Concise Explanatory Statement – Regarding the Regulation of Products Containing THC

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Introduction

The Washington State Liquor and Cannabis Board (Board or LCB) is adopting final rules modifying Chapter 314-55 of the Washington Administrative Code (WAC) to implement Engrossed Second Substitute Senate Bill (E2SSB) 5367, (chapter 365, Laws of 2023), passed during the 2023 legislative session. This legislation makes significant changes to the regulation of products containing tetrahydrocannabinols (THC). In addition, the rules are updated to reflect statutory changes resulting from Substitute House Bill (SHB) 1249, (chapter 9, Laws of 2024), which amended transaction limits for cannabis-infused liquid beverages.

RCW 34.05.325 of the Administrative Procedures Act (APA) requires agencies to complete a Concise Explanatory Statement before filing adopted rules with the Office of the Code Reviser and provide it to any person upon request or from whom the LCB received comment. This Concise Explanatory Statement concerns the adoption of rules amending Chapter 314-55 WAC, as necessary, to implement E2SSB 5367 and align the rule requirements with SHB 1249.

The LCB appreciates and encourages your involvement in the rule making process. If you have questions about this or other rulemaking activities, please email at rules@lcb.wa.gov.

Rulemaking History for Final Adopted Rule:

- June 21, 2023: CR-101 filed as WSR 23-13-129
- June 2023 February 2024: Informal comment period
- December 2023 April 2024: Public engagement
- July 31, 2024: Board approved filing proposed rules (CR-102)
- August 6, 2024: CR-102 filed as WSR 24-16-126
- September 11, 2024: Public hearing

Purpose of the Rules and Reason for Adoption

The final rules for adoption are necessary to align current rules with statutory changes resulting from E2SSB 5367 and SHB 1249. Several sections of WAC 314-55 require amendments to implement the legislation. Tables 1 – 7 provided below summarize the proposed rule changes.

Table 1: WAC 314-55-010 - Definitions

"Cannabis"	Defined to have the same meaning as the corresponding statute in RCW 69.50.101. E2SSB 5367 amended the definition of "cannabis."
"Cannabis concentrates"	Defined to have the same meaning as the corresponding statute in RCW 69.50.101.
"Cannabis-infused products"	Defined to have the same meaning as the corresponding statute in RCW 69.50.101.
"Cannabis products"	Defined to have the same meaning as the corresponding statute in RCW 69.50.101. E2SSB 5367 amended the definition of "cannabis products" to include products containing any detectable amount of THC and products containing only THC.
"CBD concentration"	Defined to have the same meaning as the corresponding statute in RCW 69.50.101.
"LCB"	A new definition for the agency acronym that reflects the current name of the agency Washington State Liquor and Cannabis Board is added to WAC 314-55-010. The existing rule definition with the outdated agency acronym, "WSLCB," referring to the Washington State Liquor Control Board, is repealed. The definition of "Applicant" is also updated to reflect this acronym change – "LCB" replaces "WLSCB."
"Package"	Defined to have the same meaning as the corresponding statute in RCW 69.50.101. E2SSB 5367 created a new definition for "package" to mean a container that has a single unit or a group of units.
"Synthetic Cannabinoid"	Defined to have the same meaning as the corresponding statute in RCW 69.50.455. "Synthetic cannabinoid"

	includes any chemical compound identified in RCW 69.50.204(c)(30) [(3)(dd)] or by the pharmacy quality assurance commission under RCW 69.50.201.
"THC concentration"	Defined to have the same meaning as the corresponding statute in RCW 69.50.101. E2SSB 5367 amended the definition of "THC concentration" to encompass multiple THC compounds, not just delta-9 THC.
"Tetrahydrocannabinols"	Defined to have the same meaning as the corresponding statute in RCW 69.50.204. The definition of "tetrahydrocannabinols" had limited relevance prior to the legislative change amending the definition of "THC concentration."
	The broader legal definition of "THC concentration" required a recalibration of how THC content is quantified in rule and standardization to ensure consistency across testing procedures and labeling, which also previously focused only on delta-9 THC.
"Total THC"	Total THC is the measurement of THC content present in cannabis and cannabis products. It includes both the active THC (THC) and the potential THC that can be converted from acidic precursors such as THCA through decarboxylation. Decarboxylation is a heating process that transforms acidic cannabinoids into their neutral, psychoactive forms (i.e., delta-9 THCA is converted to delta-9 THC).
	Replaced the existing definition of "unit" in rule and redefined to have the same meaning as the corresponding statute in RCW 69.50.101 .
"Unit"	E2SSB 5367 created a new definition for "unit" to mean one or more consumable items within a "package." The new statutory definition conflicts with the existing definition of "unit" in rule. The definition of "unit" in rule referred to an individually packaged cannabis-infused product containing no more than 10 servings, with each serving containing no more than 10 milligrams of active delta-9 THC, for up to a total of up to 100 milligrams of THC per unit.
"WSDA"	A new definition is created in rule for the acronym used to reference the Washington State Department of Agriculture.

Table 2: WAC 314-55-095 - Cannabis Servings and Transaction Limits

Limits on THC Content Per Serving	The rules are amended to clarify the THC limit in cannabis- infused products meant to be eaten, swallowed, or otherwise taken into the body (edibles).
	Each serving may contain up to 10 mg of active delta-9 THC and no more than 0.5 mg of any other tetrahydrocannabinol compound, with a combined maximum of 1.0 mg for all THC compounds, other than delta-9 THC.
	These adjustments ensure that the regulation of THC isomers is comprehensive, enhancing consumer safety by addressing the potential effects of lesser-known compounds. Clear limits help licensees comply with the rules and reduce the risk of unintentional violations, promoting consistency in product potency.
	The established thresholds maintain a reliable consumer experience while managing cumulative effects of other THC compounds. Proposed limits align with market data that reflects minimal concentrations of non-delta-9 THC compounds, enabling feasible compliance without major reformulations.
Replacement of "Unit" with "Package"	The term "package" replaces "unit" for consistency with the new definitions created by E2SSB 5367.
Transaction Limits	Subsections (1) and (2) outlining transaction limits for cannabis-infused liquid products are amended to align with SHB 1249.
	Additionally, the allowance for ten units of cannabis-infused product otherwise taken into the body under subsection (1)(c)(i) was repealed in the proposed rule.

Table 3: WAC 314-55-102 - Quality Assurance and Quality Control

Updated Potency Testing	Throughout <u>WAC 314-55-102</u> , the term "cannabinoid concentration analysis" replaces "potency analysis." Additionally, subsection (3)(a)(i) is amended to clarify the purpose and requirements of the cannabinoid concentration analysis.
Terminology	The term, "cannabinoid concentration analysis" is consistent with the terminology used in WSDA's rules governing cannabis testing laboratory standards and accreditation, provided in chapter 16-309

	and <u>16-310</u> WAC. The change is necessary to ensure consistency across regulatory frameworks.
THC Compounds Marketed, Advertised, or Labeled as Part of the Product	A new testing mandate is added to subsection (3) under <u>WAC 314-55-102</u> requiring any THC compound that is marketed, advertised, or labeled as part of a cannabis product to undergo cannabinoid concentration analysis testing. This ensures that all THC compounds promoted are accurately measured and reported, enhancing consumer transparency, and product safety.
	The amendment focuses on mandatory testing for delta-9 THC and other significant compounds rather than all compounds that are classified as "tetrahydrocannabinols," as defined in RCW 69.50.204 . This targeted approach provides relevant information to consumers, while minimizing unnecessary complexity.
	By balancing regulatory requirements with industry innovation, the rule prevents excessive burdens on licensees and testing labs. The regulatory framework can evolve to include additional cannabinoids as they gain market significance.
Reporting Total THC	A new mandate requires reporting total THC for all tetrahydrocannabinol compounds present in the cannabis product detected during the testing process and present in amounts greater than 0.2 mg/g.
	The 0.2 mg/g threshold being in rule captures meaningful levels of THC compounds that may contribute to the product's potency, without unnecessarily focusing on trace amounts that do not likely significantly affect the product's effectiveness or consumer safety. This threshold balances the need for correct reporting without burdening producers with testing and reporting of trace amounts of THC that are not likely to affect the product.
Total THC Calculation Formula	The equation to calculate total THC has been amended to account for tetrahydrocannabinol compounds, other than delta-9 THC, when present in amounts greater than 0.2 mg/g. The new calculation uses a variable conversion based on the molar mass of the neutral and acidic THC compounds, rather than a fixed factor of 0.877, which only applies to delta-9 THC.
	The revised formula ensures that all tested THC compounds are accounted for according to their individual molar masses, aligning with current cannabinoid chemistry and the expanded definition of "THC concentration" amended by E2SSB 5367. This change enhances consumer transparency, allowing for more informed decision-making and fostering trust in the regulatory system.
	The amendment addresses legislative requirements of E2SSB 5367,

	reflecting an evolving understanding of the diverse psychoactive compounds in cannabis. By incorporating specific molar mass ratios, the new formula offers precise measurement of total THC that accurately reflects the potency of each compound. The flexible approach enables the regulatory framework to adapt to emerging THC isomers, ensuring ongoing consumer protection and compliance with scientific standards.
Certified Laboratories	The language regarding testing roles has been amended to specify that it is the responsibility of cannabis licensees to ensure their products are tested by laboratories certified by the board and accredited by the WSDA. This update shifts the accountability to the licensees, aligning with recent legislative changes outside in 2SHB 2151. The legislation transfers accreditation authority to WSDA and reflects LCB's limited regulatory control of laboratories directly. Please note, these rule changes do not encompass all the modifications required to fully implement 2SHB 2151 and related legislation. Current rulemaking efforts implementing the legislation is ongoing and addresses other pertinent aspects of testing procedures, ensuring they remain comprehensive and aligned with the evolving

Table 4: WAC 314-55-105 - Packaging and Labeling

Total THC	The total THC must be on the retail product label and calculated individually for each tetrahydrocannabinol compound present in a product in amounts greater than 0.2 mg/g, consistent with the amended testing requirements under WAC 314-55-102(3)(a)(i). The new rule ensures that all significant THC compounds that are likely to significantly affect the product's effects are on the label, enhancing consumer transparency.
Replace "Container" with "Package"	The term "container" has been replaced with "package" in <u>WAC 314-55-105</u> to align with statutory changes made to <u>RCW 69.50.346</u> , which also replaced "container" with "package." This change ensures consistency between the rule and statue.
Remove of Reference to Unique ID Generated by State Traceability	The language referencing the lot number as the unique identifier generated by the state's traceability system that must be on the product label is no longer in section WAC 314-55-105 of the amended rules. The number is no longer applicable due to the changes in the traceability system, and the update ensures that the regulatory language reflects current practices.
Update Serving Size –	The serving size labeling requirements in section WAC 314-55-105 of the amended rule incorporates the new statutory definitions of

Replaced "Unit" with	"package" and "unit."
"Package	The amended rules require the label to include the serving size, the amount of product per serving, and the total number of servings in a package. This adjustment aligns labeling requirements with the current statutory definitions and enhances transparency and safety by providing consumers with clearer information about serving sizes in cannabis products.

Table 5: WAC 314-55-106 - Cannabis Warning Symbol Requirement

Table 6: WAC 314-55-109 - Cannabinoid Additives

New Statutory Definition of "Cannabis Products"	Updated regulations on the use of CBD products as additives in cannabis products, specifying that such CBD products must not be "cannabis products," as defined in RCW 69.50.101 .
Testing Cannabinoid Content	Amended testing requirements for CBD product additives to comply with the cannabinoid concentration analysis (potency) testing requirements outlined in

Table 7: Title 314-55 Misc.

Corrected WAC Citation	The citation for the rule definition of "financier" in <u>WAC 314-55-035</u> was updated to reflect the changes made to <u>WAC 314-55-010</u> in numbering because of new definitions added as a result of this rulemaking.
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Summary of Public Comments and Agency Response

WACA and The Cannabis Alliance Comments – Regarding Serving Size Limits

The Washington CannaBusiness Association (WACA) expressed support for the changes made in the CR-102 language of the THC bill (E2SSB 5367). However, they requested further clarification regarding the rule's definition of a single serving of tetrahydrocannabinol (THC) under <u>WAC 314-55-095</u>. WACA

emphasized that while they understand the rule aims to limit impairing cannabinoids such as delta-8 THC and delta-10 THC, non-impairing cannabinoids such as CBG, CBGV, CBDV, CBL, CBC, CBN, and TCHV should be exempt from the 0.5 mg and 1.0 mg serving size threshold. They asked that this exemption be explicitly stated in the rule to avoid confusion. WACA reiterated that the legislation is intended to regulate intoxicating cannabinoids, not naturally occurring non-impairing cannabinoids, and urged the LCB to ensure this clearly reflected in the final rule language.

The Cannabis Alliance raised concerns that ambiguous rules could penalize businesses that are already complying with strict regulations, potentially threatening their operations. They emphasized the already heavy regulatory burden on cannabis businesses regarding testing, labeling, and packaging. While they support maintaining high safety standards, they argue that the new rules unfairly add to the burden on compliant businesses without addressing sales of unregulated cannabinoids. The Cannabis Alliance raised three key concerns regarding the proposed regulations:

- <u>Scientific Basis</u>: Cannabinoid limits, especially for non-intoxicating compounds such as THCV, CBG, and CBN, need to be grounded in scientific evidence to avoid hindering innovation and limiting patient access.
- Alignment with Other States: Stricter regulations on non-intoxicating cannabinoids could place the state's cannabis industry at a competitive disadvantage compared with other states.
- <u>Unclear THC Definition</u>: Clearer language is needed to distinguish intoxicating cannabinoids, such as delta-8 THC and delta-10 THC, from non-intoxicating ones, to prevent confusion and inconsistent enforcement.

To address the concerns, they proposed the LCB create a list based on scientific knowledge of allowable cannabinoids that would not be subject to the proposed THC limits. This list would include compounds that are non-intoxicating and known to have therapeutic potential. Specifically, these compounds include CBG, CBGV, CBDV, CBL, CBC, CBN, and TCHV and their acid precursors. They emphasized that excluding these cannabinoids from the serving size limits would promote industry innovation, ensure patient access to necessary medicine, and maintain product safety. The Alliance urged the LCB to ensure that this list is flexible and easily updated as research evolves.

LCB Response: In response to concerns raised by The Cannabis Alliance and WACA regarding serving size limits established in WAC 314-55-095, the LCB has included additional language in the final rules for adoption that states LCB will maintain a publicly available list on the internet that includes cannabinoids

not subject to the serving size limits. This list will be based on current scientific research and be updated as needed to reflect the most up-to-date scientific research. By implementing this approach, the LCB aims to promote innovation within the cannabis industry, ensure patient access to non-intoxicating cannabinoids with potential therapeutic benefits, and enhance consumer safety. This addresses stakeholder concerns about balancing regulatory oversight in product development.

Treeline Analytics Comment – Testing Requirements

Overall, Treeline Analytics the proposed changes in the CR-102 for implementing the legislation, particularly the removal of the exhaustive list of THC compounds, which they find burdensome and costly. However, they raised concerns about the clarity of the formula for calculating total THC for compounds other than ddelta-9 THC and suggested revising the equation. Treeline opposed the blanket prohibition on remediating pesticide failures, and certain pesticide testing requirements for CBD product additives are redundant.

Treeline also questioned the regulatory authority of laboratory operation rules, suggesting they fall under WSDA, and suggested that the rules be amended to allow labs to reference samples for any field of testing. They emphasized the need for clearer definitions of terms like "extracted plant material" in WAC 314-55-010. Finally, they objected to existing rules related to the determination of pass/fail status and sought clarification on whether the 12-month expiration requirement for Certificates if Analysis (COA) applies to products already in retail stores.

LCB Response: In response to the comment regarding the calculation of total THC, the final rules have been amended to incorporate the molar mass ratio into the equation for accuracy and clarity. Other comments related to testing procedures, lab accreditation, and pesticide testing are outside the scope of this rulemaking, which focuses on implementing E2SSB 5367.

WASAVP, HCA, and Seattle & Public Health Seattle King County Public Comments

Low THC Beverage Purchase Limits

Concerns were raised by WASAVP, HCA, and Public Health Seattle King County regarding increased purchase limits for low-THC beverages in <u>WAC 314-55-095</u>, citing risks of greater youth access and accidental consumption. They recommended clearer labeling with cannabis warnings and requested a review of new products for youth consumption risks.

LCB Response: The new purchase limits for low THC beverages in rule align with SHB 1249. The existing packaging and labeling requirements under <u>WAC</u>

<u>314-55-105</u> and <u>WAC 314-55-106</u> for cannabis-infused liquid beverages, including mandatory cannabis warnings and symbol, remain unchanged.

Testing and Labeling Cannabinoids

Regarding synthetic cannabinoids, HCA and WASAVP called for enhanced regulations and mandatory testing of synthetic cannabinoids to ensure consumer safety. Additionally, concerns were raised that the current regulations may create loopholes by not requiring mandated testing for all cannabinoids, potentially allowing some compounds to be overlooked. Furthermore, because labeling of total THC is only required for tetrahydrocannabinol compounds exceeding 0.2 mg/g, which may leave compounds that are present in the product untested and unlabeled.

LCB Response: The LCB evaluated the feasibility of mandatory testing but decided against it due to significant cost impacts, laboratory capacity limitations, and potential adverse effects on smaller businesses.

The LCB is committed to ensuring compliance while maintaining high consumer protection standards. The agency will refine and strengthen rules as needed to address any gaps to uphold the law. A selective testing approach allows the rules to remain practical, scientifically sound, and adaptable, fostering innovation in cannabis product development while ensuring consumer safety and transparency. The rule changes establish a foundation that can evolve with the industry as new compounds become significant.

Differences Between the Proposed Rule and Adopted Rule

WAC Section	Proposed Rule (CR-102)
WAC 314-55-095 Cannabis Servings and Transaction Limits	In the proposed rules for WAC 314-55-095, the term "serving" was intended to be replaced with "package" to align with the new definitions of "package" and "unit." This change was made in other subsections but was not accurately reflected throughout the section. The final rule corrects the oversight to ensure consistency with the updated terminology used throughout the regulation, promoting clarity and compliance.
	The transaction allowance for cannabis-infused products, allowing purchase of up to ten cannabis-infused products that can be otherwise taken into the body was inadvertently removed in the proposed rule and added back in the final rules for adoption.
	A new subsection (3) is created to specify that the LCB will maintain a non-exhaustive list of cannabinoid compounds that are not classified as THC and not subject to the single serving limits. This list will be publicly accessible via the internet, providing clarity for consumers and licensees regarding which cannabinoid compounds fall outside the THC classification. This addition aims to enhance consumer transparency and ensure that all parties are informed about the applicable regulations concerning THC content.
WAC 314-55-102 Quality Assurance and Quality Control Testing	The total THC calculation equation is updated in the final rules to incorporate the molar mass ratio, which was inadvertently left out. While the equation was previously written incorrectly, the actual calculation method remains unchanged.

Implementation Date

The final rules will take effect 90 days after filing.