

Торіс:	Petition for Adoption, Amendment, or Repeal of a State Administrative Rule – (WAC 314-55-095) Cannabis- Infused Product Serving Size
Date:	For Board action on July 17, 2024
Presented by:	Denise Laflamme, Policy & Rules Coordinator

# **Background**

On May 20, 2024, Tanner Odenthal ("Petitioner") submitted a Petition for adoption, amendment or repeal of a state administrative rule requesting amendments to <u>WAC</u> <u>314-55-095</u> which limits cannabis-infused products<sup>1</sup> intended to be consumed orally ("edible") to 10 milligrams of active delta-9 THC ("THC")<sup>2</sup> per serving. The Petitioner is requesting to increase the allowable amount of THC that may be in a single serving above 10 milligrams.<sup>1</sup>

### Rationale for Adjusting THC Limits in Edibles

The Petitioner asserts the current 10mg THC per serving limit for edibles poses challenges for medical users and that the proposed change would address these challenges by enhancing the consistency, safety, and efficacy for those who rely on edibles for medical or therapeutic purposes. The following outlines the Petitioner's rational for the requested change:

- 1. **Availability Challenges**: High THC products are not consistently available in retail outlets, and as a result, medical users being able to obtain safe and standardized doses.
- DIY Alternatives and Risks: Some patients resort to purchasing cannabis concentrates and creating their own edibles, which may lack consistency in THC content increasing safety risks that could result from inconsistent dosing and preparation methods.

### Current Rules

As provided in WAC 314-55-095, a single serving of cannabis-infused products sold at a licensed retail outlet must not have more than 10 milligrams of THC in a single serving. A single package must not contain no more than 100 milligrams of THC.

Except, retailers who hold a medical cannabis endorsement may sell high THCcompliant products ("high THC products") to qualified patients and designated providers, as provided in the Washington State Department of Health ("DOH") rules (chapter <u>246-70</u> WAC). High THC products contain more than 10 milligrams of active THC in a single serving but must not exceed 50 milligrams per serving. Multiple units of the product may be in a single package, as long as the package does not contain more

<sup>&</sup>lt;sup>1</sup> The Washington State Department of Health uses "marijuana" and the LCB uses "cannabis," however both terms refer to the same substance.

<sup>&</sup>lt;sup>2</sup> For purposes of this response, "THC" refers to active delta-9 THC.

than 500 milligrams of THC. High THC products are restricted to only certain types of cannabis-infused products: capsules and tablets; tinctures; transdermal patches; and suppositories. High THC products must be tested for heavy metals, unlike non-medically compliant products, potentially making high THC products safer due to testing, independent of THC concentration.

# <u>Issue</u>

Whether the Board should accept or deny the petition for rulemaking to consider initiating formal rulemaking proceedings to amend <u>WAC 314-55-095</u> and increase the maximum amount of THC that may be in a single serving of a cannabis-infused products above 10 milligrams.

# <u>Analysis</u>

When making a recommendation to the Board regarding whether to accept or deny a petition for rulemaking, the Director's Office considers the following factors, as appropriate and to the extent practicable:

- 1. **Statutory Authority**: Whether the agency has the statutory authority to adopt the proposed rule.
- 2. **Statutory Obligation and Legislative Intent**: Whether the agency is statutorily obligated to consider or adopt the proposed rule, and determination of whether the proposed rule conflicts with legislative intent or statutory obligations.
- 3. **Consistency with Existing Laws and Rules**: Whether the proposed rule conflicts with or duplicates other state, federal, or local laws.
- 4. **Agency Priorities**: Alignment of the proposed rule with the agency's priorities and strategic goals; and whether the Petitioner's concerns are being addressed either through rulemaking or otherwise.
- 5. **Public interest**: Whether the proposed rule serves the public interest; consideration of the potential impact on public health, safety, and welfare; and level of interest in the proposed change.
- 6. **Merits of the Petitioner's Request**: Thorough review of the merits and supporting arguments provided by the Petitioner.
- 7. **Necessity and Reasonability**: Assessing whether the proposed rule addresses a clearly identified problem with sufficient evidence; and considerations of reasonable alternatives to ensure the rule is essential and practical.
- 8. **Risks and Unintended Consequences**: Evaluation of potential risks and unintended consequences associated with implementing the proposed rule; and consideration of possible negative outcomes or challenges that may arise from the proposed changes.
- 9. **Alternatives**: Whether there are less costly or less intrusive alternatives to address the Petitioner's concerns.
- 10. **Economic Impact**: Evaluation of the economic impact of the proposed rule on businesses, government entities, and the public; and assessment of whether the benefits of the proposed rule justify the costs.
- 11. Equity Impact: Evaluation of how the proposed rule affects equity, including impacts on historically marginalized and disadvantaged communities.

- 12. Interagency and Intra-agency Coordination and Impacts: Assessment of how the proposed rule affects other agencies and intra-agency resources and functions; and consideration of potential coordination or conflict with other agencies' rules and operations.
- 13. **Tribal Relations**: Evaluate the necessity for consultation with affected Tribal governments, respecting their sovereignty and unique status.
- 14. Local Government Impact: Assess the effect of the proposed rule on local governments, including cities, towns, or counties.

# **Rulemaking Process**

As provided in the Administrative Procedures Act (APA), chapter <u>34.05</u> RCW, if the Board accepts a petition for rulemaking, a CR-101 (Preproposal Statement of Inquiry) is filed to notify the public that the agency is considering rulemaking on the proposed topic. The CR-101 filing initiates the preliminary phase where the agency gathers information, conducts research, and seeks input from interested parties to assess whether rulemaking is needed and/or how a regulation should be modified to ensure the most favorable outcomes. If it is determined that rulemaking is necessary, the agency will draft the proposed rule and proceed to file a CR-102 (Proposed Rulemaking), formally beginning the rulemaking process which includes public hearings and a comment period before finalizing the rule with a CR-103 (Rule Adoption). Rules are typically effective 31 days after filing unless otherwise specified.

# Appeals Process

Under the <u>Administration Procedure Act (APA)</u>, the Petitioner has the right to appeal the Board's decision to the Governor. Per <u>RCW 34.05.330(3)</u>, within 30 days of a denial, the petitioner may appeal the denial to the governor. This can be done through a letter to the Governor.<sup>2</sup>

# **Statutory Authority**

The Revised Code of Washington (RCW) 69.50 does not explicitly state a maximum THC per serving limit for cannabis-infused products. The statute provides a broader legal framework for the control and regulation of cannabis but does not specify detailed product standards such as THC limits per serving.<sup>3</sup> The specific THC limits are set by rules (WAC 314-55-095) implemented by LCB under their statutory authority regulate cannabis products. These rules are created under the authority granted by the statute but are not detailed in the RCW itself. Therefore, while the statutory law (RCW 69.50) provides the legal foundation for the regulation, the specific THC limits are established through administrative rules.

RCW <u>69.50.101</u> defines cannabis-infused products<sup>4</sup> as products that are derived from cannabis or cannabis extracts, intended for human use, typically consumed orally or applied topically, but not intended for smoking. The THC concentration of these products must not exceed 10%.

# THC Concentration and THC per Serving

A 10% THC concentration does not directly translate to 10 mg of THC per serving. The concentration indicates the proportion of THC in the entire product, while the serving size limit ensures each portion contains a standardized amount of cannabis. THC per serving refers to the amount of all THC present in each serving of the product. Under WAC 314-55-095, cannabis-infused products are limited to 10 mg of THC per serving, regardless of the products' total THC concentration.

<u>Example</u>: A 100-gram cannabis-infused product with a 10% concentration would contain 10 grams (or 10,000 mg) divided into 100 servings, each serving would contain 1 gram of product, equating to 100 mg of THC per serving.

As amended by Engrossed Second Substitute Senate Bill (E2SSB) 5367 (chapter 365, Laws of 2023), the definition of THC concentration includes not only delta-9 THC but also other various tetrahydrocannabinols compounds, including but not limited to isomers such as delta-8 THC and delta-10 THC. The comprehensive definition of THC

#### <sup>4</sup> RCW <u>69.50.101</u>

<sup>&</sup>lt;sup>3</sup> RCW <u>69.50.342</u> identifies the Board's authority to engage in rulemaking including, but not limited to, methods for producing, processing, and packaging; labeling requirements, and standards of ingredients and quality pertaining to useable cannabis, cannabis concentrates, and cannabis-infused products.

RCW <u>69.50.345</u> identifies the Board's authority to engage in rulemaking including establishing classes of cannabis, cannabis concentrates, useable cannabis, and cannabis-infused products according to grade, condition, cannabinoid profile, THC concentration, CBD concentration, or other qualitative measurements deemed appropriate by the board.

<sup>(</sup>k) [(11)] "Cannabis-infused products" means products that contain cannabis or cannabis extracts, are intended for human use, are derived from cannabis as defined in subsection (d) [(4)] of this section, and have a THC concentration no greater than ten percent. The term "cannabis-infused products" does not include either useable cannabis or cannabis concentrates.

affects the overall THC content in cannabis products. Rulemaking to implement the legislation is underway to reflect these amendments.

# **Statutory Obligation and Legislative Intent**

As part of the LCB's statutory obligations under the Revised Code of Washington (RCW) 69.50, the LCB is mandated to regulate the production, distribution, and sale of cannabis to protect health and safety. The legislative intent behind these regulations emphasizes the need for strict control of cannabis products to prevent misuse and ensure that products are safely consumed.

# **Agency Priorities**

The LCB is committed to ensuring safe and responsible use of cannabis products while also considering public health, consumer safety, and economic impacts. The current rule limiting THC content to 10 mg per serving was established to mitigate the risk of overconsumption and potential adverse effects associated with high THC doses.

The agency is currently engaged in rulemaking to implement Engrossed Second Substitute Senate Bill (E2SSB) 5367, chapter 365, Laws of 2023, concerning THC concentration. The legislation expanded the definition of THC concentration to include multiple forms of the compound. This effort further complicates any attempt to change the serving size of THC limits.<sup>3</sup> Until the new rule goes into effect, rulemaking to consider changes to the serving size or packaging limits is not feasible.

# **Consistency with Existing Laws and Rules**

Increasing the 10 mg THC serving size limit for cannabis-infused products would conflict with DOH rules for high THC products, as outlined in WAC 246-70. These rules ensure consumer safety through strict labeling and dosage controls. Additionally, DOH has open rulemaking<sup>5</sup> and is considering expanding the types of products in the high THC category based on patient feedback in its' ongoing rulemaking activities<sup>6</sup>, aiming to make edibles a cost-effective option for patients. Moreover, DOH is considering feedback suggesting that sugar-based products should not be included in high THC categories. Maintaining the current 10 mg limit is necessary to align with DOH regulations and ongoing considerations.

# **Public Interest**

Studies have highlighted the challenges of accurately measuring and maintaining consistent potency in homemade edibles, which can result in either underdosing or overdosing, posing potential health risks.<sup>4</sup> However, research has also shown that higher doses of THC can lead to increased incidences of acute intoxication, impaired judgement, and other adverse health effects. Keeping the limit at 10 mg per serving

<sup>&</sup>lt;sup>5</sup> DOH CR-101. WSR 22-23-001 (Nov. 2, 2022)

<sup>&</sup>lt;sup>6</sup> WSR 22-23-001

helps to prevent accidental overconsumption and promotes responsible use. Ensuring a lower THC per serving limit supports braider public health and prevention goals by minimizing the potential for misuse and reducing the likelihood of negative health outcomes. It also helps protect vulnerable populations, including those who may be inexperienced with cannabis consumption. Maintaining a lower THC per serving helps safeguard against unintentional consumption by minors. Packaging and dosing controls are crucial in preventing youth access and ensuring the responsible marketing of cannabis products. Feedback from public health partners support the following reasons for not expanding the types of allowable higher THC products: this would present a higher chance of overuse or misuse, it would be inconsistent with existing public health efforts around better protecting consumers related to high THC products, there are concerns about access to children that could lead to higher unintended intake, and the opportunity for consumers to increase their intake using currently available products. DOH indicated that they are not in favor of LCB raising the THC limits in non-medical cannabis edible. They cite concerns about the increased risk of products that may appeal to children, as well as other reasons listed above under public health/prevention. They are considering adding edibles to their high-THC category based on patient feedback, including the fact that edibles are an important cost-effective option for patients. They have received mixed feedback from patients about adding these products and are considering them as part of their open rulemaking.

# **Potential Benefits**

Increasing the 10 mg THC serving size limit for edibles could offer several benefits, including catering to consumer preferences for higher doses, enhancing cost efficiency, reducing packaging waste, and providing greater convenience by requiring fewer servings for desired effects. It may also spur product innovation, improve market competitiveness, and better serve patients needing higher doses. Additionally, it could drive better consumer education and awareness regarding responsible use. Each of the benefits needs to be carefully weighed against potential risks to public health and safety, as well as regulatory and societal impacts.

# **Risks and Unintended Consequences**

The 10 milligram THC single serving limit is a long-standing industry practice in both Washington and across the United States, established to ensure consumer safety and standardization. In Washington, the limit was implemented in 2013 following the passage of Initiative 502 (I-502) and has set a well-recognized standard for both consumers and retailers.<sup>7</sup> Most other states currently have a limit of 10 mg THC per serving, or less, for adult use products. A recent review cites that of 17 adult-use jurisdictions surveyed, thirteen states limit serving size to 10 mg of THC in edible cannabis products. <sup>5</sup> The remaining four states limit serving size to either 5 mg or 5.5 mg. Consumers and retailers are familiar with the maximum 10 mg amount per serving for adult-use products and an increase may lead to confusion.

<sup>7</sup> WSR 13-14-124

### **Necessity and Reasonableness**

The current 10 mg per serving limit is both reasonable and necessary to balance consumer freedom with public health considerations. It provides consumers with flexibility to purchase multiple servings or packages within a transaction limit, as long as it does not exceed the possession limits and transaction limits (<u>WAC 314-55-095</u>), while also ensuring consumers have access to their desired quantities without compromising safety standards. Additionally, there are other ways to access high THC products, such as through cannabis concentrates.

Although the Agency is not currently aware of these products on the market, an increase in high THC products is anticipated due to the tax exemption. The Agency recognizes that due to limited availability some consumers may resort to making homemade edibles with concentrates, which may pose significant health and safety risks. However, homemade products often lack standardization and proper dosing, leading to a higher likelihood of accidental overconsumption and adverse effects.

High THC products are already available under existing DOH regulations. Although the current availability of high THC products is limited, the <u>Substitute House Bill (SHB) 1249</u> exempting retailers holding a medical cannabis endorsement from the 37% excise tax has led to an increase in heavy metal testing and interest by retailers to obtain a medical cannabis endorsement.

Furthermore, current rulemaking to implement <u>HB 5367</u> (chapter 365, Laws of 2023) is proposed to change the definition of THC concentrations to include other forms of THC besides delta-9. Any rule changes to increase the THC amount in servings would be affected by this open rulemaking as the THC amount would have to align with new definitions. Until the new rules are in effect, adjusting serving size or packaging limits is not feasible.

### Economic Impact - none expected

### **Equity Impacts**

Ensuring equitable access to cannabis products is a key priority. Maintaining the current limit helps prevent the proliferation of high-potency products that may disproportionately impact marginalized communities.

#### Intra-agency Impacts

<u>Licensing and Regulation Division</u>: The proposed rule change would impact resources necessary in Licensing and Regulation Division since division is responsible for reviewing edible product labels for compliance.

<u>Enforcement & Education Division</u>: Proposed rule change would require resources to develop education materials, educate licensee, and enforce new compliance standards. In addition, CCRS may require updates to be able to track the new product types.

Finance Division: None expected.

IT Division: None expected.

# Interagency Impacts

DOH – coordination required – DOH currently doing rules.

# **Tribal Relations**

No impact to Tribal governments has been identified. Local Government Relations

No impact to local governments has been identified.

# **Conclusion**

Considering the evolving nature of cannabis research, it may be prudent to consider revisiting THC serving size limits as new evidence and best practices emerge. Ongoing dialogue with stakeholders and community partners will help ensure that regulations reflect current knowledge and societal needs. While the perspectives and reasons behind the request are understood, maintaining the 10 mg THC per serving limit for edibles aligns with statutory obligations under RCW 69.50, legislative intent and agency priorities to protect public health and safety, considering economic, equity, reasonability, and necessity impacts.

#### **Recommendation**

Based on the reasons described above, the Director's Office staff recommend that consistent with  $\frac{\text{RCW } 34.05.330(1)(a)}{\text{m}}$ , the Board deny the petition for adoption, repeal or amendment of rules related to increasing the 10 mg THC serving size limit for edibles.

#### **Board Action**

After considering the recommendation of Director's Office staff, the Board accepts/denies the petition for rulemaking submitted by Tanner Odenthal on May 20, 2024.

\_\_\_\_ Accept \_\_\_X\_\_ Deny

David Postman, Chair

<u>7.17.2024</u> Date

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\_\_\_\_\_ Accept \_\_\_X\_\_ Deny

Ollie Garrett, Board Member

<u>7.17.2024</u> Date

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\_\_\_\_ Accept \_\_X\_ Deny

Jim Vollendroff, Board Member

Attachments:

- 1. Petition form and supplemental letter from Petitioner
- 2. Report about THC limits in other states.

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List rule number (WAC), if known: WAC 314-55-095

$\overleftarrow{\times}$ I am requesting the following change:	l am requesting the Washington State Liquor and Cannabis Board to amend the current regulation that limits edibles to 10mg of THC per serving.
∑ This change is needed because:	The current 10mg THC limit for edibles is not effective for medical users, as many locations do not carry High THC Compliant products. This limitation restricts medical users from obtaining safe and standardized doses. Many locations recommend buying
☑ The effect of this rule change will be:	This change will allow medical users to access professionally produced high THC edibles, ensuring consistency, safety, and efficacy in their medication. It will reduce the need for patients to make their own edibles from concentrates, thereby

The rule is not clearly or simply stated:

The Director's Office sought additional clarification from the Petitioner due to the truncated text boxes on the petition form. Subsequently, the Petitioner provided the following additional information to clarify the request:

"I am requesting the following change: I am requesting the Washington State Liquor and Cannabis Board to amend the current regulation that limits edibles to 10mg of THC per serving.

This change is needed because: The current 10mg THC limit for edibles is not effective for medical users, as many locations do not carry High THC Compliant products. This limitation restricts medical users from obtaining safe and standardized doses. Many locations recommend buying concentrates due to their high THC allowances and making their own edibles, which are not as consistent or safe as professionally produced high THC products. Allowing higher THC products to be bought recreationally would ensure medical users have access to safe and standard doses. The effect of this rule change will be: This change will allow medical users to access professionally produced high THC edibles, ensuring consistency, safety, and efficacy in their medication. It will reduce the need for patients to make their own edibles from concentrates, thereby minimizing potential risks associated with inconsistent dosing and preparation."

<sup>2</sup> <u>https://governor.wa.gov/contacting-governor/contacting-governors-office/contact-gov-inslee</u>

<sup>3</sup> "Cannabis products" means useable cannabis, cannabis concentrates, and cannabis-infused products as defined in this section, including any product intended to be consumed or absorbed inside the body by any means including inhalation, ingestion, or insertion, with any detectable amount of THC.

<sup>4</sup> <u>Cannabis Legalization and Acute Harm from High Potency Cannabis Products: A Narrative Review and</u> <u>Recommendations for Public Health. Frontiers in Psychiatry. Sept. 23, 2020</u>. <sup>5</sup> The Network for Public Health Law, 2022. Fact Sheet – THC limits for adult-use cannabis products. Available at: <u>https://www.networkforphl.org/wp-content/uploads/2022/11/THC-limits-for-Adult-Use-Cannabis-Products.pdf</u>