN would be embraced by the industry. By contrast, shutting down the operators who provide tested, curated CBN ingredients that would be prohibited under the Proposed Rules and will create a gap for the unregulated market to fill. OLCC staff also contends that a naturally-derived CBN is allowed, but a bio-identical, “artificially-derived” form of CBN is not. However, we are not aware of a scientific or regulatory basis for making this distinction, which again appears to be an attempt to impose arbitrary and unreasonable restrictions on non-intoxicating hemp products. Non-intoxicating artificially derived hemp cannabinoids, such as CBN, should be available in the general market and subject to the same regulatory oversight as other hemp products.

We therefore request the following revisions to the definition of “adult use cannabis item” under Proposed Rule 845-026-0300, and to the limits set forth under Proposed Rule 845-026-0400:

Requested Revision to 845-026-0300:

(2) An industrial hemp commodity or product is an adult use cannabis item if it:

...

(b) Contains any quantity of **intoxicating** artificially derived cannabinoids;

Requested Revision to 845-026-0400:

(4) An industrial hemp product may not contain any **intoxicating** artificially derived cannabinoids.

III. The Rule’s THC Limits for Non-Tincture Products Should Be Aligned to Reflect the Current Marketplace as Well as the Science of Intoxication.

OLCC’s Proposed Rule 845-026-0400 sets per serving limits for most non-tincture cannabinoid products at 1 mg of total delta-9 THC, with product limits at 10 mg of total delta-9 THC. These arbitrary numbers do not appear to be based on any scientific justification, and they are inconsistent with the practice of the marketplace. Instead, they should be aligned with science and market experience.

Many non-intoxicating, full-spectrum hemp products in the marketplace contain delta-9 THC serving levels between 1 and 2 mg. Most full-spectrum products, such as gummies and capsules, contain well over 10 mg per package. However, these products are often packaged to provide a 30, 60, or 90 day supply of the product, and include instructions for use that direct users not to consume more than the recommended daily serving. As currently written, the Proposed Rule will force a significant number of companies to reformulate and repackage products in order to achieve compliance. Not only will this come at a great expense for these companies, consumers will be forced to purchase multiple products at once, and the additional packaging will create unnecessary waste.

In establishing a standard unit for research regarding delta-9 THC, the [National Institute on Drug Abuse](#) (“NIDA”) notes that 5 mg of delta-9 THC “may produce a high in both experienced and occasional users, but in most studies, has not produced adverse effects.”⁵ Although the standard unit is not a limit or recommendation from NIDA, it was developed based on extensive deliberation and scientific input. It is also important to note that delta-9 THC and CBD are both constituents of the cannabis

⁵ National Institute on Drug Abuse, Establishing 5 mg of THC as the Standard Unit for Research (May 10, 2021), available at: <https://www.drugabuse.gov/about-nida/noras-blog/2021/05/establishing-5mg-thc-standard-unit-research>.

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plant and essentially share space in that plant. In effect, the more CBD there is in the plant or the extract from that plant, the less THC, and vice versa. CBD and delta-9 THC also work differently on the body. Research has shown that CBD effectively can help offset the intoxicating effects of delta-9 THC, due to CBD's ability to minimize the opportunities for THC to bind with receptors in the body. Simply put, CBD "crowds out" the THC, which can prevent intoxication. It is this physiological dynamic that was instrumental in the federal government adopting 0.3% delta-9 THC on a dry weight basis as the upper limit in hemp, because at that very low limit, the THC will be overwhelmed by the counteracting influence of the CBD.

Further, as discussed in more detail below, it makes no sense for consumers to purchase multi-serving tablet or gummy products for the purposes of getting high from a financial or consumption standpoint. OLCC staff points to rare products, such as chocolate bars, marketed as multi-serving products and that are likely to cause intoxication. We concur that such intoxicating products should be limited to adult-use channels; however, the arbitrary 1mg/10mg limits sweep in far too many non-intoxicating hemp products.

As such, we request that OLCC engage in a full notice-and-comment rulemaking, consulting scientists and industry leaders, to set appropriate, science-based delta-9 THC limits for hemp products.

If OLCC deems it necessary to establish preliminary limits, we strongly recommend that they align with the current practice in the marketplace. We ask that OLCC revise the serving and package limits for hemp products under Proposed Rule 845-026-0400, Table 1 as indicated below, and also create a category for multi-serving products labeled as dietary supplements under the category of "Hemp Edibles," to allow higher limits for these types of products.

As noted above, the U.S. Hemp Roundtable will submit supplementary comments before the deadline providing a survey of non-intoxicating hemp products that are currently sold in the general market in Oregon and across the country, and have proved broadly popular with little, if any, incident of abuse or lack of safety. These more reasonable limits outlined below are reflective of most non-intoxicating hemp products currently sold in the marketplace.

Requested Revision:

| THC CONCENTRATION LIMITS FOR INDUSTRIAL HEMP ITEMS | | | |
|---|--|--|--|
| Type of Industrial Hemp Product | Maximum Amount of Total Delta-9- THC Per Serving | Maximum Amount of Total Delta-9- THC per Container | Maximum Concentration of Total Delta-9-THC |
| Hemp Edibles - Food & Beverages | 12 mg | 10 mg | 0.3% |
| Hemp Edibles - Dietary Supplements | 2 mg | 30 mg | 0.3% |
| Hemp Topicals | N/A | N/A | 0.3% |
| Hemp Transdermal Patches | 1 mg | 10 mg | 0.3% |
| Hemp Tinctures | N/A | 50 mg | 0.3% |
| Usable Hemp | N/A | N/A | 0.3% |
| Industrial Hemp Concentrations or Extracts | N/A | N/A | 0.3% |
| Cannabinoid Hemp Product Other than Hemp Edibles, Topicals, Tinctures, Capsules, or Transdermal Patches | 1 mg | 10 mg | 0.3% |

IV. The Rule's Definition of "Hemp Tincture" Should Include Products With Added Sweeteners.

OLCC's Proposed Rule 845-026-0400 provides a reasonable product serving limit for cannabinoid tincture products: 50 mg per product (up to 4 fluid ounces). Unfortunately, the definition of "hemp tincture" under Proposed Rule 845-026-0100 excludes sweetened tinctures from this product category; rather, sweetened tinctures are considered "hemp edibles" with much lower and more onerous THC limits, presumably because OLCC staff believes that sweeteners could encourage

overconsumption and lead to intoxication. However, this argument has no basis in reality and is not rooted in any experience. The definition of "hemp tincture" should be revised to permit the use of added sweeteners.

It has been suggested that a person could drink an entire bottle of a hemp tincture in order to get intoxicated. In reality, the effect will not be intoxication, but nausea and diarrhea. Indeed, the clear experience in states like Oregon with established hemp and cannabis programs indicates that people are not bypassing cannabis products for hemp products in order to get intoxicated. For consumers, even younger consumers, it doesn't make sense from a financial standpoint (purchasing and ingesting an inordinate number of products in pursuit of a possible buzz) or from a consumption standpoint (ingesting a great deal of product, with the consequential physical ailments that come with it). Therefore, we request that OLCC revise the definition of "hemp tincture" as follows under Proposed Rule 845-026-0100 to permit sweetened tinctures to have up to 50 mg of delta-9 THC, given these products are unlikely to be abused for intoxication purposes.

Requested Revision:

(32) "Hemp tincture" means a liquid industrial hemp cannabinoid product packaged in a container of four fluid ounces or less that consists of either: ¶

(a) A non-potable solution of at least 25 percent non-denatured alcohol, in addition to a hemp concentrate, hemp extract, or usable hemp and perhaps other ingredients intended for human consumption that is exempt from the Liquor Control Act under ORS 471.035; or ¶ (b) A non-potable solution comprised of glycerin or plant-based oil; hemp concentrate or extract or usable hemp, and perhaps other ingredients, that ~~does not contain any added sweeteners~~ and is intended for human consumption or ingestion. ¶

* * *

In closing, we applaud Oregon policymakers for taking a strong stand protecting consumers, particularly children, from purchasing, often unwittingly, intoxicating products being sold under the guise of hemp. The U.S. Hemp Roundtable is firmly committed to reserving sales in the general market to non-intoxicating hemp products and requiring that intoxicating products be sold through adult-use channels. But it is critical not to sweep in non-intoxicating products into the more restrictive regulatory regimes. There is simply no precedent for OLCC's approach, neither in Oregon law nor anywhere else in the country. OLCC has developed a complex new regulatory regime out of whole cloth, using arbitrary numbers that appear to be based solely on anecdotal evidence.

Instead, we ask OLCC to pause before adopting final rules, and work with scientists, academia, other state regulators and the hemp industry to develop a regime that reflects House Bill 3000's true intent. If the agency deems the promulgation of rules as urgent, the necessary revisions we propose above will keep intoxicating products out of the hands of minors and others, support the hemp industry as a whole - in particular, farmers and consumers - and avoid placing undue burdens on retailers in the state.

Sincerely,



Jonathan Miller
General Counsel
U.S. Hemp Roundtable

2021 U.S. HEMP ROUNDTABLE

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